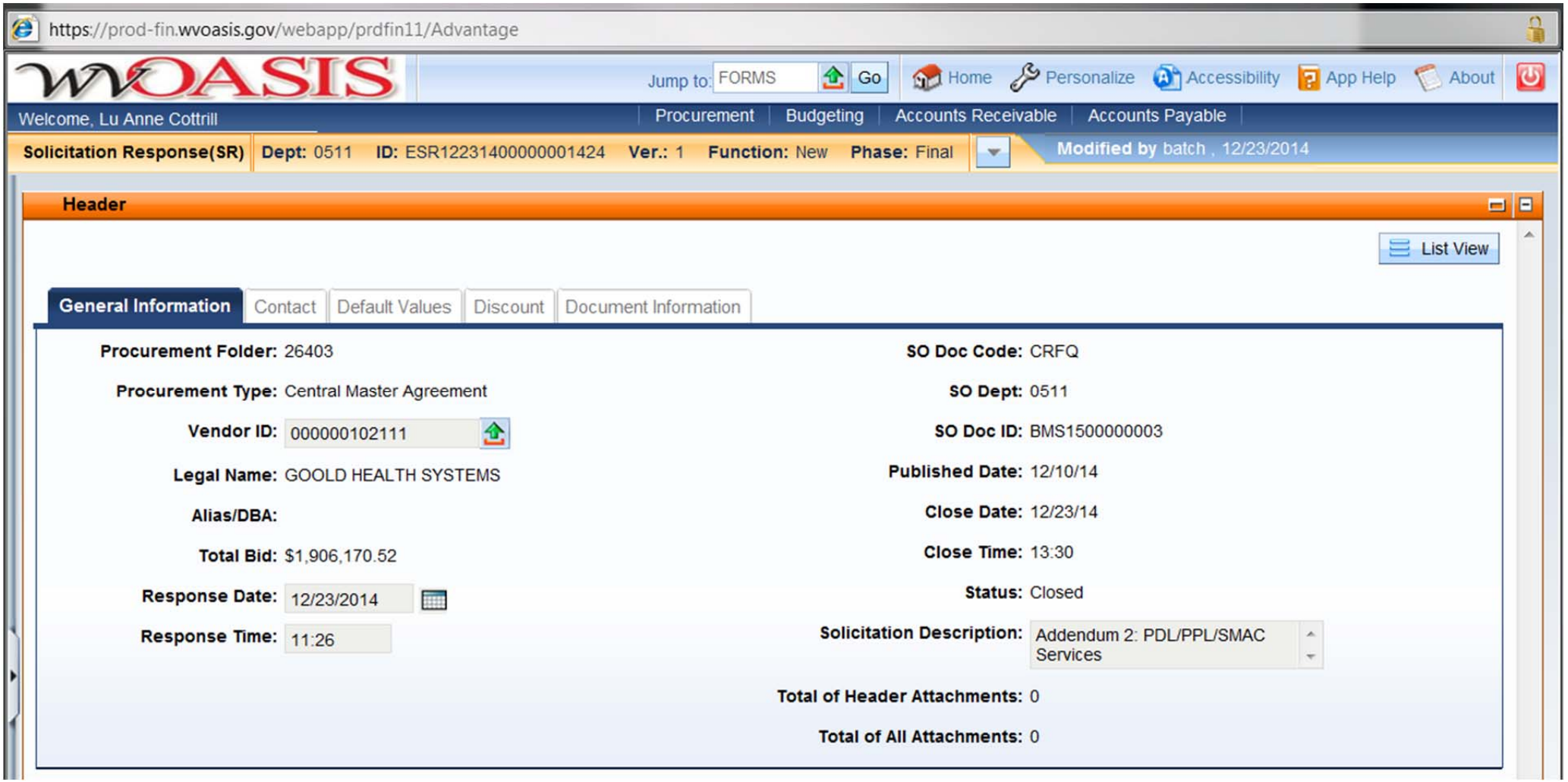
The following documentation is an electronically-submitted vendor response to an advertised solicitation from the *West Virginia Purchasing Bulletin* within the Vendor Self-Service portal at ***wvOASIS.gov***. As part of the State of West Virginia's procurement process, and to maintain the transparency of the bid-opening process, this documentation submitted online is publicly posted by the West Virginia Purchasing Division at ***WVPurchasing.gov*** with any other vendor responses to this solicitation submitted to the Purchasing Division in hard copy format.


https://prod-fin.wvoasis.gov/webapp/prdfin11/Advantage
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Welcome, Lu Anne Cottrill
Procurement
Budgeting
Accounts Receivable
Accounts Payable
Solicitation Response(SR) Dept: 0511 ID: ESR12231400000001424 Ver.: 1 Function: New Phase: Final
Modified by batch , 12/23/2014
Header
List View
General Information
Contact
Default Values
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Document Information
Procurement Folder: 26403
Procurement Type: Central Master Agreement
Vendor ID: 000000102111
Legal Name: GOOLD HEALTH SYSTEMS
Alias/DBA:
Total Bid: $1,906,170.52
Response Date: 12/23/2014
Response Time: 11:26
SO Doc Code: CRFQ
SO Dept: 0511
SO Doc ID: BMS1500000003
Published Date: 12/10/14
Close Date: 12/23/14
Close Time: 13:30
Status: Closed
Solicitation Description: Addendum 2: PDL/PPL/SMAC Services
Total of Header Attachments: 0
Total of All Attachments: 0

Purchasing Division
2019 Washington Street East
Post Office Box 50130
Charleston, WV 25305-0130

State Of West Virginia
Solicitation Response

Proc Folder : 26403

Solicitation Description : Addendum 2: PDL/PPL/SMAC Services

Proc Type : Central Master Agreement

Date issued	Solicitation Closes	Solicitation No	Version
	2014-12-23 13:30:00	SR 0511 ESR12231400000001424	1

VENDOR

000000102111

GOOLD HEALTH SYSTEMS

FOR INFORMATION CONTACT THE BUYER

Robert Kilpatrick

(304) 558-0067
robert.p.kilpatrick@wv.gov

Signature X **FEIN #** **DATE**

All offers subject to all terms and conditions contained in this solicitation

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
1	PDL/PPL/SMAC Services - Year One Startup Costs	1.00000	EA	$0.00	

Comm Code	Manufacturer	Specification	Model #
85131701			

Extended Description : Lump Sum Cost for Initial Startup Costs

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
2	PDL (FFS & MCO)/PPL & SMAC (FFS only) Services - Year One	12.00000	MO	$22,581.26	

Comm Code	Manufacturer	Specification	Model #
85131701			

Extended Description : Monthly Cost to Provide PDL for Medicaid Fee-for-Service and MCO's, and PPL and SMAC Services for Medicaid Fee-for-Service only (not MCO's)- Year One

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
3	PDL (FFS & MCO)/PPL & SMAC (FFS only) Services - Year Two	12.00000	MO	$23,032.88	

Comm Code	Manufacturer	Specification	Model #
85131701			

Extended Description : Monthly Cost to Provide PDL for Medicaid Fee-for-Service and MCO's, and PPL and SMAC Services for Medicaid Fee-for-Service only (not MCO's)- Year Two

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
4	PDL (FFS & MCO)/PPL & SMAC (FFS only) Services -Year Three	12.00000	MO	$23,493.54	

Comm Code	Manufacturer	Specification	Model #
85131701			

Extended Description : Monthly Cost to Provide PDL for Medicaid Fee-for-Service and MCO's, and PPL and SMAC Services for Medicaid Fee-for-Service only (not MCO's)- Year Three

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
5	PDL (FFS & MCO)/PPL & SMAC (FFS only) Services - Year Four	12.00000	MO	$23,963.41	

Comm Code	Manufacturer	Specification	Model #
85131701			

Extended Description : Monthly Cost to Provide PDL for Medicaid Fee-for-Service and MCO's, and PPL and SMAC Services for Medicaid Fee-for-Service only (not MCO's)- Year Four

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
6	PPL Services for MCO's - Year One	12.00000	MO	$9,408.86	

Comm Code	Manufacturer	Specification	Model #
85131701			

Extended Description : Monthly Cost to Provide PPL Services only for MCO's - Year One

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
7	PPL Services for MCO's - Year Two	12.00000	MO	$9,597.03	

Comm Code	Manufacturer	Specification	Model #
85131701			

Extended Description : Monthly Cost to Provide PPL Services only for MCO's - Year Two

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
8	PPL Services for MCO's - Year Three	12.00000	MO	$9,788.97	

Comm Code	Manufacturer	Specification	Model #
85131701			

Extended Description : Monthly Cost to Provide PPL Services only for MCO's - Year Three

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
9	PPL Services for MCO's - Year Four	12.00000	MO	$9,984.75	

Comm Code	Manufacturer	Specification	Model #
85131701			

Extended Description : Monthly Cost to Provide PPL Services only for MCO's - Year Four

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
10	SMAC Services for MCO's - Year One	12.00000	MO	$5,645.31	

Comm Code	Manufacturer	Specification	Model #
85131701			

Extended Description : Monthly Cost to Provide SMAC Services only for MCO's - Year One

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
11	SMAC Services for MCO's - Year Two	12.00000	MO	$5,758.22	

Comm Code	Manufacturer	Specification	Model #
85131701			

Extended Description : Monthly Cost to Provide SMAC Services only for MCO's - Year Two

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
12	SMAC Services for MCO's - Year Three	12.00000	MO	$5,873.38	

Comm Code	Manufacturer	Specification	Model #
85131701			

Extended Description : Monthly Cost to Provide SMAC Services only for MCO's - Year Three

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
13	SMAC Services for MCO's - Year Four	12.00000	MO	$5,990.85	

Comm Code	Manufacturer	Specification	Model #
85131701			

Extended Description : Monthly Cost to Provide SMAC Services only for MCO's - Year Four

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
14	Additional Services Hourly Rate - Year One	100.00000	HOUR	$107.00	

Comm Code	Manufacturer	Specification	Model #
85131701			

Extended Description : Additional Services $_____ (all inclusive hourly rate) X 100 Hours Section See Section 4.1.16 - Year One Hourly Rate

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
15	Additional Services Hourly Rate - Year Two	100.00000	HOUR	$109.14	

Comm Code	Manufacturer	Specification	Model #
85131701			

Extended Description : Additional Services $_____ (all inclusive hourly rate) X 100 Hours Section See Section 4.1.16 - Year Two Hourly Rate

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
16	Additional Services Hourly Rate - Year Three	100.00000	HOUR	$112.41	

Comm Code	Manufacturer	Specification	Model #
85131701			

Extended Description : Additional Services $_____ (all inclusive hourly rate) X 100 Hours Section See Section 4.1.16 - Year Three Hourly Rate

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
17	Additional Services Hourly Rate - Year Four	100.00000	HOUR	$114.66	

Comm Code	Manufacturer	Specification	Model #
85131701			

Extended Description : Additional Services $_____ (all inclusive hourly rate) X 100 Hours Section See Section 4.1.16 - Year Four Hourly Rate

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
18	Ad Hoc Reporting - per Report	1.00000	EA	$428.00	

Comm Code	Manufacturer	Specification	Model #
85131701			

Extended Description : Ad Hoc Reporting: Each additional report (in excess of the 50 per year included in the lump sum monthly bid) requested by the Agency

RESPONSE TO REQUEST FOR QUOTATION
Preferred Drug, Product List, and State Allowable Cost Services

TECHNICAL AND COST PROPOSAL
ORIGINAL

Submitted December 22, 2014

Prepared for:
Health and Human Resources
Bureau of Medical Services
350 Capitol Street, Rm 251
Charleston, WV 25301-3709

Prepared by:
Goold Health Systems,
an Emdeon company
45 Commerce Drive, Suite 5
P.O. Box 1090
Augusta, Maine 04332-1090
Phone: 800-832-9672
Fax: 207-623-5125
www.ghsinc.com

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PO Box 1090
Augusta, Maine, 04332-1090
www.ghsinc.com

Tel: 207.622.7153
800.832.9672
Fax: 207.623.5125

Transmittal Letter

December 8, 2014

Mr. Robert Kilpatrick
Department of Administration, Purchasing Division
2019 Washington Street East
Charleston, West Virginia 25305-0130

Dear Mr. Kilpatrick:

On behalf of Goold Health Systems ("GHS" or "Goold"), an Emdeon company, I am pleased to present the State of West Virginia's Bureau of Medical Services, hereinafter referred to as "BMS" or "the State", with our response to the Request for Quotation ("RFQ") for Preferred Drug/Product List and State Maximum Allowable Cost Services.

As Vice President, I am authorized to bind Goold to all statements, including services and prices contained in the proposal and to lead negotiations on behalf of the company in conjunction with our legal team. I shall be responsible for the overall management of any potential contract as a result of this RFQ, including any requests for clarification or other communication needed between the State staff and Goold. My contact information is as follows:

James A. Clair
Vice President
Goold Health Systems, an Emdeon company
45 Commerce Drive, Suite 5
P.O. Box 1090
Augusta, Maine 04332-1090

P: 800.832.9672
C: 207.242.2715
F: 207.623.5125
E: jclair@ghsinc.com

As required by the RFQ, Goold is submitted our response through the wvOasis online procurement system. All signed documents, Goold's response to the technical proposal, attachments, and price proposal have been submitted electronically.

Per the RFQ Specification document, Goold makes the following certifications to the best of its information, knowledge and belief:

(1) Goold's bid has been made without prior understanding, agreement, or connection with any corporation, firm, limited liability company, partnership, person or entity submitting a bid or offer for the same material, supplies, equipment or services;
(2) Goold's bid is in all respects fair and without collusion or fraud;
(3) A Contract as a result of this bid will be accepted or entered into without any prior understanding, agreement, or connection to any other entity that could be considered a violation of law;

PO Box 1090
Augusta, Maine, 04332-1090
www.ghsinc.com

Tel: 207.622.7153
800.832.9672
Fax: 207.623.5125

(4) The Solicitation has been reviewed in its entirety and Goold understands the requirements, terms and conditions, and other information contained herein;
(5) By signing this bid, Goold also affirms that neither it nor its representatives have any interest, nor shall acquire any interest, direct or indirect, which would compromise the performance of its services hereunder. Any such interests will be promptly presented in detail to the Agency; and
(6) To the best of our knowledge, Goold has properly registered with any State agency that may require registration.

Goold Health Systems has a long history of effective collaboration with our State Medicaid Agency partners to deliver projects on-time and on-budget. We would be honored to serve as the vendor for BMS' Preferred Drug/Product List and State Maximum Allowable Cost Services once again. It is our objective to bring the State of West Virginia a solution with excellent customer service and cost-effective pharmacy services that will improve clinical outcomes, and increase savings for tax payers with a focus on the future of Medicaid for West Virginia. We have built our pharmacy support systems and services to be accountable, flexible, scalable, and transparent.

GHS will carry out all contract responsibilities in the same highly professional and successful manner to which you were accustomed. Our commitment is to establish a transparent, quality partnership that will allow West Virginia's Bureau for Medical Services to meet its operational and financial objectives.

We thank you for your time and consideration of our proposal. We look forward to answering any questions you might have, providing any other information you might request, and working with the West Virginia staff again in the near future.

Sincerely,

James A. Clair
Vice President

Table of Contents

Figures and Tables:

Figures:

Tables:

Signed Documents

RFQ Signature Page

Purchasing Divison
2019 Washington Street East
Post Office Box 50130
Charleston, WV 25305-0130

State of West Virginia
Request for Quotation

Proc Folder: 26403
Doc Description: Addendum 2: PDL/PPL/SMAC Services
Proc Type: Central Master Agreement

Date Issued	Solicitation Closes	Solicitation No	Version
2014-12-10	2014-12-23 13:30:00	CRFQ 0511 BMS1500000003	3

BID RECEIVING LOCATION

BID CLERK
DEPARTMENT OF ADMINISTRATION
PURCHASING DIVISION
2019 WASHINGTON ST E
CHARLESTON WV 25305
US

VENDOR

Vendor Name, Address and Telephone Number:

FOR INFORMATION CONTACT THE BUYER

Robert Kilpatrick
(304) 558-0067
robert.p.kilpatrick@wv.gov

Signature X  FEIN # 01-0475134 DATE December 19, 2014

All offers subject to all terms and conditions contained in this solicitation

Page : 1 FORM ID : WV-PRC-CRFQ-001

Certification and Signature Page

CERTIFICATIONAND SIGNATURE PAGE

By signing below, or submitting documentation through wvOASIS, I certify that I have reviewed this Solicitation in its entirety; understand the requirements, terms and conditions, and other information contained herein; that I am submitting this bid, offer or proposal for review and consideration; that I am authorized by the vendor to execute and submit this bid, offer, or proposal, or any documents related thereto on vendor's behalf; that I am authorized to bind the vendor in a contractual relationship; and that to the best of my knowledge, the vendor has properly registered with any State agency that may require registration.

Goold Health Systems, an Emdeon company
(Company)

James A. Clair, Vice President
(Authorized Signature) (Representative Name, Title)

P: (800) 832-9672 F: (207) 623-5125 December 8, 2014
(Phone Number) (Fax Number) (Date)

Revised 08/08/2014

Purchasing Affidavit

CRFQ 0511
RFQ No. BMS15000000003

STATE OF WEST VIRGINIA
Purchasing Division

PURCHASING AFFIDAVIT

MANDATE: Under W. Va. Code §5A-3-10a, no contract or renewal of any contract may be awarded by the state or any of its political subdivisions to any vendor or prospective vendor when the vendor or prospective vendor or a related party to the vendor or prospective vendor is a debtor and: (1) the debt owed is an amount greater than one thousand dollars in the aggregate; or (2) the debtor is in employer default.

EXCEPTION: The prohibition listed above does not apply where a vendor has contested any tax administered pursuant to chapter eleven of the W. Va. Code, workers' compensation premium, permit fee or environmental fee or assessment and the matter has not become final or where the vendor has entered into a payment plan or agreement and the vendor is not in default of any of the provisions of such plan or agreement.

DEFINITIONS:

"Debt" means any assessment, premium, penalty, fine, tax or other amount of money owed to the state or any of its political subdivisions because of a judgment, fine, permit violation, license assessment, defaulted workers' compensation premium, penalty or other assessment presently delinquent or due and required to be paid to the state or any of its political subdivisions, including any interest or additional penalties accrued thereon.

"Employer default" means having an outstanding balance or liability to the old fund or to the uninsured employers' fund or being in policy default, as defined in W. Va. Code § 23-2c-2, failure to maintain mandatory workers' compensation coverage, or failure to fully meet its obligations as a workers' compensation self-insured employer. An employer is not in employer default if it has entered into a repayment agreement with the Insurance Commissioner and remains in compliance with the obligations under the repayment agreement.

"Related party" means a party, whether an individual, corporation, partnership, association, limited liability company or any other form or business association or other entity whatsoever, related to any vendor by blood, marriage, ownership or contract through which the party has a relationship of ownership or other interest with the vendor so that the party will actually or by effect receive or control a portion of the benefit, profit or other consideration from performance of a vendor contract with the party receiving an amount that meets or exceed five percent of the total contract amount.

AFFIRMATION: By signing this form, the vendor's authorized signer affirms and acknowledges under penalty of law for false swearing (*W. Va. Code* §61-5-3) that neither vendor nor any related party owe a debt as defined above and that neither vendor nor any related party are in employer default as defined above, unless the debt or employer default is permitted under the exception above.

WITNESS THE FOLLOWING SIGNATURE:

Vendor's Name: Goold Health Systems, an Emdeon company

Authorized Signature: _____ Date: 12/16/2014

State of Tennessee

County of Davidson, to-wit:

Taken, subscribed, and sworn to before me this 15th day of December, 2014

My Commission expires July 6, 2015

AFFIX SEAL HERE

ROBIN R. NICHOLSON
STATE OF TENNESSEE NOTARY PUBLIC
DAVIDSON COUNTY

MY COMMISSION EXPIRES:
July 6, 2015

NOTARY PUBLIC Robin R. Nicholson

Purchasing Affidavit (Revised 07/01/2012)

Addendum Acknowledgement #1

ADDENDUM ACKNOWLEDGEMENT FORM
SOLICITATION NO.: HHR1500000003

Instructions: Please acknowledge receipt of all addenda issued with this solicitation by completing this addendum acknowledgment form. Check the box next to each addendum received and sign below. Failure to acknowledge addenda may result in bid disqualification.

Acknowledgment: I hereby acknowledge receipt of the following addenda and have made the necessary revisions to my proposal, plans and/or specification, etc.

Addendum Numbers Received:
(Check the box next to each addendum received)

[X]	Addendum No. 1	[ ]	Addendum No. 6
[ ]	Addendum No. 2	[ ]	Addendum No. 7
[ ]	Addendum No. 3	[ ]	Addendum No. 8
[ ]	Addendum No. 4	[ ]	Addendum No. 9
[ ]	Addendum No. 5	[ ]	Addendum No. 10

I understand that failure to confirm the receipt of addenda may be cause for rejection of this bid. I further understand that any verbal representation made or assumed to be made during any oral discussion held between Vendor's representatives and any state personnel is not binding. Only the information issued in writing and added to the specifications by an official addendum is binding.

Goold Health Systems, an Emdeon company
Company

Authorized Signature

December 19, 2014
Date

NOTE: This addendum acknowledgement should be submitted with the bid to expedite document processing.
Revised 6/8/2012

Addendum Acknowledgement #2

ADDENDUM ACKNOWLEDGEMENT FORM
SOLICITATION NO.: HHR1500000003

Instructions: Please acknowledge receipt of all addenda issued with this solicitation by completing this addendum acknowledgment form. Check the box next to each addendum received and sign below. Failure to acknowledge addenda may result in bid disqualification.

Acknowledgment: I hereby acknowledge receipt of the following addenda and have made the necessary revisions to my proposal, plans and/or specification, etc.

Addendum Numbers Received:
(Check the box next to each addendum received)

[ ]	Addendum No. 1	[ ]	Addendum No. 6
[X]	Addendum No. 2	[ ]	Addendum No. 7
[ ]	Addendum No. 3	[ ]	Addendum No. 8
[ ]	Addendum No. 4	[ ]	Addendum No. 9
[ ]	Addendum No. 5	[ ]	Addendum No. 10

I understand that failure to confirm the receipt of addenda may be cause for rejection of this bid. I further understand that any verbal representation made or assumed to be made during any oral discussion held between Vendor's representatives and any state personnel is not binding. Only the information issued in writing and added to the specifications by an official addendum is binding.

Goold Health Systems, an Emdeon company
Company

Authorized Signature

December 19, 2014
Date

NOTE: This addendum acknowledgement should be submitted with the bid to expedite document processing.
Revised 6/8/2012

Executive Summary

Goold Health Systems (Goold), *an Emdeon company*, is pleased to present to the State of West Virginia Bureau of Medical Services (BMS or Bureau) with our proposal for Preferred Drug/ Product List and State Maximum Allowable Cost Services, CRFQ# 0511 BMS1500000003.

Goold has ***40 years of experience in providing Pharmacy Benefit Management (PBM) services and solutions to state Medicaid programs***. We presently provide a wide range of value-driven Medicaid pharmacy services in **sixteen (16) states**. Our expertise includes robust clinical management, account management, analytics, cost management, claims processing, Preferred Drug List (PDL)/ formulary management, and rebate negotiations, contracting and processing. Goold prides itself on building ongoing personal relationships, producing consistent and reliable deliverables and being responsive to our clients – **customer service and satisfaction are our priority.**

The Goold-West Virginia Advantage

- Qualified, Account Manager, staffing, and partners;
- Experience with large healthcare payers;
- Innovative clinical results;
- Trusted partnerships;
- Long history of providing quality customer service; and
- Full transparency with our State clients.

Goold welcomes the opportunity to once again provide the State of West Virginia with excellent customer service and cost-effective pharmacy services that will maintain and improve the quality of life to the citizens that rely on Medicaid. We have built our pharmacy support systems and services to be ACCOUNTABLE, FLEXIBLE, SCALABLE, AND TRANSPARENT. Our solution will meet or exceed the Bureau's requirements.

Experienced - Goold is well positioned to provide cost-effective PDL, PPL and SMAC services for the West Virginia's program as we have serviced this contract for the State before. Goold's current and historical PDL design experience includes West Virginia, as well as Iowa, Maine, Mississippi, and Wyoming. In 2015, Vermont will be included to make a total of six states for which we provide, or have provided, PDL design services. These services are provided for the nearly 2.5 million recipients for the six listed states. Goold has experience working with Medicaid programs of different sizes and with varying program and benefit designs.

Goold currently negotiates with pharmaceutical and DME manufacturers for rebates on behalf of nine state Medicaid pharmacy programs. We have acted as the vendor to the Sovereign States Drug Consortium (SSDC) since its origination and recently re-secured the contract for another four years. In addition to the eight states in the SSDC multistate pool, we also negotiate and contract for these rebates for Georgia Medicaid as a single state program. As an SSDC Member State, West Virginian recognizes the many benefits of the SSDC negotiation process that Goold has been dedicated to and has worked hard to tailored to the Member States.

In addition to our rebate negotiation services, Goold also provides the following states with other programs and services related to rebate and PDL management:

- Preferred Drug List (PDL) and Supplemental Rebate (SR) invoicing for the State of Mississippi;
- Full CMS, supplemental, J-code, managed care organization (MCO) pharmacy and MCO J-code rebate services for the State of Georgia;
- CMS, supplemental, J-code, and DME (including diabetic supply) rebate services for the State of Iowa;
- CMS, SR, DME, Prescription Drug Assistance Program (PDAP) and Aids Drug Assistance Program (ADAP) services for the State of Wyoming;
- Management of the Supplemental Rebate contracts process for Georgia, Iowa, Maine, Mississippi, and Wyoming; and
- Previously provided Preferred Drug List (PDL), Pharmacy & Therapeutic (P&T) Committee support and Supplemental Rebate (SR) contract management and State Maximum Allowable Cost services to the State of West Virginia.

Qualified Staff - Goold will be providing qualified staff to BMS with our pharmacy PDL/PPL and SMAC services team, allowing the State to maintain its commitment to members and providers, and avoid any unnecessary disruption of services. This qualified team has previously worked with BMS and achieved excellent results during our tenure. ***Goold's services are an orchestrated combination of technology and professional services. It is our people that make the difference.***

We've named experienced account manager, Dr. Chad Bissell, for the BMS project. He has over 12 years of experience in Medicaid and Pharmacy administration and has worked closely with the West Virginia pharmacy team. He is a clinical subject matter expert, has in-depth PDL and SMAC experience, as well as P&T committee presentation expertise. Goold will provide a highly skilled team of physicians, pharmacists, project managers, data analysts, rebate contract specialists, and others to the State. Our West Virginia team, collectively, has decades of experience in Medicaid PDL and SMAC operations that will be shared with BMS staff in order to further the agency's goals.

Partnership - Goold will partner with West Virginia to assure access to safe, efficacious, and clinically appropriate drug therapies at the lowest possible cost. During our partnership as the West Virginia contractor for these services in the past, Goold created a professional and trusting relationship with the involved parties. ***We will, once again, work with the Bureau to build a relationship that is based on trust and is reinforced by our commitment to BMS. Unlike companies that might have conflicts such as ownership of a commercial PBM, Goold has no such outside arrangements – our goals and visions are, by definition, the goals and visions of our customer and partner, the State of West Virginia.***

Our overall process will help reduce the administrative burdens that impact the State, providers, and beneficiaries. We will approach this project as a collaborative effort between all

stakeholders at Goold, BMS, the State, and other vendors. Goold is committed and well positioned to deliver an innovative Preferred Drug/Product List and SMAC Program that will help the State administer a highly effective and fiscally accountable Medicaid pharmacy benefit.

The Goold / West Virginia PDL/PPL and SMAC Solution

PREFERRED DRUG/PRODUCT LIST (PDL/PPL):

Goold Preferred Drug List Administration

- **Eleven (+)** years of experience in PDL services;
- PDL compliance currently **exceeds 96%;**
- Current and historical PDL design and management for **five states**, including Iowa, Maine, Mississippi, West Virginia and Wyoming, and beginning in 2015 for Vermont as the sixth state; and
- Recently, added **thirteen new PDL categories** for the Mississippi PDL program with much success.

Efficient and effective management of Medicaid PDLs is an area of excellence for Goold. Our PDL/PPL solution and supporting tools have been built to offer the maximum amount of rule capabilities as possible. Our PDL/PPL programs are aimed to optimize net savings for clients with minimal burden on clients, providers and members. ***Goold considers a clinically and financially sound PDL to be a key component to an effective pharmacy program.*** A carefully designed and closely monitored PDL will allow state Medicaid Programs to realize significant savings while maintaining or improving clinical outcomes. We have achieved this goal for each state Medicaid program that we have worked with, and will do the same for West Virginia.

STATE MAXIMUM ALLOWABLE COST (SMAC) SERVICES:

Goold's philosophy regarding SMAC rate schedules is based on the belief that chemically equivalent drug products in the same strength, dosage form, and package size available from multiple sources should be reimbursed similarly. SMACs are designed to maximize the cost-effectiveness of pharmacy services by setting reimbursement amounts for brand name and therapeutically equivalent drug products at the same price, based on the cost of the products to pharmacies. The SMAC rate usually applies to both the brand and generic drug products. The Centers for Medicare and Medicaid Services (CMS) uses the same rationale to establish Federal Upper Limits (FULs) for drug products – Effectively, SMAC rates are State Medicaid program equivalents of CMS FULs.

Goold has used its wealth of knowledge and experience in the Pharmacy Benefit Services Administration (PBSA) industry to accomplish the objectives for our clients, achievements that have been recognized nationwide as leading edge and extremely cost effective. In addition to 11 years of SMAC management experience, Goold has more than 20 years of electronic Pharmacy Point-of-Sale (POS) pharmacy claims processing, 15 years of drug rebate management, 11 years of Preferred Drug List (PDL) maintenance, and 10 years of Prior Authorization (PA) experience. Goold also helped form, and currently manages, the Sovereign States Drug Consortium (SSDC), a multi-state rebate pooling program. This collective, related

experience provides our clinical and management teams with insights into the many other aspects of pharmacy benefit management that influence SMAC rate management.

We presently support the Medicaid SMAC programs for the States of Illinois, Maine, Minnesota, New Jersey, North Dakota, South Dakota, Utah, Vermont and Wyoming. This collection of diverse state clients helps Goold realize the challenges and opportunities for MAC programs in both rural and urban settings.

REPORT MANAGEMENT:

Goold will leverage our Goold Analytics solution to support the ongoing reporting and analysis needs of the State and those who support the scope of work presented in this RFQ. Goold has a team of experienced healthcare data analysts in-house who manage and support the Goold Analytics solution. This team is also responsible for preparing customized and standard (recurring) reporting and analysis for our clients. They too are a key component of the overall Goold Analytics solution, providing knowledge, guidance, and consultation related to Medicaid pharmacy reference data and the construction of complex ad-hoc reports and long-term analysis. ***Analytics rely on quality data and knowledgeable staff that work with our analysts to create a clear, concise scope based on the needs of the client.***

The West Virginia / Goold Team

Goold has assembled a well-qualified team of professionals that will be carrying out the duties required for operation of the West Virginia Preferred Drug/Product List and State Maximum Allowable Cost Services. Our experienced team has worked with the West Virginia pharmacy team and will allow BMS to maintain its commitment to its members, providers and taxpayers through an effectively managed Medicaid PDL, PPL and SMAC program

Our team has centuries of collective experience in pharmacy benefit administration, PDL design, SR negotiations and contracting, drug rebate management, healthcare data analytics, SMAC management, participation in clinical drug trials, drug literature evaluation, and, importantly, direct patient care. This team, supported by a strong corporate management team, enables Goold to provide effective and leading-edge Medicaid pharmacy solutions.

The West Virginia / Goold team includes a core set of key personnel, supported by a dedicated support and operations team:

- Jim Clair, MPA, MS – West Virginia Contract Administrator;
- Chad Bissell, Pharm. D, MBA – West Virginia Account Manager and Clinical Pharmacist;
- Laureen Biczak, DO – West Virginia Physician and P&T Committee Support;
- Jeffrey Barkin, MD - West Virginia Physician and P&T Committee Support;
- Steve Liles, Pharm. D – West Virginia SR Support;
- Matt Pettengill, PMP – West Virginia Project Manager;
- Rossi Rowe – West Virginia Rebate Manager;

- Shari Martin – West Virginia Rebate Support;
- Pat Coffin – West Virginia Rebate Support;
- Theresa Thompson – West Virginia SMAC Pricing Manager;
- Christine Deprofio – SMAC Pricing Support; and
- Jason Rushing - West Virginia Data Analyst.

The West Virginia / Goold team, as well as the Goold / Emdeon corporate management, pledges our commitment to provide the proper resources to effectively manage the program and operate the systems described in this proposal.

Project Timeframe

With years of experience as a Medicaid Pharmacy Benefits Administration vendor, Goold is familiar with a number of different approaches used by states transitioning to a new vendor, including those used in West Virginia. We have been working with State Medicaid programs to improve efficiency and apply cost effective management practices to pharmacy benefits since the days of paper claims and continue to do so in today's technologically and clinically sophisticated environment. The Goold team has implemented numerous and varied complex pharmacy services on time and on budget. **After carefully examining the scope of services included in this RFQ, we are confident it is possible to implement these services within a timeframe that is satisfactory to BMS.** Goold will work with the Bureau to achieve the desired timeline for this project, taking into consideration the current vendor and/or any other project constraints.

Summary and Closing

Goold is distinctive in our approach to working in a collaborative, customer-centric fashion with State Medicaid Programs. Goold builds ongoing personal relationships, produces consistent and reliable deliverables, and places a priority on being responsive to our clients. The Goold approach is built upon client partnerships, fiduciary responsibility, transparency, technology adoption, and project stakeholder outreach.

We are a company focused on providing the high quality, cost-effective pharmacy solutions for public health benefits administration in partnership with our State clients. We maintain high standards of integrity, cooperation, and insight for all services we provide. Our decades of clinically-focused, cost-effective State Medicaid Pharmacy experience make us the right choice for the West Virginia Preferred Drug/Product List and State Maximum Allowable Cost Services.

Mandatory Requirements (RFP Section 4)

4.1 Mandatory Contract Services Requirements and Deliverables: Contract Services must meet or exceed the mandatory requirements listed below.

4.1.1 Vendor shall provide program management and coordination of PDL, PPL, and SMAC activities with the Bureau, the state's Medicaid Fiscal Agent, the Medicaid MCOs, the Pharmaceutical and Therapeutics (P & T) Committee, the SSDC and its vendor, the prior authorization vendor, and any other business partner associated with PDL, PPL, and SMAC programs.

Goold has worked effectively with BMS in the past, the State's Medicaid Fiscal Agent, the Medicaid MCOs, the P&T Committee, the prior authorization vendor, and other business partners within the State to coordinate updates and changes to the PDL, PPL and the SMAC list. We look forward to the opportunity to resume those relationships in West Virginia. There is a longstanding tradition of our staff and systems collaborating and integrating with other Medicaid business entities to ensure the overall success of the program. Goold intends to continue these positive relationships going forward.

As the current vendor for SSDC, Goold will continue using our collaborative approach to ensure successful outcomes for BMS. Goold will provide program management and coordination of PDL, PPL and SMAC activities with BMS, the State's Medicaid Fiscal Agent, the Medicaid MCOs, the P&T Committee, the prior authorization vendor, and other business partners.

4.1.2 Vendor shall comply with all federal regulations, including confidentiality of rebate related data, and the State Plan filed and approved by the Centers for Medicare and Medicaid Services (CMS) as stated in Attachment A and B of this RFQ.

Goold operates a fully compliant drug rebate management program and will continue to comply with all current state and federal regulations, including the Omnibus Budget Reconciliation Act (OBRA), the State Plan (RFP Attachments A and B) filed and approved by CMS and the Health Insurance Portability and Accountability Act provisions. Goold provides transparent, full disclosure of all information involved in negotiation.

Goold is acutely aware of the confidential nature of the rebate-related data and maintains strict security standards to ensure that confidential information is kept secure.

4.1.2.1 Vendor shall assist the Bureau with writing State Plan Amendments related to the PDL, PPL, and SMAC programs.

Goold has experience assisting the Bureau in development of its State Plan Amendments related to the PDL, PPL and SMAC. Our staff has many years of experience with communications and interactions with CMS. This experience includes the drafting and

submission of State Plan Amendments. Our experience in multiple states will help ensure that West Virginia is always aware of the current best practices of other Medicaid programs.

4.1.3 Vendor shall be available for appearances before the West Virginia Legislature or other interested parties as requested by the Bureau at a minimum for four (4) and maximum of six (6) times per calendar year.

Goold staff will be available on an as needed basis for appearances before the West Virginia Legislature or other interested parties as requested by BMS at a minimum of four (4) and a maximum of six (6) times per calendar year. In addition, Goold is available to assist with the preparation of reports and/or presentations for use by BMS when requested.

4.1.4 Vendor shall facilitate status meetings with the Bureau including meeting agendas and minutes. Meeting minutes must be provided to the Bureau within ten (10) working days of each meeting, including the Pharmacy and Therapeutics Committee meetings. Status meetings will be held on an agreed upon schedule by the Bureau and the Vendor, at a minimum of weekly via conference call.

Goold recognizes that the success to any endeavor is close communication with the client, the ability and willingness to think outside the box and provide comprehensive, cost savings solutions that meet the needs of the client. ***Identifying the customer's needs and accommodating them is an area where Goold excels.***

Frequent communication is the KEY TO A STRONG PARTNERSHIP and Goold will be available on a scheduled and as needed basis to work on issues in a timely manner with the State.

Goold will to comply with all of the requirements outlined in RFP Section 4.1, and will facilitate weekly conference calls (or more frequently if necessary), and provide meeting agendas and minutes within 10 working days of each meeting, including P&T meetings.

4.1.5 Staff

4.1.5 Vendor shall provide staff to work cooperatively with the Bureau and its partner vendors to assist in managing the PDL, PPL, and SMAC programs.

For West Virginia, Goold will provide experienced staff with extensive Medicaid experience to work cooperatively with BMS and its partner vendors to assist in managing the State's PDL, PPL and SMAC services. The combined Medicaid experience of our proposed staff is unparalleled and their broad Medicaid experience, combined with their specific knowledge of West Virginia's unique needs and vendor relationships will bring many benefits to the State.

Goold's Experienced Staff for West Virginia:

- Account management and Clinical Pharmacist provided by Dr. Bissell with more than 12 years of experience;
- Physicians, Dr. Biczak and Dr. Barkin bring a combined total of over 40 years of experience;
- Rebate Manager, Rossi Rowe, has been providing states with rebate program management for more than 30 years;
- SMAC Pricing management provided by Theresa Thompson with over 30 years of relevant industry experience;
- Project management provided by Matt Pettengill, PMP, with almost 10 years of industry experience; and
- Data Analytics and Reporting by Jason Rushing who brings almost 15 years of report design and data analysis experience to West Virginia.

4.1.5.1 Vendor shall submit references from three (3) state Medicaid fee-for-service programs other than West Virginia that demonstrate experience as required in this RFQ.

Goold has provided similar and more extensive set of services in multiple states. The references provided in the table on the following page will validate the scope of work and quality of services that have been provided.

Goold Business References		
Reference 1: Maine	**Reference 2: Mississippi**	**Reference 3: Georgia**
Name: Stefanie Nadeau	**Name:** Judy Clark	**Name:** Linda Wiant, Pharm. D
Title: Director of MaineCare Services	**Title:** Pharmacy Director	**Title:** Director of Pharmacy
Organization: Maine Department of Health and Human Services (DHHS)	**Organization:** Mississippi Division of Medicaid	**Organization:** Georgia Department of Community Health
Address: 221 State Street, Suite 11 Augusta, Maine 04330	**Address:** 5360 I55 North Jackson, Mississippi 39211	**Address:** 2 Peachtree Street, NW, Floor 5 Atlanta, GA 30303
Phone: (207) 287-2093	**Phone:** (601) 359-6296	**Phone:** (404) 657-9092
Email: Stefanie.nadeau@maine.gov	**Email:** Judith.Clark@medicaid.ms.gov	**Email:** lwiant@dch.ga.gov
Relevance to West Virginia: Goold has been providing a vast array of services to the State of Maine since 1995. Currently, the scope of work includes: • Pharmacy Program Benefit Management; • Pharmacy Point of Sale Claim Adjudication; • Supplemental Rebate Administration; • PDL Design and Management; • Clinical Consulting and Drug Class Reviews; • RetroDUR; • ProDUR; and • Help Desk Services. Maine is also a member of the SSDC. Many of the services that Goold provides for the State of Maine are similar to those requested of West Virginia. This experience and lessons learned with benefit the State of West Virginia.	**Relevance to West Virginia:** For Mississippi, Goold has provided PDL and SR services since 2012. After evaluating market share reports and post rebate cost data, the GHS team recommended the addition of new PDL categories to target drugs responsible for increases in the prescription drug budget. At the same time, GHS kept close tabs on new drugs and new generics that have been introduced and evaluated how they best fit within the overall goals of the Mississippi PDL., similar to the requirements of West Virginia. GHS also works with the Mississippi P&T Committee on a quarterly basis to present recommendations for PDL modifications and additions. To assist the Committee with their decision making process, GHS provides thoroughly researched drug class reviews, drug monographs, and detailed cost information that allows the Committee members to see the net cost of drugs after all applicable rebates. In addition to supporting the P&T Committee and maintaining the PDL, the GHS team also works with the state's MMIS vendor and DUR vendor to recommend prior authorization criteria and ProDUR edits on certain drugs to minimize the need for prescribers to have to submit manual prior authorization requests.	**Relevance to West Virginia:** Goold has been providing Medicaid and Supplemental outpatient drug rebate services for the State of Georgia. Since 2009, we have provided the following services: • Supplemental rebate negotiations and contracting (as a single State); • Fee-for-Service and Managed Care Organization pharmacy and medical claims (J-code) rebate invoicing, payment collections and accounting; • Rebate dispute resolution and late payment follow up; • Rebate utilization reporting to CMS; and • Rebate offset reporting. Goold has used creative, aggressive, and cost-effective methods in the Georgia that have been successful and will allow us to use this experience to provide West Virginia with an effective program.

Table 1: Goold Business References

4.1.5.2 Vendor shall submit with their quotation the names and resumes for staff assigned to this contract including account manager, clinical pharmacist, physician, rebate manager, and SMAC pricing manager.

Goold is proposing key staff that are* FAMILIAR AND EXPERIENCED *with the West Virginia PDL, PPL and SMAC services. Additional staff are named as part of this response. As Goold has provided these services to West Virginia is the past, our key staff and support personnel are familiar with the project specifications and will provide the State with the same highly professional service as they have in years past. In addition to the information below, resumes for key staff, including the Account Manager, Clinical Pharmacist, Physicians, Rebate Manager, and SMAC Pricing Manager are included in Exhibit A – Staff Resumes. Resumes for other staff that are part of the Goold West Virginia project team are also provided.

WEST VIRGINIA ACCOUNT MANAGER – Chad Bissell, Pharm. D, MBA is a registered pharmacist in the states of Iowa, Alabama, Virginia, New York, and New Jersey and in good standing. Dr. Bissell brings over 12 years of experience in the administration of Medicaid or Managed Care PDL to the State of West Virginia. He has years of experience as an Account Manager and is clinically focused, making him an ideal candidate for West Virginia.

WEST VIRGINIA CLINICAL PHARMACIST – The Clinical Pharmacist for West Virginia will also be Dr. Bissell. He is a licensed pharmacist in the five States listed above and is in good standing. He will be supported by Goold's team of pharmacists and physicians. With over 12 years of experience in the administration of Medicaid or Managed Care PDL, Dr. Bissell is an excellent fit for the State of West Virginia.

WEST VIRGINIA PHYSICIANS –Laureen Biczak, D.O. and Jeffrey Barkin, MD will together provide West Virginia with the necessary support as outlined in the RFQ specifications. They are extremely familiar with West Virginia's program and will provide excellent support for the P&T Committee, PDL and SMAC programs. Together, Dr. Biczak and Dr. Barkin have over 40 years of experience in the administration of Medicaid or Managed Care PDL.

WEST VIRGINIA REBATE MANAGER – Rossi Rowe will serve as the Rebate Manager for the State of West Virginia, as she has in the past. She brings over 30 years of experience with Medicaid policies and fee-for-services program reimbursements.

WEST VIRGINIA SMAC PRICING MANAGER – Theresa Thompson will serve as the SMAC Pricing Manager for West Virginia. She has direct experience with the SMAC program of West Virginia, having worked with the State in the past. With over 30 years of relevant industry experience and over 10 years with Goold and Medicaid fee-for-service SMAC pricing program, she brings valuable knowledge to the State program.

4.1.5.3 Vendor shall provide an account manager that will be available during business hours of 8am to 5pm Eastern Time, Monday through Friday. This person is responsible for the overall operations of the contracted deliverables.

Goold is pleased to propose that Chad Bissell, Pharm. D, MBA serve as the account manager for the services provided to BMS as a result of this RFQ. He will be available during business hours of 8 AM to 5 PM Eastern Time, Monday through Friday, and outside of business hours as needed. He will be accountable for the overall operations of the contract deliverables and will oversee clinical matters, including PDL decisions, prior authorization (PA) criteria development, and therapeutic class and new drug reviews. Dr. Bissell will attend and participate in P&T Committee meetings.

Dr. Bissell has direct familiarity with the West Virginia contract, having worked with the West Virginia contract in the past. He has provided similar services in other states for more than 12 years. His experience includes PDL, SMAC, and clinical oversight, along with Medicaid project management activities.

4.1.5.4 Vendor shall provide a clinical pharmacist as stated in section 3.2.2 of this RFQ who shall attend, in person, P & T Committee and Drug Utilization Review (DUR} Board Meetings to offer advice to the Bureau on clinical issues relating to the PDL and PPL, and be available by telephone and email to the Bureau during business hours of 8:00am and 5:00pm Eastern Time, Monday through Friday. The P & T Committee meets three (3) times annually, with two (2) meetings being held in the DHHR Building at 350 Capitol Street and one (1) meeting being held at the Charleston Civic Center. The DUR Board shall meet quarterly and meetings are held at the DHHR Building.

Goold is delighted to propose Chad Bissell, Pharm. D, MBA to also serve as the clinical pharmacist for this contract. He is actively licensed with the Board of Pharmacy in Iowa, as well as multiple other states. Dr. Bissell has over 12 years of experience in Medicaid PDL, clinical pharmacy, SMAC, and related professional services. He has been involved in providing a similar scope of services in West Virginia, Mississippi, Iowa and Alabama, and more recently, has been providing SMAC program management services for New Jersey, Illinois, Minnesota, North Dakota and South Dakota. Dr. Bissell is experienced in preparing material for, attending, and presenting at P&T Committee meetings. He will attend the West Virginia Medicaid P&T meetings in person, and will also attend in person the quarterly Drug Utilization Review Board meetings. Dr. Bissell will continue to be available by telephone and/or email to BMS during business hours of 8 AM to 5 PM Eastern Time, Monday through Friday, as well as beyond usual business hours as needed.

Dr. Bissell will provide BMS with the timely clinical, pharmaceutical, and SMAC-related expertise and responsiveness that the State has enjoyed in the past. His depth and breadth of experience will continue to benefit BMS both clinically and fiscally.

4.1.5.5 Vendor shall provide for the services of a physician, actively licensed with the Board of Medicine or Osteopathic Medicine for the state in which they are employed. This physician shall attend P & T Committee meetings three (3) times annually and quarterly DUR Board meeting in person to offer advice to the Bureau on clinical issues relating to the PDL and PPL, and be available by telephone and/or email to the Bureau during business hours of 8am to 5pm Eastern Time, Monday through Friday. P & T and DUR Board meetings are held in the DHHR Building or the Charleston Civic Center.

Goold is proposing two physicians to provide the services required by this RFQ, including the specialization of a psychiatrist, Jeffery Barkin, MD and the clinical expertise of Dr. Biczak.

Dr. Laureen Biczak has worked closely with West Virginia as the Account Manager for this contract in the past, as well as during the SSDC offer review process. She has also played a key role and attended committee meetings for our clients in Maine, Iowa and Mississippi. Dr. Biczak will work collaboratively with Dr. Barkin in support of the West Virginia contract and as one of the physicians who will attend P&T Committee meetings in person, offer advice to BMS on clinical issues related to the PDL, and be available to the State as requested. Dr. Biczak has been with Goold since 2007, but has more than 20 years of experience in the medical industry. Prior to joining Goold, Dr. Biczak spent six years as the Medical Director for Maine's Medicaid program. She currently oversees all clinical activities at Goold including the development of the Therapeutic Class Reviews and PDL criteria in multiple states. She actively participates in Drug Prior Authorization or P&T Committee meetings in multiple client states and is involved in all aspects of PDL design, prior authorization activities and pharmacy benefit administration. Her experience as a Medicaid Medical Director provides a deep understanding of Medicaid policy as it relates to the pharmacy benefit. Dr. Biczak is an actively practicing Infectious Disease specialist with significant HIV treatment experience. She takes the primary role in evaluating all infectious disease drug reviews, both clinically and financially. She was also our lead in negotiating and implementing Maine's diabetic supply bids in 2007.

Dr. Barkin has 22 years in clinical and Medicaid Pharmacy experience and provides oversight for the Medical Prior Authorization process for Maine Medicaid, as well as oversight of the pharmacy benefits for the Medicaid agencies of multiple states. He makes recommendations for both pro-DUR and retro-DUR criteria and has maintained a private and forensic psychiatry practice treating individuals with a variety of mood, anxiety, and psychotic disorders, as well as neuropsychiatry patients since 1991.

Both doctors are familiar with the West Virginia PDL and SMAC programs, having worked with the State directly in the past. Our knowledgeable staff will be available, as required, Monday through Friday, from 8 AM until 5 PM, outside of business hours as needed, and for P&T and DUR meetings as required.

4.1.5.6 Vendor shall provide for the services of a rebate manager. This individual shall be available to the Bureau by telephone and email during the business hours of 8am to 5pm Eastern Time, Monday through Friday. This individual is responsible for, at a minimum, completion and management of rebate contracts, contract tracking, contract status, contract disputes, and pricing and contract data files and reports for rebate invoicing.

Ms. Rossi Rowe will serve as the Rebate Manager for West Virginia. She has over six years of Medicaid PDL contracting services experience, including contracting services for the State of West Virginia. Prior to her current position at Goold, she served as the rebate manager for the State of Maine for 10 years.

Ms. Rowe is highly experienced in all aspects of rebate management and will be available to BMS by telephone and email at a minimum during business hours of 8 AM to 5 PM Eastern Time, Monday through Friday, and beyond those hours as needed. She will oversee, at a minimum, completion and management of all supplemental rebate contracts, contract tracking, contract status, contract disputes, data files, and rebate invoicing reports. She has, in recent years, provided these same services and overseen the staff involved for the West Virginia contract and is familiar with the State's program. In addition, she has in-depth experience for the full scope of rebate contracting and invoicing, having provided these services for Wyoming, Iowa and Georgia.

4.1.5.7 Vendor shall provide for the services of a SMAC pricing manager. This individual shall be available to the Bureau by ·telephone and email during business hours of 8am to 5pm Eastern Time, Monday through Friday. This individual is responsible, at a minimum, for management of the SMAC program, oversight of the selection of generic, other drugs, and products to which SMAC prices will be applied, calculation and tracking SMAC pricing, providing documentation for price posting, and advising the Bureau when pricing disputes occur.

Goold is pleased to propose Theresa Thompson as SMAC pricing manager. Ms. Thompson has previously worked in the background on West Virginia SMAC issues in the past. Overall, she has almost 30 years of relevant industry experience but she has been involved in SMAC work for Maine for more than 10 years, having served as the Pharmacy Helpdesk Supervisor for Maine, with daily exposure to resolution of issues regarding payment, pricing, and POS concerns. In addition, she has been involved in SMAC issues for Wyoming Medicaid for the last 6 years and more recently has been involved in pricing issues and SMAC setting for Illinois, New Jersey, Minnesota, North Dakota, and South Dakota. Her daily immersion in SMAC and other Medicaid pricing issues in multiple states makes her the ideal person for this role.

Ms. Thompson will be available to BMS by telephone and email at a minimum during the business hours of 8 AM to 5 PM Eastern Time, Monday through Friday. She will be responsible for and will oversee, in collaboration with Dr. Biczak and Dr. Barkin, as well as the Goold analytic team, at a minimum, the management of the SMAC program, selection of generic and specialty drugs to which SMAC prices will be applied, calculation and tracking of SMAC pricing, providing documentation for price posting, and advising BMS when pricing disputes occur. She will provide these services in coordination with the clinical pharmacist and account manager, Dr. Bissell, ensuring that PDL changes are in synchronization with SMAC pricing changes. This coordination of efforts is essential to continue to strive for the lowest net cost available for drugs purchased by West Virginia Medicaid.

4.1.5.8 Vendor shall complete background checks for current and potential employees to ensure that staff meets the minimum requirement under state and federal statute and/or regulations. See Attachment A and B. Vendor shall not employ persons who are excluded from Medicare or Medicaid participation by the Federal Office of the Inspector General or any state Medicaid program.

Goold conducts background checks internally on all prospective employees and will comply with State checks for current and potential employees as a result of this contract. The scope of

the background check includes employment and education verification, criminal record screen/social security trace, and professional employment reference checks. All employees have completed HIPAA privacy training. Additionally, all employees must sign confidentiality agreements.

4.1.5.9 Changes in staff positions of account manager, clinical pharmacist, physician, rebate manager and SMAC pricing manager shall be approved by the Bureau.

Goold and Emdeon's company vision is to make healthcare more efficient. We are always seeking talented people who work together as a team and are committed to Emdeon's Values of INTEGRITY, HONESTY, TRUST, ACCOUNTABILITY, CUSTOMER FOCUS, QUALITY, INNOVATION, TEAMWORK, and COMMUNICATION. These values and our commitment to quality staffing will directly benefit the quality of the West Virginia project.

Goold and Emdeon are guided by industry expertise, innovation, and foresight. New product development, high quality of service, an advanced technology infrastructure, a great company culture, and engaging employee programs are just some of the positive by-products. Our employees work hard, generously giving their passion and dedication in pursuit of our shared vision with our clients and making this a great place to work.

As our business continues to grow and develop, we realize the need to attract and retain our most valuable asset, our employees. ***Emdeon is committed to equipping employees with the training, tools and opportunities needed to advance not only the business, but themselves.*** Goold and Emdeon have a comprehensive employee retention program consisting of employee recognition, awards, and career advancement opportunities. We monitor our employee retention, attrition, and satisfaction on a continuous basis.

Goold pays competitive salaries relative to the location of work and the employees' experience. We make all efforts to ensure that staff are not over-allocated and that project and operational teams are sufficiently staffed.

Staff turnover is typically the result of an employee pursuing other career opportunities. There are any number of reasons that may trigger this type of move, and they are completely unique to each individual. As a testament to the quality of our work environment, however, we have experienced key employees returning to Goold after one to two years with another organization.

Should Goold experience changes in key staff position for the BMS project, all changes will be approved by the State prior to implementing the new personnel. Goold realizes our commitment to provide the proper resources to operate the applications, program and services described in this RFQ. Goold has assembled a staff of extremely talented, competent, and capable employees who collectively bring decades of experience in Medicaid PDL, supplemental rebate negotiation and contracting, clinical, and SMAC operations. These staff members are

familiar with West Virginia, having worked on the project with the State in the past. See Project Organizational Chart in the figure below.

West Virginia
Preferred Drug/Product List and State Maximum Allowable Cost Services
CRFQ 0511
BMS1500000003
December 2014

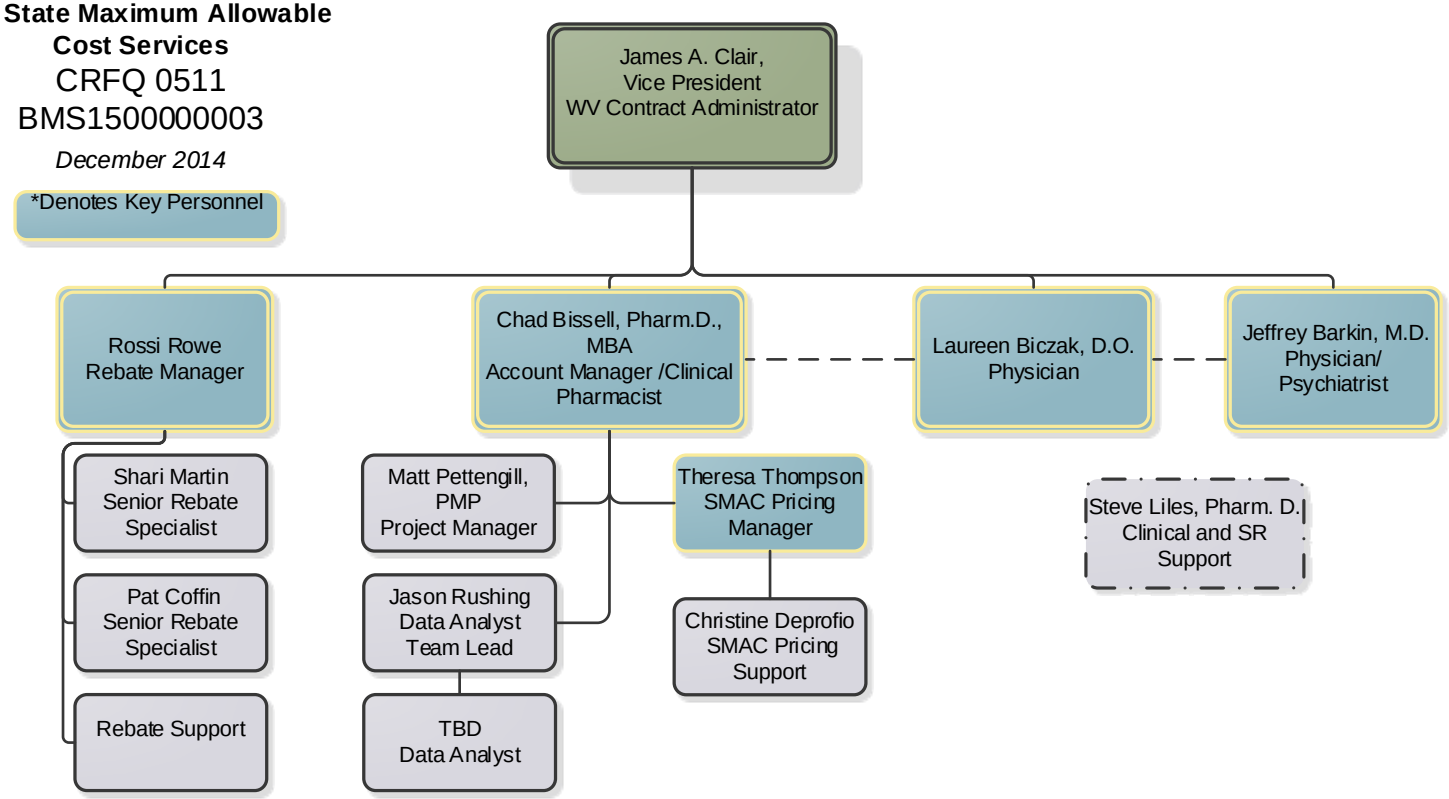


Figure 1: Goold-West Virginia Team - Organizational Chart

Our expert staff members are available at a moment's notice to answer questions, provide technical support, address concerns and assist with legislative requests. Named staff are available to attend meetings via teleconference or online, and are also able to travel in order to attend meetings in person, as appropriate. Goold has named the following key staff:

West Virginia Contract Administrator – Jim Clair, Vice President

- Contract management;
- JAD session coordination and senior level discussion;
- Scope verification;
- Deliverable review and approval;
- Conflict resolution; and
- Change management review and approval.

Jim Clair, Vice President of Goold, will serve as the Contract Administrator for West Virginia. Mr. Clair will be the primary point of contact for the State on any contractual or performance issues.

West Virginia Account Manager / Clinical Pharmacist – Chad Bissell, Pharm. D, MBA,

- Be responsible for the overall operations of the contract and for contract deliverables;
- Recommend therapeutic classes or subclasses of drugs for inclusion on the Preferred Drug List;
- Provide direction, oversight and acts as Senior Editor of clinical therapeutic class and drug reviews, including evidence rating of the studies;
- Attend P&T Committee and DUR board meetings in person;
- Recommend the inclusion or exclusion of drugs in clinical reviews and onto the Preferred Drug List;
- Present clinical information, fiscal and clinical reports, and PDL recommendations to the P&T Committee;
- Coordinate all aspects of Preferred Drug List development and maintenance;
- Provide fiscal analysis of therapeutic classes or subclasses added to the Preferred Drug List;
- Participate in the clinical and fiscal aspects of PDL design, including participating in supplemental rebate negotiation and integration with State Maximum Allowable Cost activities;
- Recommend policy interventions, both to improve quality and contain costs for West Virginia Medicaid;
- Work with analytic team to develop routine and specialized reports and analyses of trends relating to drugs, categories of drugs or in relation to topics of interest, such as disease state management;
- Provide clinical information and utilization data based on state trends in prescribing and dispensing patterns;

- Oversee the development and recommend criteria for prior authorization;
- Assist with ongoing provider education, including maintaining Preferred Drug Lists for posting, preparing meeting agendas, and develop mailings to update providers of current policies and procedures;
- JAD session participant;
- Scope verification – review planned work against RFQ and proposal material;
- Serve as subject matter expert on existing Preferred Drug List operations and client needs;
- Offer advice to BMS on clinical issues relating to the PDL;
- Coordinate the PDL with SMAC changes;
- Serve as the liaison between the GHS SMAC team and BMS staff regarding pricing issues and SMAC disputes;
- Coordinate weekly status meetings;
- Work with analytic team to develop routine and specialized reports and analyses of trends relating to drugs, categories of drugs, or in relation to topics of interest, such as disease state management;
- Available to quickly answer fiscal, billing, drug or other questions including those requiring desktop analytic tools;
- Prepare for and attend in person as well as facilitate meetings with the provider industry, interested parties, and internal work groups in regard to the SMAC program upon request from BMS;
- Responsible for weekly files that coordinate SMAC pricing, PDL status of new NDCs and for files that change the PDL status of NDCs with changes in the PDL;
- Coordinate all changes with the West Virginia Fiscal Agent and PA vendor;
- Be available by telephone and/or email to BMS during business hours of 8AM to 5PM Eastern Time, Monday through Friday and after hours as needed for consultation regarding PDL, supplemental rebate, SMAC , policy or clinical issues;
- Attend weekly status meetings; and
- Be available for appearances before the West Virginia Legislature or other interested parties as requested by BMS.

West Virginia Clinical Support – Laureen Biczak, D.O. and Jeffrey Barkin, M.D., DFAPA

Dr. Biczak and Dr. Barkin will share the responsibility of the physician position for West Virginia. Both are personally familiar with the West Virginia program, having handled the contact in the past as part of Goold's prior contract. The following responsibilities will fall under their direction:

- Serve as the senior clinical directors;
- Oversee the processes for and makes final determinations as to the clinical appropriateness of all aspects of GHS' client services including PDL design, P&T Committee support, SR negotiation, individual case review, retro and pro-DUR criteria, State Maximum Allowable Cost determination, report design and PA criteria and decisions;

- Directly negotiates with drug manufacturers to obtain supplemental rebates with skillful, experienced use of both clinical and fiscal information;
- Attend and lead the annual SSDC drug rebate negotiations and meetings;
- Develop and maintain a working knowledge of the clinical and budgetary issues that are unique to West Virginia;
- Provide subject matter support for clinical, coding and billing, drug file and other areas of technical/clinical expertise;
- Work on all aspects of implementing innovative projects for West Virginia states upon demand (e.g. overseeing the collection of supplemental rebates for diabetic supplies);
- Responsible for working with GHS analysts to analyze and forecast drug trends, summarizing data and preparing reports;
- Responsible for oversight of all pricing and SMAC related issues and PDL coordination;
- Attend P&T Committee meetings in person;
- Offer advice to BMS on clinical issues related to the PDL;
    - Be available by telephone and/or email to BMS during business hours of 8AM to 5PM Eastern Time, Monday through Friday and after hours as needed; and
    - Be available for development and presentation of budgetary and other reports to the Legislature or other interested parties as needed.

West Virginia Supplemental Rebate, Clinical Support and Analysis – Steve Liles, R. PH, Pharm.D

- Provide leading expertise in development of data and statistical models, impact assessments of healthcare interventions, clinical and pharmacy prescribing practices, healthcare quality, policies and financing, research design, data and statistical analysis;
- Conduct complex and ad hoc analytic projects and provide information for high-level internal and external users, ensure completion of client requests and deliverables according to project deadlines;
- Provide substantive assistance in development and maintenance of Preferred Drug Lists (PDL); Develop and conduct analyses of significant cost savings generated by Medicaid PDL implementation;
- Develop projections of federal and supplemental rebates; and
- Develop and execute complex algorithms (packages, procedures, functions, etc.) and ad hoc queries in Transact SQL on MS SQL Server databases, perform data and statistical analysis in SQL and Excel, and use Crystal Reports and MS Access for reporting results of analyses.

Dr. Liles serves as a lead negotiator for the SSDC, responsible for supplemental rebate negotiations and Preferred Drug List strategy, including monitoring and evaluation of the brand and generic drug pipelines. Dr. Liles also works closely with Dr. Clifford and Dr. Biczak to study and define new cost saving and quality of care strategies to be implemented in the PDLs that GHS maintains. He will also provide clinical support to Dr. Bissell through the contract with West Virginia.

West Virginia Rebate Manager – Rossi Rowe

- Coordinate Supplemental Rebate operation and implementation activities;
- Ensure that all project participants are communicating effectively;
- JAD session participant;
- Scope verification – Review planned work against RFP and proposal material;
- Serve as SR subject matter expert on existing operations and client needs;
- Review Implementation progress;
- Responsible for day to day operations and oversight of the GHS Rebate Team;
- Project coordination including: project tracking, work plans, manage project scope, and stakeholder communication;
- Insure contract management process is timely and accurate;
- Lead dispute resolution process;
- Training lead;
- Operational technical team coordination;
- Oversight of rebate staff and responsible for completion and management of all supplemental rebate contracts, contract tracking, contract status, contract disputes, as well as data files and reports for rebate invoicing; and
- Be available by telephone and/or email to BMS during business hours of 8AM to 5PM Eastern Time, Monday through Friday.

West Virginia SMAC Pricing Manager – Theresa Thompson

- Management of the SMAC program;
- Oversight of the selection of generic and specialty drugs to which SMAC prices will be applied;
- Calculation and tracking of SMAC pricing;
- SMAC pricing development;
- Advising BMS when pricing disputes occur and timely resolution of disputes;
- Providing documentation for price posting;
- New drug pricing evaluations;
- Be available by telephone and/or email to BMS during business hours of 8AM to 5PM Eastern Time, Monday through Friday and after hours as needed; and
- Established generic price rebasing (weekly, monthly, and quarterly).

West Virginia Data Analyst Team, Lead Analyst – Jason Rushing

- Develop SQL queries, reports, data extracts, models, and databases;

- Develop and deploy cyclical and Ad-Hoc reports and will work with various reporting and analysis tools;
- Assist in the design, coding, and implementation of new production and data storage systems; and
- Data quality control.

West Virginia Project Manager – Matthew Pettengill, PMP

- Assists clinical team with preparation of materials for P&T Committee meetings and the quarterly provider newsletter;
- Prepares reports and confidential packets for the Executive Session of P&T Committee meetings;
- Coordinates all ancillary activities related to P&T Meeting, including transcription and preparation of minutes, transport of materials and delivery to members;
- Prepares agenda, transcribes and distributes minutes for weekly status and other meetings as needed;
- Tracks deliverables and ensures timely delivery;
- Assists Account Manager and Clinical Pharmacist with coordination of all activities;
- Responsible for project management of new deliverables, coordinates activities; and
- Tracks and provides input on contract requirements.

4.1.5.10 Vendor attendants at meetings shall be consistent. Attendant changes for any given meeting shall be approved by the Bureau at least five (5) business days prior to the scheduled meeting date.

Goold will provide consistent, experienced staff to the State of West Virginia in order to carry out all services related to this RFQ. Goold agrees to inform and receive approval from BMS for any Goold attendee changes five (5) days prior to P&T Committee meetings. We are pleased to be able to provide BMS with an experienced team that has provided these services for many of our client States.

4.1.6 Cooperation with Bureau and its Partners

4.1.6 Vendor shall agree that any and all data provided to the Vendor by the Bureau or the Bureau's partners, and any and all data collected, created, summarized, and/or aggregated, deliverables submitted to the Bureau or the Bureau's partners, and reports created under the contract awarded pursuant to this RFQ, are the sole property of the State of West Virginia, intended for the purposes of supporting the Medicaid and Pharmacy programs in any manner deemed appropriate by the State. None of these materials may be used by the Vendor at any time or in any manner without the express approval of the State.

Goold agrees with West Virginia that the following information is the sole property of the State, intended for the purposes of supporting the Medicaid and Pharmacy programs. None of the following materials will be used by Goold, at any time or in any manner, without the express approval of the State:

- Any, and all, data provided to the Vendor by the Bureau or its partners; and
- Any and all data:
    - Collected;
    - Created;
    - Summarized and/or aggregated;
    - Deliverables submitted to the Bureau or its partners and reports; and
    - Reports created under the contract awarded pursuant to this RFQ.

Information that will remain proprietary to Goold includes our methodologies, as well as our applications used in servicing the West Virginia project.

It is Goold's goal to work collaboratively with a State and its Vendors during all phases of the project. We've done this in the past during transitions to and from our Systems in West Virginia and will continue to provide this same level of professionalism moving forward with BMS.

4.1.7 Support of P&T Committee

4.1.7 Vendor shall develop and provide support for clinically sound and cost effective recommendations to the Bureau and the West Virginia Medicaid P & T Committee to refine and manage the PDL and PPL.

As with our other clients, Goold will provide innovative, clinically sound and cost-effective recommendations to the West Virginia Medicaid P&T Committee in ongoing efforts to refine and manage the PDL and PPL.

4.1.7.1 Vendor shall facilitate meetings, present clinical and cost information, develop print, copy, collate, and distribute meeting materials such as, but not limited to, agendas, minutes, reports, and handouts for all P & T Committee meetings, and provide ad hoc reports or other requested clinical and/or financial information for the DUR Board meetings throughout the year as approved by the Bureau.

Goold prides itself on the expert management of all facets of PDL administration, including P&T Committee support. Our proposed staff is experienced at providing these very specialized services and will provide West Virginia with the same level of professionalism that West Virginia experienced and that our other clients have come to rely upon. We will facilitate the presentation of clinical and cost information and develop, print, collate, and distribute meeting

materials such as, but not limited to, agendas, minutes, reports and handouts for all P&T Committee meetings throughout the year, as approved by BMS. Furthermore, Goold will provide ad hoc reports or other requested clinical and/or financial information for the DUR Board meetings throughout the year as approved by BMS.

4.1.7.1.1 Vendor shall develop and provide P & T Committee meeting agendas for each P & T Committee meeting at a minimum of thirty-five (35) calendar days prior to meetings. Content shall be approved by the Bureau for release.

Goold's experienced, trained administrative staff will provide any and all required administrative support for meetings, including preparation of P&T Committee meeting agendas and transcription of meeting minutes. Our staff has performed this function for the State in the past and continues to do so for our other State clients. We are knowledgeable and practiced at providing the necessary support to ensure the ongoing success and effective operation of the P&T Committee.

All draft meeting agendas will be sent to BMS for approval no less than thirty-five (35) days prior to the meeting and will be approved by BMS prior to release.

4.1.7.1.2 Vendor physician(s) and clinical pharmacist(s) shall review therapeutic classes including new medications or indications as approved by the Food and Drug Administration (FDA) and present in person recommendations to the P & T Committee and the Bureau for appropriate revisions to the PDL.

Goold will provide our physicians and clinical pharmacists to review therapeutic classes, including new medications and/or indications approved by the Food and Drug Administration. These updates to the therapeutic class reviews and monographs will be presented in person to the P&T Committee and BMS along with recommendations for revisions to the PDL.

Goold has over seven years of experience in conducting comprehensive drug class reviews. This knowledge base and experience will be available to West Virginia.

Goold is an industry leader in providing evidence-based clinical information for our clients. Our experienced staff includes pharmacists, physicians, analysts and statisticians. Goold will apply this expertise and our proven processes and procedures to therapeutic class reviews, in the form of clinical monographs. **Goold currently has a library of over 85 active therapeutic class reviews.** We will partner with the Bureau to propose content and classes to be reviewed, with final determinations to be made by BMS. Classes will include groups of drugs that are therapeutically similar and will be approved by the Bureau for inclusion via a mutually agreeable process. Drugs will be assessed, at a minimum, for comparative efficacy and the other key attributes listed on at least an annual basis. The format developed by Goold is presented in an attractive, user-friendly format with new information from the last review highlighted for the Committee's convenience. Additional details regarding the therapeutic class reviews are discussed in sections 4.1.8.1, 4.1.8.2 and 4.1.8.3 that follow.

In summary, Goold will provide in-person, timely reviews and recommendations by physicians and pharmacist to the State and the Committee regarding new drugs, new indications, new safety issues, and positive or negative studies, both for the scheduled Committee meetings and for any interim drug decisions.

4.1.7.1.3 Vendor shall provide meeting documents to the Bureau and Committee members fourteen (14) calendar days prior to meetings.

As stated previously, Goold's experienced administrative staff will provide any and all required administrative support for meetings, including preparation of agendas and transcribing meeting minutes. Our staff has provided this function for the State in the past and continues to do so for our other State clients. Our staff is knowledgeable and practiced at providing the necessary support to ensure the ongoing success and effective operation of the P&T Committee. All draft meeting documents will be sent to BMS and Committee members at least fourteen (14) calendar days prior to the meeting.

4.1.7.1.4 Vendor shall provide meeting minutes for all P & T Committee meetings. Meeting minutes will follow the current format as found on the Bureaus' website. Minutes are due no later than ten (10) business days after each P & T Committee meeting.

Goold will provide comprehensive meeting minutes in a format specified by the State for all P&T Committee meetings. All minutes will be provided to the State no later than 10 business days after each P&T Committee meeting.

4.1.8 Therapeutic Class Reviews/Monographs

4.1.8 Vendor shall provide the Bureau and the P & T Committee with therapeutic class reviews that compare drugs and products, at a minimum, for efficacy, safety, side effects, dosing, indications, prescribing trends, and cost efficiencies of each drug or product within the therapeutic drug or product class. These reviews will be delivered as monographs. Vendor shall submit a monograph example with their quotation.

Goold has experience in providing West Virginia with Therapeutic Class Reviews, which will be delivered as monographs for the life of the existing contract, updating each class at least annually. In these class reviews, all medications available in a therapeutic class are reviewed, at a minimum, for comparative efficacy, safety, side effects, dosing, prescribing trends, indications, and cost efficiencies. Sample Therapeutic Class Review Monographs have been included in Exhibit B- Sample Therapeutic Class Reviews.

4.1.8.1 Vendor shall provide to the Bureau and the P & T Committee members concise and systematic reviews of each therapeutic drug or product class or specific drugs or products to be presented for review by the Bureau or P & T Committee, including monographs, pricing information, and other pertinent information, no later than fourteen (14) calendar days prior to each P & T Committee meeting.

Goold produces high quality, evidence based therapeutic class reviews. Goold will provide BMS and West Virginia's P&T Committee members with concise and systematic reviews of each therapeutic class and/or specific drugs or products to be presented to the Committee for

review. Goold will be responsible for all delivery costs of these monographs and associated materials. The materials will be distributed no later than fourteen (14) calendar days prior to each P&T Committee meeting. Goold has a history of providing these materials early to our clients and will strive to exceed deadlines set forth by BMS.

In addition to the clinical information mentioned, the financial information will be presented in a clear, concise format that is based on actual net costs per usual course of therapy. Accurate comparison between treatments costs is presented to allow ready comparisons. Current and projected utilization is also presented for consideration. Dr. Bissell and the Goold Medical Directors are highly experienced at presenting information to Medicaid P&T Committees and West Virginia will benefit from their depth and breadth of experience. Our Medical Directors are Board Certified physicians with specialties in Internal Medicine, Infectious Disease and Psychiatry. They are adept at focusing on the issues that are of interest to the Committee and providing the factual, evidence-based information needed to allow the Committee to arrive at prudent PDL determinations that will balance the medical needs of West Virginia citizens with the financial realities of relative drug costs. The goal of the evidence-based clinical monographs, which we refer to as Therapeutic Class Reviews (TCRs) and related analyses, is to assist our partner states and their respective P&T Committee members in arriving at a rational assessment of which drugs represent the best value for their members. As described below, Goold's experienced pharmacists and physicians identify and review pertinent information from the clinical literature, including full text journal articles, evidence-based clinical guidelines, prescribing information, the FDA, and compendia such as Micromedex to provide an analysis comparing the safety, efficacy and appropriate place in therapy of the drugs within a therapeutic class. We also include information on the current state of therapeutics by reviewing information in DynaMed, UptoDate and full textbooks on the topic being reviewed. Finally, we include in our reviews information from the Cochrane library and have a license to utilize information from the National Comprehensive Cancer Network (NCCN) in the reviews when appropriate. We have found that providing our clinical staff with access to cutting edge, full text journal articles (not abstracts) as well as a broad range of drug and medical information resources is critical to support a comprehensive review of the current state of the art in a given drug class. This allows us to produce clinically relevant information for the P&T Committee to review.

Key to any comparative clinical analysis is a thorough understanding of clinical trial design. Goold's staff includes clinicians with decades of experience evaluating clinical drug trials. These clinicians routinely assess effect size measures, and normalizing comparative data. Effect sizes are calculated, when possible, using quantitative techniques such as Number Needed to Treat (NNT), and, as appropriate, Number Needed to Harm (NNH). This makes for ready and easy quantitative comparisons amongst treatments. When calculated, this information is incorporated into the clinical trial section of the Therapeutic Class Reviews in a comment field. Our rigorous analysis of the clinical trials provides excellent supporting information in the case of administrative hearing proceedings or in discussions with providers or manufacturers.

Goold also actively monitors FDA actions related to labeling. In cases where the FDA makes significant changes, especially when related to safety, Goold will make timely recommendations to the state regarding appropriate changes to the PDL and/or PA criteria. Additionally, Goold can regularly provide the State with a report summarizing significant labeling changes made by the FDA.

Goold's clinical team regularly receives clinical presentations from pharmaceutical manufacturers. While the information in these presentations is verified by the Goold clinical team prior to incorporation in our evaluation, these meetings do provide manufacturers the opportunity to ensure that their perspective is considered. This proactive, open and transparent relationship with the manufacturers minimizes disputes and similar issues. In fact, because of this relationship, disputes are very uncommon in states in which Goold provides these services.

The West Virginia Account Manager, Dr. Bissell, will also receive additional support from Goold's staff of pharmacists and physicians. Our extensive experience regarding best practices from multiple states will benefit West Virginia and allow insight into various approaches to PDL issues. We will create and provide customized drug monographs and savings analyses to the Committee, according to the State's specifications.

Although West Virginia has a mature PDL, it is essential to continue analyzing relevant, timely clinical trial data, including updates on efficacy, safety and added indications or patient populations. The Committee needs to focus on the most important essentials of a drug to maintain PDL therapeutic classes, including the following elements:

- Significant, clinically positive drug characteristics, especially if unique to class;
- Significant, clinically negative drug characteristics, especially if unique to class; and
- What financial effect a drug will have on a PDL class if it is preferred or non-preferred or if the drug undergoes a significant price change or becomes available generically or in another form (XR or ODT, for example).

Going forward, the primary operational concerns for a mature PDL such as West Virginia's are the annual negotiations and the interim drug considerations between Committee meetings. Goold will proactively make recommendations to BMS on how to make adjustments to the PDL and PPL based on timely clinical and net pricing information.

4.1.8.2 Vendor shall designate to the Bureau and the P & T Committee the Vendor's recommendation as to preferred or non-preferred status for each drug or product within each class based on current clinical and cost data.

All of our reviews and cost models are thoroughly researched by experienced pharmacists, with oversight by our Medical Directors, with multiple sources referenced and based on full text

article review and net cost information. Articles are rated for the quality of the study based on a specified set of parameters and the type of outcome measured.

Our current therapeutic class review process can easily be modified if the Bureau has aspects they would like tailored to meet their specific needs. For example, some clients have wanted intravenous formulations removed from their class reviews. Our process begins by using several drug databases, including our formulary management tools, that allow us to view medications within therapeutic categories based on any of several therapeutic classifications systems including Medispan®, First DataBank® and others (such as AHFS) to determine the drugs that are potentially appropriate to be incorporated into the review. Once the drug names are obtained, it is determined if the individual drugs have active NDCs and if they participate in the Federal rebate program. Drugs that meet these criteria are then proposed to be included in the review. The proposed list of included drugs would then be submitted to the Bureau for approval.

Once the approved list of drugs to be included is available, the data for each individual drug product is obtained, using the prescribing information and other information databases such as Micromedex®, Facts and Comparisons®, DynaMed® and UpToDate®. The drug information is then incorporated into the class review template.

The Goold class review template is a format that was created and developed by the Goold clinical team specifically for the purpose of P&T Committee review for PDL determinations. The template includes sections containing various types of drug information that are useful when considering the clinical value of the different drugs. The initial section is the Synopsis which generally includes a basic overview of the disease state under review, along with any interesting or historical data about the class that may help with an understanding of the current state of therapy. Once the Synopsis is written, specific drug information is added to each of the following sections: FDA Approved Indications, Dosage Form/Dose/Manufacturer, Pharmacology, Pharmacokinetics, Contraindications, Special Populations, Adverse Drug Reactions, and Drug Interactions. Information regarding the drug products is typically included in a table format for ease of use, but information may also be included in text format when appropriate. Pertinent FDA memos and Drug Safety Communications are also included in the text portion of any particular section. For example, an FDA bulletin released regarding clarifying use of a drug in the pediatric population would go in the Special Populations section.

In addition to the sections listed above, a critical section of the review is the Clinical Trials Section. The details of this section are explained in detail in section 4.1.8.3 below.

When the clinical information is combined with our financial analysis, along with our recommended preferred/non-preferred status for each drug, P&T Committee members will have all the necessary information presented to them to make an informed decision on the PDL placement of a new drug. This approach has worked well with the West Virginia P&T

Committee; we look forward to working with the State once again on this process and refining it as needed to meet the Committee's needs.

4.1.8.3 Vendor shall update and keep current all therapeutic drug and product class monographs using peer reviewed referenced materials and must grade the strength of evidence used. Monographs shall be updated no less than annually.

It is Goold's overall belief that a PDL needs to provide a selection of preferred drugs that allows primary care physicians to care for the majority of their patients without prior authorization requests being necessary on a daily basis. The driving force for or against recommending PDL placement is the drug's unique clinical contribution. Our clinical reviews are thoroughly researched; using peer reviewed reference materials, and uniquely edited to provide the P&T Committee with enough information to decipher differences in drugs, without overwhelming the Committee members with irrelevant details. Goold will update and keep current all therapeutic drug and product class reviews using peer referenced materials and grading the strength of the evidence used no less than annually.

Goold prides itself on providing unbiased, thorough therapeutic class reviews that are tailored to the specific needs of our clients and their respective Committees for evaluating the relative value of drugs for inclusion and status on their Preferred Drug Lists (PDLs). In each case, a robust review of the literature is undertaken and the information is rated not only for the quality of the studies, but also on whether there is clinical outcome data associated with the study versus less direct surrogate or proxy outcomes. For example, new drugs for pulmonary hypertension may have data to show that they improve hemodynamics, but may not yet have any data that demonstrate that they improve survival or the ability to function. Most studies regarding drugs in this class have used the six minute walk test as a proxy indicator of efficacy. Even this proxy marker has recently been called into question as there is a lack of evidence that a change in this parameter actually correlates with true outcomes such as survival or the need for lung transplantation. Goold clinicians routinely follow the literature and critically evaluate studies for both statistical significance and clinical relevance and present this information in an attractive format that is focused on the specific purpose of comparing drugs and their place in therapy.

New class reviews are developed in conjunction with our client states based on clinical and/or fiscal considerations that make a class of interest for review. At times, there are new entrants to a class that warrant consideration of breaking out a new class or sub-class, such as when Daliresp© became available for chronic obstructive pulmonary disease. At other times, it may make sense to combine two chemically distinct types of drugs into a single class review based on the clinical indication, such as combining the H2 blockers in conjunction with the proton pump inhibitors in a single review that covers the major types of drugs used to control gastric acid to allow review of the two similar therapies and develop a PDL category that allows step therapies between the different classes of drugs. Our medical directors and pharmacists will work with the Department to determine how best to develop a new or changed medication class to meet the unique needs of West Virginia.

The clinical trials section consists of both table and text formats, depending on the type and amount of information about a particular topic. Pertinent clinical trials, with an emphasis on comparator trials are included, as well as safety trials, meta-analysis, indirect analyses (e.g. network analyses) and Cochrane Reviews. The process for reviewing the literature and including articles in the class review is methodical and unbiased. An English language literature search is initially done for each drug in the review using PubMed. The studies are reviewed and the abstracts are scanned to be certain the topic and information is appropriate for possible inclusion in the review. If the study is pertinent, the full-text of the study is obtained and kept on file. If review of the full text article or study confirms it meets criteria for inclusion to the class review, it is first added to the study table. This information includes: author(s), reference citation, and year of the study, level of evidence; design and comparators; sample size & duration; patient characteristics; assessed outcomes; results; and authors' conclusions & Goold comments.

Goold Comments and Level of Evidence ratings are two unique features included in our therapeutic class reviews. These proprietary elements were developed by the Goold clinical team to specifically meet the unique information requirements of our state clients and their respective Pharmacy and Therapeutics Committees. Goold comments are specific to the study reviewed and, when appropriate, include additional information about the study. For example, Goold comments may include information about specific limitations of the study or may include the effect size of a drug in a comparator trial by determining the number needed to treat (NNT). The Level of Evidence rating is performed for each study to categorize the quality of the study as well as to specify whether the outcome was a true clinical outcome (mortality, morbidity, quality of life) versus a proxy marker (blood pressure, cholesterol level). The Addendum to each TCR contains a chart explaining the Goold Level of Evidence (LOE) rating and the criteria for determining this, as well as definitions. The summary and the references are the last two sections of each class review. Information about the place in therapy of the medications is included in the summary. In addition, guidelines recommending certain medications may also be included in the summary section. Overall, the summary attempts to identify places in therapy for particular products in a class and outline if a specific product is more effective or safer than another medication in general or for specific populations or settings.

Once the entire review has been written, the entire review is edited by the writer, along with a final edit by one or both of the medical directors.

This process is used for both new class reviews and when updating older class reviews. When new drug products come onto the market, they are added to the class review, along with any additional studies found after a repeated search of the literature. When new information is added to the class review, the date of the latest change is added to the title page along with the date of the last literature search for the review. Any new text is highlighted in yellow to allow

the Department and Committee members to easily recognize new information since their last review of the class.

The goal of the therapeutic class reviews and related analyses is to assist Committee members in arriving at a rational assessment of what drugs represent the best value. Goold's experienced clinical and pharmaceutical staff provides a high-level analysis to determine the safety and efficacy of drugs within targeted therapy classes. It is of the utmost importance to make the P&T Committee aware of all clinically significant positive and negative drug attributes that could potentially affect the health of its members. It is critical to track PDL compliance and ensure that decisions made on preferred drugs are borne out through their utilization.

Our drug monographs and therapeutic class reviews are thoroughly researched and uniquely edited to provide the Drug Prior Authorization Committee with enough information to decipher differences in drugs without being overwhelmed with irrelevant details. Evidence-based guidelines are instrumental to the ultimate success of PDL Management.

We give a preferential rating and consideration to clinical trials designed appropriately in accordance with the goal of the study and to those studies which include clinically relevant outcomes data as opposed to proxy measures or other intermediate variables. A key to this rating scale is included at the end of every Therapeutic Class Review that reviews specific studies. In our evaluation of studies, we use a formal clinical evaluation process to assist in reviewing relevant literature. This process evaluates a number of characteristics including:

- Population studied (inclusion / exclusion criteria);
- Treatments compared (active versus placebo comparators, bio pharmaceutics);
- Experimental design detail (controls, randomized);
- Data collection (reproducible);
- Bias control (randomization and blinding);
- Results (measures, drop outs, and assessment of clinical relevance in the context of statistical findings); and
- Data analysis (statistical tests, clinically significant).

Our pharmacists are adept at reviewing studies for the level of evidence and we have found that our evidence ratings have a high level of reproducibility and inter-rater reliability. All class reviews are also reviewed by one or both of our Medical Directors prior to being submitted for approval to our clients. Our evidence rating scale of 1a, 1b, 2 and 3 corresponds to a level of evidence that would be considered: good, fair or poor, with additional information provided regarding whether the higher quality studies provide information about true clinical versus proxy outcomes. We feel that this critical analysis of literature presented in a clear, straightforward rating system is very valuable to our client states and their P&T Committees.

Goold most commonly determines that a study is not appropriate for inclusion in our therapeutic class reviews for one of the following reasons:

1. Study was focused only on use for non-FDA approved/not compendia recognized indications;
2. Small or inadequate sample size;
3. Study limited to information on cost ;
4. Low level of evidence , such as case reports/series or expert opinions;
5. Study uses a different dosage form than what is included in the class (e.g. study utilizes IV dosage while the oral formulation is discussed in the review);
6. Non-human studies;
7. Studies that do not have full-text available; and/or
8. Unable to obtain full-text (e.g. obscure journal; extremely low impact journal not typically available.)

In summary, Goold's class reviews are designed and written for the purpose of supporting Preferred Drug List determinations. They are written in an unbiased fashion by experienced pharmacists using extensive information resources including full text journal articles, textbooks, and multiple, respected sources of medical and drug information. New information is always reviewed by the Medical Directors prior to being presented and the updates are done at least annually or as needed to incorporate new drugs or new information. The proprietary evidence rating, including an indication of the type of outcome measured, has been developed to meet the unique needs of our state clients and their Committees to inform their Preferred Drugs List determinations. In addition, **we have found that a "one size fits all" class review format does not work for every therapeutic class.** In conjunction with our clients, certain reviews are tailored to suit the class being considered. For example, there is little practical utility to extensive reviews of the studies relating to all of the different birth control preparations available. Research on the efficacy of the various preparations and various studies related to their positive and negative effects is voluminous, but a detailed review of this extensive database would be of little help in determining relative PDL positioning for these products. Instead, we developed a review that focuses on the various types of preparations available (biphasic, triphasic, progesterone only, etc.) and discusses the considerations between the types of these preparations. We then worked with our clients to propose to their Committee a cost effective selection of the various types of birth control agents for preferred status, making sure that an appropriate selection of products was available. We will be proactive in working with the Bureau to ensure that the class reviews provided meet the unique needs of West Virginia.

Please see Exhibit B for a Sample of our Therapeutic Class Monograph.

4.1.8.4 Vendor shall review new drugs or drug formulations or products using a schedule agreed upon by the Vendor and the Bureau, at a minimum quarterly.

Goold has over seven years of experience conducting comprehensive annual drug class reviews. Our review schedule allows for off-cycle reviews of new products on an as needed basis. New drugs and new indications are routinely assessed weekly as part of normal PDL maintenance

activities. New drug monographs are created promptly and net pricing is immediately calculated so that interim PDL determinations can be made. New indications are assessed relative to other products with similar indications so that PDL status can be reconsidered and/or PA criteria adjusted. In advance of each quarter's P&T Committee meeting, Goold's clinical staff will review with BMS a proposed list of new monographs, which will be presented for consideration at the next scheduled meeting.

In summary, Goold will work with BMS to develop a schedule for review of new drugs or drug formulations which will, at a minimum, be quarterly.

4.1.8.5 Vendor shall advise the Bureau monthly and the P & T Committee at regularly scheduled meetings on comparative value of new drugs or drug formulations or products that fall into categories already established on the PDL and PPL.

In cases where a new drug or formulation enters a category that is already established on the Preferred Drug List or Product List, Goold will prepare a new drug monograph and provide a recommendation based on the comparative clinical efficacy of other drugs in the category, in addition to cost comparisons. As part of the routine SSDC process, supplemental rebates will be sought as appropriate and included in pricing considerations. We will prepare cost analyses for consideration of the Bureau at least monthly and for distribution to the Committee members at regularly scheduled meetings. Other brand name drugs will be included if an appropriate supplemental rebate (SR) is obtained from the manufacturer. We will include in these analyses considerations regarding current contract requirements within the category and upcoming changes in the category such as predicted new generic or branded entrants. These analyses will enable informed recommendations that balance clinical and cost considerations, based on current and forecasted conditions in the category.

At a detailed level, all cost analyses are performed comparing net costs within PDL classes to help decide best values. Most drugs, especially the one unit per day drugs, are easily compared. Other drugs require adjustments in order to arrive at fair comparisons. We determine the most frequently prescribed courses of therapy and model out net costs to arrive at net cost per course of therapy.

The last major component of the cost analysis relates to market share. The Committee needs to know how many people are using (tentatively) preferred and non-preferred drugs. They also need to know if any data exists that would help predict the probability of success if drug A was made preferred and drug B non-preferred. This data assists the Committee in making sound, well-informed decisions.

4.1.8.6 Vendor shall incorporate multisource drugs into the PDL, maximizing the use of the most cost-effective drugs for inclusion on the PDL.

Goold routinely assesses the relative cost and availability of multi-source drugs. We review pricing on a continuing basis to make sure our client states are aware of savings opportunities when new multisource drugs become available or, as we have seen more recently, have significant price increases that warrant reconsideration of a PDL categories preferred choices. Many PDL drug categories are well suited to generic-first design requirements and Goold is experienced at leveraging multisource drugs when it is clinically appropriate and fiscally prudent. However, there have been recent examples of rising generic drug prices, such as the erythromycins, that emphasize the need for proactive monitoring of relative prices within PDL categories. West Virginia will benefit from our industry-leading, proven practices and procedures that will actively monitor for opportunities to take advantage of net price differences between similar drugs both based on actual drug price changes, but also based on predictions regarding upcoming multisource entries to the PDL categories.

Although the flurry of patent expirations of major drugs has abated somewhat over the last year, closely tracking patent expirations and applications for new generic approvals allows prediction of the entry of lower cost generics to the market. It is essential that these upcoming generics be tracked and planned for. The entry of a lower cost generic to the market in the following year may actually affect PDL decisions in the current year, as the Bureau may want more people to be using the drug scheduled to become generic in the near future, rather than accepting a more generous supplemental rebate offer for a drug that has no generic on the horizon.

It is also critical that net costs after all rebates be tracked closely, and for PDL determinations to include this information. It has become common for many new generics to be produced with an exclusive license or by a very limited number of labelers. These generics are often *higher* priced on a net basis than the existing brand formulations for a period of time. It is critical that this pricing be followed, and the PDL switch to the generic not be made unless, and until, it is cost effective to do so. It is appropriate to prefer the generic formulation only when it is priced like a generic. Goold will continue to incorporate multisource drugs into the PDL, maximizing the use of the most cost-effective drugs for inclusion on the PDL.

4.1.8.7 Vendor shall advise the Bureau of new drugs appearing on the weekly reference drug data file including, but not limited to, the drug name, PDL category, its indication, the overall value of the drug and its impact to the Medicaid pharmacy program.

Goold provides preferred drug list services to multiple Medicaid clients and West Virginia will benefit from our established tools, procedures and experienced account staff in providing information about new drugs appearing on the weekly reference drug data file. This will include important details including, but not limited to the drug name, its PDL category,

indication, the overall value of the drug and considerations regarding the drug's potential impact on the Medicaid pharmacy program. Information regarding potential supplemental rebate considerations is often included as appropriate. The format and method of delivery of this information will be proposed and approved by BMS in advance. A sample format for this report is provided below.

Reference Drug Data File				
Drug Name	***PDL Category***	***Indication***	***Overall Value***	***Impact on Program***
[Example]	[Example]	[Example]	[Example]	[Example]
[Example]	[Example]	[Example]	[Example]	[Example]
[Example]	[Example]	[Example]	[Example]	[Example]

Table 2: Sample Drug Data File Table

SSDC-Negotiated Supplemental Rebates and Financial Analysis

4.1.8.8 Vendor will provide to the Bureau and the members of the P & T Committee SSDC-negotiated supplemental rebates and financial analysis information for each therapeutic class or specific drugs or products under review by the Bureau and P & T Committee. Drug and product rebate information shall be kept confidential as required by 42 USC 1396r-8(b) (3) (D) or future update(s).

Goold is the current vendor for the SSDC and has been for the past nine years, having recently re-procured this contract. We will continue to provide to all members of the P&T Committee and BMS staff, as appropriate, SSDC-negotiated supplemental rebates and financial analysis information for each therapeutic class or specific drug under review by the P&T Committee. Goold acknowledges that all drug rebate information must be kept confidential as required by 42 USC 1396r-8(b) (3) (D).

4.1.8.8.1 Vendor will provide financial information for the P & T Committee for each therapeutic drug or product class at least annually, and new drugs or products as they are reviewed by the Bureau or P & T Committee at least quarterly, in a format that contains at a minimum, drug or product class, drug or product name, brand or generic status, current PDL or PPL status, average quantity dispensed per prescription, net cost after all rebates per prescription.

Goold will comply with all of the requirements outlined in Section 4.1.8.8. Goold will perform and provide to all members of the P&T Committee and BMS staff, as appropriate, SSDC-negotiated supplemental rebates and financial analyses, in the form of cost sheets, for each therapeutic class and specific drug under review by the P&T Committee. This information will be provided for each therapeutic class at least annually and financial information on new drugs will be prepared for review by the P&T Committee at least quarterly. The format will, at a minimum, include the drug class, drug name, brand/generic status, current PDL/PPL status, and utilization information, including average quantity dispensed per prescription, and net cost (after all rebates) per prescription. Recommendations will be made in all therapeutic classes for inclusion or exclusion of each drug, based upon clinical factors, net cost, past utilization, forecasted utilization and expenditures. Goold recognizes the confidentially of rebate information and will continue to be vigilant with regard to keeping this information confidential as required by 42 USC 1396r-8(b)(3)(D).

Most often, Goold's cost sheets are designed to follow the PDL so that one can easily transition from the cost sheets to the PDL when reviewing recommendations. While this is the typical approach, our cost sheets can be developed in any way necessary. In states that use First Data Bank as their drug reference, the cost sheets are most frequently designed using the Enhanced Therapeutic Classification (ETC) to identify the drug categories and include all Generic Sequence Numbers (GSNs) and/or NDCs that are managed and fall under that ETC on the PDL. The cost sheets could also use Hierarchical Ingredient Codes (HIC) or the Ingredient List Identifier (HICL) if the need arises.

Rebates (CMS and supplemental), offset amounts, FULs, MACs and West Virginia's utilization will be pulled in and reported on the cost sheets and modeling analyses. In cases where there is

no historical rebate data that will allow net cost computations, we will use estimations based on our understanding of WAC and its relationship to AMP, especially for newly released brand drugs. A draft form of the cost sheets will be provided, along with a discussion with Goold's clinical staff, as part of the overall process to gain approval for the list of drugs to be included in the cost modeling.

Goold will be able to present various cost sheets and models that will show what the net cost and projected utilization based on how the drug will be placed on the PDL depending on which rebate offer is selected. Cost sheets will be prepared showing the various offers submitted and how we anticipate the net spend and utilization will flow based on various factors. These factors include variables such as anticipated PDL compliance, percent of population using drugs, use by age groups, location, eligibility category and medical conditions/diagnoses. This way, the State will have all the information needed to make an informed decision as to whether or not to take the larger supplemental rebate offer that is available only if multiple states accept.

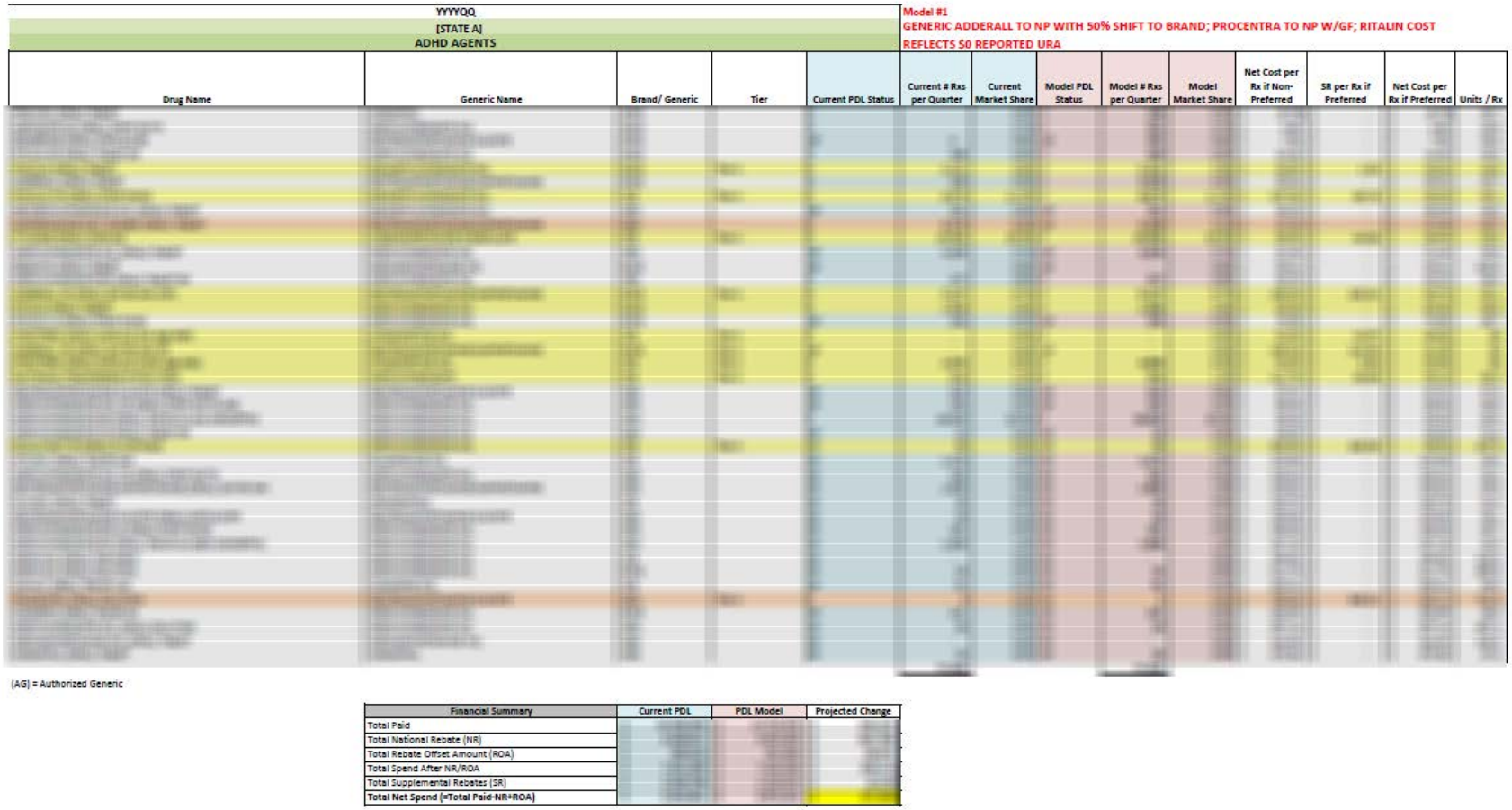
Results of supplemental rebate negotiations and savings analyses of specific drugs/drug categories will be provided by Goold on a mutually acceptable schedule. At a minimum, they will be prepared before each P&T Committee meeting. We will present estimated savings in a manner agreeable to the Bureau. This will involve estimations based on both current and projected utilization.

Of course, pharmacoeconomic information is not the only factor that must be considered when making PDL decisions. As the provider of a full scope of pharmacy benefit management services, Goold also has the capability to bring to light relevant clinical ramifications that must be considered as well. For example, medical claims data (if made available to Goold) and clinical information will be presented and reviewed prior to making recommendations on the PDL placement of a drug. It does little good to make a recommendation that saves money in one category but increases expenditures in another. That is why Goold takes a holistic approach to guiding clients through new SR offers and PDL changes.

An important distinction of Goold's financial models is that they do not represent a report of what has happened in a previous quarter (there are reports for that as well, of course) but rather, a projection of what will happen in subsequent quarters. While recent utilization and rebate data forms the foundation of our models, future changes that are likely to affect drug costs/utilization are factored into the models. One example of such a change is the provision of the Affordable Care Act (ACA) that applies higher Federal rebates that are fully offset to line extension drugs. CMS has not yet specifically identified what drug products are line extensions, but has published the proposed methodology for the implementation of this provision. Goold incorporates this methodology into the financial models so that the net cost of drugs affected by the provision can more accurately be projected. Goold also closely monitors the brand and generic drug pipeline, trends and anomalies in the Federal rebates so that those factors can be incorporated into our financial projections.

Our financial models are “live” and can be generated on an ad hoc basis when the need arises, such as when there are changes in the market (new brand drugs, new generics, etc.) or significant changes in drug prices or rebate amounts. They provide the ability to determine the financial impact of supplemental rebate offers, including positioned/tiered offers (such as 1 of 1 preferred brands, etc.). They also incorporate the critical component of likely shifts in market share resulting from various PDL decisions. ***Our clinical staff leverages their experience, over a decade in modeling and monitoring state Medicaid PDLs, to estimate market shifts and the resulting financial impact.***

An example of the Cost Sheets that Goold can provide is included on the following page. These reports demonstrate a more current utilization and more current and accurate pricing and rebate information for a State. West Virginia can easily see and compare net costs and rebate data for all the drugs in one glance and see the summary of the financial impact of the PDL decision. The Cost Sheets clearly present the impact of the SR offers on the net cost of drugs and on net expenditures.



YYYYQQ
[STATE A]
ADHD AGENTS

Model #1
GENERIC ADDERALL TO NP WITH 50% SHIFT TO BRAND; PROCENTRA TO NP W/GF; RITALIN COST
REFLECTS $0 REPORTED URA

Drug Name	Generic Name	Brand/ Generic	Tier	Current PDL Status	Current # Rxs per Quarter	Current Market Share	Model PDL Status	Model # Rxs per Quarter	Model Market Share	Net Cost per Rx if Non-Preferred	SR per Rx if Preferred	Net Cost per Rx if Preferred	Units / Rx

(AG) = Authorized Generic

Financial Summary	Current PDL	PDL Model	Projected Change
Total Paid			
Total National Rebate (NR)			
Total Rebate Offset Amount (ROA)			
Total Spend After NR/ROA			
Total Supplemental Rebates (SR)			
Total Net Spend (=Total Paid-NR+ROA)			

Figure 2: Excerpt from Cost Sheets

YYYYQQ
[STATE A]
ANTICOAGULANT

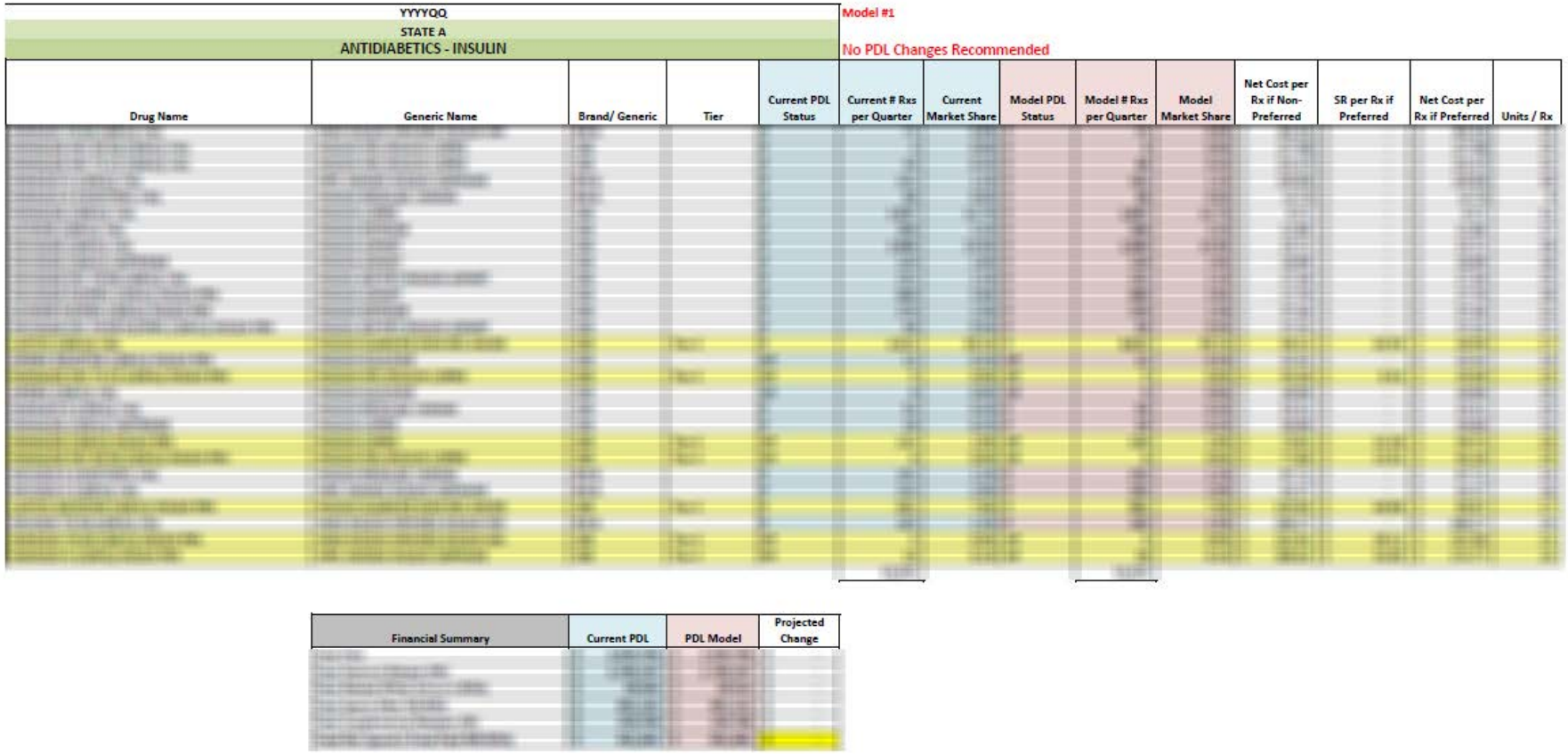
Model #1
COUMADIN TO P; LOVENOX TO P (ADJUSTED FOR REMOVAL OF 10 DAY LIMIT), GENERIC TO NP (WITH 70% SHIFT)

Drug Name	Generic Name	Brand/ Generic	Tier	Current PDL Status	Current # Rxs per Quarter	Current Market Share	Model PDL Status	Model # Rxs per Quarter	Model Market Share	Net Cost per Rx if Non-Preferred	Supplemental Rebate per Rx if Preferred	Net Cost per Rx if Preferred	Units / Rx
[redacted]													

(AG) = Authorized Generic

Financial Summary	Current PDL	PDL Model	Projected Change
Total Paid			
Total National Rebate (NR)			
Total Rebate Offset Amount (ROA)			
Total Spend After NR/ROA			
Total Supplemental Rebates (SR)			
Total Net Spend (=Total Paid-NR+ROA)			

Figure 3: Excerpt from Cost Sheets, continued


YYYYQQ
STATE A
ANTIDIABETICS - INSULIN
Model #1
No PDL Changes Recommended

Drug Name	Generic Name	Brand/ Generic	Tier	Current PDL Status	Current # Rxs per Quarter	Current Market Share	Model PDL Status	Model # Rxs per Quarter	Model Market Share	Net Cost per Rx if Non-Preferred	SR per Rx if Preferred	Net Cost per Rx if Preferred	Units / Rx

Financial Summary	Current PDL	PDL Model	Projected Change

Figure 4: Excerpt from Cost Sheet, continued

4.1.8.8.2 Vendor shall incorporate SSDC negotiated pricing into its PDL and PPL business models, analyze SSDC pricing, and produce recommendations for a PDL and PPL using SSDC negotiated pricing on an annual basis for review of the entire PDL and daily as information becomes available.

As the vendor for the SSDC, Goold has access to and is completely knowledgeable about the details of SSDC pricing. Goold will incorporate SSDC-negotiated pricing into its PDL/PPL business model, pricing analyses, and all financial models provided to BMS to produce PDL and PPL recommendations. There are many synergies that can be realized for West Virginia to have the same vendor negotiate supplemental rebates and also design the Preferred Drug List.

Goold is the Experienced SSDC Vendor:

- Goold negotiates rebates for Iowa, Maine, Mississippi, Oregon, Utah, Vermont, West Virginia, and Wyoming
- Representing approximately 3,000,000 covered lives;
- Full PDL autonomy;
- Total drug spend $1,550,555,930;
- Diabetic supply negotiations;
- Terms of pool participation are set by the member states; and
- Goold has negotiated nine annual pool negotiations to date.

If selected as the successful bidder for West Virginia, Goold will provide supplemental rebate negotiations and saving analyses of specific drugs/drug categories to the State. We will present estimated savings in a manner agreeable to the State on at least an annual basis and, as frequently as daily, if requested by the State. This will involve estimations based on both current and projected utilization. Depending on the Bureau's preference, we can present a simple summary version of estimated savings within each class, reflecting shifts in market share utilization, average blended net cost per unit, and supplemental rebates. These summaries can accompany the more complex analysis that incorporates all utilization, including that of minor drugs.

4.1.8.8.3 Vendor shall keep confidential SSDC pricing information and keep SSDC pricing information separate from the Vendor's other lines of business.

As an experienced vendor to the SSDC, Goold is familiar with the need to keep all confidential SSDC pricing information separate from other lines of business. Our System is specifically designed to the SSDC confidential needs and we will continue to provide this service successfully.

Goold agrees to maintain manufacturer price and rebate information as strictly confidential in accordance with State and Federal statutes and requirements. Goold will maintain the Bureau's supplemental rebate agreements/contracts separately from our other clients. Goold is committed to protecting the confidentiality, integrity, privacy and physical security of Protected Health Information (PHI), confidential information, data information, personnel, and supporting technological information resources created, obtained by, and provided to the organization. Goold will execute all appropriate business associate agreements as required by the Health Insurance Portability and Accountability Act (HIPAA).

Preferred Drug List

4.1.8.9 Vendor shall manage the Bureau's PDL and PPL, including but not limited to, the production of documents and data needed for claims processing, and PDL updates as recommended by the P & T Committee that are approved by the Bureau and the Secretary of the West Virginia Department of Health and Human Resources (DHHR) or PPL updates as approved by the Bureau.

Goold considers the PDL to be one of the most important aspects of a high quality pharmacy solution. We take great pride in the PDL's we have helped to create and maintain.

Efficient application of the PDL and PPL is an area of excellence for Goold. Our interface system, used by our clinicians to help track, appropriately report on, and send PDL/PPL status to the POS vendor, has been built to offer the maximum amount of functionality possible. ***We have learned that a highly intelligent and flexible system reduces both administrative costs and provider burdens, while optimizing net savings for clients.*** A carefully designed PDL/PPL, in combination with PA's and supplemental drug rebates, allow state Medicaid Programs to realize significant savings without sacrificing clinical outcomes. We have done this successfully in the States of Maine, Iowa and for the State of West Virginia.

Goold will produce documents and data files required for claims processing, as well as PDL updates from P&T Committee meetings, which have been approved by the Bureau and the Secretary of DHHR.

4.1.8.10 Vendor must ensure that the PDL and PPL are in compliance with all applicable Federal and State statues and regulation and the State Plan approved by CMS.

As stated previously, it is Goold's overall belief that a PDL should provide a selection of preferred drugs and products that allows primary care physicians to care for the majority of their patients without prior authorization requests being necessary on a daily basis. The driving force for or against recommending PDL/PPL placement is the drug's unique clinical contribution. Goold will assist the State of West Virginia in refining and managing a PDL and PPL so that it is CLINICALLY SOUND, COST-EFFECTIVE AND MINIMALLY DISRUPTIVE to West Virginia Medicaid members and their providers. In addition, Goold will ensure that the PDL/ PPL is in compliance with all Federal and State statutes and regulations, and the CMS-approved State Plan.

4.1.8.11 Vendor shall prepare the PDL and PPL documents electronically in a file format that is compatible with the West Virginia Office of Technology's currently supported versions of Microsoft Office® Suite to be displayed on the Bureau's website for interested parties.

Goold is experienced and familiar with providing necessary PDL/PPL documents to our client States and will prepare all PDL documents in a file format compatible with the WV Office of Technology, currently supported in versions of Microsoft™ Office Suite, for display on the BMS website for interested parties.

4.1.8.12 Vendor shall comply with the standards of the Bureau and the Bureau's business partners for drug and product data-file maintenance including, but not limited to, the use of therapeutic class codes, enhanced therapeutic class codes, generic sequence numbers, prior authorization requirements, injectable or other dosage form indicators, replacement or change files as desired, catch-up files, or any other drug and product data file standards required by the Bureau and the Bureau's business partners.

Goold agrees to comply with the standards of the Bureau and its business partners for all drug and product data-file maintenance including, but not limited to:

- The use of therapeutic class codes;
- Enhanced therapeutic class codes;
- Generic sequence numbers;
- Prior authorization requirements;
- Injectable or other dosage form indicators;
- Replacement or change files (as desired);
- Catch up files; and
- Any other drug or product data file standards required by BMS.

4.1.8.13 Vendor shall comply with the requirements of the Bureau and the Bureau's business partners for weekly, monthly, and quarterly file deliveries.

Goold continually works with our client States and is familiar with requirements to provide frequent file deliveries. We will utilize our Secure File Transfer Protocol (SFTP) site which we have used in the past to transmit files on behalf of West Virginia. We will work with the Bureau and its partners to provide weekly, monthly and quarterly file deliveries in a method that is requested by the State.

4.1.8.14 Vendor shall establish and maintain an interface with the Bureau's fiscal agent for secure document and file exchanges on a weekly basis.

Goold works cooperatively with various Fiscal Agents in order to provide secure document and file exchanges on a schedule decided by the State. We currently do this with Molina in Maine, Noridian in Iowa, HP in Georgia, the State in Utah, Xerox in Wyoming and Mississippi and have done so for West Virginia in the past as well. We will provide the PDL/PPL data files for exportation to external sources, including, but not limited to, the Bureau’s Fiscal Agent.

Our highly trained network services staff has experience establishing and maintaining data interfaces with external third parties. This includes network infrastructure for all internal and external connectivity and the Secure File Transfer Protocol (SFTP) processes employed at Goold for operating data interfaces. In addition they automate data feeds, create automated subroutines to drive file processes, conduct file transfer quality control, support Data Warehouse and development staff for code deployments, and provide ongoing network support for internal staff, server and network maintenance and monitor systems operations and up-time. These resources will be available and used for the West Virginia project.

The following tables demonstrate Goold's experience with integrating with various vendors, both currently and in the past.

Vendor	Services	State
Molina	MIHMS	Maine, West Virginia
Noridian	MMIS	Iowa
Xerox	MMIS	Iowa
State administered legacy system	MMIS	Utah
CNSI	MMIS	Utah *(currently developing interface)*
HP Enterprise Services	MMIS	Georgia
HP Enterprise Services	MMIS	Alabama

Table 3: Goold's List of MMIS Integrations

In the past, Goold was integrated with the following MMIS implementations:

Vendor	Services	State
State administered mainframe	MMIS	Maine
CNSI-built system	MECMS	Maine
ACS (now Xerox)	MMIS	Iowa

Table 4: Goold's List of Past Integrations

Goold integrated with the following PBM/POS Systems to support Rebate services contracts:

Vendor	Services	State
Molina (Unisys)	POS	West Virginia
Catamaran (SXC)	POS	Georgia
Xerox	POS	Mississippi

Table 5: Goold's List of PBM/POS Rebate Service Integrations

Goold was one of the first PBMS vendors to successfully integrate and invoice rebates for Managed Care Organization (MCO) encounter claims. Goold is currently interfacing with over 30 MCO vendors.

Goold is currently working on deployment of a complete PBMS solution for Illinois and Vermont Medicaid. The vendors for integration under these contracts are:

Vendor	Services	State
State administered mainframe	MMIS	Illinois
HP Enterprise Services	MMIS	Vermont
Catamaran (SXC)	POS	Vermont

Table 6: Goold's List of MMIS Integrations In-Progress

4.1.8.15 Vendor shall comply with the requirements of the Bureau and the Bureau's business partners relating to the method of file exchanges, i.e., "pushing" or "pulling" data.

Goold can provide file exchanges in the method requested of the State. We are experienced in both “pushing” and “pulling” data and will comply with the Bureau’s requirement to provide file exchanges to BMS and its partners in such a manner.

4.1.8.16 Vendor shall apply an effective date and a unique version number for each PDL, PPL, and other business documents.

Goold is familiar with the State’s document identification system and will ensure that each PDL, PPL and other business document submitted has an effective date and a unique version number.

4.1.8.17 Vendor shall ensure that the quality of all files delivered to the Bureau and the Bureau's business partners contain error-free data.

Goold’s staff is meticulous in providing detailed documents and reports to our clients and making every effort to ensure that they are error-free. For example, our dedicated personnel have worked collaboratively with the Member States of the SSDC to create reports that are held to very high formatting and data standards.

We strive to provide all of our client States and their business partners with documents that are error-free and will work with the State of West Virginia to provide the same high-level of service.

4.1.8.18 Vendor shall update the PDL document after each P & T Committee meeting and when changes are made to the PDL, at a minimum monthly. The PPL document shall be updated weekly if requested by the Bureau.

Goold agrees to update the PDL after each P&T Committee meeting, as well as when major changes are made to the PDL, at a minimum of monthly, and provide the list to the State. The PPL may be updated as often as weekly, if requested, and when these updates occur, Goold will supply the updated version to the State.

4.1.8.19 Vendor shall assist in development of step-care therapy and prior authorization (P A) criteria to promote appropriate utilization and to enhance PDL compliance and achieve optimal savings.

Pharmacy prior authorization (PA) is a successful cost saving strategy for Medicaid programs. Our approach to Prior Authorization criteria development allows Medicaid pharmacy program managers to reduce costs by requiring physicians to receive authorization before prescribing cost restrictive and/or clinically questionable drugs to patients. This process allows our customers to limit expensive pharmaceuticals to those patients for whom the drug is therapeutically necessary. At the same time, we ensure that the majority of primary care

providers can prescribe the majority of the drugs they need to treat their patients without requiring prior authorizations. Goold will serve in an advisory role in developing and maintaining PA criteria and step-care therapy to promote appropriate drug utilization, enhance PDL compliance and achieve optimal savings. We have often had success in discussing potential step-care therapy and PA criteria with the Bureau in advance of signing a supplemental rebate offer, such that approved criteria can be incorporated into the supplemental rebate offer.

4.1.8.20 Vendor will update the PDL document when PA criteria is changed or updated by the Bureau and/or the DUR Board and issue an updated version for web posting, at a minimum monthly.

When updates are necessary to the PDL document due to PA criteria that has been changed or updated by the DUR Board, Goold will provide an updated version to the Bureau, at least monthly, for web posting.

PDL Data Files

4.1.8.21 Vendor shall provide the PDL and PPL data files in an electronic file format that is compatible with the WV Office of Technology's currently supported versions of Microsoft Office® Suite.

Goold will provide the PDL and PPL data files to external sources, including, but not limited to the Bureau's Fiscal Agent, in a format that is compatible with the WV Office of Technology currently supported versions of Microsoft Office™ Suite.

4.1.8.22 Vendor will provide PDL and PPL data files in accordance with a schedule agreed upon by the Bureau and the Vendor, at a minimum of weekly.

Goold will provide PDL and PPL data files in accordance with a schedule agreed upon by BMS and Goold, at a minimum of weekly.

PDL Communication and Documentation

4.1.8.23 Vendor shall assist the Bureau in developing documents and responding to inquiries regarding the PDL and PPL.

Goold will work with the Bureau to assist with developing documents and responses to inquiries regarding the PDL and PPL in addition to assisting with any State Plan Amendments required by changes to the PDL and PPL. Our staff has experience in doing this, not only for our other client States, but for West Virginia as well. We will use this past experience to provide excellent collaboration with BMS during this contract.

4.1.8.24 Vendor will draft letters and/or make telephone calls that respond to inquiries from providers and other interested parties concerning the PDL and PPL within five (5) business days of the receipt of the inquiry.

Goold will draft letters and/or make telephone calls in response to inquiries from providers and other interested parties concerning the PDL and PPL within five (5) business days of the receipt

of the inquiry. Our staff is experienced at providing timely, helpful responses to inquiries from any interested stakeholders.

4.1.9 Supplemental Rebate Administration

4.1.9 Vendor shall work cooperatively with the Bureau, its SSDC partners, and the Bureau's fiscal agent to assist the State in drug supplemental and product rebate contract administration.

Goold excels at working cooperatively with numerous vendors and stakeholders in multiple states. We will work cooperatively with BMS, the SSDC partners, and the Bureau's Fiscal Agent to assist the State in supplemental rebate contract administration. As the current SSDC vendor, we are ideally positioned and uniquely qualified to provide coordinated services.

4.1.9.1 All rebate agreements or contracts shall be made between the West Virginia Department of Health and Human Resources (DHHR), Bureau for Medical Services, and manufacturers using the Bureau and/or CMS approved templates.

Our approach to rebate negotiation on behalf of the SSDC is completely transparent. Goold is not party to the rebate agreements we negotiate, and as such, all supplemental rebate agreements/contracts will be made between the West Virginia Department of Health and Human Resources (DHHR), Bureau for Medical Services, and the pharmaceutical manufacturers using the CMS approved template.

4.1.9.2 Rebate contracts must be in an electronic file format that is compatible with the WV Office of Technology's currently supported version of Microsoft Office® Suite.

Goold is exclusively familiar with providing the rebate contracts to the State, and other client States, and will make these documents available in a file format that is compatible with the WV Office of Technology currently supported versions of Microsoft™ Office Suite.

4.1.9.3 Vendor shall work cooperatively with SSDC partners to accurately determine supplemental drug or product rebate contract data.

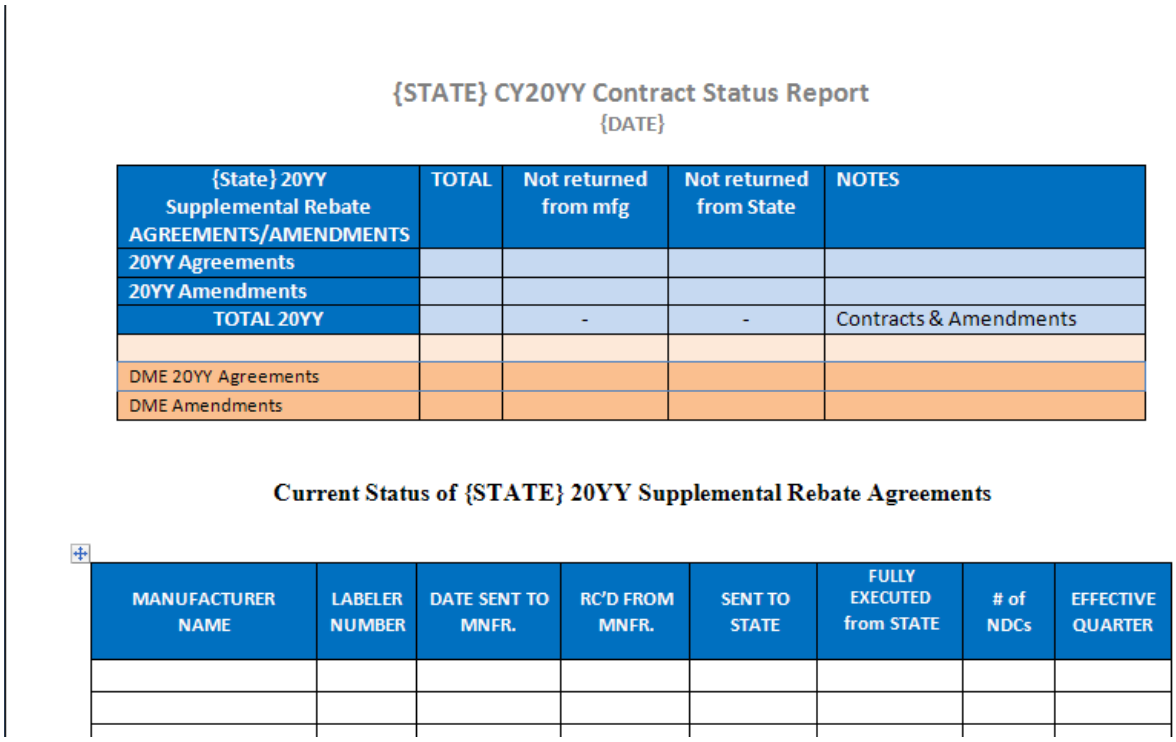
As the SSDC vendor, Goold has experience working with SSDC partners to accurately determine supplemental rebate contract data; West Virginia will continue to benefit from this relationship

4.1.9.4 Vendor shall produce and facilitate the signing of supplemental drug rebate or product rebate contracts with manufacturers, the Bureau, and the West Virginia DHHR.

It can be surprisingly complex to track dozens of contracts and amendments as they move through the process requiring multiple signatures. Goold will produce and facilitate the signing of supplemental rebate contracts with pharmaceutical manufacturers, the Bureau and the DHHR. We will use our experience to provide a focused resource that will attend weekly status meetings and update the status of all contracts and amendments currently in process.

4.1.9.5 Vendor shall track contracts and documents at all points from origin to completion.

Goold Rebate Administration (Rebate Admin) is the web-based secure tool that is used to create, process, and track all Supplemental Rebate Agreements/contracts/and amendment documents from start to completion. Tracking begins as soon as the document is sent to the manufacturer and continues until the fully executed documents are mailed back to the manufacturer. Rebate Admin includes a log of the shipping tracking number for a full audit trail of delivery recipient and delivery date. A monthly Contract Status report (shown in the example below) will be provided to BMS to report the current year's contract activity.



{STATE} CY20YY Contract Status Report
{DATE}

{State} 20YY Supplemental Rebate AGREEMENTS/AMENDMENTS	TOTAL	Not returned from mfg	Not returned from State	NOTES
20YY Agreements				
20YY Amendments				
TOTAL 20YY		-	-	Contracts & Amendments
DME 20YY Agreements				
DME Amendments				

Current Status of {STATE} 20YY Supplemental Rebate Agreements

MANUFACTURER NAME	LABELER NUMBER	DATE SENT TO MNFR.	RC'D FROM MNFR.	SENT TO STATE	FULLY EXECUTED from STATE	# of NDCs	EFFECTIVE QUARTER

Figure 5: Contract Status Report

The following screenshot is an example of the Contract Dashboard with displays the Active Contracts, Unverified Manufacturers, Pending Verifications, and Verified Manufacturers. This is an at-a-glance view of contracts, their signature process status and manufacturer contact information.

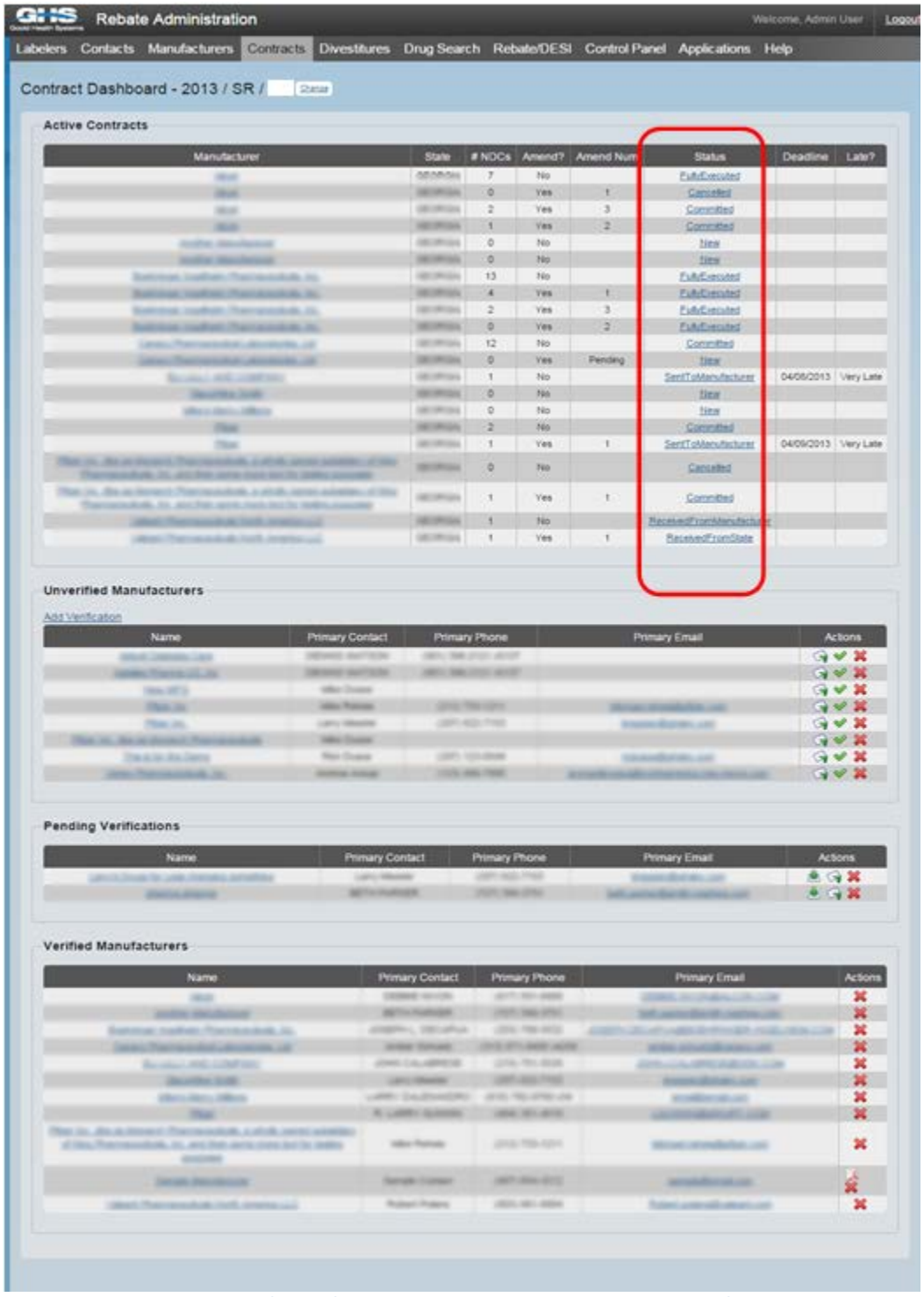


Figure 6: Rebate Administration Contract Management Screen Shot

As outlined above, Goold recognizes the importance of contract tracking and does a complete and thorough job at it. We will track contracts and documents from origin to completion.

4.1.9.6 Vendor shall assume administration of existing supplemental drug and product rebate agreements and/or contracts.

Goold is experienced in the migration of existing contracts. Documents will be scanned and data files will be integrated and stored in the Goold data warehouse for use in the invoicing and SR management process.

Goold will draw upon our past experience to administer existing supplemental rebate agreements and contracts. We have an entire process and dedicated staff whose main concentration is on the proper administration of rebate agreement and contracts. Our process includes working collaboratively with States to define the Contract Management Business Rules document used for contract processing, as demonstrated in the example below. This process has proven successful for many of our States and will be provided to West Virginia as well.

Goold Health Systems

Sample Contract Management Business Rules for the State of XX: 20XX Contracts

Receiving and Processing Contracts

Item	Standard Required
Cover Letters	**Not allowed.** Inform manufacturer that cover letter needs to be rescinded in order for the contract to be forwarded on to State for execution.
Manufacturer Letters	**Not allowed.** An assignment letter from the manufacturer requires a new Supplemental Rebate Agreement to be signed (such as product acquisitions).
Deadline	Manufacturers will be given twenty-one days (21) from the date the contract is sent to them to have it partially executed and returned to GHS for processing.
Handwriting on contracts	No handwriting is permitted on contracts with the exception of the signature field, date and FEIN.
Requests for changes to the contract outside of corrections to name, address etc.	None permitted. Changes requested will be logged and presented to the Department after all SRAs are returned for their consideration when drafting a new SRA. Changes requested to Covered Products following SRA execution will follow Amendments, Assignments and Termination contracting procedures, as outlined below.
Request for changes to the comment field on Attachment B	Not permitted without the express permission of the Department.
Other	State specified instructions. Contracts must include a Confidential watermark on all pages. Amendments must refer back to tracking number of original SRA.
Contracts sent to State for signature	On a weekly basis, or as requested by the Department.
Contracts signed by	**Signatory Name, Title, Department Name.**
Contracts sent to	State Contact Name. Title Agency Name Street Mailing address City, State, zip (Phone number Email: contact email
Quality Assurance	Contracts should not be forwarded to the Department without being checked that they are complete as per the requirements above. Incomplete or incorrect contracts should be sent back to manufacturers for their attention. Exceptions to these standards are not permitted without the permission of the Department.
Contract Tracking	Contracts should be tracked from their generation to the point of being fully executed in the Rebate Admin database.

Figure 7: Sample Contract Management Business Rules

4.1.9.7 Vendor shall maintain the Bureau's supplemental drug or product rebate agreements and/or contracts separately from its other clients, ensuring strict confidentiality and controls that meet Federal and State requirements.

Goold agrees to maintain manufacturer price and rebate information as strictly confidential in accordance with State and Federal statutes and requirements in accordance with Section 1927(b) (3) (D) of the Social Security Act. Goold will maintain the Bureau's supplemental rebate agreements/contracts separately from our other clients, as we have done in the past and

continue to do for our other client States. The pertinent data from the SRAs (specific NDCs and their respective rebate amounts) are maintained using our eROMS application, which is secured from unauthorized access according to our internal security plan job roles within our rebate services department.

Goold is committed to protecting the confidentiality, integrity, privacy and physical security of Protected Health Information (PHI), confidential information, data information, personnel, and supporting technological information resources created, obtained by, and provided to the organization. Goold will execute all appropriate business associate agreements as required by the Health Insurance Portability and Accountability Act (HIPAA).

Through user roles and permissions, access is managed to ensure only approved users can view the contract information stored in Rebate Admin, as demonstrated in the image below.

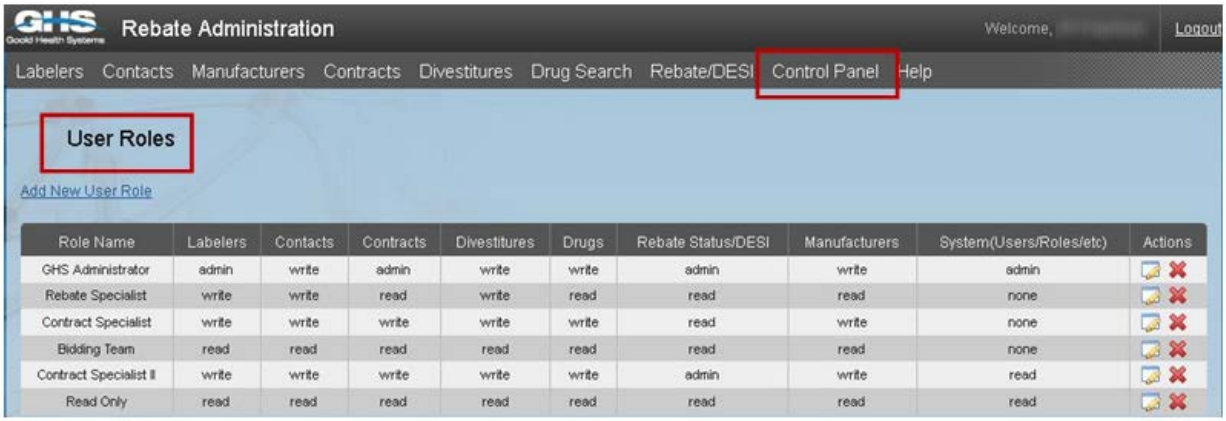


Figure 8: Rebate Admin User Roles

4.1.9.8 Vendor shall ensure that both the Bureau and manufacturers receive original signed agreements or contracts.

Goold assures that both BMS and manufacturers will receive an original signed agreement/ contract.

SURA and NDURA Files

4.1.9.9 Vendor shall provide electronic files containing calculated drug supplemental unit rebate amounts (SURA) and non-drug unit rebate amounts (NDURA), along with additional specified information to the Bureau and to the Bureau's fiscal agent. See Attachment C.

Goold has provided this service to BMS in the past. After referring to RFQ Attachment C-Supplemental Rebate Rate File, Goold agrees to provide a quarterly electronic file containing the calculated supplemental unit rebate amounts (SURA) and non-drug unit rebate amounts (NDURA), along with additional specified information to BMS and its Fiscal Agent.

Upon receipt of historical SR pricing, Goold will merge the pricing into the Goold SR Pricing file for use in invoice and collecting past rebates.

4.1.9.10 Vendor shall provide electronic files containing specific supplemental drug or product rebate contract and amendment data to the Bureau and to the Bureau's fiscal agent. See Attachment D.

Per RFQ Attachment D- Supplemental Rebate Contract File, Goold has reviewed the criteria and agrees to provide the Bureau and its fiscal agent with electronic files with specific supplemental drug or product rebate contract and amendment data.

4.1.9.11 Vendor shall provide SURA and NDURA files, and contract files, to the Bureau and its fiscal agent within fifty (50) calendar days of the end of a quarter, in an electronic file format that is compatible with the WV Office of Technology's currently supported versions of Microsoft Office® Suite. See Attachments C and D. Specific reports shall accompany these files and be due within the same timeframe. Vendor shall provide data, including but not limited to, current and prior quarter adjustment data; historical data; and contract and contract amendment data necessary for the Bureau to invoice manufacturers on a quarterly basis for supplemental drug rebates and product rebates in a file format that is compatible with the WV Office of Technology's currently supported versions of Microsoft Office® Suite.

Goold has previous experience in providing the State with the SURA files within a timeframe defined by the State. We agree to provide electronic files containing calculated SURA, as well as NDURA files, and contract files to the Bureau and its Fiscal Agent within fifty (50) calendar days of the end of the quarter in a file format compatible with the WV Office of Technology currently supported versions of Microsoft Office™ Suite. Upon referring the RFQ Attachment C and D, Goold agrees that the specific reports will comply with these files and will be supplied within the same timeframe to the State and is Fiscal Agent.

Data to be provided will include, but is not limited to:

- Current and prior quarter adjustment data;
- Historical data; and
- Contract and contract amendment data necessary for BMS to invoice manufacturers on a quarterly basis.

Product rebates will be provided in a file format that is compatible with the WV Office of Technology currently supported versions of Microsoft Office™ Suite.

4.1.9.12 Vendor must coordinate supplemental drug rebate and product rebate submissions with submission of traditional federal drug rebates.

Upon availability of the CMS DDR quarterly file, Goold agrees to coordinate submission of the supplemental / non drug rebate pricing file to the State within a timeframe designated by the State. In addition to the data file, BMS will receive the SR Pricing file Report and a QA Document that outlines changes processed for current and historical files, as demonstrated in the example below.

Additions and Corrections 2014Q3

DRUG NAME	MANUFACTURER	NDC	CHANGE MADE	QUARTERS AFFECTED	Data Value	formula type	REASON	CONTRACT START	CONTRACT END	Pricing file type
NAMENDA SX CAP TITRAT	Forest Laboratories Inc.	12345678911	Add	2014Q3		GNP	Amendment 1	8/1/2014	12/31/2014	SR
NAMENDA SX CAP 7MG	Forest Laboratories Inc.	23456789112	Add	2014Q3		GNP	Amendment 1	8/1/2014	12/31/2014	SR
NAMENDA SX CAP 14MG	Forest Laboratories Inc.	34567891123	Add	2014Q3		GNP	Amendment 1	8/1/2014	12/31/2014	SR

Figure 9: Example of the QA document Additions and Corrections tab

4.1.9.13 Vendor shall provide documentation to the Bureau and/or its designee to support supplemental drug rebate and product rebate invoicing at the NDC level in an electronic file format that is compatible with the WV Office of Technology's currently supported versions of Microsoft® Suite.

Goold agrees to provide necessary documentation to the Bureau and/or its designee to support supplemental rebate invoicing at the NDC level in a file format that is compatible with the WV Office of Technology currently supported versions of Microsoft™ Office Suite.

4.1.9.14 Vendor shall ensure that the quality of all rebate files delivered to the Bureau and the Bureau's business partners contain error-free data.

As previously discussed, Goold's staff is experienced and careful to make every effort to provide detailed documents and reports to our clients that are error-free. For example, our dedicated personnel have worked collaboratively with the Member States of the SSDC to create reports that are held to very high formatting and data standards.

We strive to provide all of our client States and their business partners with documents that are error-free and will work with the State of West Virginia to provide the same high-level of service.

Dispute Resolution Services

4.1.9.15 Vendor shall assist the Bureau and/or its designee in dispute resolution activities with manufacturers as they pertain to supplemental drug rebate or product rebate calculations and contracts.

Goold works diligently to minimize the occurrence of disputes related to supplemental rebates. For one of our clients, we have worked with the State in an aggressive approach to dispute avoidance which resulted in a 55% decrease in disputes reported by labelers.

We will assist the Bureau and/or its designee in dispute resolution activities that pertain to supplemental rebate calculations, negotiated rates, PDL conditions, contract dates and contract status.

4.1.9.16 Vendor shall communicate directly with manufacturers to resolve disputes arising from supplemental drug rebate or product rebate calculations or contract issues within five (5) business days of receipt of the dispute.

As demonstrated above, Goold is experienced in resolving disputes that arise. We will assist the Bureau and/or its designee in dispute resolution activities with pharmaceutical manufacturers

as they pertain to supplemental rebate calculations and contacts. All contracts undergo a quality assurance (QA) process before they are sent out. This ensures that what was agreed to during the bidding process is accurately represented on the contracts, minimizing disputes. Contracts tracked throughout the signatory process data is collected and used for QA of the pricing file, which prevents contracting issues that may cause disputes.

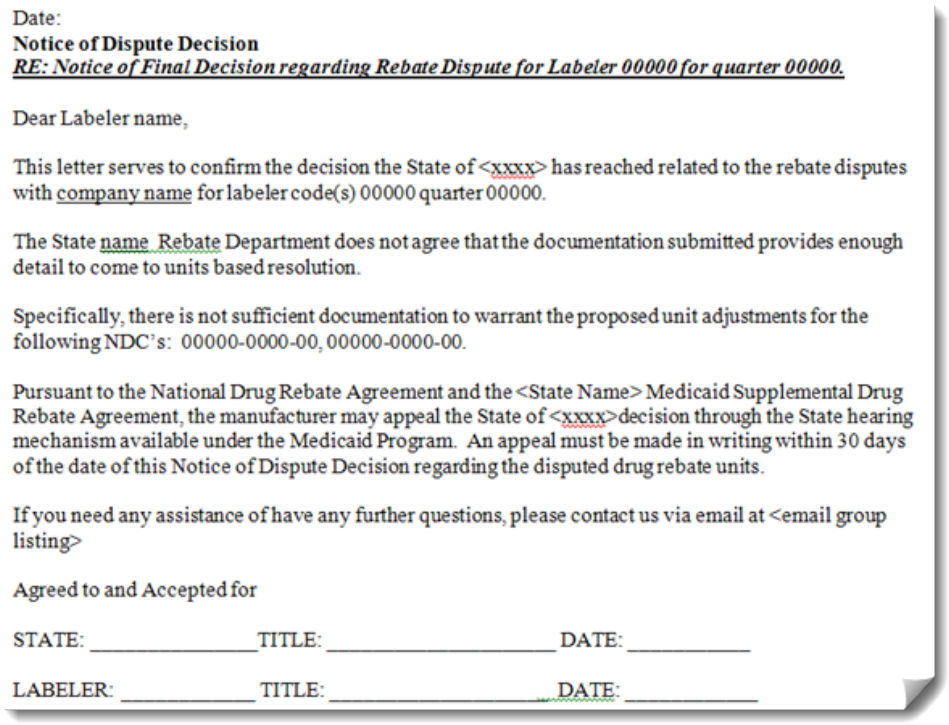
Goold Rebate Specialist staff will reach out directly to manufacturers to open discussions within five (5) business days of the receipt of the dispute. Designated staff will continue working with the manufacturer to resolve disputes through completion for issues arising from supplemental rebate calculations negotiated rates, PDL conditions, contract dates and /or contract status issues.

Rebate specialists are trained in supplemental dispute resolution and work closely with rebate supervisors on more complex disputes. The integrity of the data throughout the process allows rebate specialists to make determinations rapidly and provides a complete audit trail from the initial bid onward.

4.1.9.17 Vendor shall communicate directly with manufacturers regarding unpaid supplemental drug rebates or product rebates upon request by the Bureau.

In our many years of experience in the Medicaid industry, Goold has established close working relationships with manufacturers. We agree to communicate directly with manufactures regarding unpaid supplemental rebates upon request by BMS. Non-payment of invoiced SR amounts is treated very seriously and is rapidly elevated until a satisfactory resolution is reached.

The designated Rebate Specialist will log conversations, emails and resolution responses. This information will be made available to the State for review and intervention in cases when the Labeler is uncooperative or an agreement cannot be reach. In rare cases where a resolution cannot be reached, a customized Notice of Dispute Decision, shown in the example below, will be completed and submitted to BMS.



Date:
Notice of Dispute Decision
RE: Notice of Final Decision regarding Rebate Dispute for Labeler 00000 for quarter 00000.

Dear Labeler name,

This letter serves to confirm the decision the State of <xxxx> has reached related to the rebate disputes with company name for labeler code(s) 00000 quarter 00000.

The State name Rebate Department does not agree that the documentation submitted provides enough detail to come to units based resolution.

Specifically, there is not sufficient documentation to warrant the proposed unit adjustments for the following NDC's: 00000-0000-00, 00000-0000-00.

Pursuant to the National Drug Rebate Agreement and the <State Name> Medicaid Supplemental Drug Rebate Agreement, the manufacturer may appeal the State of <xxxx>decision through the State hearing mechanism available under the Medicaid Program. An appeal must be made in writing within 30 days of the date of this Notice of Dispute Decision regarding the disputed drug rebate units.

If you need any assistance of have any further questions, please contact us via email at <email group listing>

Agreed to and Accepted for

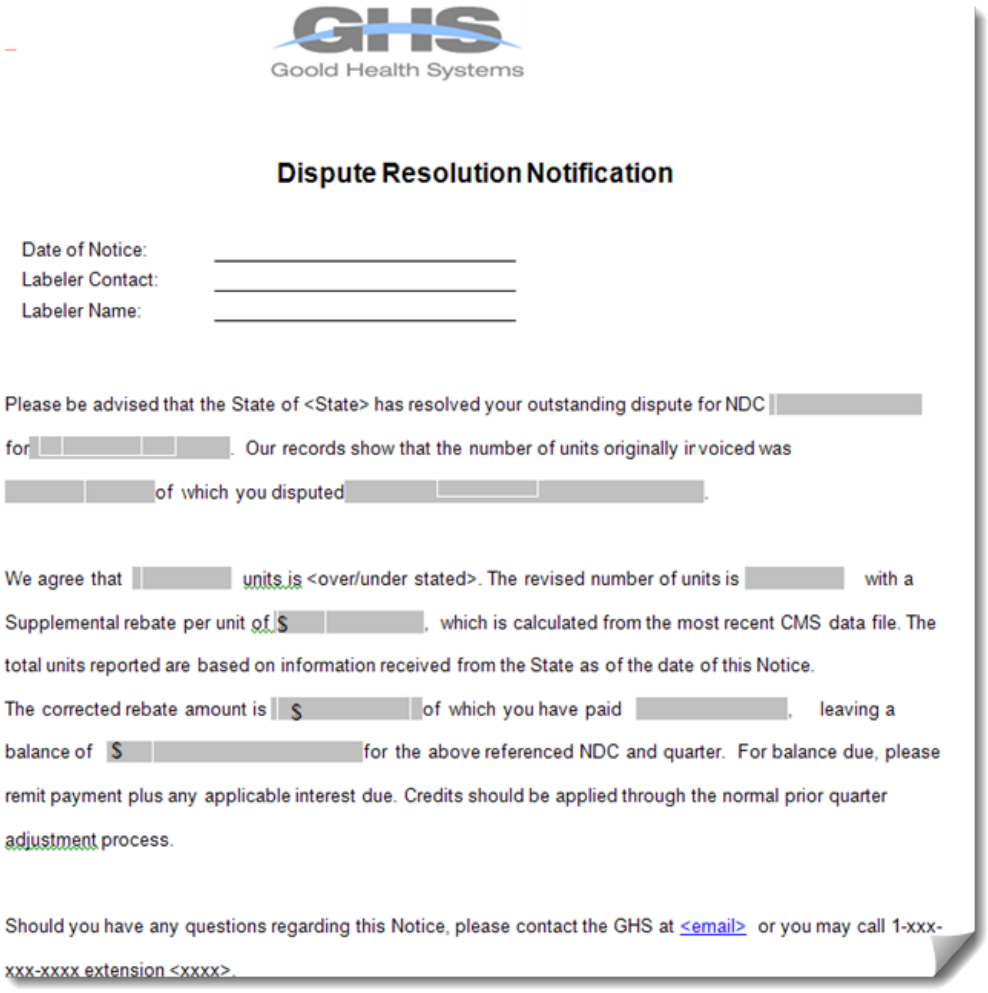
STATE: _____ TITLE: _____ DATE: _____

LABELER: _____ TITLE: _____ DATE: _____

Figure 10: Example Notice of Dispute Decision

4.1.9.18 Vendor shall communicate the resolution of disputes in a written document to the Bureau within one (1) business day of resolution.

Goold will communicate the resolution of disputes in a written document to BMS within one (1) business day of resolution. A customized Dispute Resolution Notification (demonstrated below) will be used to communicate dispute resolution agreements to BMS and to the labeler using an agreed upon process.



Good Health Systems

Dispute Resolution Notification

Date of Notice: _____
Labeler Contact: _____
Labeler Name: _____

Please be advised that the State of <State> has resolved your outstanding dispute for NDC for . Our records show that the number of units originally invoiced was of which you disputed .

We agree that units is <over/under stated>. The revised number of units is with a Supplemental rebate per unit of $, which is calculated from the most recent CMS data file. The total units reported are based on information received from the State as of the date of this Notice.

The corrected rebate amount is $ of which you have paid , leaving a balance of $ for the above referenced NDC and quarter. For balance due, please remit payment plus any applicable interest due. Credits should be applied through the normal prior quarter adjustment process.

Should you have any questions regarding this Notice, please contact the GHS at <email> or you may call 1-xxx-xxx-xxxx extension <xxxx>.

Figure 11: Example Dispute Resolution Notification

4.1.10 State Maximum Allowable Cost Program

4.1.10 Vendor shall assume administration of the current State Maximum Allowable Cost (SMAC) program.

Goold has a successful track record of bringing down Medicaid drug costs through the effective implementation and management of a carefully crafted Maximum Allowable Cost (MAC) program. ***Goold's philosophy regarding MAC rate schedules is based on the belief that chemically equivalent drug products in the same strength, dosage form, and package size available from multiple sources should be reimbursed similarly.***

Goold's Success as a SMAC Program Administrator:

West Virginia's Vendor:

- The SMAC Program saved over $150 million during our tenure; and
- Monthly SMAC savings consistently averaged $4 million.

Illinois:

- As one of our largest SMAC clients, we save the State approximately $25 million per quarter.

Vermont:

- Goold will be taking over the Vermont SMAC Program in 2015.
- Goold has evaluated just 5% of the Vermont's drugs eligible for a MAC and estimates savings, so far, to be over $9 million per year.

MACs are designed to maximize the cost-effectiveness of pharmacy services by setting reimbursement amounts for brand name and therapeutically equivalent drug products at the same price, based on the cost of the products. The MAC rate usually applies to both the brand and generic drug products, unless overridden as permitted with DAW1 or prior authorization. CMS uses the same rationale to establish Federal Upper Limits (FULs) for drug products. MAC rates are state Medicaid program versions of CMS FULs.

Goold has the experience to provide West Virginia with a SMAC program that is best in its class. As was the case in Wyoming where Goold took an aggressive approach to their SMAC pricing formula and inclusion criteria and produced a significant savings for the State. Our work was recognized by CMS as a benefit to the State and the program itself.

Goold has an established SMAC management solution in place, including tools, techniques, processes, procedures, and expert staff to facilitate ongoing operation. This comprehensive solution is already implemented and currently operated by Goold in nine states:

- Illinois;
- Maine;
- Minnesota;
- New Jersey;
- Wyoming.
- North Dakota;
- South Dakota;
- Utah;
- Vermont; and

For each of our SMAC clients, Goold provides the specialized expertise, capabilities, methodologies, and technical competence necessary to meet their requirements and achieve their long-term goals.

In general, Goold applies an approach and methodology to SMAC rate setting that seeks to establish reimbursement rates with the greatest savings and to promote cost-effective utilization of prescription drugs. As the SMAC provider for the West Virginia, Goold will evaluate, as we have in the past, the existing MAC prices, make recommendations for enhancements and maintain the State's SMAC pricing at the direction of State administrators.

Goold also conducts drug acquisition cost surveys on a quarterly basis for three States in order to get current drug pricing, as well as maintains a J-Code SMAC list for another State. Our staff is experienced in SMAC lists for factor products for several of our clients, along with specialty SMAC lists.

4.1.10.1 Vendor shall create, refine and maintain the SMAC program for multiple source drug products or other drug products such as specialty drugs, and non-drug products tailored to the marketplace in West Virginia.

As West Virginia's SMAC vendor, we will create, refine and maintain the SMAC program for multiple source drug products, specialty drugs, and supplies tailored to the marketplace. We can assure that West Virginia will see significant savings each month through the MAC program and all associated services (reporting, Help Desk, etc.), as we have in the past. Ongoing maintenance of the SMAC list not only calls for the addition of new generics that have come onto the market and adjusting the prices of existing products on the SMAC list in response to market conditions, but also to always look for new ways of achieving savings, such as with adding specialty drugs and supplies. Goold has experience in bringing new-found savings with the addition of such specialty products to an existing SMAC list.

SMAC List

4.1.10.2 Vendor shall submit the SMAC data in a file format that is compatible with the WV Office of Technology's currently supported versions of Microsoft Office® Suite.

Goold will submit the SMAC list in a file format that is compatible with the WV Office of Technology currently supported versions of Microsoft Office™ Suite.

4.1.10.3 Vendor shall collaborate with the Bureau to create business rules that comply with the Bureau's business rules relating to file formats (i.e., NDC level data), schedules of delivery, type of files (i.e., change only, full files) for the SMAC program.

Goold is experienced in collaborating with our client States to create business rules that comply with each State's specification. For West Virginia, Goold will work with the Bureau to create business rules that will comply with the Bureau's rules relating to the SMAC program including:

- File formats;
- Schedule of delivery; and
- Type of files.

4.1.10.4 Vendor shall ensure that the quality of all SMAC files delivered to the Bureau and the Bureau's business partners contain error-free data.

As mentioned previously, Goold's staff is meticulous in providing detailed documents and reports to our clients and makes every effort to provide materials that are error-free.

We strive to provide all of our client States and their business partners with documents that are error-free and will work with the State of West Virginia to provide the same high-level of service for the SMAC files that are delivered to the State.

4.1.10.5 Vendor shall provide SMAC lists for public viewing on the Bureau's website and maintain archived versions that are available to the Bureau upon request.

Goold will prepare all SMAC lists in a file format compatible with the WV Office of Technology, currently supported in versions of Microsoft™ Office Suite, for display on the BMS website for interested parties. Goold will maintain archived versions of the SMAC list for the Bureau.

4.1.10.6 Vendor shall ensure that each SMAC list submitted has an effective date and a unique version number.

Goold will ensure that each SMAC list submitted has an effective date and a unique version number. We have worked collaboratively with the State in the past to name these documents in a way that best suites the Bureau and we will do so based on specifications from the State.

4.1.10.7 Vendor shall update the SMAC list no less than weekly, and as SMAC changes are approved by the Bureau.

Goold will update the SMAC list as frequently as weekly, when the State requests, and/or when modifications occur, usually as a result in changes in the market place leading to disputes.

4.1.10.8 Vendor shall coordinate activities with the Bureau's fiscal agent to support the implementation and updates of the SMAC list.

Goold will coordinate all activities with the Fiscal Agent to support the implementation and updates of the SMAC list.

4.1.10.9 Vendor shall actively pursue opportunities for expansion of the SMAC pricing list and regularly report the Vendor's SMAC activities in a schedule to be determined by the Bureau, at a minimum of monthly.

Goold is knowledgeable of this process and will actively pursue opportunities for expansion of the SMAC pricing list and regularly report on our SMAC activities on a schedule approved by BMS, at a minimum of monthly. The chart below demonstrates the trend of the total dollars paid for brand, generic and total drug spend between November 2012 and August 2014.

Goold is constantly looking for innovative ways to continue to control the prices paid for drugs. We have assisted other State MAC clients with implementing a specialty drug SMAC list to include products such as hemophilia factor drugs and Synagis®. These are just some of the ideas we would be prepared to discuss with the Bureau to expand the existing SMAC pricing list.

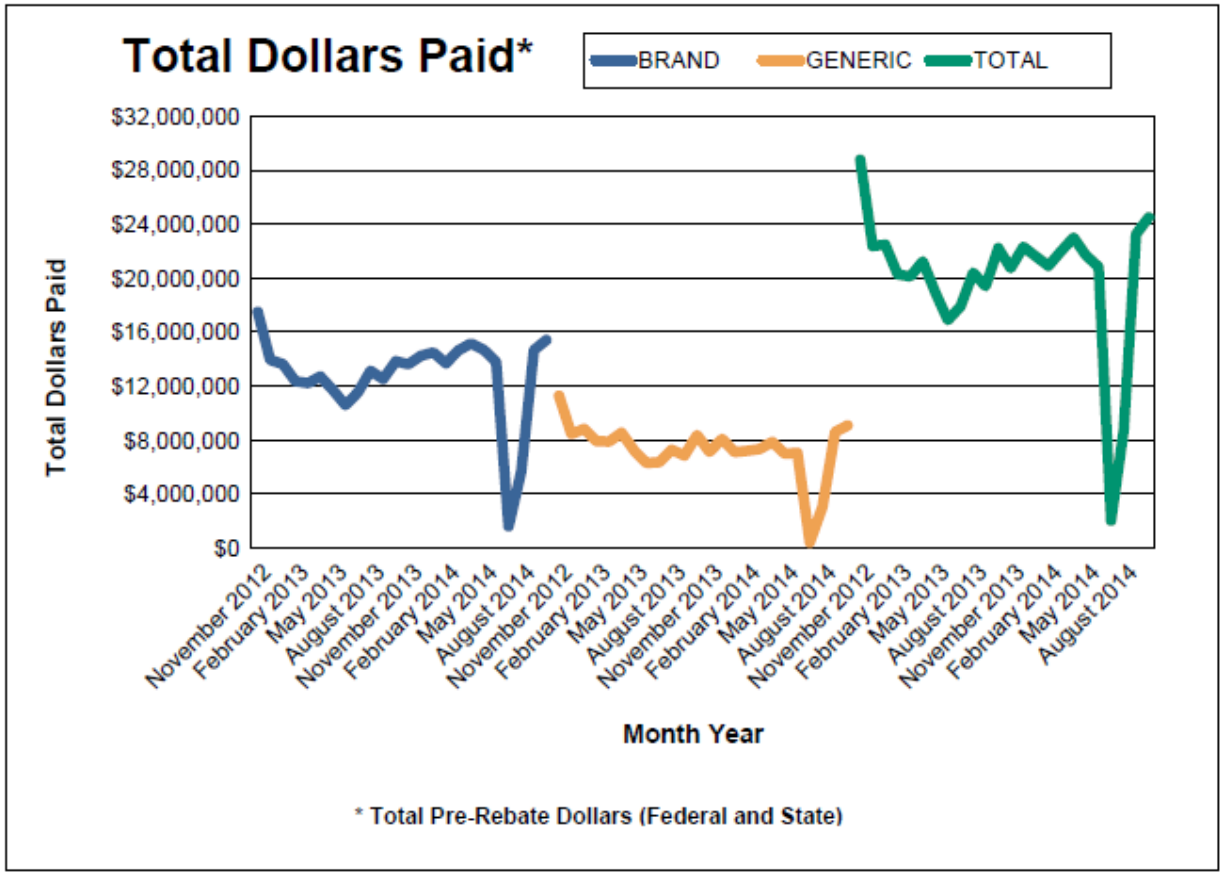


Figure 12: Total Drug Spend Example Chart

4.1.10.10 Vendor shall collect acquisition cost data and other source information to support SMAC pricing.

For West Virginia, Goold agrees to collect acquisition cost data and other required source information to support SMAC pricing. We constantly collect fresh acquisition cost data from a variety of sources, including State provider pharmacies via disputes, and surveys performed on behalf of other state Medicaid programs (both stores and wholesalers).

4.1.10.11 Vendor shall prepare for, attend in person and facilitate meetings with the provider industry, interested parties, and internal work groups in regard to the SMAC program twice a year if requested by the Bureau.

Goold will prepare for and attend in person as well as facilitate meetings with the provider industry, interested parties, and internal work groups in regard to the SMAC program twice a year, if requested by BMS.

4.1.10.12 Vendor shall develop alternative SMAC reimbursement models for the Bureau's consideration when requested by the Bureau.

Goold will develop alternative SMAC reimbursement models for the Bureau's consideration when requested by BMS. Goold utilizes multiple formulas to generate SMAC prices. This allows flexibility when developing and maintaining SMAC prices. Upon request from BMS, Goold will be prepared and happy to discuss alternative reimbursement models for the SMAC program. Some of the models are variations on applying a multiplier to actual acquisition cost, while others are more customized for the state and take into account the average number of units dispensed per script and desired gross profit.

4.1.10.13 Vendor shall coordinate the addition of drugs for SMAC pricing with drugs in the same therapeutic category on the PDL to ensure that the PDL and SMAC activities result in the most cost effective results.

The critical importance of close coordination of efforts between current and planned SMAC prices and PDL changes is often a missed savings opportunity. Goold will coordinate the addition of drugs for SMAC pricing with the drugs in the same therapeutic category on the PDL to ensure that PDL and SMAC activities result in the most cost effective results.

As the SSDC vendor and experienced PDL and SMAC vendor, we have a comprehensive view on utilization trends, PDL expenditures, and current and future SMAC pricing. We use these data to carefully coordinate additions and changes to the SMAC list, taking into account the way in which supplemental rebates and PDL placement of drugs are expected to play out. As a result, West Virginia will see the savings between the PDL and the SMAC list maximized. Related issues include exiting supplemental rebate contracts with adequate notice and timing PDL changes carefully so that the change to a preferred generic does not occur until the superior SMAC pricing is in effect.

Provider Pricing Support

4.1.10.14 Vendor shall provide outreach services to the WV Medicaid providers regarding Medicaid pharmacy pricing issues and the SMAC program.

Goold will provide outreach services to WV Medicaid providers regarding Medicaid pharmacy pricing issues and the SMAC program. The type and schedule of communications will be reviewed and presented to BMS for approval prior to initiation.

4.1.10.14.1 Vendor shall establish and staff a toll-free telephone line and be responsible for logging and responding to calls from providers regarding pricing issues. The toll-free telephone line must be available, at a minimum, Monday through Friday from 9am to 5pm Eastern Time. Vendor shall be the primary contact for all drug and product pricing inquiries.

Goold agrees to provide and staff a dedicated toll-free phone line for providers to call regarding pharmacy pricing issues. The Help Desk will be available Monday through Friday from 9AM to 5PM Eastern time.

The Goold Help Desk is staffed by competent, considerate professionals who understand and adhere to Goold's rigorous standards of accuracy, courtesy, and speed. Most of these Help Desk professionals have a background in community pharmacy, so they have a deep understanding of the rigors and demands of the community pharmacy pace and business.

Along with all other Goold employees, help desk staff are well-versed in HIPAA compliance and maintain complete confidentiality and professionalism in their work, as dictated by Goold policy. Goold has developed Help Desk manuals consisting of user documentation for the software used by staff, along with all memos, policies, mailings and internal "cheat sheets" designed to provide optimum service to the communities served. Goold has also developed a customized program that provides record keeping and performance reporting for the Help Desk. This utility allows technicians to log all calls, note the type of call, the account involved, and add comments to the call log.

4.1.10.14.2 The Vendor shall answer, log, and respond to telephone calls and/or other communicated messages from pharmacy providers and resolve disputes related to pricing.

Goold will answer, log and respond to calls from pharmacy providers and will continue to resolve disputes related to pricing. Goold will summarize provider support activities including summaries, presentation, and discussion of open pricing disputes.

Date	Company	Caller	Call Summary	Your Initials
10/9/2014	[Company Name]	[Caller Name]	Out bound call. Talked to client. She had submitted an urgent radiology request in the in-state outpaitent queue. I gave her the contact's number. She will help client submit an urgent radiology PA. I informed her that this PA will be cancelled as it wasn't submitted with the correct process.	AB
10/12/2014	[Company Name]	[Caller Name]	Calling on PA ## because the provider had sent a updates pathways form to have the CPT changed from Adomen to Abdomen/pelvis but because this was an auto approved never came to us, I changed the Code after speaking with caller to make sure that it was ok thru the ACR.	CD
10/21/2014	[Company Name]	[Caller Name]	[Name] called on PA ## because it was cancelled as a duplicate to PA ##. However one was a RT AFO and one was a LT AFO. I told her I would create a new PA for review. Though our error will submit both AFO's on one request in the future.	EF
10/26/2014	[Company Name]	[Caller Name]	Direct call from caller wanting to discuss the denied claim on a radiology PA. She looked into it and found that the hospital billed the wrong code (###). The following 3 codes are allowed for the chest CT grouping: 71250, 71260, 71270.	GH

Figure 13: Sample Call Log

Dispute Resolution

4.1.10.14.3 Responses to providers acknowledging disputes must occur within one (1) business day of receipt.

Goold will respond to providers acknowledging disputes within one (1) business day of receipt.

4.1.10.14.4 Resolution of pricing disputes must be submitted to the Bureau and reported to the inquiring provider within fourteen (14) calendar days of the date of the complaint.

Goold will propose resolution of pricing disputes and submit them to BMS within fourteen (14) calendar days from the date of the complaint.

4.1.11 Reports

During the DDI phase, Goold will meet with State officials to discuss the specifications of the following reports, agree on report styles and formats, and, most importantly, define the purpose and parameters of the following reports. Our main interest is that the State is receiving the information that meets their requirements and our talented staff will create the reports needed. We provide robust reporting services to all of our State clients, and have for West Virginia in the past, and we do this extremely well. The samples provided are meant to serve as examples only.

In the following section we discuss our capability to meet the West Virginia specifications.

4.1.11 Vendor shall provide a suite of reports for the Bureau which reflects the components necessary to manage the PDL, PPL, and SMAC programs and to support the supplemental drug and product rebate invoicing.

Goold will produce a suite of reports for BMS which reflect the components necessary to manage the PDL, PPL, and SMAC programs. Some of these reports will include PDL savings reports, market share reports, utilization reports, and MAC savings reports. Samples have been included in the proceeding sections.

Goold will work with the Bureau during DDI to develop a regular suite of reports that will meet the needs of the Bureau staff.

4.1.11.1 Vendor shall develop standard reports desired by the Bureau. Reports requested through this contract shall include but not be limited to, those listed below. For purposes of cost estimation, vendors may assume a maximum of forty (40) standard reports. All reports shall be in an electronic file format that is compatible with the WV Office of Technology's currently supported versions of Microsoft Office® Suite.

Upon review of the RFQ sections 4.1.11.5.1.1 – 4.1.11.5.1.39, Goold is familiar with the report suite requested by the State as we have provided many of them to the State before. Goold agrees to provide the 40 reports listed in the RFQ in an electronic format that is compatible with the WV Office of Technology's currently supported versions of Microsoft Office® Suite.

4.1.11.2 Vendor shall work with the Bureau using a standardized process to define and develop standard reports including initial release notes with calculation methodologies and prototypes.

Goold will work with the Bureau using a standardized process to define and develop or improve standard reports, including initial release notes with calculation methodologies and prototype presentation. The same process will be applied to accepted and currently utilized reports to ensure that BMS has the information necessary to benefit maximally from the information they contain. Specifically, Goold agrees to produce monthly and quarterly progress reports in a format approved by BMS including, but not limited to, those reports listed in the following subsections.

Goold offers our clients robust, flexible and scalable reporting services that include both standard and ad hoc reports. Effective reporting is a critical function of Goold's proposed solution. Goold uses reporting to monitor performance and to assure that we are carrying out all our responsibilities effectively. Reporting allows State policymakers to evaluate the impact of decisions as well as opportunities for cost savings and quality improvement. Reporting is also critical to the State's ability to hold Goold accountable for performance of our contractual obligations.

Goold has, and will provide, the State with standard and ad hoc reporting on a pre-determined and pre-approved schedule with BMS-approved data elements. We have the experience and competence necessary to meet the reporting requirements outlined in this RFQ. Our team of data analysts, clinicians and support staff – our "integrated clinical data teams" – will work with key stakeholders upon contract award to document any new reporting requirements of BMS. Print-ready reports will be delivered electronically using Microsoft™ Word or Excel, using a format that is compatible with the WV Office of Technology's currently supported versions of Microsoft™ Office Suite, unless otherwise specified. Upon contract award, if desired, Goold will work with BMS to systematically review and improve any currently used reports and to evaluate the necessity for new reports in order to manage the PDL, PPL, SR or SMAC programs. Goold will also review the reporting schedule with BMS.

4.1.11.3 Vendor shall deliver standards reports monthly.

Goold agrees to deliver all standard reports to the State at least monthly on an agreed upon time frame.

4.1.11.4 Vendor shall provide report analyses to the Bureau that will assist the Bureau in making program adjustments to improve the cost efficiency of the pharmacy program. Vendor must host regularly scheduled meetings in order to discuss reports provided by the Vendor. These meetings will be held at a minimum of quarterly.

Goold has the experience to provide West Virginia with report analyses that will assist the State in making program adjustments to improve cost efficiency for the pharmacy program. If necessary, and at a minimum of quarterly, Goold will host meetings to discuss the provided reports and their usefulness to the State. Regular and frequent communication is encouraged by our account managers to ensure the program is running optimally.

4.1.11.5 Vendor shall submit standard reports per the terms of the contract when requested by the Bureau.

Goold will submit the standard reports as outlined in the RFQ per the terms of the contract when requested by the Bureau.

4.1.11.5.1 Monthly, Quarterly and Annual Pharmacy Utilization for PDL and PPL and/or All Drugs Categories: Based on a rolling twenty-four (24) months of pre-rebate expenditures in graph or chart format, to be delivered monthly, quarterly and annually:

4.1.11.5.1.1 Average dollars paid amount per member user;
4.1.11.5.1.2 Total dollars paid;
4.1.11.5.1.3 Total dollars paid by brand and by generic;
4.1.11.5.1.4 Average generic drug prescription cost;
4.1.11.5.1.5 Average brand drug prescription cost;
4.1.11.5.1.6 Percent of generic drugs by number of prescriptions;
4.1.11.5.1. 7Average number of prescriptions per member user;
4.1.11.5.1.8 Average paid amount per prescription.
4.1.11.5.1.9 Summary Monthly, Quarterly, and Annual Reports to be delivered monthly, quarterly, and annually.

Goold agrees to supply the Bureau with the above listed reports monthly, quarterly and annually, as requested by the State. Samples of some of these reports are included on the following pages and demonstrate Goold's capability to work with a State in order to create the reports desired. Our experienced, dedicated staff are more than qualified to provide this service for the State of West Virginia.

The following chart demonstrates to a State the Cost per User based on total pre-rebate dollars. In this example, the cost is displayed on a per month basis for dates between November 2012 and October 2014.

[STATE NAME] **Medicaid Drug Benefit Program**
11/1/12 - 10/31/14

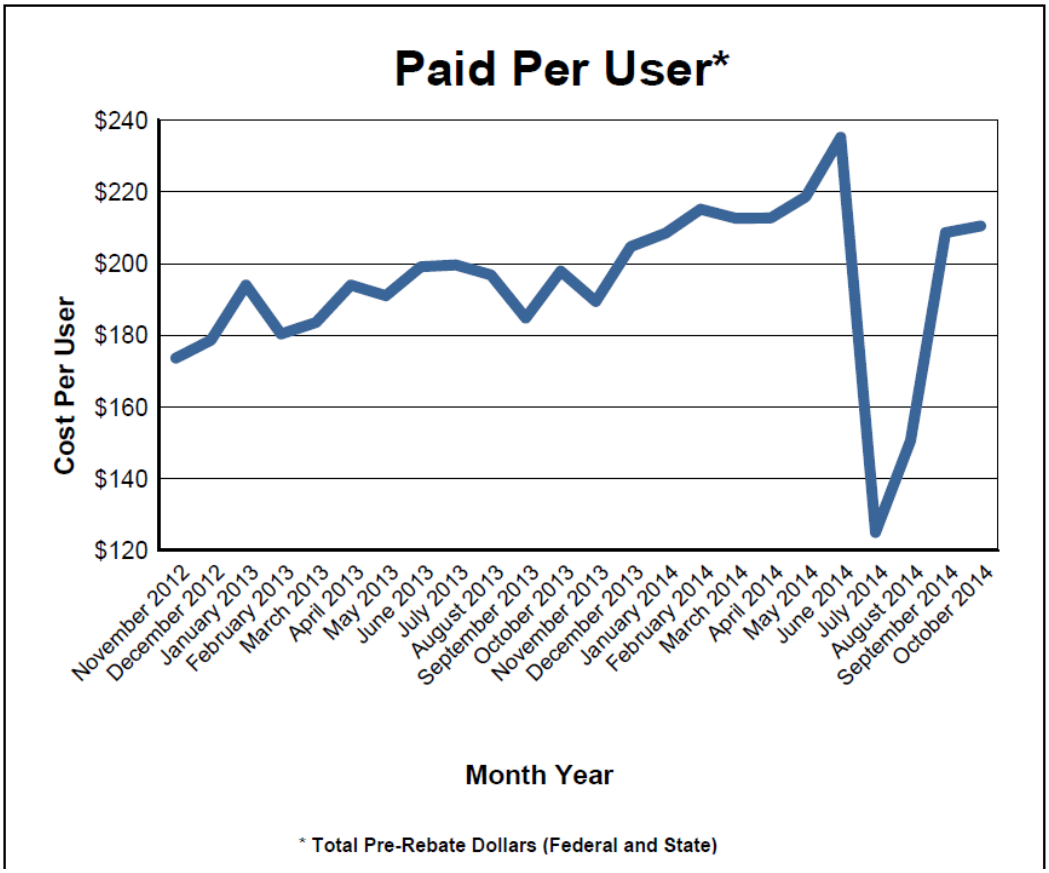


Figure 14: Monthly Cost per User Chart

The following example shows the total pre-rebate spend (state and federal dollars) for brand and generic drugs. This chart has pulled data for the months of November 2012 through October 2014 and allows for easy tracking of pre-rebate costs over time.

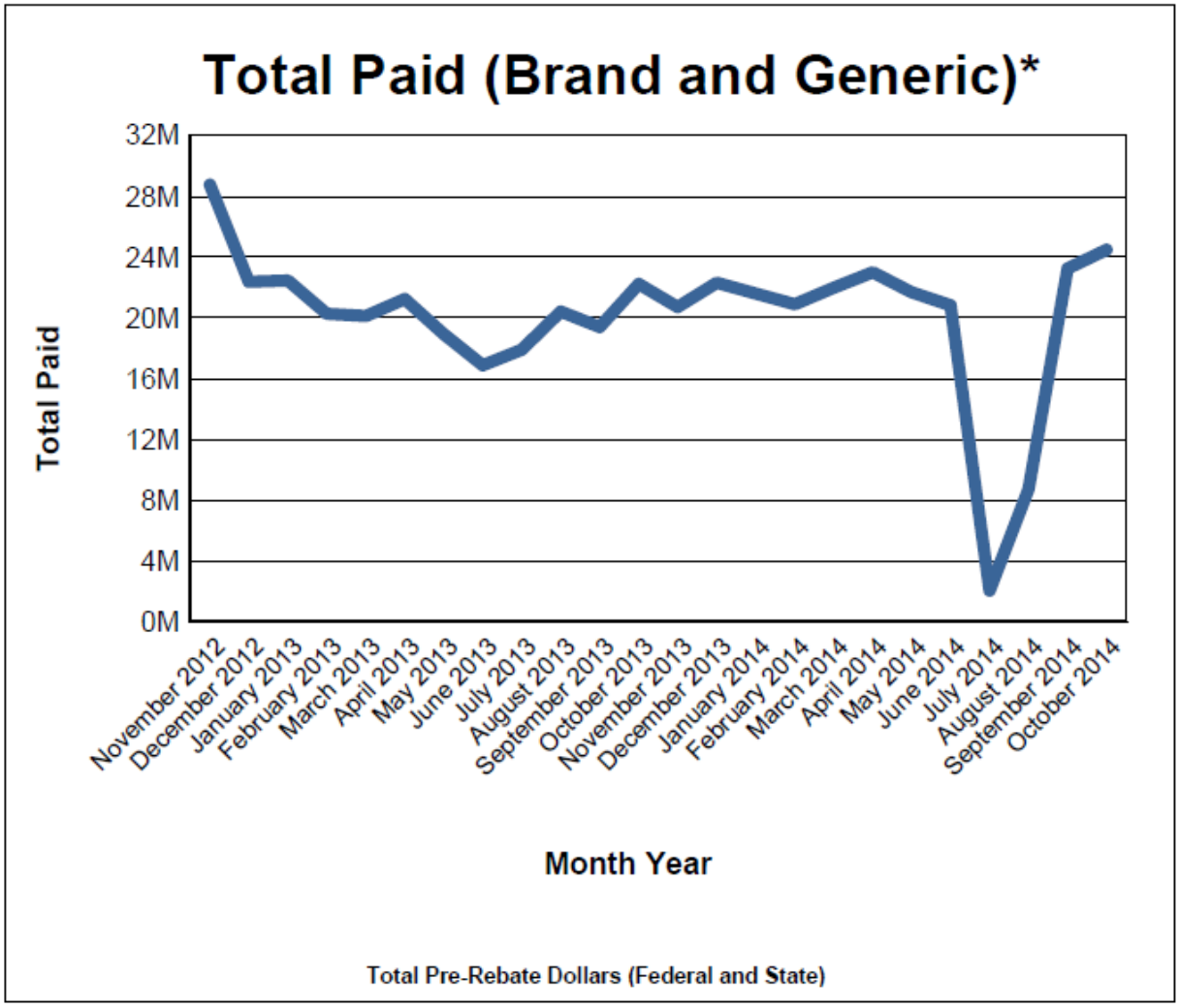


Figure 15: Total Paid (Brand and Generic) Chart

The chart below breaks out the total dollars spent (state and federal) for brand, generic and then the total dollars spent for a state on one chart. This chart shows a side-by-side comparison of the three categories. Brands and generics are broken out separately as well on other charts. The data has been compiled monthly for the date range of November 2012 through August 2014.

[STATE NAME] **Medicaid Drug Benefit Program**
11/1/12 - 10/31/14

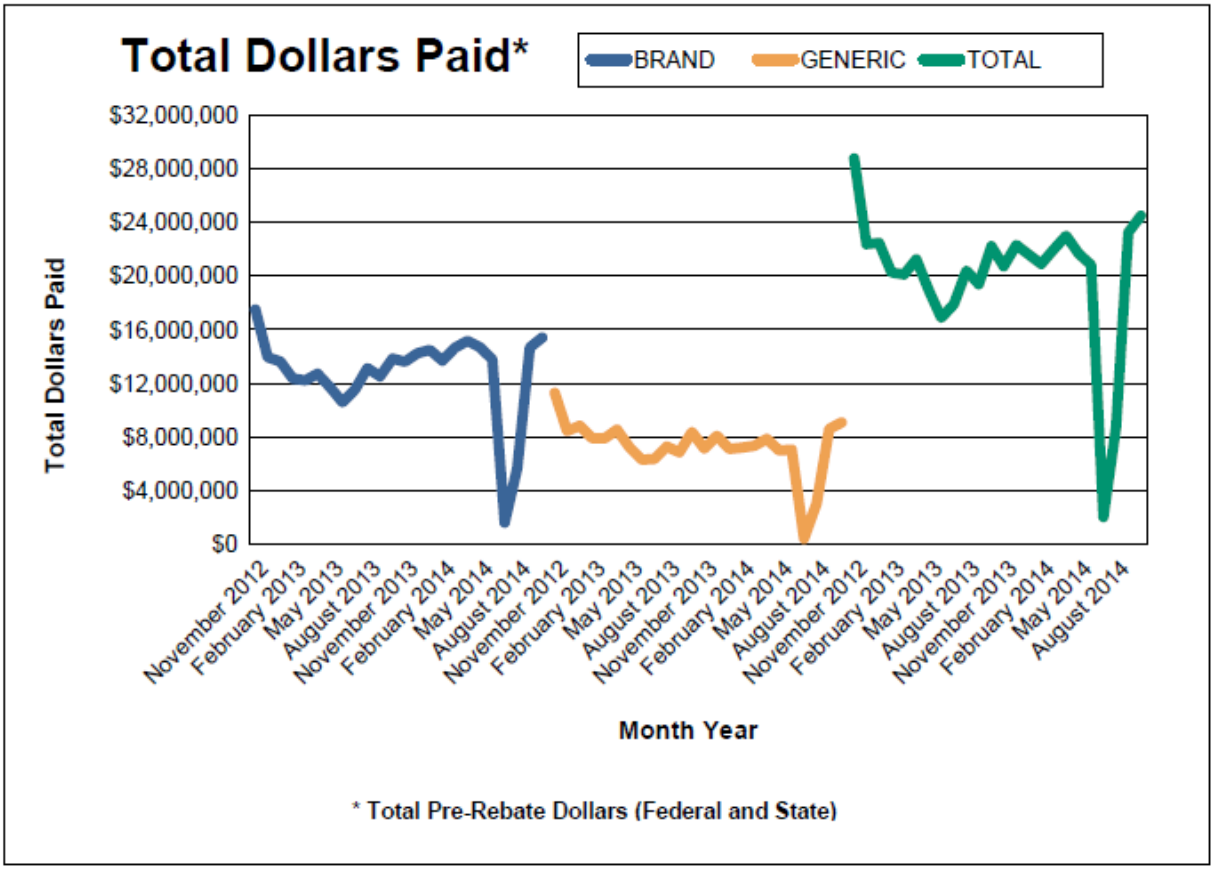


Figure 16: Total Dollars Paid for Brand, Generic and Total Chart

The following chart shows the State's average generic drug cost, a closely watched metric, on a monthly basis from November 2012 through October 2014.

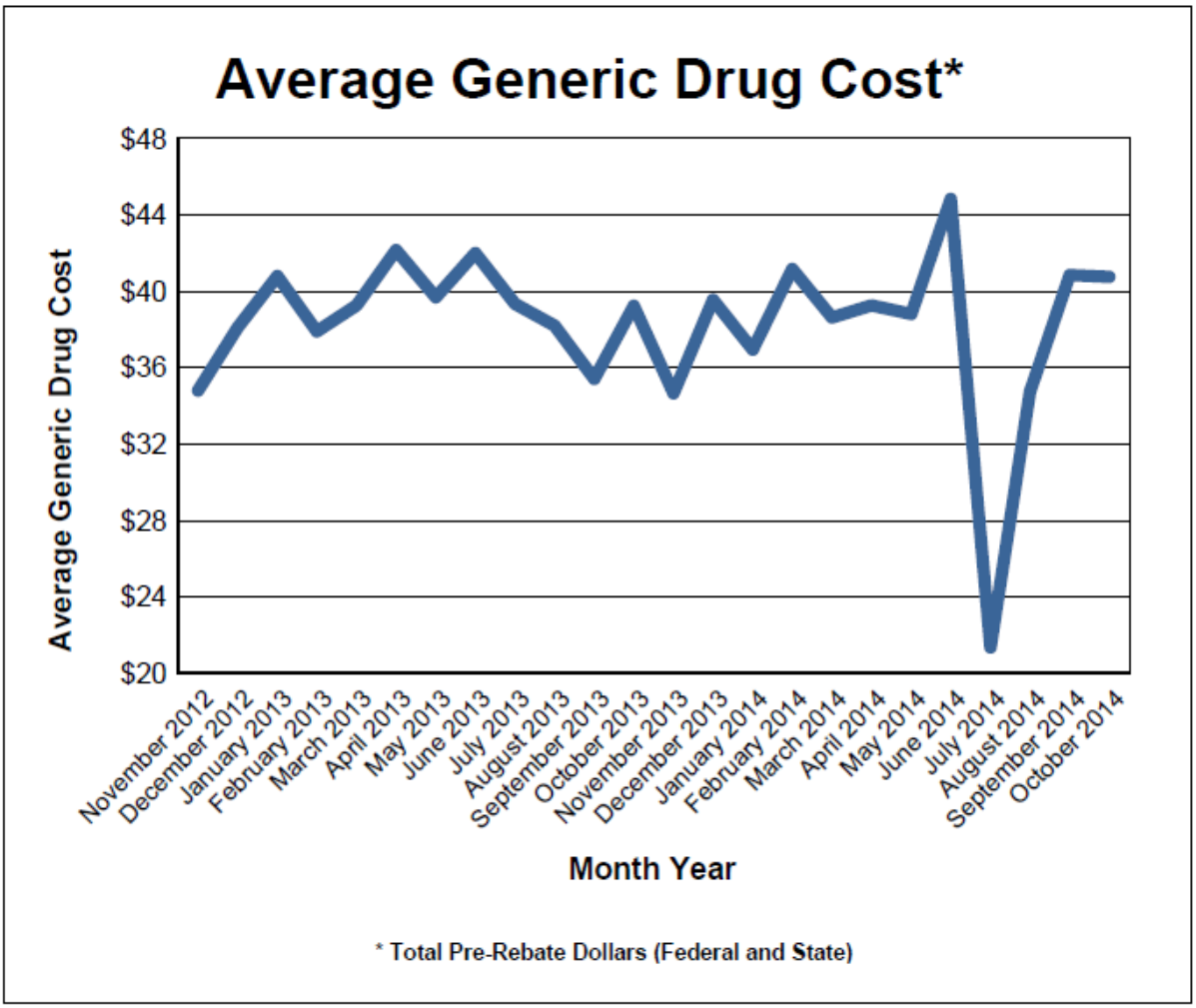


Figure 17: Average Generic Drug Cost Chart

The chart below is similar to the previous one, except that the data displayed represents average brand drug cost.

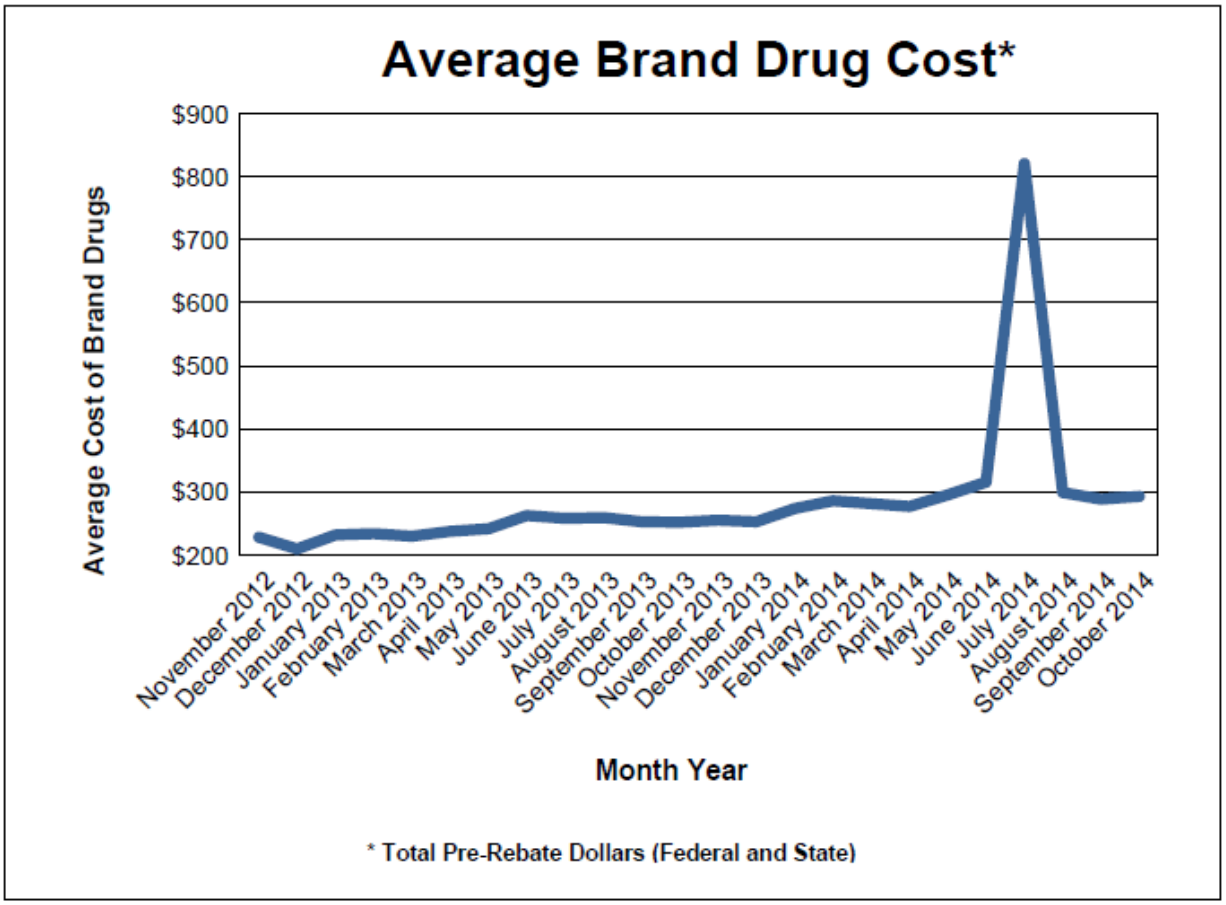


Figure 18: Average Cost of Brand Drugs Chart

The chart below demonstrates the percentage of generic drugs for a State on a monthly basis for the date range of November 2012 through October 2014.

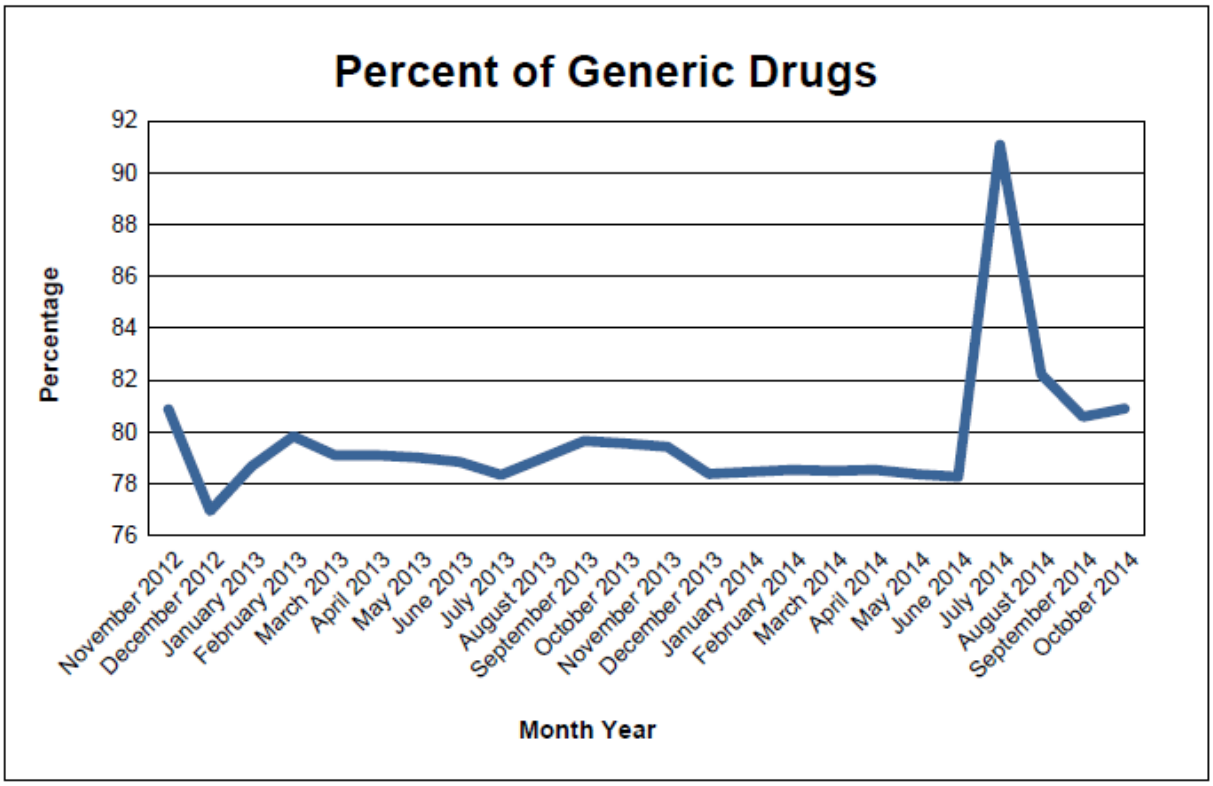


Figure 19: Percentage of Generic Drugs Chart

The example below shows the average number of prescriptions per user for a state.

[STATE NAME] **Medicaid Drug Benefit Program**
11/1/12 - 10/31/14

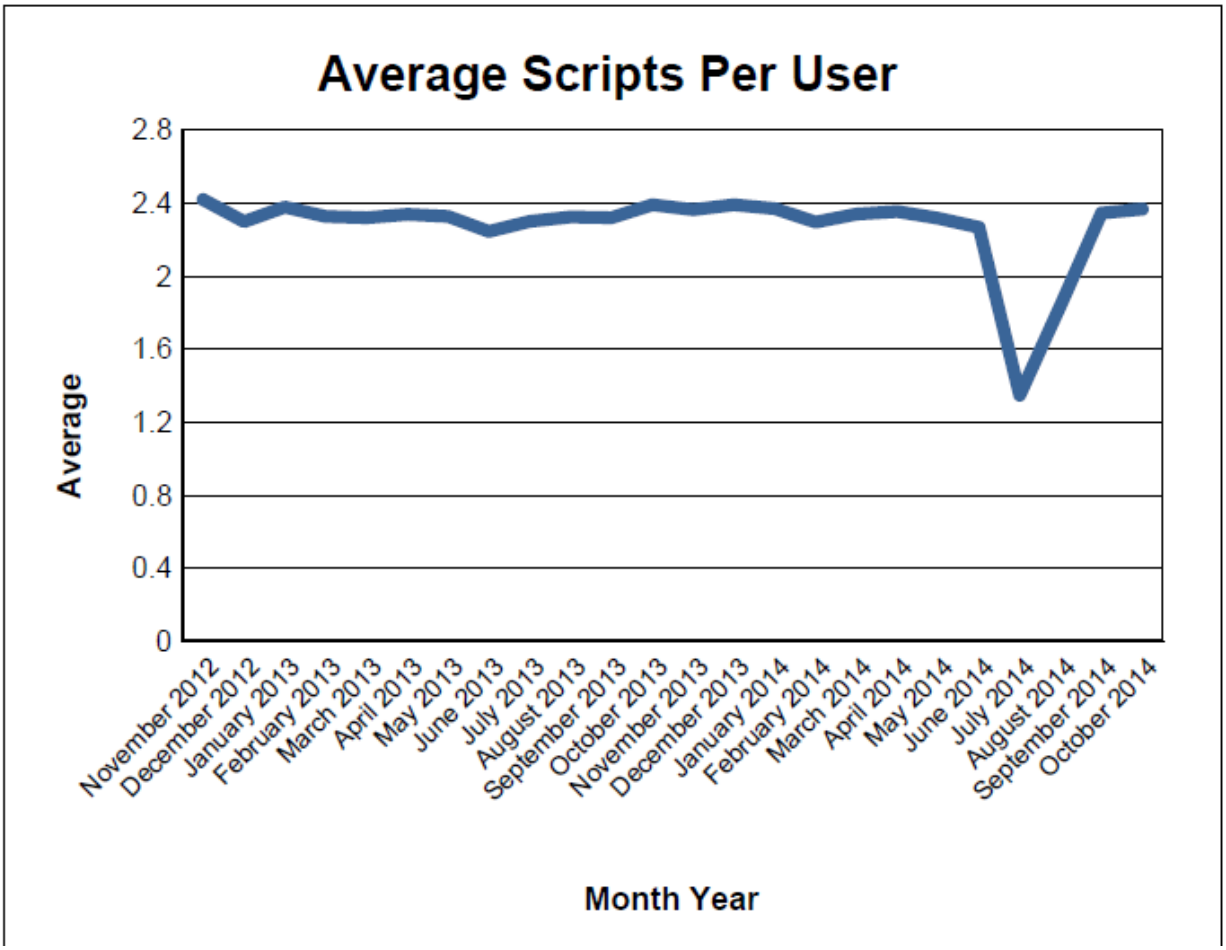


Figure 20: Average Scripts per User Chart

The following chart demonstrates the average amount paid for prescriptions on a monthly basis from November 2012 through October 2014.

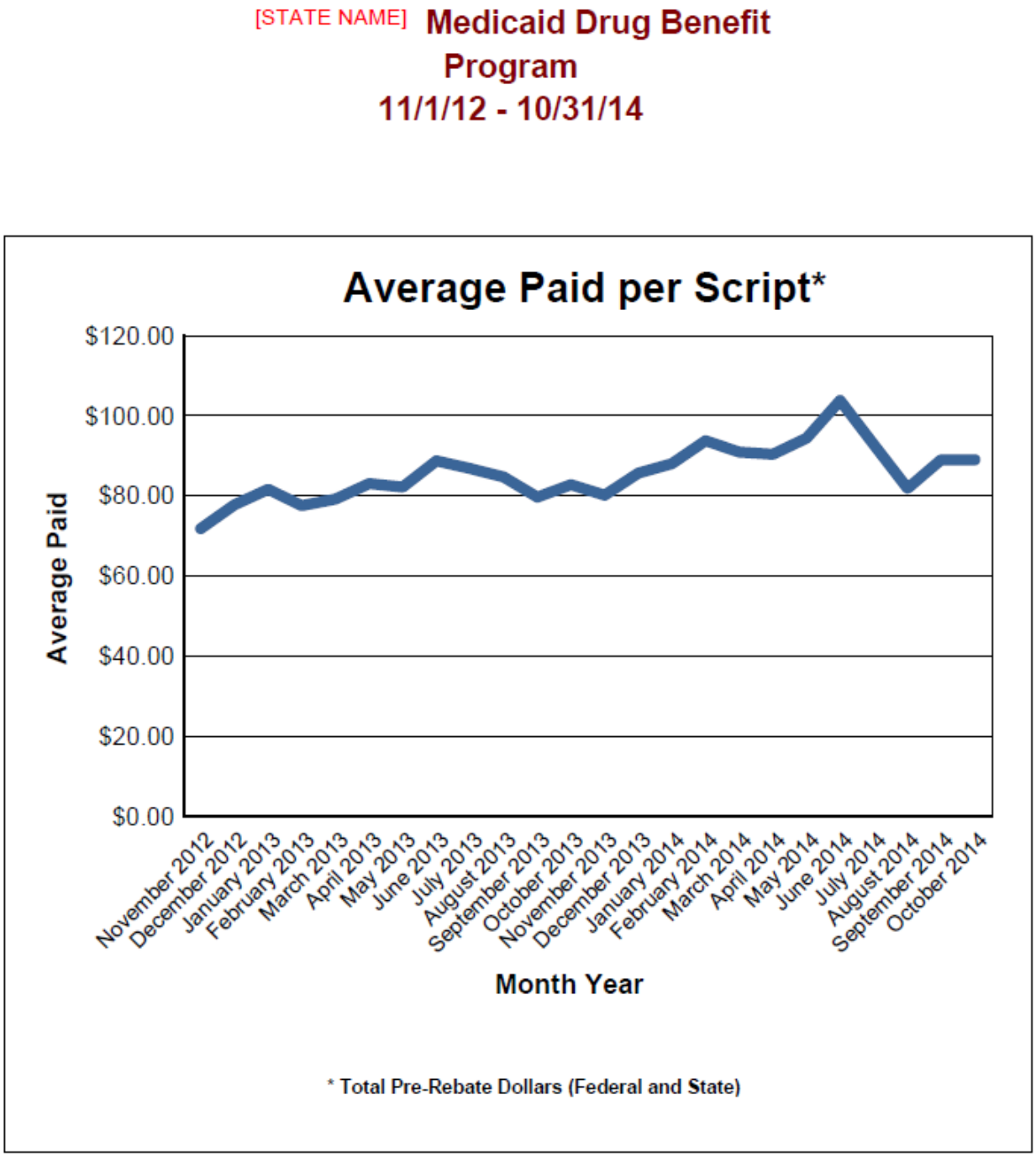


Figure 21: Average Paid Per Script Chart

4.1.11.5.1.10 Monthly and State Fiscal Year Statistics: Compares the current month to the same month for the previous year. Summarizes the calendar year-to-date for the current month and previous calendar year-to-date; shall contain the total amount paid, number of users, total number of prescriptions, average prescriptions per member user, average cost per prescription; number of generic prescriptions, percentage of generic prescriptions paid compared to the overall amount paid for all prescriptions, total amount paid for generic prescriptions, average generic prescription cost, average days' supply for generic prescriptions, number of brand prescriptions, percentage of brand prescriptions paid compared to the overall amount paid for all prescriptions, total amount paid for brand prescriptions, average brand prescription cost, average days' supply for brand prescriptions. At a minimum, this report shall be delivered monthly.

Goold will comply with the State's request for a Monthly and State Fiscal Year Statistics Report that will be supplied monthly to the Bureau. This report will summarize the calendar year-to-date for the current month to the previous calendar year-to-date and will contain all of the details as outlined in the requirement. The details of this report are commonly accompanied by the corresponding graphs shown previously.

Samples of these reports are provided on the following pages. Each can be tailored to the State's specifications.

The Fiscal Year Statistics Report below displays various data, as shown on the left column of the chart, and compares the data from a month in 2013 to the same month in 2014, as well as calendar year 2013 to calendar year 2014.

[STATE NAME] **Medicaid Drug Benefit Program**
OCTOBER 2014

Monthly Statistics

	MO 2013	MO 2014	% CHANGE	Calendar YTD 2013	Calendar YTD 2014	% CHANGE
Total Paid Amount						
Members						
Cost Per Member						
Total Scripts						
Avg Scripts Per Member						
Avg Cost Per Script						
# Generic Scripts						
Generic Scripts as % of Total						
Generic Paid Amount						
Avg Generic Script Cost						
Avg Days Supply						
# Brand Scripts						
Brand Scripts as % of Total						
Brand Paid Amount						
Avg Brand Script Cost						
Avg Days Supply						

Figure 22: Sample Fiscal Year Statistics Report

4.1.11.5.1.11 Top twenty (20) Therapeutic Classes by Dollars: Lists the therapeutic class description, ranking based on amount paid, comparison from the previous year for the same period, and the percentage change from the previous year period, the percent of the overall pharmacy expenditures for the period and the percent of the overall pharmacy expenditures for the previous year period. At a minimum, this report shall be delivered quarterly and annually.

4.1.11.5.1.12 Top twenty (20) Drugs by Dollars: Lists the drug description, ranking based on amount paid, comparison from the previous year for the same period, and the percentage change from the previous year period, the percent of the overall pharmacy expenditures for the period and the percent of the overall pharmacy expenditures for the previous year period. At a minimum, this report shall be delivered quarterly and annually.

4.1.11.5.1.13 Top twenty (20) Therapeutic Classes by Utilization: Lists the therapeutic class description, ranking based on number of prescriptions, comparison from the previous year of the same period, and the percentage change from the previous year period, the percent of the overall number of prescriptions for the period and the percent of the overall number of prescriptions for the previous year period. At a minimum, this report shall be delivered quarterly and annually.

4.1.11.5.1.14 Top twenty (20) Drugs by Utilization: Lists the drug descriptions, ranking based on number of prescriptions, comparison from the previous year for the same period, and the percentage change from the previous year period, the percent of the overall number of prescriptions for the period and the percent of the overall number of prescriptions for the previous year period. At a minimum, this report shall be delivered quarterly and annually.

4.1.11.5.1.15 Top twenty (20) Prescribing Providers: Lists for both numbers of prescriptions prescribed and by amount paid for prescriptions prescribed: the prescriber NPI, prescriber name, total amount of prescription costs for prescribed drugs, total number of paid prescriptions prescribed, number of members for which prescriptions were prescribed, average price of paid prescriptions prescribed. At a minimum, this report shall be delivered quarterly and annually.

Goold is experienced at providing the above listed reports and agrees to provide BMS with the Quarterly and Annual reports with all of the data elements listed above as required by BMS. The following reports are examples of Goold's capability to provide the suite of reports requested in this RFQ.

The following report shows the top 20 therapeutic classes by amount paid. This compares from a sample month in 2013 to the same month in 2014 to easily identify shifts in spend. This type of report can be helpful in making recommendations for PDL changes and additions. We include a metric looking at the percent of paid amount so that one can see what percent of the total drug spend a particular category takes up.

Top 20 THERAPEUTIC CLASSES BY PAID AMOUNT

	Month 2013			Month 2014			
THERAPEUTIC CLASS	PAID AMOUNT	RANK	% of PAID AMOUNT	PAID AMOUNT	RANK	% of PAID AMOUNT	% CHANGE
Unmanaged Products: Other							
Stimulants: Long-Acting							
Atypical Antipsychotic: Oral							
Leukotriene Modifiers							
GLUCOCORTICOIDS							
Stimulants: Non-Stimulants							
ANTICONVULSANTS: ADJUVANTS							
INTRANASAL RHINITIS: CORTICOSTEROIDS							
HYPOGLYCEMICS: INSULINS							
GROWTH HORMONE							
HEPATITIS C TREATMENTS							
Cephalosporin Antibiotics - 3rd Generation							
MACROLIDES							
BETA LACTAM/BETA-LACTAMASE INHIBITOR COMBINATIONS							
BRONCHODILATORS, BETA AGONIST: Inhalers, Short-Acting							
GLUCOCORTICOID/BRONCHODILATOR COMBINATIONS							
Antihistamines							
PROTON PUMP INHIBITORS							
ANTIEMETICS: 5HTS RECEPTOR BLOCKERS							
STIMULANTS: Short-Acting							
Cystic Fibrosis							
Antineoplastics - Selected Systemic Enzyme Inhibitors							

Figure 23: Top 20 Therapeutic Classes Paid by Amount

The following report shows the top 20 drugs by paid amount. This chart is designed to compare data from a sample month in 2013 to the same month in 2014. The side-by-side comparison can help identify areas where PDL changes may need to be made.

Top 20 DRUGS BY PAID AMOUNT

	Month 2013			Month 2014			
DRUG DESCRIPTION	PAID AMOUNT	RANK	% of PAID AMOUNT	PAID AMOUNT	RANK	% of PAID AMOUNT	% CHANGE
MONTELUKAST SODIUM							
LISDEXAMFETAMINE DIMESYLATE							
ARIPIPRAZOLE							
METHYLPHENIDATE HCL							
ANTIHEMOPHILIC FACTOR VIII (PLASMA/ALBUMIN-FREE)							
BUDESONIDE							
DEXTROAMPHETAMINE SULF-SACCHARATE/AMPHETAMINE							
MOMETASONE FUROATE							
GUANFACINE HCL							
ALBUTEROL SULFATE							
DEXMETHYLPHENIDATE HCL							
SOMATROPIN							
QUETIAPINE FUMARATE							
ANTI-INHIBITOR COAGULANT COMPLEX							
AMOXICILLIN/POTASSIUM CLAVULANATE							
AZITHROMYCIN							
ANTIHEMOPHILIC FACTOR, HUMAN							
CETIRIZINE HCL							
CEFDINIR							
ANTIHEMOPHILIC FACTOR VIII, HUMAN RECOMBINANT							
ESOMEPRAZOLE MAGNESIUM							

Figure 24: Top 20 Drugs sorted by Paid Amount

The following report shows the top 20 therapeutic classes by utilization. This is displayed to compare from a sample month in 2013 to the same month in 2014. This report not only looks at the raw numbers and rank, but also puts the utilization in context of the overall program by reporting on the percent of the total utilization for each category.

Top 20 THERAPEUTIC CLASSES BY UTILIZATION (# of Scripts)

	Month 2013			Month 2014			
THERAPEUTIC CLASS	UTILIZATION	RANK	% TOTAL UTILIZATION	UTILIZATION	RANK	% TOTAL UTILIZATION	% CHANGE
Unmanaged Products: Other							
Antihistamines							
Stimulants: Long-Acting							
CEPHALOSPORINS: UNMANAGED							
MACROLIDES							
Analgesics, Narcotic - Short Acting							
Leukotriene Modifiers							
NSAIDS: NONSELECTIVE							
ANTICONVULSANTS: ADJUVANTS							
Atypical Antipsychotic: Oral							
BRONCHODILATORS, BETA AGONIST: Inhalers, Short-Acting							
BRONCHODILATORS, BETA AGONIST: INHALATION							
BETA LACTAM/BETA-LACTAMASE							
INTRANASAL RHINITIS: CORTICOSTEROIDS							
Oral Contraceptives							
Antidepressants: Ssris							
ANTIBIOTICS (TOPICAL)							
Cephalosporin Antibiotics - 3rd Generation							
ANTIFUNGALS							
STIMULANTS: Short-Acting							
Stimulants: Non-Stimulants							

Figure 25: Top 20 Therapeutic Classes by Utilization

The following report shows the top 20 drugs by utilization. This chart is also designed to compare data from a sample month in 2013 to the same month in 2014 and puts the values in context of the overall program.

Top 20 DRUGS BY UTILIZATION (# of Scripts)

	Month 2013			Month 2014			
DRUG DESCRIPTION	UTILIZATION	RANK	% TOTAL UTILIZATION	UTILIZATION	RANK	% TOTAL UTILIZATION	% CHANGE
CETIRIZINE HCL							
AMOXICILLIN							
ALBUTEROL SULFATE							
BROMPHENIRAMINE MALEATE/PHENYLEPHRINE							
AZITHROMYCIN							
MONTELUKAST SODIUM							
LISDEXAMFETAMINE DIMESYLATE							
IBUPROFEN							
AMOXICILLIN/POTASSIUM CLAVULANATE							
MOMETASONE FUROATE							
METHYLPHENIDATE HCL							
HYDROCODONE BITARTRATE/ACETAMINOPHEN							
SULFAMETHOXAZOLE/TRIMETHOPRIM							
DEXTROAMPHETAMINE SULF-SACCHARATE/AMPHETAMIN							
PREDNISOLONE SOD PHOSPHATE							
MUPIROCIN							
GUANFACINE HCL							
CLONIDINE HCL							
CEFDINIR							
TRIAMCINOLONE ACETONIDE							
NORGESTIMATE-ETHINYL ESTRADIOL							

Figure 26: Top 20 Drugs by Utilization

The following report shows the top 20 pharmacy NPIs by the paid amount for a given month in 2014 and can be compared to the chart on the following page for 2013.

Top 20 Pharmacy NPIs by Paid Amount for Month 2014

NPI NUM		Paid Amount	# Scripts	# of Members	Avg Cost Per Script
[redacted]					

Figure 27: Top 20 Pharmacy NPIs by Paid Amount – 2014

Top 20 Pharmacy NPIs by Paid Amount for Month 2013

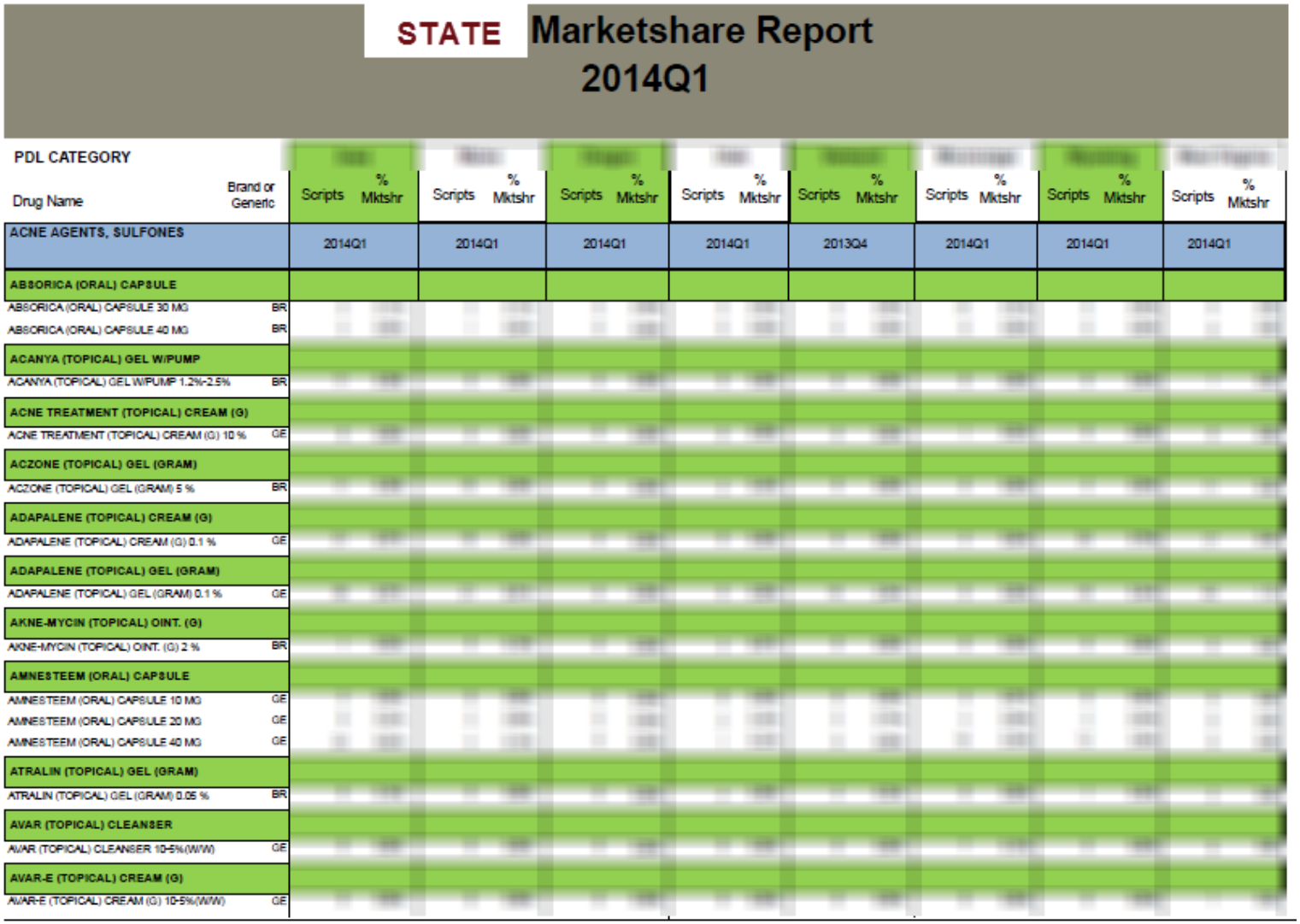
NPI NUM		Paid Amount	# Scripts	# of Members	Avg Cost Per Script
[illegible]					

Figure 28: : Top 20 Pharmacy NPIs by Paid Amount – 2014

4.1.11.5.1.16 Marketshare Summary Report: Lists the PDL and PPL therapeutic classes individually and unmanaged products collectively. This report shall provide the number of prescriptions for managed drugs and products within a therapeutic class, martketshare percentage for managed drugs and products within a therapeutic class, number of prescriptions for unmanaged drugs and products within a therapeutic class, and marketshare percentage for unmanaged drugs and products within a therapeutic class. At a minimum, this report must be provided quarterly.

Goold is familiar with the Marketshare Summary Reports and will provide the specified report to the Bureau with all of the data elements listed above quarterly, at a minimum, as required by BMS.

This report shows the market share of drug products in PDL classes in a recent quarter in each state. Using a standardized data format facilitates comparison of information across states. This better enables both Goold and the end user to identify issues or anomalies that might require additional review (such as higher than average utilization of a non-preferred drug in a particular state suggesting that a modification of PA criteria might be warranted). An excerpt of this report is provided on the following page but can be tailored to the State's specifications upon further discussions.



STATE Marketshare Report
2014Q1

PDL CATEGORY / Drug Name	Brand or Generic	Scripts	% Mktshr	Scripts	% Mktshr	Scripts	% Mktshr	Scripts	% Mktshr	Scripts	% Mktshr	Scripts	% Mktshr	Scripts	% Mktshr
ACNE AGENTS, SULFONES		2014Q1		2014Q1		2014Q1		2014Q1		2013Q4		2014Q1		2014Q1		2014Q1	
ABSORICA (ORAL) CAPSULE																	
ABSORICA (ORAL) CAPSULE 30 MG	BR																
ABSORICA (ORAL) CAPSULE 40 MG	BR																
ACANYA (TOPICAL) GEL W/PUMP																	
ACANYA (TOPICAL) GEL W/PUMP 1.2%-2.5%	BR																
ACNE TREATMENT (TOPICAL) CREAM (G)																	
ACNE TREATMENT (TOPICAL) CREAM (G) 10 %	GE																
ACZONE (TOPICAL) GEL (GRAM)																	
ACZONE (TOPICAL) GEL (GRAM) 5 %	BR																
ADAPALENE (TOPICAL) CREAM (G)																	
ADAPALENE (TOPICAL) CREAM (G) 0.1 %	GE																
ADAPALENE (TOPICAL) GEL (GRAM)																	
ADAPALENE (TOPICAL) GEL (GRAM) 0.1 %	GE																
AKNE-MYCIN (TOPICAL) OINT. (G)																	
AKNE-MYCIN (TOPICAL) OINT. (G) 2 %	BR																
AMNESTEEM (ORAL) CAPSULE																	
AMNESTEEM (ORAL) CAPSULE 10 MG	GE																
AMNESTEEM (ORAL) CAPSULE 20 MG	GE																
AMNESTEEM (ORAL) CAPSULE 40 MG	GE																
ATRALIN (TOPICAL) GEL (GRAM)																	
ATRALIN (TOPICAL) GEL (GRAM) 0.05 %	BR																
AVAR (TOPICAL) CLEANSER																	
AVAR (TOPICAL) CLEANSER 10-5%(W/W)	GE																
AVAR-E (TOPICAL) CREAM (G)																	
AVAR-E (TOPICAL) CREAM (G) 10-5%(W/W)	GE																

Figure 29: Marketshare Report

4.1.11.5.1.17 Therapeutic Class Marketshare Report: This report shall display within each therapeutic class, the drug or product name, brand or generic status, PDL or PPL status, number of units dispensed, number of paid prescriptions for the period, percentage of prescription marketshare within the therapeutic class, average units per prescription, pre-rebate paid amount, and average expenditures per prescription. At a minimum, this report must be provided quarterly.

Goold will provide the Therapeutic Class Marketshare Report with all of the data elements listed above quarterly, at a minimum, as required by BMS and demonstrated on the previous page.

4.1.11.5.1.18 Generic Compliance Report: This report will show the total number of prescriptions of brand versus generic drugs for a specific timeframe. This report shall display the POL managed therapeutic classes and report the number of prescriptions number of units paid total paid amount generic percentage for the therapeutic class and the generic percentage for the previous quarter. In additional this report shall report the overall generic percentage of managed and unmanaged products. At a minimum this report shall be provided quarterly.

Goold will provide the Generic Compliance Report with all of the data elements listed above quarterly, at a minimum, as required by BMS.

An example is shown on the following page.

[State logo]

[State]
Generic Percent Report
3rd Qtr 2014

GHS an Emdeon company

CATEGORY GROUP DESCR	SCRIPTS	QUANTITY	PAID AMT	GENERIC	PRIOR QTR
ACNE AGENTS					
ALZHEIMER'S AGENTS					
ANALGESICS, NARCOTIC - LONG ACTING					
ANALGESICS, NARCOTIC - SHORT ACTING					
ANALGESICS, TOPICAL					
ANDROGENIC AGENTS					
ANGIOTENSIN MODULATORS					
ANTIBIOTICS, GI					
ANTIBIOTICS, MISCELLANEOUS					
ANTIBIOTICS, TOPICAL					
ANTIBIOTICS, VAGINAL					
ANTICOAGULANTS					
ANTICONVULSANTS					
ANTIDEPRESSANTS, OTHER AND SNRIS					
ANTIDEPRESSANTS, SSRIS					
ANTIEMETICS					
ANTIFUNGALS, ORAL					
ANTIFUNGALS, TOPICAL					
ANTIFUNGALS, VAGINAL					
ANTIHISTAMINES, MINIMALLY SEDATING					
ANTIMIGRAINE AGENTS					
ANTINEOPLASTICS - SELECTED SYSTEMIC ENZYME INHIBITORS					
ANTIPARASITICS, TOPICAL					
ANTIPARKINSON'S AGENTS (ORAL)					
ANTIPSYCHOTICS, ATYPICAL					
ANTIVIRALS (ORAL)					
ANTIVIRALS (TOPICAL)					
AROMATASE INHIBITORS					
ATOPIC DERMATITIS					
BETA BLOCKERS AND MISCELLANEOUS ANTIANGINALS (ORAL)					
BILE SALTS					
BLADDER RELAXANT PREPARATIONS					
BONE RESORPTION SUPPRESSION AND RELATED AGENTS					
BPH AGENTS					
BRONCHODILATORS AND RESPIRATORY DRUGS					
BRONCHODILATORS, BETA AGONIST					
CALCIUM CHANNEL BLOCKERS					
CALORIC AGENTS					
CEPHALOSPORINS AND RELATED ANTIBIOTICS (ORAL)					
COLONY STIMULATING FACTOR					
CYSTIC FIBROSIS					

Confidential and Proprietary

Figure 30: Sample Generic Compliance Report

4.1.11.5.1.19 PDL and PPL Compliance Report: This report will show the percent compliance with the PDL and PPL. It shall display the PDL and PPL managed therapeutic classes and report the number of prescriptions number of units paid total paid amount percentage of preferred products paid for the therapeutic class, and the percentage of preferred products paid for the previous quarter. In addition, this report shall report the overall preferred percentage of managed and unmanaged products collectively. At a minimum this report must be provided quarterly.

Goold will provide the PDL and PPL Compliance Report with all of the data elements listed above quarterly, at a minimum, as required by BMS.

An example of the PDL compliance report is shown on the following page. A report similar to this will be compiled for the State for the PPL.

[State logo]

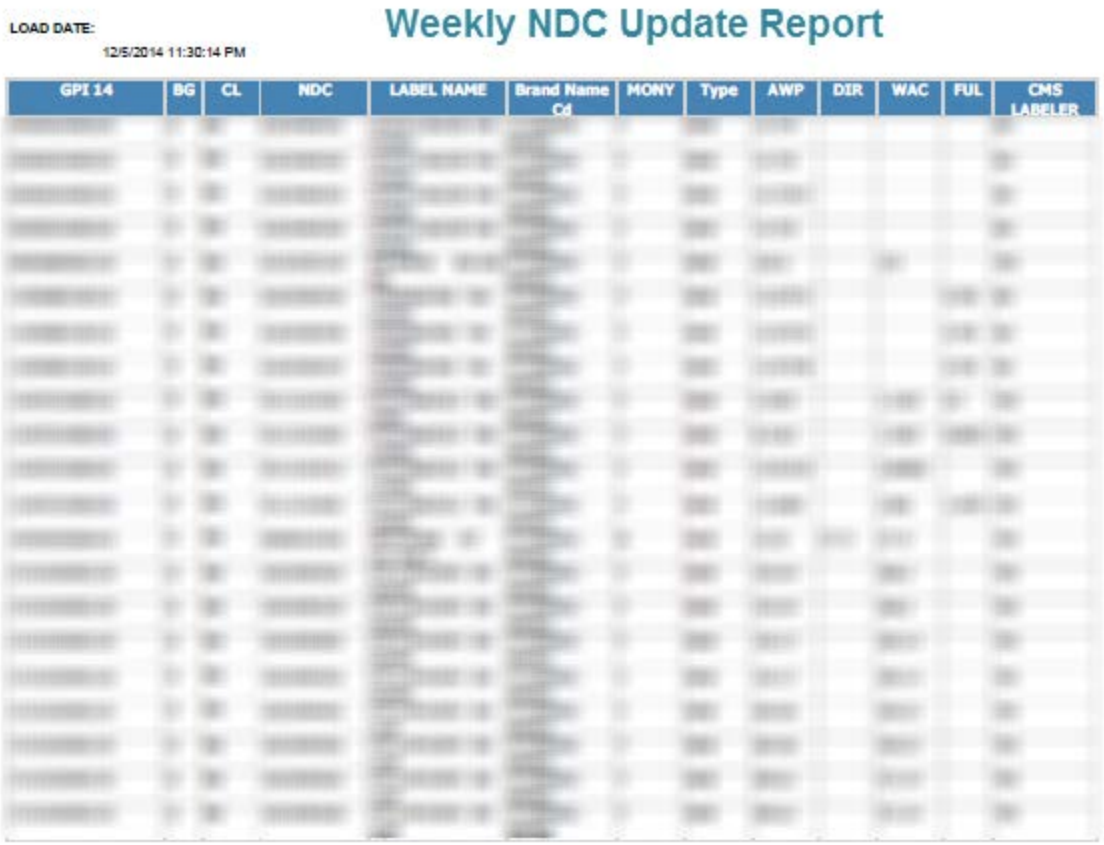
[State]
PDL Compliance Report
3rd Qtr 2014

CATEGORY GROUP DESCRIPTION	SCRIPTS	QUANTITY	PAID AMT	PREFERRED	PRIOR PREF PCT
Acne Agents					
ALZHEIMER'S AGENTS					
Analgesics, Narcotic - Long Acting					
Analgesics, Narcotic - Short Acting					
ANALGESICS, TOPICAL					
ANDROGENIC AGENTS					
ANGIOTENSIN MODULATORS					
ANTIBIOTICS, GI					
Antibiotics, Miscellaneous					
Antibiotics, Topical					
Antibiotics, Vaginal					
ANTICOAGULANTS					
ANTICONVULSANTS					
ANTIDEPRESSANTS, OTHER and SNRIs					
Antidepressants, Ssris					
ANTIEMETICS					
ANTIFUNGALS, ORAL					
ANTIFUNGALS, TOPICAL					
Antifungals, Vaginal					
ANTIHISTAMINES, MINIMALLY SEDATING					
ANTIMIGRAINE AGENTS					
Antineoplastics - Selected Systemic Enzyme Inhibitors					
Antiparasitics, Topical					
ANTIPARKINSON'S AGENTS (Oral)					
Antipsychotics, Atypical					
ANTIVIRALS (Oral)					
Antivirals (Topical)					
Aromatase Inhibitors					
ATOPIC DERMATITIS					
BETA BLOCKERS and MISCELLANEOUS ANTIANGINALS (Oral)					
BILE SALTS					
BLADDER RELAXANT PREPARATIONS					
BONE RESORPTION SUPPRESSION AND RELATED AGENTS					
BPH AGENTS					
Bronchodilators And Respiratory Drugs					
BRONCHODILATORS, BETA AGONIST					
CALCIUM CHANNEL BLOCKERS					
Caloric Agents					
CEPHALOSPORINS AND RELATED ANTIBIOTICS (Oral)					
Colony Stimulating Factor					
Cystic Fibrosis					
CYTOKINE & CAM ANTAGONISTS					
ERYTHROPOIESIS STIMULATING PROTEINS					
Fibromyalgia Agents					
FLUOROQUINOLONES, ORAL					
Genital Warts And Related Agents					
Gi Ulcer Therapies					
GLUCOCORTICOIDS, INHALED					
GROWTH HORMONE					
H.Pylori Combination Treatments					
HEPATITIS TREATMENTS					

Figure 31: Sample PDL Compliance Report

4.1.11.5.1.20 Weekly NDC Update Report: This report will summarize new additions to the drug reference file. At a minimum this report shall display the PDL or PPL category drug or product name, generic name, NDC or product code date of FDA approval, date of database entry, and comments. This report shall be provided weekly.

Goold will provide the Weekly NDC Update Report with all of the data elements listed above weekly, at a minimum, as required by BMS. Goold currently produces the following similar report and will tailor it to meet West Virginia's specifications. A sample is included below.


LOAD DATE:
12/5/2014 11:30:14 PM

Weekly NDC Update Report

GPI 14	BG	CL	NDC	LABEL NAME	Brand Name Cd	MONY	Type	AWP	DIR	WAC	FUL	CMS LABELER

Figure 32: Sample Weekly NDC Update Report

4.1.11.5.1.21 Rebate Dispute Status Report: No later than fourteen (14) calendar days after the end of each month, the Vendor will submit a written report detailing the status of any disputes that the Bureau has requested the Vendor to assist in resolving. At a minimum, this report shall be provided monthly.

All dispute activity is documented in a weekly status report. Dispute resolution is discussed, and labeler communication is documented in the weekly meeting minutes, including client comments and/or related action items. Goold will provide a Rebate Dispute Status Report monthly, at a minimum, no later than fourteen (14) calendar days after the end of each month, as required by BMS.

4.1.11.5.1.22 SMAC Savings Report: This report shall document savings generated from the SMAC pricing program. At a minimum, this report must be provided quarterly.

Goold will provide the SMAC Savings Report quarterly, at a minimum, as required by BMS. A sample of this report is provided below. This demonstrates the Actual Savings from the SMAC program in a summary by Month. The Total Units, Actual SMAC Savings and then the SMAC Savings by Quarter are displayed within this sample report and can be tailored to the State's specifications upon further discussions.

[STATE] Medicaid Pharmacy SMAC Program

Actual SMAC Savings

Based on [STATE] utilization data

Notes: [STATE] first started implementing GHS SMACs on [DATE]
EAC = AWP - 25% prior to [Date]
EAC = Consolidated Price 1 - 10% from [Date] through [Date]
EAC = SWP - 25% from [Date] through [Date]
EAC = WAC + 1% for [Date]
EAC = WAC since [Date]

Summary by Month

Month	Total Units with SMAC	Actual SMAC savings = (Difference between [Lesser of EAC and FUL] and SMAC) x Total Units with SMAC	Actual SMAC savings by Quarter	Quarter
Jan-10				
Feb-10			$ 14,587,500	Q1 CY2010
Mar-10	92,749,734	$ 14,587,500		
Apr-10	84,118,446	$ 13,603,995		
May-10	83,068,470	$ 13,017,853	$ 39,786,489	Q2 CY2010
Jun-10	83,481,005	$ 13,164,641		
Jul-10	80,463,475	$ 13,059,503		
Aug-10	82,913,093	$ 13,661,662	$ 40,386,097	Q3 CY2010
Sep-10	84,400,265	$ 13,664,933		
Oct-10	86,306,969	$ 14,576,612		
Nov-10	87,156,681	$ 15,601,533	$ 46,843,596	Q4 CY2010
Dec-10	90,009,301	$ 16,665,451		
Jan-11	99,579,304	$ 18,075,450		
Feb-11	90,339,075	$ 16,683,081	$ 54,182,977	Q1 CY2011
Mar-11	104,376,528	$ 19,424,447		
Apr-11	93,519,889	$ 18,154,552		
May-11	93,576,243	$ 18,842,984	$ 55,493,674	Q2 CY2011
Jun-11	90,899,556	$ 18,496,139		
Jul-11	86,022,146	$ 17,869,273		
Aug-11	91,628,320	$ 19,471,326	$ 56,704,940	Q3 CY2011
Sep-11	87,446,041	$ 19,364,342		
Oct-11	89,756,783	$ 9,409,424		
Nov-11	88,573,971	$ 9,458,590	$ 28,803,586	Q4 CY2011
Dec-11	90,518,249	$ 9,935,572		
Jan-12	82,203,801	$ 19,865,327		
Feb-12	83,841,697	$ 20,806,852	$ 63,048,844	Q1 CY2012
Mar-12	86,587,005	$ 22,376,665		
Apr-12	80,500,890	$ 22,013,749		
May-12	80,991,747	$ 24,642,327	$ 58,458,269	Q2 CY2012
Jun-12	80,855,086	$ 11,802,194		
Jul-12	74,671,753	$ 10,322,923		
Aug-12	69,634,320	$ 11,751,235	$ 35,412,902	Q3 CY2012
Sep-12	73,460,659	$ 13,338,744		
Oct-12	80,513,276	$ 13,586,810		
Nov-12	77,597,691	$ 13,260,010	$ 38,649,094	Q4 CY2012
Dec-12	77,095,039	$ 11,802,274		
Jan-13	79,242,852	$ 12,166,334		
Feb-13	67,447,153	$ 10,386,071	$ 33,803,659	Q1 CY2013
Mar-13	71,412,256	$ 11,251,254		
Apr-13	68,309,154	$ 11,110,351		
May-13	67,150,158	$ 11,509,819	$ 32,585,905	Q2 CY2013
Jun-13	58,381,896	$ 9,965,735		
Jul-13	60,859,724	$ 10,186,017		
Aug-13	59,910,825	$ 10,423,786	$ 31,012,928	Q3 CY2013
Sep-13	59,714,676	$ 10,403,124		
Oct-13	62,840,817	$ 10,387,956		
Nov-13	58,449,609	$ 9,831,686	$ 30,607,415	Q4 CY2013
Dec-13	60,054,788	$ 10,387,773		

Figure 33: Actual SMAC Savings Summary Report

4.1.11.5.1.23 PDL and PPL Savings Report: This report shall document savings generated from the PDL and PPL. At a minimum, this report must be provided quarterly.

Goold will provide the PDL Savings Report quarterly, at a minimum, as required by BMS. Goold will work with the Bureau during DDI to clearly define how savings should be considered and subsequently calculated.

4.1.11.5.1.24 SMAC Savings Beyond Aggregate FUL Cap: This report will document assurances that multisource drug pricing is in compliance with federal regulations (42 CFR 447.332 or revision). At a minimum, this report shall be provided quarterly.

Goold will provide the SMAC Savings Beyond Aggregate FUL Cap Report, which assures that generic pricing is in compliance with 42 CFR 447.332, quarterly, at a minimum, as required by BMS.

The following is a sample of this report. The table displays the Total Units for FUL and SMAC, the Aggregate SMAC Savings, and then the Aggregate SMAC savings by quarter. This could be tailored to the State's specifications upon further discussions.

[STATE] Medicaid Pharmacy SMAC Program

"Aggregate" SMAC savings, or SMAC Savings Beyond Aggregate FUL Cap

Includes only NDCs with both FUL and SMAC
Based on [STATE] utilization data
Note: [STATE] first started implementing GHS SMACs on [DATE]

Summary by Month

Month	Total Units with both FUL and SMAC	"Aggregate" SMAC savings, or SMAC savings beyond aggregate FUL = (FUL - SMAC) x Total Units with both FUL and SMAC	"Aggregate" SMAC savings by Quarter	Quarter
Jan-10				
Feb-10			$ 8,650,936	Q1 CY2010
Mar-10	56,724,782	$ 8,650,936		
Apr-10	52,205,323	$ 8,056,199		
May-10	51,030,183	$ 7,985,766	$ 24,117,209	Q2 CY2010
Jun-10	51,993,616	$ 8,075,244		
Jul-10	49,520,963	$ 7,818,523		
Aug-10	50,595,010	$ 8,026,966	$ 23,808,088	Q3 CY2010
Sep-10	50,916,772	$ 7,962,598		
Oct-10	51,366,477	$ 8,272,518		
Nov-10	52,014,022	$ 8,755,689	$ 26,094,906	Q4 CY2010
Dec-10	52,603,649	$ 9,066,698		
Jan-11	55,707,961	$ 9,782,728		
Feb-11	50,314,520	$ 9,068,398	$ 29,325,517	Q1 CY2011
Mar-11	58,101,142	$ 10,474,391		
Apr-11	52,420,043	$ 9,784,156		
May-11	53,692,258	$ 10,325,732	$ 30,246,204	Q2 CY2011
Jun-11	51,953,293	$ 10,136,316		
Jul-11	49,665,892	$ 9,700,296		
Aug-11	52,363,662	$ 10,121,928	$ 29,715,538	Q3 CY2011
Sep-11	51,121,527	$ 9,893,314		
Oct-11	51,672,052	$ 10,017,822		
Nov-11	51,133,065	$ 9,989,742	$ 30,177,049	Q4 CY2011
Dec-11	51,980,885	$ 10,169,486		
Jan-12	52,154,387	$ 10,147,625		
Feb-12	51,588,813	$ 10,242,161	$ 31,193,707	Q1 CY2012
Mar-12	53,431,944	$ 10,803,921		
Apr-12	52,086,840	$ 10,308,400		
May-12	51,539,322	$ 10,415,292	$ 30,395,136	Q2 CY2012
Jun-12	48,234,399	$ 9,671,443		
Jul-12	42,365,874	$ 8,644,536		
Aug-12	42,470,291	$ 8,667,622	$ 25,695,113	Q3 CY2012
Sep-12	40,995,437	$ 8,382,954		
Oct-12	44,341,341	$ 8,985,505		
Nov-12	42,259,365	$ 8,671,962	$ 26,071,489	Q4 CY2012
Dec-12	42,231,920	$ 8,414,022		
Jan-13	41,639,864	$ 8,759,042		
Feb-13	35,087,126	$ 7,472,870	$ 24,114,874	Q1 CY2013
Mar-13	36,992,758	$ 7,882,962		
Apr-13	34,981,523	$ 7,635,351		
May-13	34,159,563	$ 7,526,198	$ 21,853,913	Q2 CY2013
Jun-13	30,142,792	$ 6,692,364		
Jul-13	31,575,426	$ 6,995,732		
Aug-13	30,877,591	$ 6,897,092	$ 20,647,972	Q3 CY2013
Sep-13	30,333,142	$ 6,755,148		
Oct-13	31,670,621	$ 6,920,665		
Nov-13	28,941,508	$ 6,363,588	$ 19,875,814	Q4 CY2013
Dec-13	29,552,085	$ 6,591,560		

Figure 34: Sample SMAC Savings Beyond Aggregate FUL Cap

4.1.11.5.1.25 WV Provider Pricing Support and Dispute Resolution Report: This report shall log and track all pricing issues from providers and resolutions reached. This report must detail the dispute, and track both approved and resolved issues during the state fiscal year (7/1/XX-6/30/XX) as well as open disputes still being considered. This report shall include, but not be limited to: product name, NDC, prescription number, inquiry date, date of service, Average Wholesale Price (A WP), Wholesale Acquisition Cost (WAC), Federal Upper Limit (FUL), SMAC, provider acquisition cost, dispensing fee, quantity, reviewer identifier, date of outcome returned, recommendation, final outcome, comments, new SMAC, effective date, provider name, and removal of FUL effective date. At a minimum, this report must be provided weekly.

Goold will provide the WV Provider Pricing Support and Dispute Resolution Report, which will track all pricing issues from providers and resolutions reached. Detail about the dispute will be reported and both approved and resolved issues will be tracked. We currently do this for our

other SMAC clients on a weekly basis and will include this for West Virginia. All other report information outlined above will be included in the report to be provided weekly to the Bureau.

4.1.11.5.1.26 New GSN SMAC Report: Vendor shall provide a report of new products for which a SMAC is recommended. This report shall include, but not be limited to, the Generic Sequence Number (GSN), product name, SMAC, effective date, and comments. 1bis report shall be delivered weekly.

Goold will provide the New GSN SMAC Report weekly and will include the information specified by the State. We currently provide this report for our existing SMAC clients and, although changes may not occur weekly, our staff will be happy to supply this report to the State on a weekly basis or on any frequency requested. Goold regularly monitors the First Data Bank and MediSpan drug files for opportunities for savings on newly released generic drugs and drugs where WAC prices have decreased.

4.1.11.5.1.27 PDL and PPL Changes Report: This report will highlight changes to the PDL and /or PPL approved by the P & T Committee and/or Bureau, and must be provided no later than fourteen (14) calendar days after each P & T Committee meeting.

Goold will provide the PDL and PPL Changes Report which will highlight changes to the PDL approved by the P&T Committee no later than fourteen (14) calendar days after every P&T Committee meeting, as required by BMS. An excerpt of this report is included on the following page and can be tailored to the State's specifications.

[STATE] Medicaid PDL
Recommended Changes Summary
Pharmaceutical and Therapeutics Committee Meeting
[DATE]

Drug	Current PDL Status	01/1/15 Planned PDL Status	Recommend Grandfather existing users	Comments
ACNE AGENTS				
AZELEX (azelaic acid)	Preferred	Non-Preferred	No	
DUAC (benzoyl peroxide/clindamycin)	Preferred	Non-Preferred	No	
ERYGEL (erythromycin)	Preferred	Non-Preferred	No	
TAZORAC (tazarotene)	Preferred	Non-Preferred	No	
tretinoin	Preferred	Non-Preferred	No	
ALZHEIMER'S AGENTS				
ARICEPT 23 MG (donepezil)	Preferred	Non-Preferred	Yes	
donepezil 23mg	Preferred	Non-Preferred	Yes	
ANDROGENIC AGENTS				
ANDROGEL (testosterone gel)	Non-Preferred	Preferred	No	
STRIANT (testosterone)	New to PDL	Non-Preferred	No	
VOGELXO (testosterone)	New to PDL	Non-Preferred	No	
ANGIOTENSIN MODULATORS				
BENICAR (olmesartan)	Preferred	Non-Preferred	No	
BENICAR HCT (olmesartan/HCTZ)	Preferred	Non-Preferred	No	
irbesartan	Preferred	Non-Preferred	No	
irbesartan/HCTZ	Preferred	Non-Preferred	No	

Figure 35: Excerpt of PDL Change Report

4.1.11.5.1.28 Supplemental Drug Rebate Contract and Product Rebate Contract Tracking Report: This report will track all supplemental drug rebate and product rebate contracts between the Bureau and manufacturers in the process of being finalized. This report must include the status of each contract at all points toward completion. The report shall contain, at a minimum: labeler identifier, manufacturer name, labeler number, date contract mailed, date returned form the manufacturer, date sent to state, date sent to manufacturer, contract term, contract end date, contract year. This report shall be provided monthly and more often if requested.

Goold will provide the Supplemental Rebate Contract and Product Rebate Tracking Report with all of the data elements listed above monthly, or more often if requested, as required by BMS. A sample of this report is shown below but can be tailored to the State's specifications.

2015 Contracts Update								
Manufacturer Name	**Labeler Code 1**	**Labeler Code 2**	**Type**	**Date Contract Mailed to MFG**	**Date Returned from MFG**	**Date Sent to State**	**Fully executed sent to MFG**	**Notes**
AbbVie US LLC	00032	00074	SRA	9/29/2014	10/14/2014	10/16/2014	11/10/2014	7717 9723 8530
Actelion Pharma	66215		SRA	9/29/2014	10/15/2014	10/16/2014	11/10/2014	7717 9740 3519
Alcon Labs	00065		SRA	9/29/2014	10/24/2014	10/30/2014	11/12/2014	7718 2818 7777
Allergan USA, Inc.	00023		SRA	9/29/2014	10/6/2014	10/9/2014	10/31/2014	7716 9802 3899
Amgen USA, Inc.	55513	58406	SRA	9/29/2014	10/31/2014	10/31/2014	10/31/2014	7716 9816 8154
Aptalis Pharma US	42865	58914	SRA	9/29/2014				
Astellas Pharma US, Inc.	51248		SRA	10/1/2014	10/7/2014	10/9/2014	10/31/2014	7716 9809 9632
AstraZeneca LP	00186		SRA	9/29/2014	10/28/2014	10/30/2014	11/12/2014	7718 2814 1558
AstraZeneca Pharma	00310		SRA	9/29/2014	10/28/2014	10/30/2014	11/12/2014	7718 2825 4322
Biogen Idec U.S.	59627		SRA	10/6/2014	10/31/2014	11/7/2014	11/20/2014	7719 3017 2424
Boehringer Ingelheim	00597		SRA	9/29/2014	10/24/2014	11/4/2014	11/12/2014	7718 2828 6810
Chiesi (fka Cornerstone)	10122		SRA	9/29/2014	Sent to State	11/5/2014	11/5/2014	7717 4858 7858
Forest Labs	00456		SRA	9/29/2014				
Fresenius Medical Care NA	49230		SRA	9/29/2014	10/6/2014	10/9/2014	10/31/2014	7716 9795 5333

Table 7: SR Contract and Product Rebate Tracking Report

4.1.11.5.1.29 Supplemental Drug and Product Rebate Contract Details Report: This report will document all contracts finalized between the Bureau and manufacturers, and must include contract details such as, but not limited to: product description, NDC, labeler, contracted guaranteed net price (GNP), contracted percent of price, contract type. This report shall be provided monthly.

Goold will provide a Supplemental Rebate Contract Details Report with all of the data elements listed above monthly, as required by BMS.

4.1.11.5.1.30 Supplemental Drug Rebate and Product Rebate Pricing Files Quality Assurance Checklists: These reports will track the steps that are taken by the Vendor to ensure that supplemental drug rebate and product rebate pricing files are correct and accurately contain contract data. At a minimum, these reports must be provided quarterly.

Goold will provide the Supplemental Drug Rebate and Product Rebate Pricing Files Quality Assurance Checklist, which will track the steps that are taken by Goold to assure that the supplemental rebate pricing file is correct and that it accurately contains the supplemental rebate contract data quarterly, at a minimum, as required by BMS.

4.1.11.5.1.31 Supplemental Drug Rebate and Product Rebate Contract Files Quality Assurance Checklists: These reports will track the steps that are taken by the Vendor to ensure that supplemental drug rebate and product rebate contract files are correct and accurately contain contract data. At a minimum, these reports must be provided quarterly.

Goold will provide a Supplemental Drug Rebate and Product Rebate Contract Files Quality Assurance Checklist with all of the data elements listed above monthly, as required by BMS.

4.1.11.5.1.32 Supplemental Drug Rebate and Product Rebate Pricing Files -Additions and Corrections Reports: These reports will track adjustments that are included on the supplemental drug rebate and product rebate pricing files and the reasons for the adjustments. At a minimum, this report must be provided quarterly.

Goold will provide the Supplemental Drug Rebate and Product Rebate Pricing Files - Additions and Corrections Report that will track adjustments that are included on the supplemental rebate pricing file and the reasons for the adjustments quarterly, at a minimum, as required by BMS.

4.1.11.5.1.33 Supplemental Drug Rebate and Product Rebate Contract Files -Additions and Corrections Reports: These reports will track adjustments that are included on the supplemental drug rebate and product rebate contract files and the reasons for the adjustments. At a minimum, this report must be provided quarterly.

Goold will provide the Supplemental Drug Rebate and Product Rebate Contract Files - Additions and Corrections Report that will track adjustments that are included on the supplemental rebate pricing file and the reasons for the adjustments quarterly, at a minimum, as required by BMS.

4.1.11.5.1.34 Supplemental Drug Rebate and Product Rebate Pricing Files Spreadsheets: These reports will contain all the data for each NDC included on the supplemental drug rebate and product rebate pricing files, along with any other pertinent rebate contract or pricing information. At a minimum, this report must be provided quarterly.

Goold will provide the Supplemental Drug Rebate and Product Rebate Pricing Files Spreadsheet with all of the data elements listed above quarterly, at a minimum, as required by BMS.

4.1.11.5.1.35 Supplemental Drug Rebate and Product Rebate Contract Files Spreadsheets: These reports will contain all the data for each NDC included on the supplemental drug rebate and product rebate contract files, along with any other pertinent rebate contract information. At a minimum, this report must be provided quarterly.

Goold will provide the Supplemental Drug Rebate and Product Rebate Contract Files Spreadsheet with all of the data elements listed above quarterly, at a minimum, as required by BMS.

4.1.11.5.1.36 NDC Conversion Factor Report: This report will track the drugs and products that require a unit of measure conversion factor in the rate calculation. At a minimum, this report shall be provided quarterly.

Goold will provide the NDC Conversion Factor Report with all of the data elements listed above quarterly, at a minimum, as required by BMS.

Ad Hoc Reports

4.1.11.5.1.37 Ad Hoc Reports: Vendor shall provide responses to ad hoc reporting requests by the Bureau within five (5) business days of the request throughout the duration of the contract at no additional cost to the State. For cost estimation purposes, assume fifty (50) ad hoc reports per year. Ad hoc reports shall include the report methodology and parameters used in developing the reports.

Goold will provide the Bureau with timely responses to requests for ad hoc reports when requested by the Bureau throughout the duration of the contract, at no additional cost to the State; Goold will include the methodology and parameters used to develop the reports. In addition, Goold is pleased to provide BMS with a license to use a Web Intelligence (WEBI) tool that is loaded with West Virginia Medicaid pharmacy data. This tool will provide a desktop resource for rapid answers to utilization questions, including detail to the claim level. Goold will provide any information or ad hoc report upon request in compliance with this RFQ, and will provide this tool for use by the Bureau as well.

4.1.11.5.1.38 Additional Ad Hoc Reports: Vendor shall include in the Pricing Pages (Line I 0) the cost of each additional ad hoc report that exceed the estimated fifty (50) ad hoc reports per year that are included in the base contract.

Per the State's request, Goold has provided an hourly rate for additional services in the pricing pages of this response. For ad hoc reporting purposes, reports requested beyond the estimated 50 of this this RFQ, the State should refer to Goold's hourly rate for an additional cost estimate.

Business Rules Document

4.1.11.5.1.39 Business Rules Document: Vendor shall provide a document that details all business rules that apply to the PDL, PPL, and SMAC programs, as well as to the supplemental drug and product rebate invoicing, in an electronic format. This document shall contain at a minimum: processes, standard operational procedures, details regarding data file layouts, delivery schedules and maintenance of reports, management of NDCs, prior authorization requirements, contracting deliverables, pricing methodologies, telephone line processes, and all details of other business rules and procedures.

Goold will provide the Business Rules Document in an electronic format as required by BMS. Information to be included in the Document will include at a minimum:

- Processes;
- Standard operations procedures;
- Details regarding data file layouts;
- Delivery schedules and maintenance of reports,
- Management of NDCs;
- Prior authorization requirements;
- Contracting deliverables;
- Pricing methodologies;
- Telephone line processes;
- All other details of other business rules and procedures.

Training Handbook

4.1.11.5.1.40 Training Handbook: Vendor will develop a Training Handbook that describes all major processes being conducted by the Vendor to meet the needs of each requirement and deliverable of this contract. This handbook shall be developed at contract initiation and maintained throughout the life of the contract. Any changes will be added to the Handbook and provided to the Bureau within five (5) days after the change is made. It will be used for purposes of training new Bureau staff on what is currently being accomplished by the Vendor, as well as to help guide the transition of knowledge at the end of the contract.

Goold will develop a Training Handbook that describes all major processes being conducted by Goold to meet the needs of each requirement and deliverable of this contract. Goold understands that this document will be developed during the contract initiation phase and is to be maintained throughout the life of the contract for training purposes for new staff as well as a to guide through the transition at the end of the contract. As changes and updates occur, Goold will provide the Bureau with an updated Handbook within five days of making the changes.

4.1.12 Data Files

4.1.12 Vendor shall create data files to be shared with the Bureau and Bureau's partners relating to the PDL, PPL, and SMAC programs.

Goold agrees to create data files relating to the PDL, PPL and SMAC programs for West Virginia to be shared with the Bureau and its partners.

4.1.12.1 Vendor shall, at a minimum, create and distribute to the Bureau or Bureau's designee the following data files in an electronic that are compatible with the WV Office of Technology's currently supported versions of Microsoft Office® Suite:

- ***4.1.12.1.1 Weekly SMAC update file;***
- ***4.1.12.1.2 Weekly SMAC web list;***
- ***4.1.12.1.3 Weekly PDL and PPL files. These files shall contain all available NDCs regardless of their rebate statues;***
- ***4.1.12.1.4 Quarterly supplemental rebate rate, product rebate rate, and contract files; See Attachment C and D;***
- ***4.1.12.1.5 PDL and PPL reconciliation files when needed;***
- ***4.1.12.1.6 Complete PDL and PPL files when needed;***
- ***4.1.12.1.7 PDL and PPL file updates or complete files to be delivered to the Medicaid MCOs, Bureau, or other Bureau designees as needed;***
- ***4.1.12.1.8 Pharmacy utilization files to be delivered to the SSDC vendor, the Bureau, or Bureau's designee quarterly;***
- ***4.1.12.1.9 Other data files when identified that support the PDL, PPL, and SMAC programs quarterly***

As outlined in the requirement above, Goold will create and distribute, at a minimum, the listed data files in electronic format. These files will be compatible with the WV Office of Technology's currently supported versions of Microsoft Office® Suite.

4.1.13 Newsletter

4.1.13 Vendor shall develop, create, and mail to 15,000 prescribers and pharmacies quarterly newsletters containing information relating to changes to the PDL, PPL and other pharmacy program matters in a file format that is compatible with the WV Office of Technology's currently supported versions of Microsoft Office® Suite. Mailing shall be via United States Postal service or other nationally recognized carrier. Vendor shall also provide an electronic final version that will be displayed on the Bureau's website. Newsletter content and schedule must be approved by the Bureau, at a maximum of quarterly.

Goold will work with the State to develop, create and mail 15,000 newsletters quarterly to prescribers and pharmacies. Content of the newsletter will include, but not be limited to, information relating to changes in the PDL, PPL and other pharmacy programs matters. The newsletter will be compatible with the WV Office of Technology's currently supported versions of Microsoft Office® Suite and Goold will use the United State Postal service or other recognized carrier to distribute the newsletters.

An electronic, final version of the newsletter will be made available to the State for use on the BMS website. All versions of the newsletter will be approved by the Bureau prior to any distribution.

4.1.14 Contract Execution and Implementation Plan

4.1.14 Vendor shall assist and fully cooperate with the Bureau in the implementation of the contract executed from this RFQ upon effective date of the contract.

As Goold has done in the past with West Virginia, we agree to assist and fully cooperate with the Bureau during the implementation of any contract that is executed as a result of this RFQ.

4.1.14.1 Vendor shall submit with their quotation an Implementation Plan that demonstrate the Vendor's ability to assume the responsibilities for the Bureau's PDL, PPL, and SMAC programs upon award of this contract.

Goold will comply with all of the requirements outlined above in the RFQ Specification document. A draft Implementation Plan can be found in Exhibit C.

4.1.14.2 Vendor's Implementation Plan must describe major task assignments considered to meet PDL, PPL, and SMAC program services, including but not limited to, project start-up, project status, project updates, and project reassignments.

The Implementation Plan included in Exhibit C describes the major task assignments which need to be considered in order to meet PDL, PPL and SMAC program requirements. Detailed information regarding the resources assigned to the major tasks is supplied, including additional information related to Goold's comprehensive approach to the project.

4.1.14.3 Vendor shall conduct face-to-face meetings with the Bureau's staff and Vendor's key staff and other support staff to initiate the contract deliverables and services. These meetings shall be conducted at the Bureau's offices in Charleston, West Virginia.

Upon project initiation, Goold's key staff will meet with BMS in person to discuss contract deliverables and services. Goold understands that these meetings will be held at the Bureau's office in Charleston, West Virginia.

4.1.15 Transition and Turnover

4.1.15 Vendor shall assist and fully cooperate with the Bureau when transitioning to a new vendor at the end of the contract executed from this RFQ.

In the event that a replacement vendor is selected as the result of a future re-procurement, Goold is prepared to assist and fully cooperate with the State, as directed. Goold will support transition planning services to enable a new PDL, PPL, SMAC vendor or the State to continue providing the pharmacy services specified in the RFQ.

4.1.15.1 Vendor shall provide a Close-Out and Turnover Plan that identifies the Vendor's approach, tasks, staffing, and schedule for turnover of contract responsibilities.

Goold will provide a Close-Out and Turnover Plan that identifies and details Goold's approach, tasks, staffing, and schedule for turnover of contract responsibilities.

4.1.15.2 Vendor will provide the Close-Out and Turnover Plan within thirty (30) calendar days of receiving Bureau notification to initiate the Close-Out and Turnover Phase.

Goold will agrees to provide a Close-Out and Turnover Plan within thirty (30) calendar days of receiving notification from BMS to initiate the Close-Out and Turnover Phase.

4.1.15.3 Vendor shall dedicate resources consistent with the approved Close-Out and Turnover Plan.

Goold will dedicate appropriate resources consistent with the approved Close-Out and Turnover Plan for the State of West Virginia.

4.1.15.4 Upon request, Vendor shall transfer to the Bureau's ownership any and all data collected, created, summarized, and/or aggregated, and any deliverables and reports created specifically for the Bureau during the contract period.

Upon request, Goold will transfer to the Bureau any and all data collected, created, summarized and/or aggregated, and any deliverables and reports created during the contract period. Data transferred will be limited to the data that belongs to the State only, as outlined in Section 4.1.6 – Cooperation with Bureau and its Partners. Goold methodologies and applications used to serve the West Virginia project are proprietary to Goold.

4.1.15.4.1 Data, deliverables, and reports shall be transferred in a file format that is compatible with the WV Office of Technology's currently supported versions of Microsoft Office® Suite.

Goold will transfer data, deliverables and reports in a file format compatible with the WV Office of Technology's currently supported versions of Microsoft Office™ Suite. As stated above, data transferred will be limited to the data that belongs to the State only, as outlined in Section 4.1.6 – Cooperation with Bureau and its Partners. Goold methodologies and applications used to serve the West Virginia project are proprietary to Goold.

4.1.15.4.2 Data, deliverables, and reports will be transferred in accordance with a schedule and in an electronic format, no longer than thirty (30) calendar days prior to the end of the contract.

Goold assures that all data, deliverables and reports will be transferred in accordance with a schedule approved by the Bureau, but no later than thirty (30) calendar days prior to the end of the contract.

4.1.15.4.3 Vendor shall provide a Turnover Results Report which documents the completion and results of each task identified in the Turnover Plan.

Goold agrees to provide the Turnover Results Report which will document the completion and results of east task identified in the Turnover Plan to the Bureau as requested.

4.1.15.4.4 The Turnover Results Report shall be submitted in a file format that is compatible with the WV Office of Technology's currently supported versions of Microsoft Office® Suite.

Goold will submit the Turnover Results Report, documenting the completion and results of each task identified in the Turnover Plan in a file format that is compatible with the WV Office of Technology's currently supported versions of Microsoft Office™ Suite.

4.1.15.4.5 The Turnover Results Report shall be submitted in accordance with a schedule approved by the Bureau, no later than thirty (30) calendar days prior to the end of the contract.

Goold will submit the Turnover Results Report in accordance with a schedule approved by the Bureau and no later than thirty (30) days prior to the end of the contract.

4.1.16 Additional Services

4.1.16 Vendor shall provide a pool of one hundred (100) hours annually that can be used by the Bureau for assistance, advice and consultation for Medicaid pharmacy activities, such as additional clinical consultation, reports related to the PDL, PPL, or pricing of a complex nature, direct contact by telephone or by other agreed upon means to prescribers regarding appropriate drug utilization. Vendor shall provide on the Pricing Pages the all-inclusive hourly rate for additional services requested by the Bureau during each of the possible Contract years. The one hundred (I 00) hour pool is an estimate only; actual quantities requested by the Bureau during the life of contract may vary.

Goold prides itself on being available and providing expertise to our client States for any and all issues related to their PDL and SMAC programs. Goold will provide an outstanding customer service experience in support of the BMS staff. In addition, Goold will provide a pool of at least 100 hours annually that can be used by BMS for assistance, advice and consultation for Medicaid pharmacy activities.

These hours will be available to BMS for additional clinical consultation, reports related to the PDL, PPL and/or pricing of a complex nature (e.g., drugs not currently managed through the PDL) or direct contact by phone or by other agreed upon mean to prescribers regarding appropriate drug utilization.

For further services beyond the 100 annual pooled hours, Goold has provided an all-inclusive hourly rate in the pricing pages, as requested by the Bureau.

4.1.17 Location of Vendor Services

4.1.17 Vendor's primary business site from which the services described in this RFQ will be provided shall be located within the continental United States of America.

Goold's primary business site is located at the address below. All services for this RFQ will be provided to the State of West Virginia from within the continental United States of America.

Primary Business Site:
Goold Health Systems, an Emdeon company 45 Commerce Drive, Suite 5 PO Box 1090 Augusta, Maine 04332-1090

Contract Award (RFP Section 5)

Goold has provided a purchase price for the services outlined in the RFQ. Per the instructions in RFQ Section 5.2 – Pricing Page, we have completed the Pricing Page with an annual not-to-exceed cost for the combined program deliverables for the Preferred Drug List, Preferred Product List, and State Maximum Allowable Cost program, plus the Additional Ad Hoc Reports and Additional Services Hours for each year of the contract.

Goold understands that all mailing costs and other requirements contained in the RFQ are included in the cost; furthermore, all requirements contained in this RFQ are included in the price quotation.

Goold's Pricing Page has been submitted electronically through the wvOasis online service.

General Contract Terms

Performance (RFP Section 6)

Upon contract award, Goold will work with the Agency to come to an agreement on the schedule for performance of contract services and deliverables as a part of this RFQ.

Payment (RFP Section 7)

Goold has reviewed and understands the Agency's payment methods as outlined in RFQ Section 7.

Travel (RFP Section 8)

Goold understands that we are responsible for all mileage and travel costs, including travel time, associated with performance of this contract. Anticipated mileage and travel costs are included in the price quotation of this RFQ.

Facilities Access (RFP Section 9)

Upon contract award, Goold understands we may be required to comply with the following facility access requirements:

9.1 Identify the principle service personnel that will be issued access cards and/or keys to perform services;
9.2 Responsibility for controlling cards and keys, and will pay the replacement fee if the cards/keys are lost or stolen;
9.3 Notify the Agency immediately of lost, stolen, or missing cards or keys;
9.4 Personnel performing under the resulting contract may be subject to security protocol and procedures; and
9.5 Informing all Goold staff of the Agency's security protocol and procedures.

Vendor Default (RFP Section 10)

Goold has reviewed and understands the vendor default conditions outlined in RFQ Section 10.1.1 – 10.2.3.

Miscellaneous (RFP Section 11)

During the performance of the contract with West Virginia, Goold has designated the following as the Contract Manager. We will maintain a primary contact responsible for overseeing the vendor responsibilities under the contract as a result of this RFQ.

Contract Manager

Contract Manager: *James A. Clair*

Telephone Number: *(800) 832-9672*

Fax Number: *(207) 623-5125*

Email Address: *jclair@ghsinc.com*

General Terms and Conditions

Pursuant to Section 11 of the WV RFQ Instructions to Vendors Submitting Bids, Goold Health Systems ("GHS") submits the following exceptions to the State of West Virginia RFQ General Terms and Conditions:

Section	Exception Statement/Explanation
10. Litigation Bond	GHS requests the opportunity to negotiate the requirements of this section upon award.
19. Compliance	Because it is unclear which local laws, regulations and/or ordinances may be applicable, GHS requests the opportunity to negotiate this section upon award.
29. Confidentiality.	The documents associated with this section require detailed review by GHS information security, compliance and legal teams. Therefore, GHS requests the opportunity to negotiate this section upon award.
36. Indemnification.	This section requires detailed review by GHS' legal team and internal approvals. Therefore, GHS requests the opportunity to negotiate this section upon award.
38. Additional Agency and Local Government	GHS is uncertain at this time if any awarded contract with the State of WV can be extended to any other WV governmental agency. Therefore, GHS requests that this section be considered 'not approved' at this time.

Table 8: Terms & Conditions Exemptions and Explanation

Disclosure

Per the RFQ Instructions to Vendors document, Section 30 – Disclosure, Goold is submitting a separate response to the RFQ that contains redacted information which we consider is exempt from public disclosure. This redacted copy is suitable for public viewing and has been uploaded to the wvOasis website and is labeled with the following filename:

Filename: Goold_WV PDL SMAC CRFQ # 0511 BMS1500000003_Redacted.pdf

The following table outlines the information Goold has redacted, as well as the justification for redacting the material.

Exempt Information	Justification for Exemption
All specific descriptions of how Gold has been managing and addressing recent changes to Medicaid pharmacy programs.	Goold's executed plans for these changes were designed by Goold to support or specific client base. These plans were not / are not known by our competitors.
All names, resumes, and other identifying information regarding our proposed staffing for the project.	Goold considers the qualifications of our key staff to be a unique aspect of the solution we provide. If disclosed, the names and credentials of our named staff could be used by other vendors to align their staffing with our own, or even attempt to recruit our staff.
Any calculations of business and technical staffing resources.	These estimates were calculated using Goold proprietary methodology. This information is only known to certain people within Goold and provides us with a business advantage over competitors who do not use it.
All application screen shots and descriptions of functionality.	Goold considers the functionality of our software tools to be a trade secret.
All sample reports.	Goold considers the form and function of our proprietary reporting and analysis to be a trade secret.
Substantive descriptions of our processes for developing reports and documentation.	Goold considers these methods and procedures to be a trade secret.
Substantive descriptions of our SMAC rate setting process.	Goold considers these methods and procedures to be a trade secret.
Substantive descriptions of our preferred drug list management process.	Goold considers these methods and procedures to be a trade secret.
All system workflow diagrams.	Goold considers the internal workflow to be a trade secret.
Descriptions of internal programming practices.	Goold considers the internal workflow to be a trade secret.

Table 9: Redaction Justifications

Exhibit A – Staff Resumes

4.1.5.2 Vendor shall submit with their quotation the names and resumes for staff assigned to this contract including account manager, clinical pharmacist, physician, rebate manager, and SMAC pricing manager.

Goold has assembled an experienced staff that is familiar with West Virginia's unique PDL/PPL and SMAC needs. Our team of key personnel collectively has more than a century of collaborated knowledge and industry related experience to bring to BMS through this contract. We have provided these services to the State in the past successfully and look forward to the opportunity to bring our expertise to the State's programs once again.

The following section includes the resumes for the staff assigned to this contract. Licenses for Registered Pharmacists and Registered Physicians, per RFQ Instructions Section 8 – Required Documents, have also been included with the appropriate resumes. Criteria can be found on the following pages as follows:

- Contract Administrator – James Clair, M.P.A., M.S.;
- Account Manager and Clinical Pharmacist – Chad Bissell, Pharm. D, MBA;
- Physician – Laureen Biczak, D.O.;
- Physician – Jeffrey Barkin, M.D., DFAPA;
- SR and Clinical Support – Steve Liles, RPh, Pharm.D;
- Rebate Manager – Rosemary 'Rossi' Rowe;
- Senior Rebate Specialist – Shari Martin;
- SMAC Pricing Manager – Theresa Thompson;
- Project Manager – Matthew Pettengill; and
- Data Analyst Team Lead – Jason Rushing.

JAMES A. CLAIR, M.P.A., M.S.
Vice President

SUMMARY OF EXPERIENCE

Mr. James Clair has more than 20 years of experience in senior management and over 12 years of program management experience in healthcare, Medicaid, and Pharmacy Benefits Management (PBM). Mr. Clair currently serves as account executive for all Goold Health Systems (Goold) contracts, ensuring that all Goold projects are designed, developed, tested, and implemented on time and on schedule; that resources are appropriately allocated; and that strategic planning is implemented. He holds responsibility for day-to-day activities and evaluates all aspects of operations.

In addition to these high-level management functions, he assumes hands-on roles as needed. He manages and provides technical leadership for sixteen (16) state Medicaid clients. He implemented cost containment strategies that accrued savings in pharmacy benefits in Maine and Iowa, as measured by per-user per-year costs. In 2004-2005 he served as Iowa Medicaid Enterprise account manager during the design, development, and implementation (DDI) phase of the Pharmacy Point of Sale (POS) contract and as Iowa Medicaid Enterprise operations manager during the DDI phase of the Clinical Pharmacy contract, delivering the pharmacy project on time and the POS project one week early.

EMPLOYMENT

2007 – Present **Vice President, Pharmacy Benefits Administration**
Goold Health Systems, an Emdeon Company

- Holds responsibility for day-to-day operations of all business units within GHS, a wholly-owned subsidiary of Emdeon
- Member of the Emdeon executive team guiding operational, financial and strategic results

2007 – 2013 **Chief Executive Officer**
Goold Health Systems, Augusta, ME

- Responsible for day-to-day operations of all business units at GHS and for the strategic direction of the company
- Special focus is on the company's contract administration, project management, business development, strategic planning, and financial analysis activities
- Executed sale of Goold Health Systems to Emdeon, effective June 2013.

2008 – 2013 **President**
Goold Health Analytics, LLC, Augusta, ME

- Managed a start-up woman-owned enterprise focused on healthcare consulting and program integrity services
- Responsible for business development and management oversight of initial contracts

2004 – 2007 Chief Operating Officer
Goold Health Systems, Augusta, ME

- Responsible for day-to-day operations of all business units at GHS
- Special focus is on the company's contract administration, project management, business development, strategic planning, and financial analysis activities
- Served as Iowa Medicaid Enterprise Account Manager during Design-Development-Implementation (DDI) Phase of Pharmacy POS contract.
- Served as Iowa Medicaid Enterprise Operations Manager during DDI Phase of Clinical Pharmacy (PDL-SR-PA) contract

2001 – 2004 Vice President
The Waldron Group, Falmouth and Augusta, Maine

- Responsible for strategic planning, budgeting, financial analysis, and marketing for the following companies:
    - Goold Health Systems
    - Community Pharmacies
    - Sable Oaks Golf Club
- Served as consultant to other Waldron Group companies.

1984 – 2001 Various non-partisan management and analytical positions
Maine State House, Augusta, ME

- Executive Director, Legislative Council (2000–2001):
    - Implemented a cost-containment process for the $33 million State House Renovation project.
    - Led effort to develop or reform operating policies including auditing, budgeting, purchasing and security.
    - Initiated numerous process reviews oriented toward improved communication and increased efficiency.
    - Formulated and implemented a $20 million annual budget; 200+ employees.
- Director, Office of Fiscal & Program Review (1998–2000)
    - Primary fiscal advisor to the Maine State Legislature.
    - Supervise and coordinate office's professional and administrative staff.
    - Member, Consensus Revenue Forecasting Committee.
    - Served as staff person to the Commission on Performance Budgeting.
    - Lead office's analysis and design of client-server technology to replace certain WANG applications
- Deputy Director, Office of Fiscal & Program Review (1990–1998)
- Principal Analyst, Office of Fiscal & Program Review (1986–1990)
- Legislative Analyst, Office of Fiscal & Program Review (1984–1986)

1981 – 1983 New Jersey Transit Corporation

- Management Trainee (1981–1982)
- Policy and Legislative Analyst (1982–1984)

EDUCATION

Syracuse University, Syracuse, New York
Master of Public Administration

State University of New York, Syracuse, New York
Master of Science

University of Massachusetts, Amherst, Massachusetts
Bachelor of Science

PROFESSIONAL QUALIFICATIONS, CERTIFICATIONS, MEMBERSHIPS

Leadership Maine, Maine Development Foundation (beta class)

CHAD BISSELL, PHARM. D, MBA
Regional Account Manager

SUMMARY OF EXPERIENCE

Dr. Chad Bissell is a Regional Pharmacy Manager who has been with GHS for over nine (9) years. As a PBM Clinical Account Manager, he is responsible for ensuring that clinical business rules are appropriately represented, and he provides clinical subject matter expertise for all of the GOOLD technical modules. His duties have included advising State policy staffs on pharmacy issues, serving on the professional staff to support the P&T Committees, oversight of the Iowa Drug Utilization Review Committee, performing pharmacy prior authorization reviews, oversight of several state maximum allowable cost programs, and supporting the Mississippi PDL/SR process.

Dr. Bissell has provided clinical management to a number of GHS clients, such as: the Iowa Medicaid Enterprise, where he served as Clinical Pharmacy Manager and DUR Director; Alabama Medicaid, where he served as interim account manager; and the West Virginia Bureau for Medical Services (Medicaid) where he assisted with preferred Drug List development and maintenance, oversaw their State Maximum Allowable Cost program, and assisted with guiding the West Virginia pharmacy staff through the supplemental rebate processes. In 2011, Dr. Bissell began oversight of the Mississippi Division of Medicaid PDL/SR account where his duties have included PDL maintenance, P&T Committee support and assisting with Mississippi joining the Sovereign States Drug Consortium. So far, these efforts have saved the state of Mississippi nearly $9 million in the first year of operations.

Five of the eight Maximum Allowable Cost accounts held by Goold are under Dr. Bissell's stewardship. States have saved several millions of dollars each year as a result of the management of the MAC programs. By way of example, Illinois and Minnesota have seen over $100 million in savings per state per year through their MAC programs. In addition to regular maintenance of the lists, Dr. Bissell has served as a trusted advisor to these states as CMS begins the transition to AMP-based FULs and ensuring states pay less, in the aggregate, than the FUL cap.

Most recently, Dr. Bissell began serving as a clinical pharmacy consultant for the World Trade Center Health Program; lending his expertise in the management of the pharmacy benefits for the first responders of the September 11, 2001 terrorist attacks.

EMPLOYMENT

2009 – Present **Regional Pharmacy Manager**
Goold Health Systems, Des Moines, Iowa

- Pharmacy Consultant for the World Trade Center Health Program;
    - Partnering with Computer Sciences Corporation (CSC) and CDC's National Institute for Occupational Safety and Health to provide pharmacy benefit management for the 63,000 enrolled members.

  - Made recommendations on pharmacy cost savings initiatives as program's budget has been reduced.
- Account manager for the Mississippi Division of Medicaid Preferred Drug List and Supplemental Rebate services.
  - Assist the Division of Medicaid with Preferred Drug List maintenance and supplemental rebate process;
  - Advise on clinical and pharmacoeconomic information
  - Assisted the Division of Medicaid with joining the SSDC multi-state drug purchasing pool
  - Present/administer quarterly P&T Committee meetings
  - First year of operations generated approximately $9 million in savings
- Account manager for the State Maximum Allowable Cost (SMAC) program for the Illinois Department of Healthcare and Family Services (Medicaid).
  - Efforts result in nearly $140 million/year in savings
- Account manager for the State Upper Limit program for the New Jersey Division of Medical Assistance and Health Services (Medicaid)
  - Efforts result in nearly $17 million/year in savings
  - Provide annual program summary report, forecasted savings and budget report
  - Provide a 153:1 return on investment.
- Account manager for the State Maximum Allowable Cost (SMAC) program for the Minnesota Health Services and Medical Management Division (Medicaid)
  - Efforts result in nearly $119 million/year in savings
- Account manager for the State Maximum Allowable Cost (SMAC) program for the North Dakota Department of Human Services Medical Services Division (Medicaid)
- Account manager for the State Maximum Allowable Cost (SMAC) program for the South Dakota Department of Social Services
- Assisted with Preferred Drug List development and maintenance, State Maximum Allowable Cost (SMAC) program, and Pharmacy & Therapeutics Committee support for the West Virginia Bureau for Medical Services (Medicaid); 2009-2012.
- Write therapeutic drug class reviews for multiple state clients.
- Perform pharmacy prior authorization reviews.

2005 – 2009 Clinical Pharmacy Manager / DUR Director / PA Pharmacist
Goold Health Systems, Des Moines, IA

- Oversee the Retrospective Drug Utilization Review services for the Iowa Medicaid Enterprise and facilitate the meetings of the DUR Commission.
  - Oversaw transition of contract to Goold with only two months to prepare for operations.
  - Presented/administered eight meetings each year
  - Prepared the annual CMS DUR report
  - Oversaw day-to-day operations of DUR activities
  - Efforts resulted in approximately $785,000/year in savings
- Advise the Iowa Medicaid Enterprise policy staff on pharmacy issues.

- Prepare Exception to Policy and Appeal hearings for the State and represent the Iowa Medicaid Enterprise at legal hearings.
- Serve on the professional staff of the Iowa Medicaid Pharmacy and Therapeutics Committee.
    - Presented new drug monographs and class reviews at the quarterly P&T Committee meetings
- Respond to inquiries from legislators and government officials on the Department's execution of pharmacy policy.
- Serve as the main clinical contact for Iowa Medicaid providers and pharmaceutical manufacturer representatives.
- Update the Iowa Medicaid Pharmacy Provider's Manual, the Iowa Pharmacy and Therapeutics Committee Policies and Procedures Manual, and the Drug Utilization Review Commission Policies and Procedures Manual.
- Perform pharmacy prior authorization reviews.

2003 – 2005 Staff Pharmacist
Hy-Vee Foods, Inc., Pleasant Hill, Iowa

- Performed day-to-day retail pharmacy duties, including: filling prescriptions, compounding, over-the-counter consultation, patient counseling, interacting with other healthcare professionals, performing thorough drug regimen reviews, and recommending drug therapy changes to patients and physicians.
- Maintained volunteer efforts for the Des Moines Group, which provided health screening services and immunization clinics for community events and local businesses.
- Oversaw and provided services for Outcomes Medication Therapy Management program at store location.
- Administered immunizations.

2002 – 2003 Des Moines Float Pharmacist
Hy-Vee Foods, Inc., West Des Moines, Iowa

- Fulfilled staffing needs for Hy-Vee Pharmacies and Hy-Vee Drugstores (formerly Drug Town) in Central Iowa, as well as Hy-Vee corporate office.
- Participated in "usual & customary" pricing methodology overhaul with Hy-Vee Corporate.
- Oversaw startup of new Hy-Vee Pharmacy operation in Grinnell, Iowa, and served as interim pharmacy manager for the beginning months of operation.

EDUCATION

Drake University
Des Moines, Iowa
Doctor of Pharmacy, Cum Laude, May 2002

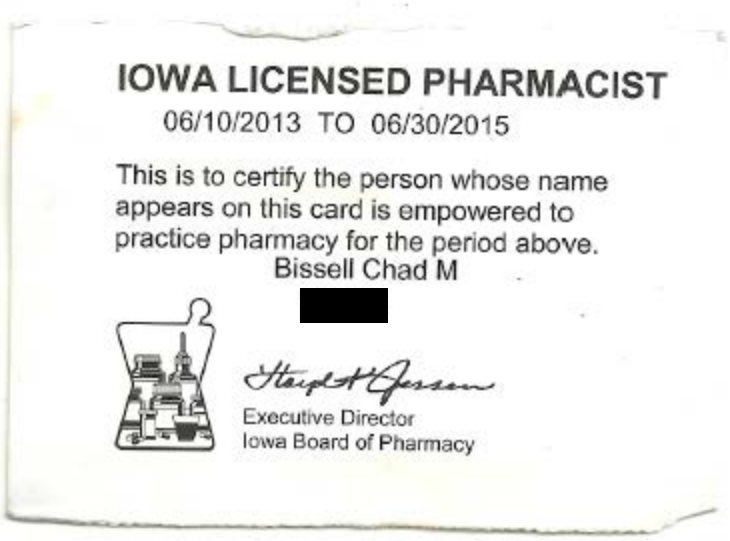
Grantham University

Kansas City, Missouri
Master's in Business Administration, Summa Cum Laude, October 2013

PROFESSIONAL LICENSES, CERTIFICATIONS, AND MEMBERSHIPS

Registered Pharmacist in the following states:

- State of Vermont, *In progress*
- Commonwealth of Virginia Pharmacist License, [redacted]
- State of Alabama Pharmacist License, [redacted]
- State of Iowa Pharmacist License, [redacted]
- State of New Jersey Pharmacist License, [redacted]
- State of New York Pharmacist License, [redacted]
- Qualified to administer immunizations as prescribed by Iowa law
- Recipient of the Russ Johnson, Jr. Award for Outstanding Community Pharmacy Practice, 2002



IOWA LICENSED PHARMACIST

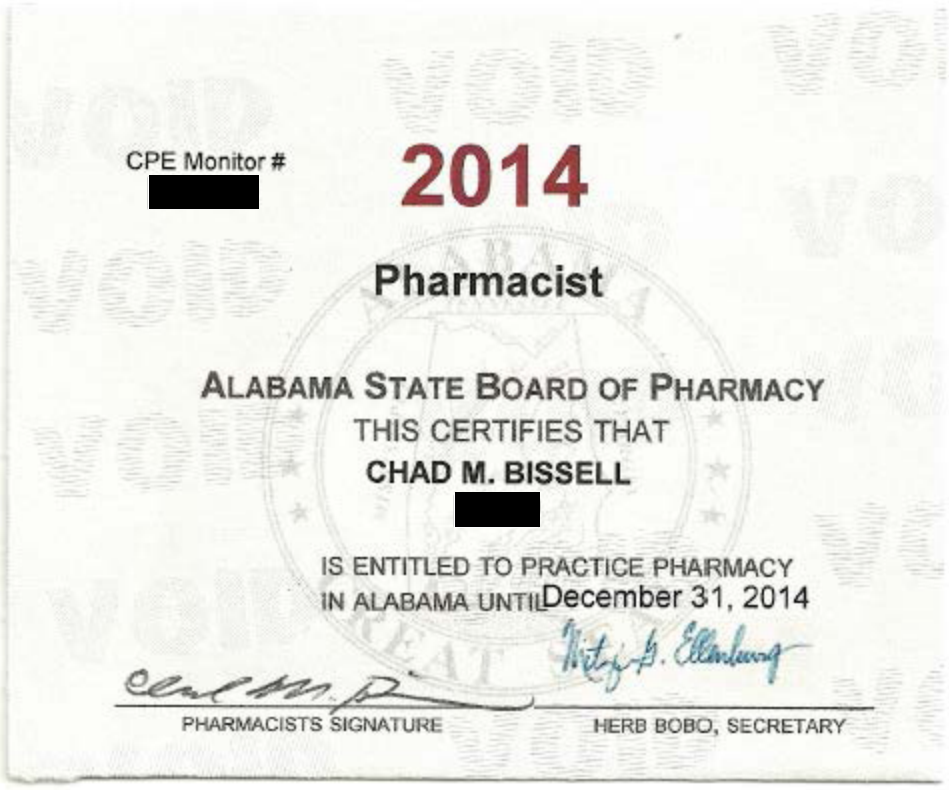
06/10/2013 TO 06/30/2015

This is to certify the person whose name appears on this card is empowered to practice pharmacy for the period above.

Bissell Chad M

[redacted]

Executive Director
Iowa Board of Pharmacy



CPE Monitor # [redacted]

2014

Pharmacist

ALABAMA STATE BOARD OF PHARMACY

THIS CERTIFIES THAT

CHAD M. BISSELL

[redacted]

IS ENTITLED TO PRACTICE PHARMACY IN ALABAMA UNTIL December 31, 2014

PHARMACISTS SIGNATURE

HERB BOBO, SECRETARY

COMMONWEALTH OF VIRGINIA
DEPARTMENT OF HEALTH PROFESSIONS

Dianne L. Reynolds-Cane, M.D., Director

Caroline D. Juran
Executive Director
(804) 367-4456

BOARD OF PHARMACY

9960 Mayland Drive, Suite 300
Richmond, VA 23233-1463
www.dhp.virginia.gov/pharmacy

Pharmacist License

Chad M. Bissell

Expires	Number
12/31/2014	0202209704

The University of the State of New York
Education Department
Office of the Professions

REGISTRATION CERTIFICATE

Do not accept a copy of this certificate

License Number: [redacted] Certificate Number: 8346486

BISSELL CHAD MATTHEW
[redacted]

is registered to practice in New York State through 10/31/2015 as a(n)
PHARMACIST

LICENSEE/REGISTRANT

Lawrence H. Mohlhiser
EXECUTIVE SECRETARY

COMMISSIONER OF EDUCATION

DEPUTY COMMISSIONER
FOR THE PROFESSIONS

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State Of New Jersey
New Jersey Office of the Attorney General
Division of Consumer Affairs

THIS IS TO CERTIFY THAT THE
Board of Pharmacy

HAS LICENSED

Chad M. Bissell
[redacted]

FOR PRACTICE IN NEW JERSEY AS A(N): Pharmacist

03/28/2013 TO 04/30/2015
VALID

[redacted]
LICENSE/REGISTRATION/CERTIFICATION #

Signature of Licensee/Registrant/Certificate Holder

ACTING DIRECTOR

LAUREEN BICZAK, DO
Medical Director

SUMMARY OF EXPERIENCE

Dr. Biczak has been employed at Goold Health Systems for seven years, as both an Associate Medical Director and now Medical Director. Prior to joining GHS, Dr. Biczak spent over six years as the Medical Director for Maine's Medicaid program, MaineCare, at the Department of Health and Human Services. Dr. Biczak is Board certified in both Internal Medicine and Infectious Diseases. Her continued part-time clinical practice provides her with a unique view of pharmacy issues as seen from both the State's and the provider's perspective. She has served as a gubernatorial appointee to the Maine Quality Forum Advisory Committee, which is devoted to not only improving the quality of healthcare in Maine but also the transparency of that quality for Maine citizens. As Medical Director, she oversees clinical and fiscal aspects of the pharmacy benefits and Medical Prior Authorization programs for the Medicaid Agencies in multiple states.

EMPLOYMENT

4/2012-present: Medical Director
2007-3/2012: Associate Medical Director
Goold Health Systems, an Emdeon company, Augusta, Maine

- Oversees clinical aspects of the pharmacy benefits for the Medicaid Agencies in multiple states
- Recommends both pro-DUR and retro-DUR criteria and oversees clinical prior authorization activities
- Oversees clinical and fiscal aspects of PDL design including supplemental rebate negotiation, and integration with State Maximum Allowable Cost activities
- Oversees development of clinical therapeutic class and drug reviews
- Active participant in the P&T and DUR meetings in multiple states
- Oversees clinical aspects of pharmacy benefit care management services for Maine Medicaid including narcotic restriction programs and high cost specialty pharmacy management
- Oversees all clinical activities at Goold, including the medical and radiology benefit management services

2005-2007: Maine Medicaid MMIS Remediation Project Lead
Maine Department of Health and Human Services, Augusta, Maine

- Served as project lead for remediation of the State's MMIS system
- Oversaw both business and technical plans to improve claim throughput, reduce the backlog of suspended claims, and implemented a system to systematically recover interim payments

2000-2007: Medical Director

Maine Department of Health and Human Services, Augusta, Maine

- Medical Director for the Maine Bureau of Medical Services (Medicaid Program).
    - Served as a voting member of the Drug Utilization Review Committee
    - Participated in clinical and fiscal aspects of PDL design and management activities
    - Participation in medical and pharmacy clinical determinations including fair hearings
    - Participated as a member of the Senior Management Team and was actively involved in all aspects of health care management activities including benefit design, including the pharmacy benefit, pay for performance initiatives, budgetary issues, interpretation of Federal Medicaid law, and quality projects
    - Consultant for coverage and medical necessity determinations, prior authorization and development of agency rules
    - Consultant for policy development, as well as coding and reimbursement determinations, including pharmacy policy
    - Served as the medical expert in the development of waivers
    - Communicated frequently with CMS and other States on a wide range of issues regarding MaineCare including pharmacy issues
    - Served as the liaison for the Department with professional associations, often publicly speaking at meetings and conventions on the Department's behalf
    - Responded on behalf of the Commissioner of Health and Human Services and the Governor to concerns and complaints from providers, legislators, and members
    - Testified at legislative hearings when requested by the Commissioner
    - Developed reports to support quality and programmatic activities
    - Participated in multiple quality related workgroups and committees

- Chaired Covered Services Team
    - Reviewed new services for coverage determinations and budgetary implications
- Created Code Committee which oversaw decision analysis around new or changed codes and dealt with complex coding issues

1996-present: Infectious Disease Teaching Service

- Actively involved in teaching students, interns, residents and fellows (including Infectious Disease Fellows) in the clinical setting
- Direct patient care for hospitalized patients with infectious disease problems at three hospitals

1990-present: Clinical Practice

- Infectious Diseases and Travel/Tropical Medicine direct patient care
  - Inpatient and outpatient settings

EDUCATION

1988-1990 University of Connecticut, Farmington, CT

- Clinical and Research Fellow, Infectious Disease Program
- Program Director: Sam T. Donta, MD

1986-1988 Osteopathic Hospital of Maine, Portland, ME

- Internal Medicine Residency
- Program Director: David A Weed, DO

1985-1986 Osteopathic Hospital of Maine, Portland, ME

- Rotating Internship
- Program Director: Jon Karol, DO

1981-1985 University of New England College of Osteopathic Medicine

- Doctor of Osteopathy
- Appointed to Sigma Sigma Phi (Osteopathic Honor Society)

1978-1981 University of Maine at Orono

- B.A., Zoology, Summa cum Laude
- Appointed to Phi Beta Kappa

PROFESSIONAL APPOINTMENTS

- Chief of Staff, 1995-1997, *Brighton Medical Center*
- Chief of the Department of Medicine, 1993-1995 *Brighton Medical Center*
- Institutional Review Board, 1993-1995, *Brighton Medical Center*
- Staff Executive Committee, 1993-1997, *Brighton Medical Center*
- Chair, Infection Control Committee, 1990-1997, *Brighton Medical Center*
- Chair, Medical Quality Review Committee, 1995-1997, *Brighton Medical Center*
- Clinical Monitoring Committee, 1990-1997, *Brighton Medical Center*
- Chair, Antibiotic Agents Subcommittee, 1990-1993, *Brighton Medical Center*
- Library Monitoring Committee, 1996-1997, *Maine Medical Center*
- Physician's Information Services Committee, 1998-1999, *Maine Medical Center*
- Pharmacy and Therapeutics Committee, 1998-2002, *Maine Medical Center*
- Maine Quality Forum Advisory Committee, 2005-2007

LICENSURE AND BOARD CERTIFICATIONS

State of Maine, License #1167, Expiration 07/31/16
American Osteopathic Board of Internal Medicine, Certificate [redacted]
Internal Medicine, 03/1990
Infectious Disease, 1991

HOSPITAL AFFILIATIONS

Staff Physician, Division of Infectious Diseases/Internal Medicine

- Maine Medical Center, Portland, ME: 1996-present
- Mercy Hospital, Portland, ME: 1995-present

Consulting Physician, Infectious Diseases

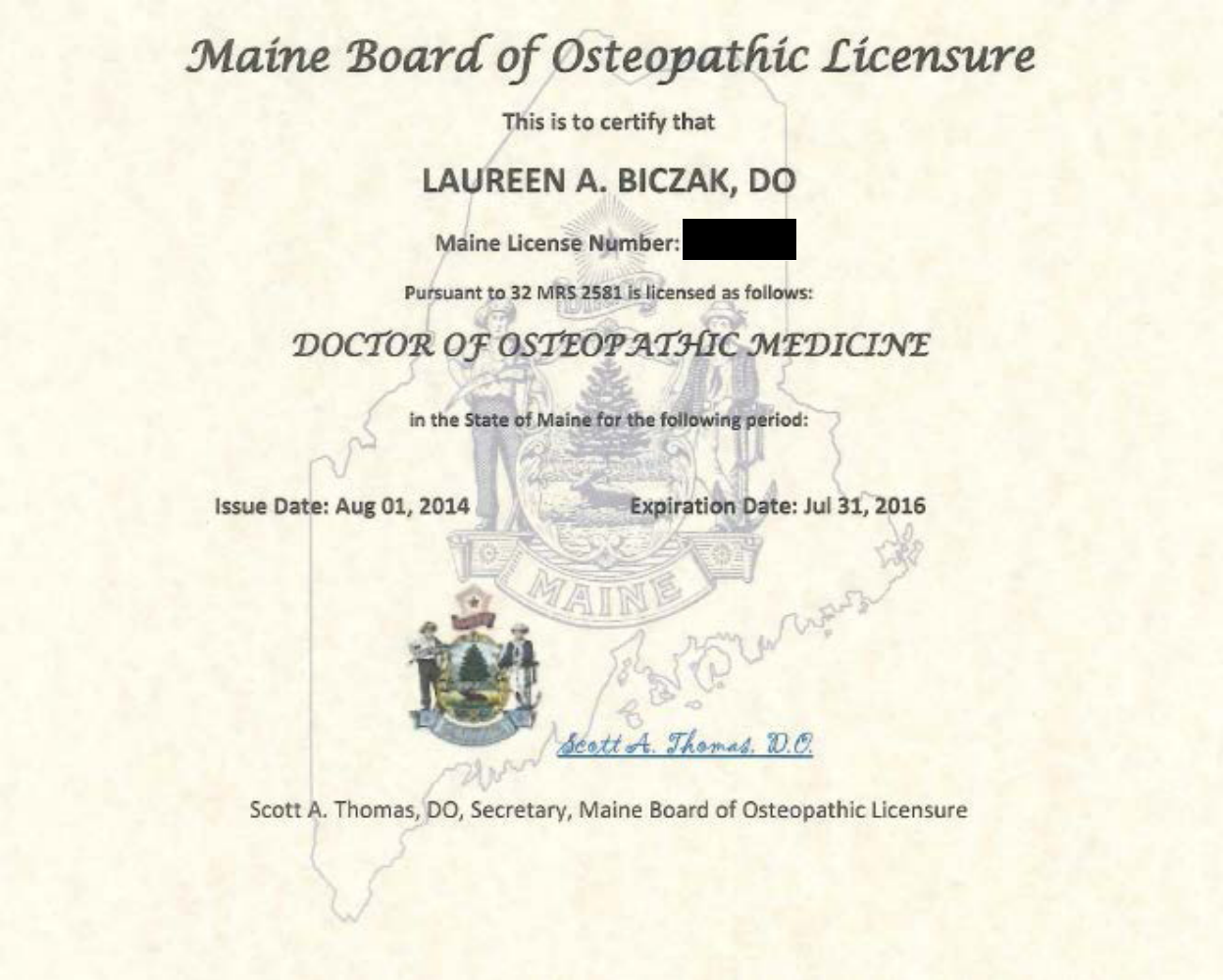
- New England Rehabilitation Hospital, Portland, ME: 2005-present
- Southern Maine Medical Center, Biddeford, ME: 1996-present

RESEARCH PROJECTS

HIV Infection and Endocarditis: 1989-1990, presented at International AIDs Conference; San Francisco, CA
Murine CMV Infection: Published, Journal of Infectious Disease; citation available upon request

PROFESSIONAL MEMBERSHIPS

American College of Physicians
Maine Osteopathic Association
American Osteopathic Association
Maine Medical Association
Infectious Disease Society of America
HIV Medicine Association
Northern New England Infectious Disease Society
Southern Maine Osteopathic Medical Group



Maine Board of Osteopathic Licensure

This is to certify that

LAUREEN A. BICZAK, DO

Maine License Number: [redacted]

Pursuant to 32 MRS 2581 is licensed as follows:

DOCTOR OF OSTEOPATHIC MEDICINE

in the State of Maine for the following period:

Issue Date: Aug 01, 2014 Expiration Date: Jul 31, 2016

Scott A. Thomas, D.O.

Scott A. Thomas, DO, Secretary, Maine Board of Osteopathic Licensure

JEFFREY BARKIN, M.D., DFAPA
Associate Medical Director

SUMMARY OF EXPERIENCE

Dr. Barkin has been employed as an Associate Medical Director with Goold Health Systems since 2010. Dr. Barkin maintains a private and forensic psychiatry practice treating individuals with a variety of mood, anxiety, and psychotic disorders, as well as neuropsychiatry patients since 1991. His clinical expertise enables him to accurately diagnose and effectively treat people, vastly improving their quality of life. Dr. Barkin has special expertise in clinical trial design and analysis, and is especially interested in applying evidence based best practices in administrative and legal settings. Prior to his current position, Dr. Barkin served as Chair of the Maine Medicaid DUR Committee and Chair of the Psychiatric Work Group. He is currently President of the state of Maine Association of Psychiatric Physicians and is a member of the State of Maine Board of Bar Examiners.

EMPLOYMENT

2010 – Present Associate Medical Director
Goold Health Systems, Augusta, ME

- Oversees clinical aspects of Medical PA services for Maine Medicaid;
- Provides medical director guidance to client states pharmacy clinical programs;
- Participates in development of clinical therapeutic class and drug reviews;
- Provides input to pharmacy and therapeutics and drug utilization review committees;
- Recommend both pro-DUR and retro-DUR criteria and oversee clinical prior authorization activities;
- Five years of experience with medical director responsibilities for Medicaid pharmacy programs in Maine, Iowa, Mississippi, and Wyoming. Involved in all clinical programs related to Medicaid at Goold Health Systems, An Emdeon Company. Multiple years of experience in interpreting clinical trial data to help inform placement of products on preferred drug lists. Application of research methods and outcomes in numerous settings including administrative and legal;
- Medical director responsibilities in multiple state pharmacy programs including Maine, Iowa, and Wyoming. Ongoing work in developing other (non-pharmacy) Medicaid programs;
- Capable of applying medical analytics to assess population impact of pharmacy management strategies;
- Developed a dose consolidation program for high cost antipsychotics for multiple client states which demonstrated robust cost savings with no deleterious impacts on adherence or compliance. Presented results at national conferences;
- Developed geographic modeling assessing differential utilization of opiates employing Dartmouth Atlas methodology; and

- Active member of clinical team which oversees pharmaceutical utilization for multiple client states, multi-state drug negotiation pool, as well as high cost (specialty) pharmacy services.

2004 – Present **Private Practice**
Portland, ME

- Clinical & Forensic Psychiatry;
- Health Care Policy;
- Complex healthcare Analysis;
- Consultation to Business; and
- Teaching.

2000 – 2004 **Neurology Associates of Eastern Maine**
Bangor, Maine

1998 – 1999 **Acadia Hospital/Eastern Maine Medical Center**
Bangor, Maine

1994 – 1998 **Department of Psychiatry**
The Medical Center of Central Massachusetts, Worcester, Massachusetts

1993 – 1994 **Addiction Psychiatrist**
Adcare Hospital Worcester, Massachusetts

1992 – 1993 **Attending Psychiatrist**
Charles River Hospital, West Chicopee, Massachusetts

1992 – 1993 **Medicplex Psychiatric Nursing Home Holyoke, MA**
Center for Human Development West Springfield, MA
Private Practice Springfield, MA

1991 – 1992 **Therapeutic Associates Longmeadow, MA**

1989 – 1991 **On-Call Services**
Griffin Hospital Derby, Connecticut

1989 – 1991 **On-Call Services**
Silver Hill Hospital, New Canaan, Connecticut

EDUCATION

- 1988 – 1991 Residency in Psychiatry – Yale University New Haven, CT
- 1987 – 1988 Internship, Internal Medicine – University Hospital Boston, MA
- 1983 – 1987 M.D. – Yale University School of Medicine New Haven, CT

- 1979 – 1983 B.A. – Swarthmore College, Swarthmore, PA
- Graduated with Distinction – Phi Beta Kappa, Sigma Xi

ASSOCIATIONS

President, Maine Association of Psychiatric Physicians

- Chairman, Maine Psychiatric Work Group
- Chairman, Drug Utilization Review Board – State of Maine
- American Psychiatric Association
- American Society of Clinical Psychopharmacology
- American Neuropsychiatric Association
- Maine Medical Association
- Member, Maine State Board of Bar Examiners
- Founder, Maine Women's Mental Health list serve
- Founder & Director , Maine Psychiatric Journal Club

ACADEMIC APPOINTMENTS

- Assistant Professor of Psychiatry – University of Massachusetts Medical Center Worcester, MA
- Distinguished Fellow, American Psychiatric Association

PUBLICATIONS

- Founder – The Barkin Mental Health Report
- Contributing writer – The Carlat Psychiatry Report
- Introduction of Mania by Risperidone
- Journal of Clinical Psychopharmacology 17;(1) 57-58
- Towards Understanding the Mechanisms of Lithium Toxicity in the Proximal Tubule
- April, 1994 (letter) American Journal of Psychiatry
- M.D. Thesis, "Mechanisms of Drug Resistance"
- Contributing Writer for Carlat
- Contributing Interviewee – Currents in Affective Disorders September/October 2009
- Psychiatric Services Book Reviews – 2009

RESEARCH

- Phase IV CARE (Compliance Assessment for Reminyl)
- Best Trial, Betaserone
- Characterization of the Mechanism of Action of Iprindole, an atypical antidepressant
- Effects of Low-Level Radio-Frequency Radiation on Beta - Adrenergic Function

RESEARCH AWARDS

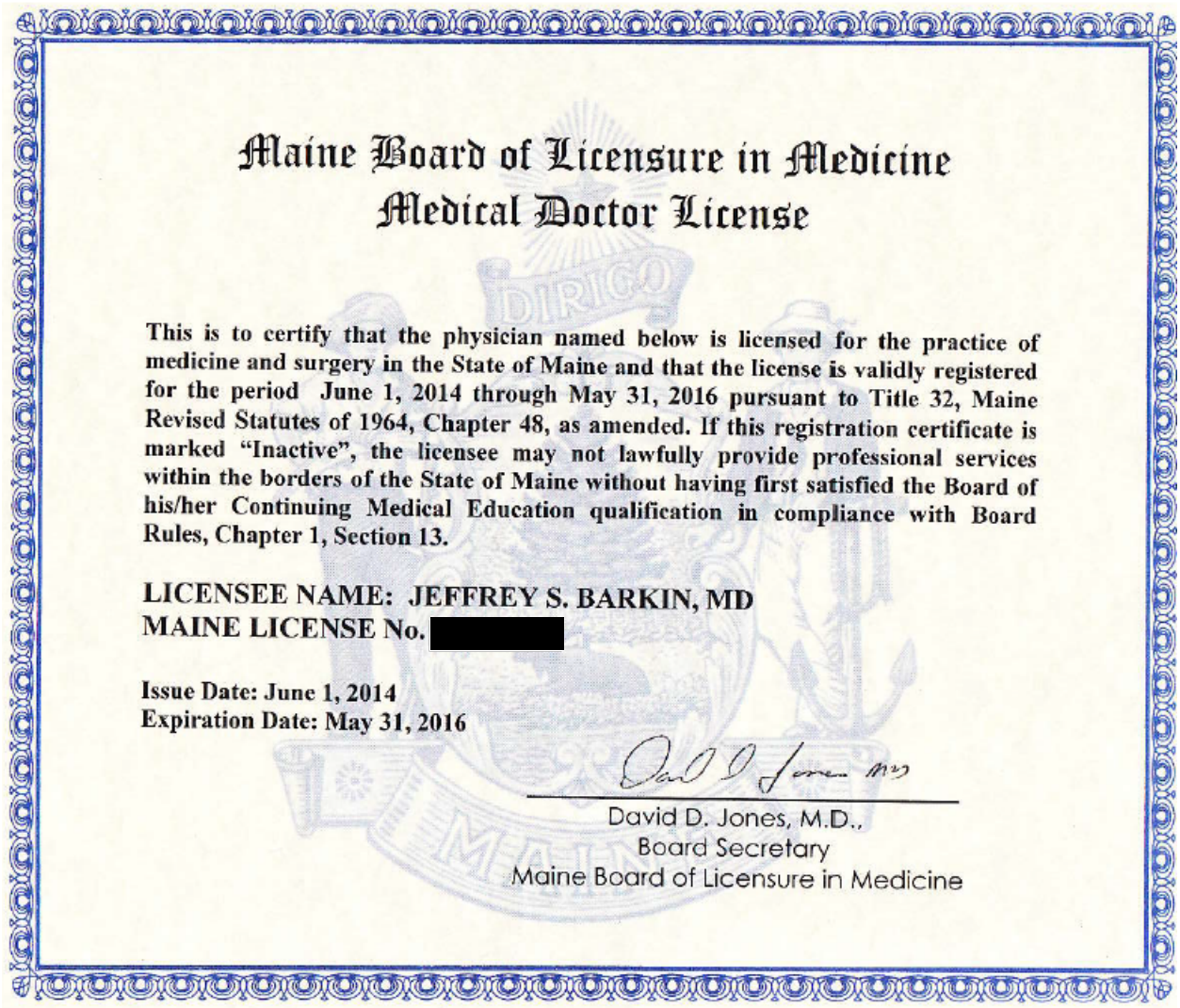
- **1982 First Prize,** Thomas Jefferson University Division of Sigma Xi
- **1982 First Prize,** Intercollegiate Society of Chemists: Biochemistry

PROFESSIONAL LICENSES, CERTIFICATIONS, AND MEMBERSHIPS:

- 1996 Added Certification – Geriatric Psychiatry Certificate [redacted]
- 1993 Board Certified in Psychiatry Certificate #[redacted]
- 1998 State of Maine Certificate [redacted]
- 1991 State of Massachusetts Certificate #[redacted]
- 1989 State of Connecticut Certificate [redacted]
- 1988 Diplomate NBME

LICENSURE

Dr. Jeffrey Barkin is a licensed physician in the States of Maine, Massachusetts, and Connecticut.



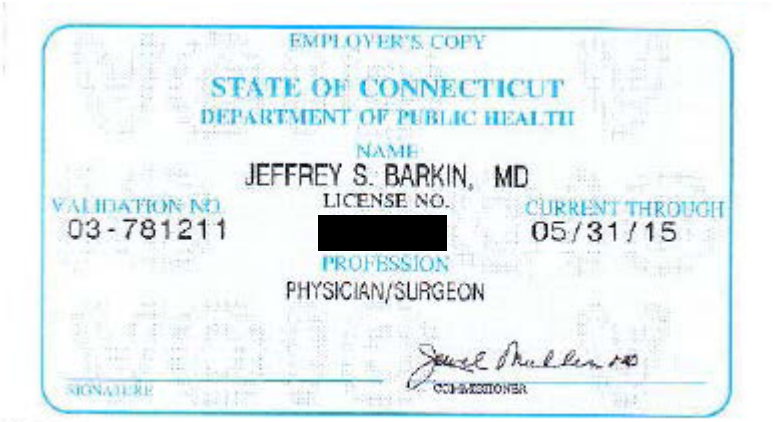
Maine Board of Licensure in Medicine
Medical Doctor License

This is to certify that the physician named below is licensed for the practice of medicine and surgery in the State of Maine and that the license is validly registered for the period June 1, 2014 through May 31, 2016 pursuant to Title 32, Maine Revised Statutes of 1964, Chapter 48, as amended. If this registration certificate is marked "Inactive", the licensee may not lawfully provide professional services within the borders of the State of Maine without having first satisfied the Board of his/her Continuing Medical Education qualification in compliance with Board Rules, Chapter 1, Section 13.

LICENSEE NAME: JEFFREY S. BARKIN, MD
MAINE LICENSE No. [redacted]

Issue Date: June 1, 2014
Expiration Date: May 31, 2016

David D. Jones, M.D.,
Board Secretary
Maine Board of Licensure in Medicine



EMPLOYER'S COPY

STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH

NAME
JEFFREY S. BARKIN, MD

VALIDATION NO.
03-781211

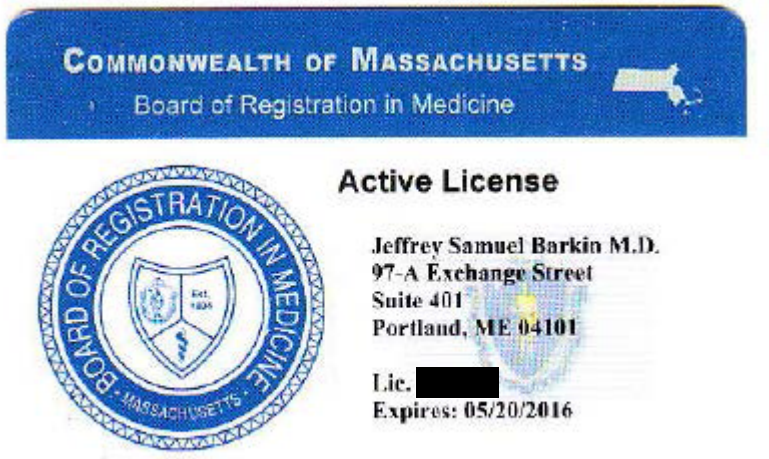
LICENSE NO.
[redacted]

CURRENT THROUGH
05/31/15

PROFESSION
PHYSICIAN/SURGEON

SIGNATURE

COMMISSIONER



COMMONWEALTH OF MASSACHUSETTS
Board of Registration in Medicine

BOARD OF REGISTRATION IN MEDICINE · MASSACHUSETTS ·

Active License

Jeffrey Samuel Barkin M.D.
97-A Exchange Street
Suite 401
Portland, ME 04101

Lic. [redacted]
Expires: 05/20/2016

STEVE LILES, RPH, PHARM.D
Senior Director of Pharmacy Services

SUMMARY OF EXPERIENCE

Steve Liles, RPh, Pharm.D joined Goold Health Systems in April 2012. In his role, Dr. Liles has responsibility for supplemental rebate negotiations and Preferred Drug List strategy, including monitoring and evaluation of the brand and generic drug pipelines.

EMPLOYMENT

April 2012-present Senior Director of Pharmacy Services
Goold Health Systems, an Emdeon company, Augusta, Maine

- Dr. Liles has responsibility for negotiation of supplemental rebates with drug manufacturers for both the SSDC multistate pool and Georgia Medicaid. Dr. Liles also advises client states on Preferred Drug List strategies, taking into account changes in the drug marketplace (such as drug shortages, price/rebate changes, recent and expected brand and generic drug launches), market share shifts and clinical evidence. Since joining Goold, Dr. Liles has implemented an enhanced cost modeling program that shows client states, in transparent fashion, the average net costs of drugs and the projected impact of PDL strategies on reimbursement, rebates, rebate offset and net spend. This program facilitates the modeling of alternate PDL options to ensure that the most cost- and clinically-effective PDL strategies are identified.
- Dr. Liles monitors and analyzes state and federal legislation and policies affecting Medicaid pharmacy and advises client states on the likely impact of such legislation and, when required, appropriate action for the states to take in response to, or preparation for, the legislation.
- Dr. Liles presents supplemental rebate information, cost modeling and PDL recommendations to several client states' P&T/DUR Committees, as well as to the SSDC states during their annual meeting.
- Dr. Liles is a member of both the Goold and Emdeon corporate clinical teams. One of his responsibilities in his work with these teams is to present pharmacoeconomic impact models of the impact of newly launched and pipeline drugs. Utilizing his experience monitoring the drug marketplace and unparalleled knowledge of Medicaid pharmacy, Dr. Liles not only reports where the drug market (and the associated spend) has been, but where it is likely to go.

April 2010-February 2012 Magellan Medicaid Administration,
Senior Director, Value Based Purchasing, *Glen Allen, Virginia*

- In this position, Dr. Liles oversaw the PDL/Supplemental Rebate programs for 25 state Medicaid agencies, including the two largest Medicaid drug rebate pools in the country and single state programs in Connecticut, Florida, Mississippi and Texas. These programs generated over $600 million in Supplemental Rebates annually. Dr. Liles had responsibility for the rebate contracting and analytics/reporting teams. He also oversaw the clinical team and functions supporting the PDL/SR program, including drug

information and therapeutic class review development. Additionally, Dr. Liles had budget responsibility for the SR/PDL department and for 16 state PDL contracts.

- During his tenure, Dr. Liles integrated the First Health Services and Provider Synergies PDL/SR programs into one cohesive, streamlined Magellan Medicaid Administration program. He also coordinated analysis of the Affordable Care Act and provided timely information related to that and other state and federal legislation to client states.
- Dr. Liles also continued direct involvement with state Medicaid clients, serving as Clinical Account Manager for several states, including Idaho, Mississippi, Pennsylvania, Wisconsin and Texas.

March 2007-April 2010 Director of Operations
Provider Synergies, LLC (now subsidiary of Magellan Medicaid Administration), Cincinnati, Ohio

- In this role, Dr. Liles directed the PDL/Supplemental Rebate programs for 12 state Medicaid agencies, including Provider Synergies' eight state pool (TOP$) and four single state programs. He has responsibility for oversight and management of the Provider Synergies' rebate contracting, analytics/reporting and clinical teams, as well as for the company budget and for operations of the Provider Synergies' office in Cincinnati. He also served as Clinical Account Manager for several states.

Clinical Coordinator, June 2002-March 2007

- As a Clinical Coordinator with Provider Synergies, Dr. Liles had clinical and account management responsibilities for seven state Medicaid PDL/supplemental rebate clients. He was responsible for preparing clinical drug evaluations and presenting clinical and financial evaluations to those states' P&T Committees. He had an active role in research and writing of therapeutic class reviews used by Provider Synergies for all state Medicaid clients. He analyzed medications for PDL management with an emphasis on therapeutics, business and market factors and current and future technologies and consulted on and developed prior authorization criteria. Dr. Liles was responsible for coordination of the Provider Synergies Drug Policy Development (DPD) Committee. He also coordinated manufacturer clinical presentations and development and submission of responses to RFPs.

June 2000-June 2002 Clinical Coordinator, The Christ Hospital
Health Alliance of Greater Cincinnati, Cincinnati, Ohio

- At Christ Hospital, Dr. Liles served as Secretary of the P&T Committee and represented the hospital on the Health Alliance Drug Policy Development (DPD) Committee. He was a member of the Health Alliance Formulary and Antibiotic Subcommittees and The Christ Hospital Clinical Cardiovascular Committee. He worked with the Pharmacy and Medical staffs on the implementation of the decisions and policies of those Committees, as well as on other cost containment and clinical quality policies that he developed. He participated in formulary development and implementation of appropriate procedures, including therapeutic interchanges, for inpatients as well as the outpatient indigent care

clinic. Dr. Liles developed the hospital's first pharmacy residency program and obtained ASHP accreditation for that program. He also initiated a decentralized clinical pharmacy program that included servicing to and rounding with the medical residents.

January 1990-June 2000 Clinical Pharmacist
St Luke Hospital

- Dr. Liles trialed and implemented the hospital's first decentralized clinical pharmacist program, which was subsequently expanded throughout the hospital. He provided direct patient care and interacted with physicians and nurses on the care of patients with a focus on critical care and cardiology. He provided drug information classes for hospital staff and patients and participated in the hospital P&T Committee, including in the development of clinical care paths for multiple disease states. Dr. Liles also served as an ACLS instructor and site coordinator for numerous clinical trials in the areas of critical care medicine and cardiology.

September 1998-May 2006 Instructor of Pharmacology
Northern Kentucky University, Highland Heights, Kentucky

- Dr. Liles was the primary pharmacology instructor in the Master's level Advanced Nurse Practitioner program at NKU.

Prior Experience
Upper Valley Medical Center, Troy, Ohio, March 1984-January 1990– Lead Pharmacist
Gray Drug Stores, Dayton, Ohio, May 1982-March 1984 – Pharmacist/Assistant Manager

EDUCATION

University of Kentucky – College of Pharmacy, Lexington, Kentucky
Doctor of Pharmacy, 1998
Ohio Northern University – Raabe College of Pharmacy, Ada, Ohio
Bachelor of Science in Pharmacy, 1982

PROFESSIONAL LICENSES, CERTIFICATIONS, AND MEMBERSHIPS

- Academy of Managed Care Pharmacy (AMCP) - member
- Registered Pharmacist – State of Ohio

OHIO STATE BOARD OF PHARMACY

77 S. High St., Room 1702; Columbus, OH 43215-6126

Phone: 614/466-4143 **Fax**: 614/752-4836 **Website**: www.pharmacy.ohio.gov

Identification Number [redacted]

Be it known that the individual named below is entitled to practice in the State of Ohio until the expiration date of SEPTEMBER 15, 2015.

STEVEN RAY LILES RPH

The pharmacist or pharmacy intern signing below shall have this card on his/her person while engaged in the practice of pharmacy according to Section 4729.12, Ohio Revised Code.

X _____

Signature of Individual Named Above

PHA-0402 (6/10) Completion of this form is required by OAC Rule 4729-5-02

ROSEMARY 'ROSSI' ROWE
Manager of Rebate Operations

SUMMARY OF EXPERIENCE

Ms. Rossi Rowe was invited to join Rebate Services at GHS in February 2008 to be part of the company's vision to expand rebate services offerings across states. During her six years with the company, Ms. Rowe has led the GHS Rebate Services Team in their transformation by leveraging the respective strengths across departments. With input from claims processing, accounting, negotiations, contracting, and clinical teams, GHS's internal processes, standard operating procedures and tools now accommodate the multiple challenges of rebate. Ms. Rowe has been the Subject Matter Expert on numerous implementations, and has provided valuable input during design sessions. This has resulted in new systems and tools that reflect best practices in all areas of rebate invoicing, accounting, dispute resolution, and reporting. During the past six years, Ms. Rowe has managed the GHS rebate services expansion from a single state to multiple states which currently include IA, GA, UT, WY, ME, and MS. Our offerings have expanded to include many new rebate types such as Supplemental and Durable Medical Equipment rebates as well as pharmacy and physician administered drugs for Managed Care Claims under the Affordable Care Act.

Ms. Rowe has more than 25 years of experience in Medicaid policies and reimbursement, PBM, and rebate programs. She has extensive knowledge of Medicaid programs, policies, and procedures; Medicaid medical and pharmacy claims processing; third-party coordination of benefits and recovery; drug rebate collections; and contract negotiations. She has administered and managed large benefit recovery programs, including OBRA rebates and supplemental rebates. For Goold Health Systems, she currently manages operations and oversight of the rebate team, including federal, state specific and special durable medical equipment rebate collections for Iowa, Wyoming, Mississippi, and Georgia. She manages the SR staff responsible for administering the Sovereign State Drug Consortium (SSDC) pool bid process, contract management, and creation and management of the SR pricing file for SR and special rebate invoice processing. She also supervises the contract negotiation team for the SSDC pool and Georgia SR program. She previously provided strategic leadership for the Maine Medicaid (MaineCare) program, which supplies healthcare services to more than 350,000 Maine citizens, including directing a 56-member staff responsible for all aspects of rebate management and third-party-liability (TPL), such as rebate collections, dispute resolution, and TPL estate recovery, casualty recovery, insurance recovery, private health insurance premium payment, and insurance research units. She managed day-to-day operations of the Maine Drug Rebate Program including Drugs for the Elderly Program.

EMPLOYMENT

February 2008 – Present **Manager Rebate Services**
Goold Health Systems, Augusta, Maine

- Ensures contract compliance for GHS rebate accounts. Directs all rebate team operations, negotiates contracts, and monitors and applies Federal and state laws and regulations as appropriate.
- Manages day-to-day operations and oversight of the rebate team, for multiple programs for states of Iowa, Wyoming, Mississippi and Georgia.
- Oversees the SR staff responsible for administering the SSDC pool bid process, contract management, and creation and management of the SR pricing file for SR and special rebate invoice processing and contract negotiation administration team for the SSDC pool and Georgia SR program.
- Manages project planning and coordination among development groups and internal teams, consistent with CMS guidelines, customer needs, and technical prudence.
- Facilitates requirements gathering and the associated documentation needed to define and track the scope of work. Coordinates and assists in developing QA standards. Works with project management teams to create and manage project tracking and work plans.
- Helps coordinate with stakeholders, including identification of obstacles, strategies to overcome them, and possible adjustments in project scope for both short-term and long-term solutions. Maintains and manages project scope, updating and educating stakeholders throughout the life of each project.

January 2007 to February 2008 Director, Third Party Liability, Division of Third Party Liability
Maine Department of Health and Human Services, Office of MaineCare Services, Augusta, Maine

- Provided strategic leadership for agency supplying healthcare services to more than 350,000 Maine citizens, directing a staff of 56 employees responsible for all aspects of rebate management and TPL, including rebate collections, dispute resolution, and TPL estate recovery, casualty recovery, insurance recovery, private health insurance premium payment, and insurance research units.
- Managed and oversaw development, implementation, and evaluation of division policies and programs. Held responsibility for oversight and efficient operations of the division, which identifies and recoups MaineCare (Medicaid) member benefit payments from liable parties (e.g., private insurance carriers) to maximize benefit availability for MaineCare members.
- Enforced state and Federal third-party liability rules and managed drug rebate collection efforts of the Office of MaineCare Services, including planning, coordinating, and directing division and personnel activities.
- Directly supervised four unit managers of the insurance research program and recovery programs and indirectly supervised staff working on daily third-party recovery and drug rebate efforts. Established partnerships with other departments utilizing MaineCare as a source of funding for healthcare services provided.

July 1989 – January 2007 Manager, Third Party Liability, Division of Third Party Liability

- In 1998, assumed responsibility for managing day-to-day operations of the Maine Drug Rebate Program, OBRA, J-code, supplemental rebates (SRs), and Drugs for the Elderly.

Supervised rebate staff and managed rebate-related contractual obligations of POS vendor GHS, which generated invoices and provided data support.

- Reviewed, analyzed, and developed rebate policies and operating procedures to comply with Federal and State program rules, regulations, and mandates. Supported staff during dispute resolution process and attended CMS National Dispute Resolution meetings.
- Assessed problems and proposed improved processes and procedural solutions. Identified rebate accounting application requirements and worked as subject matter expert during application design, development, and testing. Coordinated state and federal auditor requests for information and responded to or assessed the responses to audit findings.

EDUCATION

- BS, Special Education, Learning Disabilities, University of Maine (Farmington), 1996
    - Cum Laude
- AD, Liberal Studies, University of Maine (Augusta), 1977

SHARI MARTIN
Rebate Operations Supervisor

SUMMARY OF EXPERIENCE

Shari Martin joined GHS in July 2008 as a Rebate Specialist in our Rebate Services department and focused her efforts in all areas of rebates. Drawing upon expertise she has acquired over the years in her professional career in government health, she currently serves as the Rebate Operations Supervisor for the contracts and negotiated rebate department. In her current role she supports our rebate products and services. Ms. Martin has extensive knowledge of CMS rebate guidelines and medical claims billing as well as operational processes, she has performed as our Jcode and Supplemental Rebate Subject Matter Expert on many implementations, including most recently Minnesota Jcode SMAC, Mississippi Supplemental Rebate services, Utah Software as a Service and Georgia MCO Rebate Services implementations. Over the last five years, she has led diabetic negotiations and oversaw the administration of SR negotiations, while managing the supplemental rebate pricing file generation for three different negotiated rebate types and six State accounts. Ms. Martin has worked closely with project managers and technical engineers to develop business requirement documentation and standards for new complex technology solutions to support Rebate Collections, State contracting, labeler status and demographics, rebate flag determinations Jcode/NDC crosswalk, POS edits and labeler divestitures. Ms. Martin is adept at streamlining processes, troubleshooting system issues and various software packages, including Microsoft Excel, Word, and Access.

EMPLOYMENT

1/2012 –Present Rebate Operations Supervisor

Goold Health Services, an Emdeon Company, Augusta, Maine

- Shari Martin serves in a full-time role supervising our contract processing staff and negotiations administrative staff.
- Her responsibilities include supplemental rebate dispute resolution assistance to rebate specialists for four client state Medicaid supplemental rebate accounts, diabetic rebate negotiations/ assistance to client States transitioning to diabetic supply category management.
- Ms. Martin oversees the MS Supplemental Rebate account, the GA Electronic Offer Management System (eROMS) application administration, and Sovereign States Drug Consortium (SSDC) eROMS application administration with a focus on operational functionality.
- She is the business owner of the Supplemental / Diabetic Pricing file application. Ms Martin works closely with project management and the IT Development team on product documentation for new systems.
- Her tasks include testing and business logic requirements gathering. She assists rebate pharmacists and analysts with special projects, as client requests arise and creates all client states supplemental and diabetic pricing files on a quarterly basis.

7/2009-12/2011 Senior Rebate Specialist

Goold Health Systems, Augusta, Maine

- In this role, Ms. Martin managed the Jcode/ NDC crosswalk and edit tables used for invoicing, this was accomplished by performing quarterly pre-invoicing review of unit of measure (UOM) mismatches and validating Jcode/ NDC combinations to ensure drug dispensed matches the procedure code billed.
- She performed quarterly quality assurance checks for OBRA, JCODE, SR, and DME rebate types, researched and communicated with drug manufacturers regarding pharmacy claims activity and claim dispute resolution.
- She worked closely with rebate team management to automate the contract processing for five client states. Ms. Martin assisted in the building of invoice business rules, quality assurance standardized procedures, and rebate specific standard operational procedures. Focusing on a proactive approach to minimize disputes and identify/address claim billing outliers prior to invoicing.

7/2008-6/2009 Rebate Specialist

Goold Health Systems, Augusta, Maine

- In this role, Ms. Martin was responsible for processing Maine and Iowa Medicaid Drug Rebate invoicing and collection processes.
- She posted ROSI and PQA payments into the eREB system, created and logged dispute records for dispute resolution processing, created reports to preview and review account records, reviewed claim level detail (CLD) to identify billing issues, processed quarterly 38 day late payment notifications.
- She was responsible for researching and auditing claims to ensure accurate balances were maintained by both the state office and the individual manufacturers. She also worked with technical staff to create a rate table for negotiated rebate types specific to state and program type.

12/2003-7/2008 Social Service Program Specialist I

State of Maine Office of MaineCare Services, Augusta, Maine

- She recruited and enrolled providers in the Maine Medicaid Managed Care program. She worked closely with providers, provided education, processed enrollment paperwork, monitored the 24/7 access coverage plan.
- She worked closely with the vendor that managed the member services helpdesk, meeting weekly to obtain listing of member's and/or staff s provider coverage shortage areas.
- Ms. Martin also worked closely with technical staff to resolve member file load issues and was instrumental in creating load rules and documentation to handle file error load procedures.
- While in this role she provided back up to the Medicaid Pain Management staff and assisted with monitoring patient's medications and coordinating health assessments

with in- house nursing staff, processing authorizations, and enrolling high risk members into the program.

- She was the team lead for Medicaid report specification documentation. In this role, she worked collaboratively with State subject matter expert's, and vendor reporting staff with gathering, recording and creating, report specification documentation for complex Medicaid internal and external reports.

1/2001-12/2003 Provider Relations Specialist

- In the role of a Medicaid Provider Relations Specialist responsibilities included interpreting complex Medicaid policy, and assisting providers with billing issues.
- This work required in depth knowledge of hospital and professional claims billing and processing medical claims. During this capacity Ms. Martin was also responsible for enrolling members and providers in the Maine Eye Care State program
- She was also tasked with writing billing instructions for specific programs/ claim types, holding regional meetings with providers to educate them on billing changes, outreach and education to new Medicaid providers as needed, tracking and documenting new billing changes due to policy revisions.

10/1998-12/2000 Pharmacy Purchasing manager

- As a Pharmacy Purchasing manager, Ms. Martin was responsible for ordering pharmaceuticals specialty products and drugs, managing and maintaining inventory, overseeing the pre-packaging operations, managing the returns department, and assisting the pharmacist in filling prescriptions. She implemented an internal electronic database to track returns, called long term care facilities and recorded pharmaceutical items returned by them. In addition, she managed staff performing quarterly stock inventory and was successful in negotiating overstock returns with large distributers of prepackaged drugs. These negotiations allowed the pharmacy to reduce stock for items that were bought in bulk by the previous purchasing manager but not moving fast enough to use before the expiration date.

1/1998-12/2000 Pharmacy Technician:

- Licensed with the Maine Board of Pharmacy as a Pharmacy Technician, Ms Martin assisted resident Pharmacists with accurate and efficient preparation of prescription orders, verification of prescription information and dosage, entering patient and order information into the pharmacy system, and processing and submitting insurance claims.
- Ms. Martin worked collaboratively with long term nursing facility staff, providing quality customer service and assistance with claim submission issues while ensuring that every effort was made to fill and deliver prescriptions in a timely matter with minimal medication disruption to patients.
- She also worked with the returns department processing medications and durable medical equipment returns, providing quality assurance checks and recording refund

details which were submitted to the billing department for processing refunds or notifications back to facilities.

PROFESSIONAL QUALIFICATIONS, CERTIFICATIONS, SKILLS

- In depth knowledge of Medicaid Programs, Policies and Procedures
- Extensive knowledge of Medicaid medical and pharmacy claims processing, and drug rebate collections
- Research/analytical ability
- Adept in problem resolution

THERESA THOMPSON
Pharmacy Business Analyst

SUMMARY OF EXPERIENCE

Ms. Thompson joined the Goold team in 2000, but has been working in the pharmaceutical and pharmacy industry for almost 30 years. She began her career as a pharmaceutical purchaser for a small chain drug store that consisted of 32 pharmacies for almost 10 years and then spent another six years as a pharmacy technician for Rite Aid pharmacy before coming to Goold. Her past experience included training staff at newly opened pharmacy locations on the drug dispensing systems.

When she joined Goold in 2000, she began as a pharmacy helpdesk technician, working with clients and callers to answer pharmacy and claims processing questions. A year later, she became the Pharmacy Helpdesk supervisor and Training Coordinator. She has been actively involved in setting up and training the staff for the new pharmacy helpdesk in Iowa and Wyoming.

Ms. Thompson has taken on another role at Goold as the Program Integrity Supervisor and SMAC Program Pricing Manager since 2010. She has been actively involved in implementing the SMAC programs in eight states and is currently responsible for maintaining and reviewing all SMAC pricing, as well as creating the greatest savings possible for our State clients. In Maine, she has been involved in SMAC work for more than 10 years, having served as the Pharmacy Helpdesk Supervisor, with daily exposure to resolution of issues regarding payment, pricing, and POS concerns. In addition, she has been involved in SMAC issues for Wyoming Medicaid for the last six years and more recently has been involved in pricing issues and SMAC setting for Illinois, New Jersey, Minnesota, and North Dakota. Previously, Ms. Thompson worked with the West Virginia SMAC program, achieving millions of dollars in savings, and beginning in 2015, she will oversee the Vermont program as well. Her daily immersion in SMAC and other Medicaid pricing issues in multiple states makes her the ideal person for her current role.

EMPLOYMENT

2010 – Present **Program Integrity Supervisor/SMAC Programs Pricing Manager**
Goold Health Systems, Augusta, ME

State Maximum Allowable Cost (SMAC) Experience

Actively involved in implementing and ongoing operations of the SMAC programs for: Illinois, Maine, Minnesota, New Jersey, North Dakota, South Dakota, Utah and Wyoming, and beginning in 2015, Vermont.

- Provide SMAC pricing development and timely resolution of disputes;
- Responsible for new brand and generic drug pricing evaluations;
- Provide calculation and tracking of new generic pricing (weekly, monthly);
- Oversee rebasing of established generic prices (weekly, monthly, quarterly);

- Worked with Wyoming through re-implementation of the SMAC program and have accomplished one of the most robust SMAC programs in the country, achieving recognition from CMS for the program savings through aggressive pricing formulas and inclusion criteria;
- Through the initial implementation of a new client's SMAC program, have evaluated just 135 drugs out of approximately 3,000 drugs so far and are projecting to save the State approximately $9 million per year based on initial evaluations; and
- Previously provided operations and support for the West Virginia SMAC program, which saved the State an average of $4 million per month during the contract period.

Preferred Drug List (PDL) Experience

- Provide comparisons of generic and brand net prices for PDL status determinations
- Create financial modeling of brand and generic drugs , with and without supplemental rebates, federal rebates, and SMAC pricing; and
- Partner to coordinate and create the P&T financial costs sheets for Iowa, Georgia, Maine, and Mississippi.

Multi-State Pool Support Experience

- Work with account managers when the clients have special reporting requests;
- Provide various financial modeling based on client's needs; and
- Partner to pull together information and create the multi-state pool financial cost sheets for nine State clients;

Program Integrity Experience

Responsible for reviewing /correcting pharmacy provider compliance with State and Federal payment policies and guidelines, identifying/preventing fraud for State of Maine;

- Provide quality assurance reporting;
- Responsible for billing review practices;
- Provide case Development through desk reviews and evaluation, including utilizing reporting and algorithms to flag potential recoveries; and
- Initiate and document recovery activities.

2000 – 2010 Pharmacy Helpdesk Coordinator/Member Services

Goold Health Systems, Augusta, ME

- Responds to calls from Pharmacists and Technicians
- Supervises Helpdesk Technicians and the entire customer service process for all plans
- Responsible for all quality control issues relevant to accounts and customer service relations
- Maintains documentation for training
- Oversees staff training to ensure all staff members are up-to-date on current processes
- Out-of-state staff training on new POS and Prior Authorization Programs:
    - Iowa

- Wyoming

1994 – 2000 Pharmacy Technician
Rite Aid Pharmacy, Skowhegan, ME

- Assisted with prescriptions by counting pills
- Measured medications
- Labeled products
- Verified prescriptions from doctors
- Maintained patient records
- Tracked insurance information
- Assisted patients with insurance forms

1985 – 1994 Pharmaceutical Buyer/Pharmacy Operations
Laverdiere's Super Drug Maine Office, Winslow, ME

- Ordered drugs for all Laverdiere's Pharmacies.
- Completed payroll for all Pharmacy employees
- Completed daily office paperwork
- Education

EDUCATION

Waterville Senior High School
General Diploma earned

PROFESSIONAL LICENSES, CERTIFICATIONS, AND MEMBERSHIPS

- National Certified Pharmacy Technician (through PTCB) – currently in process

MATTHEW PETTENGILL, PMP
Project Manager

SUMMARY OF EXPERIENCE

Matthew Pettengill has been an employee of Goold Health Systems (GHS) since 2005. In that time he has transitioned roles from Technical Writer, to Project Coordinator, to Project Manager. He currently holds a Project Management Professional (PMP) certification from the Project Management Institute (PMI). During his time with the company, GHS has grown significantly, from two large Medicaid pharmacy contracts to the six Goold now has. Mr. Pettengill played a supporting role in each of these projects and has an insider's knowledge of each contract as well as the products and tools making up each solution.

Mr. Pettengill played a significant role in developing new business during the two years he worked directly with GHS' Business Development team. In particular, he participated in the development of the winning bids for the Illinois PBMS solution and the Vermont PBM solution, respectively. He also worked on the winning bid to re-procure Maine's Assessing Services Agency contract, which included significant new scope of work.

EMPLOYMENT

August 2014 – Present Project Manager
Emdeon (through acquisition of Goold Health Systems), Augusta, Maine

- Work in a mixed-matrix organization with strong functional departments and executive management.
  - Communicate with stakeholders and team members through the duration of an activity or project.
  - Create documents required to facilitate successful execution of project phases.
  - Define scope of work and capture requirements with internal and external stakeholders.
  - Coordinate and schedule tasks, activities, and change requests, setting agreeable deadlines.
  - Prepare reports and provide updates on project development and operational phase activities.
  - Perform business process analysis.

11/2011 – 08/013 Associate Project Coordinator (Business Development).
Goold Health Systems, Portland, Oregon and Augusta, Maine

- Transferred to Goold's Business Development team, leveraging my experience as a technical writer and comprehensive understanding of Goold's products and services:
  - Coordinated and executed the production of responses to Request for Proposal (RFP) releases.
  - Co-lead the team that produced the winning proposal for the State of Vermont Pharmacy Benefit Management project (March, 2014)

- Coordinated the production of the winning RFP response for an Assessing Services Agency contractor for Maine's Office of Aging and Disability. (November, 2013)
- Participated as a key member of a team that produced the winning proposal for the State of Illinois Medicaid Pharmacy Benefit Management project. (Fall, 2013)
- Designed and Implemented process improvements for the GHS Business Development team.

03/2007 – 11/2011 Associate Project Coordinator (Pharmacy Operations)
Goold Health Systems, Augusta, Maine

- Worked in a cross-functional department supporting all aspects of ongoing operations, change requests, new projects, and other activities:
  - Conducted all business analysis and planning for the State of Maine's initiative to limit members to 4 brand-name prescriptions in any 30-day period.
  - Coordinated the addition of certain diabetic supplies to Maine's Preferred Drug List.
  - Supported the design, development, and implementation phases of the Wyoming Pharmacy Benefit Management project.
  - Conducted all business analysis and planning for the State of Maine's initiative to limit a member's supply of narcotics and high-cost medications to no more than 15 days.
  - Supported the design, development, and implementation phases of the Georgia Drug Rebate project.
  - Conducted requirements gathering activities and documented specifications and workflow procedures for Maine's Pharmacy Program Integrity Pilot Project.
  - Developed specifications to re-configure an internal time tracking system so support reporting by project phase.
  - Developed and presented uniform change management procedures for use by Account Managers.
  - Developed and operated a quarterly data collection process for pharmaceutical manufacturers.
  - Worked with the State Maximum Allowable Cost rate setting team to document and improved quality assurance processes.
  - Facilitated the change request process for Medicaid contracts in Maine, Iowa, Wyoming, Utah, and others.
  - Continued to serve in the Technical Writer role as needed.

02/2005 – 03/2007 Technical Writer
Goold Health Systems, Augusta, Maine

- Created operational procedures for end-users and functional staff.
- Created training materials and user manuals for GHS's desktop and web-based applications.
- Coordinated and prepare Request for Proposal (RFP) responses.
- Prepared presentation materials for potential clients.
- Prepared other written material as needed, such as website and marketing copy.

01/2004 – 05/2004 Student Intern, Fogler Library
University of Maine, Orono, Maine

- Wrote several articles for the Fogler Friends Newsletter.
- Designed layout for Friends Newsletter using Adobe InDesign.cs.
- Photographed, scanned, and manipulated images for Newsletter.
- Helped teach a workshop on Macromedia Dreamweaver for UMaine Faculty / Staff.
- Wrote and edited supplemental materials for the above workshop.

2004 Customer Service Representative
Microdyne Outsourcing, Orono, Maine

- Dell Computer, Small Business Division.

05/2003 – 09/2003 Student Computer Technician
ASAP Media Services, University of Maine, Orono, Maine

- Collaborated with others on X-Power Interactive, a math education program.
- Designed graphics and other visual elements for X-Power and other projects.
- Wrote student user manual for X-Power Interactive.
- Assisted with programming in Macromedia Flash and Director.

09/2001 – 05/2003 Student Field Worker
University of Maine, Department of Forest Ecosystem Science, Orono, Maine

- Designed a website for the Forest Ecosystem Research Project (FERP).
- Assisted with summer fieldwork in the Penobscot Experimental Forest and other locations across Maine and bordering Canada.
- Technical support for the Fall 2002 ECANUSA Conference.
- Entry of data collected in the field into research database.
- Maintenance of field equipment / vehicles.

CERTIFICATIONS

Project Management Professional
Project Management Institute, License [redacted]
March 2014 – March 2017

Certified Associate in Project Management
Project Management Institute, License [redacted]
February 2012 – February 2017

EDUCATION

University of Maine
BA, English. Minor in New Media
1999 – 2004

University of Southern Maine, Center for Continuing Education - Non-Degree Courses
Effective Project Management
Implementing Project Management

University of Maine at Augusta - Non-Degree Courses
Black and White Photo I (PHO-101)
Photoshop I (ART-232)
Communication in Groups and Organizations (COM-104)

JASON RUSHING
Data Analyst Team Lead

SUMMARY OF EXPERIENCE

Mr. Rushing has over fourteen years of experience in report design and data analysis. He has been with the GHS team since 2004 as the Lead Data Analyst. He is an expert in transforming complex business logic into SQL code using tools such as stored procedures, user-defined functions, views, scripting, DTS and SSIS. He has been a Crystal Reports developer since 1998 with a focus on automating and publishing reports to Business Objects Enterprise server. He is also the Business Objects Enterprise administrator responsible for maintaining Web Intelligence, OLAP cubes and user permissions and the SQL Server Reporting Services developer trained by Microsoft certified training partner.

EMPLOYMENT

12/04 – Present Data Analyst Team Lead
Goold Health Systems, an Emdeon company, Augusta, ME

- Manage group of 8 analysts
- Implemented automated reporting for all regularly scheduled production reports
- Put source control system into place and developed standards for use
- Developed coding standards and peer review process
- Launched Business Objects Enterprise for internal and external customers including OLAP cube, Web Intelligence, published Crystal Reports and document storage
- Collaborated with dba to set up development and production server environments for analyst team
- Implemented new documentation system using Confluence wiki
- Developed reporting suite for Goold Rebate Department using SQL Server Reporting Services

2003 - 2004 Information Systems Analyst
Senior Spectrum (Spectrum Generations), Augusta, ME

- Maintained client and financial databases in SQL Server and MS Access
- Developed custom reporting for internal customers, state government and federal government using Crystal Reports and MS Access.
- Implemented automated reporting for all regularly scheduled production reports
- Managed intranet, public website and all telecommunications equipment

1998 - 2003 Business Analyst
Envisionet/Microdyne, Augusta, ME

- Developed and automated operational and client reporting using Crystal Reports, MS Office and Visual Cut
- Played integral role in the development of detailed project plan for opening new call

centers
- Self-taught subject matter expert on Report Runner reporting software for ACD phone switch
- Saved Microdyne over $822,000 through consolidation and automation of reporting

1991 – 1998 Cryptologic Maintenance Technician
United States Navy
- Promoted to the rank of Petty Officer Second Class
- Received 2 Navy and Marine Corps Achievement Medals
- Granted Top Secret SCI clearance
- Directed the installation of the Automated Logistics Information System in Diego Garcia, increasing the efficiency of the supply system by over 60%
- Managed an inventory of 3,000 critical spare items
- Installed and performed preventive and corrective maintenance on a wide variety of state of the art systems and peripherals
- Managed technicians maintaining Advanced Tactical Ocean Surveillance and High Frequency Direction Finding communication systems
- Coordinated emergency actions for facility electrical power and air conditioning outages
- Focal point for fire and security system readiness
- Managed and trained ten technicians performing preventive and corrective maintenance measures for the Advanced Tactical Ocean Surveillance system
- Presented weekly briefs to the department head and commanding officer on equipment status and performance

EDUCATION

University of Maine, Augusta, ME
18 credits toward Baccalaureate degree
University of Maryland, Guam
9 credits toward Baccalaureate degree
U.S. Navy, Winter Harbor, ME
Classic Wizard Maintenance School
U.S. Navy, Pensacola, FL
Cryptologic Technician Maintenance Basic and Advanced Technical School

TECHNICAL SKILLS PROFILE

Programming Languages:
- Microsoft T-SQL
- Crystal Syntax
- VB

Database:
- SQL Server 2000/2005/2008
- Access

Development Environments:

- SQL Server Management Studio
- MS Visual Studio
- Crystal Reports
- MS Access
- Business Objects Universe Designer

Exhibit B – Sample Therapeutic Class Review Monograph

Three TCRs have been included as a sample of the thorough and industry-leading work that Goold produces for our clients. The reports include following and being on the next page:

1. Antibiotics, GI;
2. Antineoplastics, Selected Systemic Enzyme Inhibitors; and
3. Colony Stimulating Factors.

THERAPEUTIC CLASS REVIEW
OCTOBER 22, 2013

[Last Literature Review: August 29, 2013]

[Last Review Update: September 3, 2013]

ANTIBIOTICS, GI

This publication is a result of the collaboration of the Goold Health Systems Clinical Workgroup and represents the opinion of these authors based on a review of the literature available at the time it was written. It is intended for the sole purpose of providing information to committee members in order to compare medications within a specified subset of clinical parameters. It is not intended to provide specific clinical advice for any condition, or to be an exhaustive review of all potential aspects of pharmacotherapies for any given condition. Medical evidence is rapidly changing, and no representation is made regarding the use of this material beyond the stated purpose. The literature for this review was last searched through the date listed above. Please note that it may take time for published articles to be available via medical literature search engines.

SYNOPSIS

Based on a 2008 analysis by the CDC using data collected from ambulatory case visits to physician offices, there were a total of 955,969 reported office visits in the United States. Of those, 24,213 (2.5%) had a primary diagnosis of infectious and parasitic diseases.36 Furthermore, in a report by the World Health Organization (WHO) on infectious diseases (IDs),

IDs were identified as being the world's greatest killer of children and young adult, accounting for greater than 13 million deaths a year (one in two deaths in developing countries). Diarrhea diseases are among the top six infectious diseases causing death worldwide.[11] The main types of pathogens include bacterial, fungal, viral, prionic, and other parasites. Verifying and diagnosing the specific pathogen is the key to successful treatment.[10]

A plethora of medications are available on the market for the treatment of bacterial infections. The diversity of existing antibacterial medications allows for treatment of numerous bacterial pathogens that target specific areas of the body. Using bacterial agents appropriately and only with proven or strongly suspected infections will help reduce the development of drug-resistant bacteria.

The drugs included in this review range from neomycin, which was discovered in 1949 to fidaxomicin (Dificid®), which was approved in 2011. These antibiotics all have a commonality, in that they are recognized as a major treatment for primarily gastrointestinal illnesses or have a unique site of action that is local to the gastrointestinal tract. Nevertheless, many of these drugs do have approved indications outside of the GI tract. Flagyl® ER is included for completeness, but has only a single non-GI FDA indication.

Clostridium difficile infection is one of the most common hospital-acquired infections. It has been an increasingly problematic illness that is caused by changes in the GI flora due to antibiotics or possibly proton pump inhibitor therapy.38 Recommendations for the management of this illness have been evolving in recent years due to the increased prevalence, as well as due to drug resistance, increased virulence and a significant relapse rate.40

The drugs included in this therapeutic class review include: fidaxomicin (Dificid®), metronidazole (Flagyl®), metronidazole ER (Flagyl® ER), neomycin, nitazoxanide (Alinia®), rifaximin (Xifaxan®), tinidazole (Tindamax®), and oral vancomycin (Vancocin®).

FDA APPROVED INDICATIONS[1-8]

It is recommended that products be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria to reduce the development of drug-resistant bacteria.
Rifaximin (Xifaxan®) should not be used in those with diarrhea complicated by fever or blood in the stool or for diarrhea due to pathogens other than E coli. It should be discontinued if diarrhea symptoms get worse or last greater than 24-48 hours. Also, rifaximin (Xifaxan®) has not been studied in those with Model for End-Stage Liver Disease scores >[25].
The following table illustrates the approved indications for the agents in this review.

FDA Approved Indication	fidaxomicin (Dificid®)	metronidazole (Flagyl®)	metronidazole ER (Flagyl® ER)	neomycin[9]	nitazoxanide (Alinia®)	rifaximin (Xifaxan®)	tinidazole (Tindamax®)	vancomycin (Vancocin®)
Amebic liver abscess/ Intestinal Amebiasis		X					X[3]	
Anaerobic Bacterial Infections		X						
Bacterial vaginosis			X				X[4]	
CDAD[8]	X							X
Enterocolitis								X[6]
Giardiasis							X[2]	
Hepatic Coma				X[10]				
Hepatic Encephalopathy						X		
Suppression of Intestinal Bacteria				X[11]				
Treatment of asymptomatic consorts with *T. vaginalis*		X						
Treatment of diarrhea					X[1]	X[5]		
Trichomoniasis		X[7]					X	

[1] Caused only by *Giardia lamblia* or *Cryptosporidium parvum.* Has not been shown to be superior to placebo for the treatment of diarrhea caused by *Cryptosporidium parvum* in HIV-infected or immunodeficient patients. [2] Caused by *Giardia duodenalis* [3] Caused by *Entamoeba histolytica*
[4] Formerly referred to as *Haemophilus* vaginitis, *Gardnerella* vaginitis, nonspecific vaginitis, or anaerobic vaginosis. Other pathogens commonly associated with vulvovaginitis such as *Trichomonas vaginalis*, *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, *Candida albicans*, and *Herpes simplex* virus should be ruled out.
[5] For traveler's diarrhea caused by non-invasive strains of *Escherichia coli;* should not be used in those with diarrhea complicated by fever/blood in the stool or diarrhea due to pathogens other than *E. coli* [6]Caused by *Staphylococcus aureus* [7] For men/women in presence of symptomatic trichomoniasis confirmed by appropriate lab procedures and for females with asymptomatic trichomoniasis, when the organism is associated with endocervicitis, cervicitis, or cervical erosion. [8] CDAD- Clostridium difficile-Associated Diarrhea
[9] To reduce the development of drug-resistant bacteria and to maintain the effectiveness of neomycin, it should only be used to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria.

[10] (Also Portal-Systemic Encephalopathy) As adjunctive treatment by reducing the ammonia-forming bacteria in the intestinal tract, which results in neurologic improvement.[11] As adjunctive treatment as part of a regimen for suppression of normal bacterial flora of the bowel (ie pre-op preparation of the bowel). Given concomitantly with erythromycin enteric-coated base

As mentioned in the table above, metronidazole (Flagyl®) is indicated for the treatment of serious infections caused by susceptible anaerobic bacteria. Surgical procedures that are indicated should be performed in combination with metronidazole (Flagyl®) therapy. In those with the most serious infections, IV metronidazole is typically used first, and then is followed by oral therapy as per the physician. The following table includes the infections that metronidazole (Flagyl®) is indicated for.

Infection	Caused by
Intra-Abdominal Infections	*Bacteroides* species, including *B. fragilis* group, *Clostridium* species, *Eubacterium species, Peptococcus niger,* & *Peptostreptococcus* species (infections include peritonitis, intra-abdominal abscess, and liver abscess)
Skin/Skin Structure Infections	*Bacteroides* species, including *B. fragilis* group, *Clostridium* species, *Peptococcus niger, Peptostreptococcus* species, & *Fusobacterium* species
Gynecologic Infections	*Bacteroides* species, including *B. fragilis* group, *Clostridium* species, *Peptococcus niger* and *Peptostreptococcus* species (infections include endometritis, endomyometritis, tubo-ovarian abscess, & post-surgical vaginal cuff infection)
Bacterial Septicemia	*Bacteroides* species, including *B. fragilis* group & *Clostridium* species
Bone and Joint Infections	*Bacteroides* species, including *B. fragilis* group (Used as adjunctive therapy)
Central Nervous System Infections	*Bacteroides* species, including *B. fragilis* group (infections include meningitis and brain abscess)
Lower Respiratory Tract Infections	*Bacteroides* species, including *B. fragilis* group (infections include pneumonia, empyema, and lung abscess)
Endocarditis	*Bacteroides* species, including *B. fragilis* group

DOSAGE FORMS, DOSE, AND MANUFACTURER1-8

Nitazoxanide (Alinia®) should be taken with food.

Drug	Dosage Forms	Dose	Manufacturer
fidaxomicin (Dificid®)	**Tablets:** 200mg	1 tablet BID X10 days	Optimer Pharmaceuticals
metronidazole (Flagyl®)	**Tablets:** 250mg, 500mg **Capsules:** 375mg	BID-QID X5-10 days per indication *Pediatrics:* 35-50mg/kg/day, divided TID X10 days	Various generic manufacturers (G.D. Searle)

Drug	Dosage Forms	Dose	Manufacturer
metronidazole ER (Flagyl® ER)	**Extended-release tablets:** 750mg	750mg QD X7D on empty stomach	G.D. Searle, division of Pfizer
neomycin sulfate	**Tablets:** 500mg **Oral Solution:** 125mg/5ml	*Hepatic Coma*: 4-12gms/day *Colorectal Pre-op*: 3gms pre-op day 1	Various generic manufacturers
nitazoxanide (Alinia®)	**Tablets:** 500mg **Suspension, Oral:** 100mg/5ml	*≥12 yrs*: 500mg BID X3 days *4-11 yrs*: 10ml (200mg)BID X3 days *1-3yrs*: 5ml (100mg) BID X3 days	Romark Pharmaceuticals
rifaximin (Xifaxan®)	**Tablets:** 200mg, 550mg	*TD:* 200mg TID X3days *HE*: 550mg BID	Salix Pharmaceuticals
tinidazole (Tindamax®)	**Tablets:** 250mg, 500mg	*Adults*: 2gms QD w/food[1] *Children*: 50mg/kg/day up to 2gm	Various generic manufacturers (Mission Pharmacal)
vancomycin (Vancocin®)	**Capsules:** 125mg, 250mg	CDAD: 125mg QID X10D 500mg-2gm divided 3-4X/D X7-10D *Pediatrics:* 40mg/kg as 3-4X/D X7-10D	Various generic manufacturers (Viro Pharmac Inc)

[1] One dose only for Trichomoniasis and Giardiasis; 3 days of treatment for Amebiasis, intestinal; 3-5 days of treatment for Amebic liver abscess; 2 days of treatment for bacterial vaginosis. All treatment should be taken with food.
TD- Travelers' Diarrhea; HE- Hepatic Encephalopathy

PHARMACOLOGY1-9

Fidaxomicin (Dificid®) is a macrolide antibiotic, and works as a bactericidal agent against C. difficile by inhibiting RNA synthesis.

Metronidazole (Flagyl®, Flagyl® ER) and tinidazole (Tindamax®) are both oral synthetic antiprotozoal and antibacterial agents. They are thought to interact and damage DNA. This ultimately results in inhibition of protein synthesis and cell death.

Neomycin is an antibiotic obtained from the metabolic products of the actinomycete Streptomyces fradiae. It is bactericidal and acts by inhibiting the synthesis of protein in cells. Nitazoxanide (Alinia®) is a synthetic antiprotozoal agent. It is thought that nitazoxanide (Alinia®) works due to the interference with the pyruvate: ferredoxin oxidoreductase (PFOR) enzyme-dependent electron transfer reaction, which is essential to anaerobic energy metabolism.

Rifaximin (Xifaxan®) is a non-aminoglycoside semi-synthetic antibacterial agent that is derived from rifamycin SV. It works by binding to the bacterial DNA-dependent RNA polymerase, which thus causes the inhibition of bacterial RNA synthesis.

Vancomycin (Vancocin®) is a poorly absorbed antibiotic. It is a bactericidal agent that works primarily by inhibiting cell-wall biosynthesis. It also alters bacterial cell-membrane permeability and RNA synthesis. Cross-resistance between vancomycin and other antibiotics does not exist.

PHARMACOKINETICS1-9

Drug	Time to Peak Plasma Concentration	Half Life	Elimination	Other
fidaxomicin (Dificid®)	1-5 hrs	11.7 hrs	Feces: 92%	
metronidazole (Flagyl®)	1-2 hrs	8 hrs	Urine: 60-80% Feces: 6-15%	
metronidazole ER (Flagyl® ER)	4.6-6.8 hrs	7.4-8.7 hrs	Urine: 60-80% Feces: 6-15%	
neomycin	1-4 hrs	3 hrs	Feces: 97%[1]	Poorly absorbed from GI tract
nitazoxanide (Alinia®)	1-4 hrs	N/A	Urine: 33% Feces: 67%	Must be taken with food
rifaximin (Xifaxan®)	0.8 hrs	1.8-4.8 hrs	Urine: 0.32% Feces: 96.62%	
tinidazole (Tindamax®)	1.6 hrs	12-14 hrs	Urine: 20-25% Feces: 12%	May be crushed/used in artificial cherry syrup if can't swallow tabs
vancomycin (Vancocin®)	N/A	5-11 hrs	Primarily Feces	Poorly absorbed

CLINICAL TRIALS

Clinical trials performed to obtain FDA approval confirmed all the medications in this therapeutic class to be superior in efficacy when compared with placebo, as well as showing the relative safety of the drug.

C. difficile Reviews:

A 2011 Cochrane Review by Nelson et al29 included 15 randomized controlled trials (N=1152) to assess the efficacy of antibiotic therapy for C. difficile-associated diarrhea (CDAD). There were nine different antibiotics that were examined, and included vancomycin, metronidazole, fusidic acid, nitazoxanide, teicoplanin, rifampin, rifaximin, bacitracin, and fidaxomicin. Although

most studies were active-comparator studies with vancomycin, there was one placebo-controlled trial comparing placebo with vancomycin.

In the vancomycin placebo controlled trial, results suggest that vancomycin was superior to placebo for CDAD treatment, with initial symptomatic cure being 41% in the vancomycin group vs 4% in the placebo group. However, this study only included a small sample size of 44 subjects. In other studies, statistically significant differences in efficacy were not found between vancomycin and metronidazole, vancomycin and fusidic acid, vancomycin and nitazoxanide, or vancomycin and rifaximin. Additionally, statistically significant differences in efficacy were not seen between metronidazole and nitazoxanide, or between metronidazole and fusidic acid. Teicoplanin was found to be significantly superior to vancomycin and metronidazole; however, results of these comparator studies should be taken with caution as both had small sample sizes.

The authors concluded that there are 2 goals of treatment, which includes improvement of the patient's clinical condition and prevention of the spread of C. difficile infection to others. There is not enough evidence to support an antibiotic recommendation to obtain the two goals of treatment. Most studies reviewed were of small sample size and most found no statistically significant differences between active comparators.

A 2011 systematic review by Drekonja et al31 included 11 randomized controlled trials (N=1463) to assess for the effectiveness of certain antibiotics compared with others for the initial cure, recurrence, and harms in adults needing treatment for Clostridium difficile infection. Of the included studies, vancomycin was the most frequently assessed treatment, with 9 studies found. Metronidazole was assessed in 5 studies, bacitracin in 2 studies, nitazoxanide in 2 studies, fidaxomicin in 1 study, and rifampin in 1 study.

Results suggest that vancomycin and metronidazole were the most frequently compared antimicrobial agents, included in 3 studies. 84-94% of the vancomycin group was initially cured vs 73-94% of the metronidazole group. Statistically significant differences between treatments were not seen in any study. In those with severe disease (N=82), a significant difference in the % of initial cure was not different (79% vs 66%, respectively; p=0.22). 7-17% of the vancomycin group met criteria for recurrent disease vs 5-21% of the metronidazole group, which was not statistically significantly different. Of the studies that reported duration of diarrhea and clearance of toxin, there was not a statistically significant difference between treatments. Mean duration of diarrhea was 2.4-3.2 days.

There were 8 studies that compared metronidazole or vancomycin with a different antimicrobial agent, placebo, or the same drug with another antimicrobial agent added as adjunctive treatment. Various comparisons included vancomycin vs bacitracin, metronidazole vs nitazoxanide, vancomycin vs nitazoxanide, high vs low-dose vancomycin, metronidazole vs metronidazole plus rifampin, vancomycin vs fidaxomicin, and vancomycin vs placebo.

Results of these studies suggest no statistically significant differences in initial cure, except for the comparison between vancomycin and placebo. For the issue of recurrence, only the comparison between fidaxomicin vs vancomycin showed a statistically significant difference (15% vs 25%; p=0.005). In all the other trials, significant differences between treatments for the % of patients with recurrence did not occur. For mortality, 1 study showed 32% (N=6/19) of the metronidazole plus rifampin group died vs 5% of the metronidazole group. This was statistically significantly different (p=0.044). In the remaining studies, the mortality rate ranged from 0-9% and was not statistically significantly different between treatment groups. Furthermore, statistically significant differences in duration of diarrhea between treatments were not seen, or for reported adverse events. Lastly, statistically significant differences between treatments were not seen in any study reported adverse events. The authors concluded that fidaxomicin, metronidazole, and vancomycin were all effective for initial cure of C. difficile, and not one antimicrobial agent was found to be superior to another; however, for recurrent C. difficile infection, fidaxomicin resulted in fewer recurrences than vancomycin.

A 2012 meta-analysis by Crook et al49 included two phase 3 trials (N=1164) that compared fidaxomicin with vancomycin when used as treatment for Clostridium difficile infection (CDI). A meta-analysis of the results from both studies was performed to assess the cure rate. Additionally, data from the studies were combined and post hoc intent-to-treat (ITT) analyses were performed to assess the composite endpoint of persistent diarrhea or CDI recurrence or death.

Results of the meta-analysis suggest the non-inferiority of fidaxomicin as compared with vancomycin for clinical cure and the superiority of fidaxomicin over vancomycin for recurrence and global cure (p<0.0001). Overall, fidaxomicin reduced the composite outcome of persistent diarrhea, recurrence, or death by 40% as compared with vancomycin in the ITT population (p<0.0001) though day 40, with the authors calculating an NNT of 8. A significantly greater reduction in persistent diarrhea or death was seen through day 12 (37% reduction, p=0.037), driven by 7 deaths in the fidaxomicin group vs 17 in the vancomycin group at less than 12 days with fidaxomicin The authors concluded that fidaxomicin use has the capability to significantly improve outcomes from CDI. Further studies are needed.

Hepatic Encephalopathy Reviews:
A 2007 retrospective chart review by Leevy et al30 obtained information on the frequency, duration, and hospitalization charges that were associated with a discharge diagnosis of hepatic encephalopathy. There were 145 subjects eligible for inclusion, and as such all were diagnosed with hepatic encephalopathy. Additionally, all were administered lactulose for ≥6 months, and then followed by rifaximin for ≥6 months. Primary clinical endpoints included hepatic encephalopathy (HE) grade based upon West Haven criteria at the end of the treatment period, the presence of asterixis at the end of the treatment period, and safety/adverse events reported.
Results suggest that 92% of subjects took at least 75% of their prescribed doses during the rifaximin period as compared with 31% during the lactulose period. This was statistically

significantly different (p<0.001). As compared with during the lactulose period, during the rifaximin period there were fewer hospitalizations (0.5 rifaximin vs 1.6 lactulose; p<0.001), fewer days of hospitalization (2.5 vs 7.3; p<0.001), fewer total weeks hospitalized (0.4 vs 1.8; p<0.001), and lower hospitalization charges per patient ($14,222 vs $56,635).

For the clinical outcomes, the HE grade at the end of each treatment period revealed a statistically significantly less severe illness with rifaximin as compared with lactulose (p<0.001). 25% of the lactulose group were with stage 3 or stage 4 HE as compared with 6% of the rifaximin group (p<0.001). Lastly, 93% had asterixis at the end of the lactulose period as compared with 63% at the end of rifaximin period, which was statistically significantly less (p<0.001).

For adverse events, there was a significantly higher percentage of patients with diarrhea, flatulence, and abdominal pain during the lactulose period vs the rifaximin period (p<0.001 for each adverse event). Significant differences between those with headache were not seen between treatment periods (p=0.718). The authors concluded that while results suggest lower frequency and duration of hospitalization, better clinical status, and less reported adverse events during the rifaximin period vs the lactulose period, these results should be construed carefully due to the design of this study, as it was not a randomized controlled trial.

A 2011 meta-analysis by Eltawil et al32 included 12 randomized controlled trials (N=565) to assess for the efficacy of rifaximin in comparison with other oral agents for the treatment and management of hepatic encephalopathy (HE). Of the 12 studies included, 1 study compared rifaximin to a group treated with neomycin and to another group treated with disaccharides (such as lactulose). Seven studies compared rifaximin with disaccharides, and 4 studies compared rifaximin with antibiotics (such as neomycin). The primary outcomes were the effectiveness and safety of those with at least one episode of HE. Secondary outcomes included the reduction of serum ammonia levels and changes in psychometric parameters (such as mental status, asterixis, and portosystemic encephalopathy).

The pooled data demonstrated full resolution of HE (or clinical improvement that was considered significant) was seen with both rifaximin and the non-absorbable disaccharides, without reaching statistical significance (odds ratio [OR] 1.92; p=0.15). Similar findings were seen with the pooled data from the 5 trials comparing rifaximin vs other antibiotics, with a comparable effectiveness (OR 2.77; p=0.21). When results of those receiving antibiotics and disaccharides were combined and then compared with rifaximin, a non-statistical significance difference was seen, with a trend favoring rifaximin (OR 1.96; p=0.07). For adverse events, all results were pooled. The rifaximin group had less risk of diarrhea vs the control group (OR 0.20; p=0.004); however, the rate of abdominal pain/nausea/anorexia/weight loss was comparable between the two treatment groups. Overall, with the combined analysis, results suggest that there were fewer associated adverse events with rifaximin vs controls (p=0.001).

Significant reductions in serum ammonia levels were seen with comparators, rifaximin vs disaccharides and rifaximin vs neomycin. While numerically lower numbers, there was not a statistically significant amount of those who had lower ammonia levels with rifaximin vs disaccharides (p=0.30) and vs antibiotics (p=0.33). Significant differences were not seen between rifaximin and controls in regards to improvement in mental status and degree of asterixis. The authors concluded that rifaximin was found to be at least as effective as other treatments of HE, but with a better safety profile.

A 2012 review by Mohammed et al41 included 6 published trials to assess for the safety and efficacy of combination therapy for the treatment and prevention of hepatic encephalopathy (HE). Four of the included studies assessed the treatment of HE. Results suggested that 2 of these studies did not find a significant difference between lactulose/neomycin combination as compared with placebo or rifaximin/lactulose combination. One study did not have a control group to compare with rifaximin/lactulose combination, and the last study did not suggest any significant differences between lactulose/probiotics as compared with either drug used as monotherapy. There were 2 trials that assessed for the prevention of HE. These results suggested that rifaximin/lactulose combination was superior to lactulose monotherapy in regards to improving mental status, blood ammonia levels, and health-related quality of life. Reductions in HE recurrence and hospitalization were also seen with the combo group. The authors concluded that there was insufficient evidence to support the use of combination therapy for the treatment of HE; however, the combination of rifaximin and lactulose could be taken into account in the treatment of HE and in those refractory to monotherapy and should be considered for the prevention of HE.

A 2012 retrospective cohort study by Neff et al47 included data from medical records of adult subjects (N=203) with cirrhosis who received rifaximin as maintenance therapy for HE to assess the therapeutic response of rifaximin for >6 months. Of the included subjects, 149 were on rifaximin monotherapy (400-1600mg/dl), while 54 were on the combination of rifaximin (600-1200mg/day) and lactulose (90ml/d). The percentage in remission was the primary outcome. Liver disease severity was assessed every 3 months via the model for end-stage liver disease (MELD) scores.

Results suggested that remission of HE was maintained for one year in 81% (N=121) of the rifaximin monotherapy and 67% (N=36) of the combo group (rifaximin and lactulose dual therapy). Breakthrough episodes occurred in 19% (N=28) of the rifaximin monotherapy after a mean of 210 days as compared with 33% (N=18) of the combo group after a mean of 90 days. Of those who had breakthrough HE, 43% of the rifaximin group vs 39% of the combo group were hospitalized for overt HE. GI bleeding (25% vs 28%), infection (18% vs 6%), and hospitalization for dehydration and overt HE (14% vs 28%) were comparable between rifaximin monotherapy vs the combo group. The average MELD scores for those receiving rifaximin monotherapy and developed overt HE was 19. Those with a baseline mean MELD score ≤20 had few overt HE events. This suggests an increased response to rifaximin. The authors concluded

that rifaximin is an effective treatment for the long-term management of HE in this population with cirrhosis.

Miscellaneous Reviews:
A 2012 systematic review and meta-analysis by Menees at al33 included 5 randomized, placebo-controlled trials (N=1,803) to assess the efficacy and tolerability of rifaximin in those diagnosed with irritable bowel syndrome (IBS). Results suggest that compared with placebo, there was an associated improvement of global IBS symptoms with rifaximin (Odds Ratio [OR] 1.57; p<0.001). 42.2% of the rifaximin group reported global improvement as compared with 32.4% of the placebo group. This suggests an NNT of 11. The effect on bloating was a key secondary outcome. A statistically significant improvement with bloating was seen with rifaximin vs placebo (OR 1.55; p<0.001). After 10-14 days post-treatment, 41.6% of the rifaximin group vs 31.7% of the placebo group reported bloating was improved. Again, this suggests an NNT of 11. Lastly, the number reporting adverse events was comparable between treatment groups. The authors concluded that rifaximin was more effective than placebo for global symptoms and bloating in this population with IBS, but with comparable tolerability.

A 2012 systematic review and meta-analysis by Alajbegovic et al45 included 9 randomized, double-blind, placebo-controlled studies to assess for the safety and efficacy of rifaximin or a fluoroquinolone for preventing travelers diarrhea (TD). Of the included studies, 4 assessed rifaximin and 5 assessed fluoroquinolones. The primary outcome was the prevention of TD.

Two of the 4 studies assessing rifaximin suggested a statistically significant treatment effect, one suggested a marginal statistical significance, and one study did not suggest a statistically significant treatment effect. These results suggested an overall pooled relative risk of 0.33 with rifaximin (CI 0.24-0.45). This equates to a protective efficacy of 67%, in favor of chemoprophylaxis. The overall pooled relative risk with the fluoroquinolones was 0.12 (CI 0.07-0.20), favoring chemoprophylaxis. With rifaximin, reported adverse events were comparable between the treatment and control group. Clinically significant events were not reported with either treatment during chemoprophylaxis. The authors concluded that these results support the use and effectiveness of antibiotics for the prevention of TD.

A 2012 meta-analysis by Hu et al48 included 4 randomized controlled trials (N=502) to assess for the safety and efficacy of rifaximin for the prevention of travelers' diarrhea (TD). The main outcome was the occurrence of TD over a 2-week treatment period, while some secondary outcomes included the occurrence of mild diarrhea, the need for antibiotic treatment, and adverse events.

Results suggested that 142 adults developed TD, with 41 from the rifaximin group vs 101 in the placebo group. The incidence of TD was significantly different between treatment groups (RR 0.41, CI 0.30-0.56; p<0.00001). The authors calculated an NNT of 4. There were 72 adults who needed antibiotic treatment for TD (out of 404 from 3 trials), with 16 in the rifaximin group vs 56 in the placebo group. This was also a statistically significant difference (RR 0.30, CI 0.18-0.49;

p<0.00001). The authors calculated an NNT of 5. Compared with placebo, the use of rifaximin was not associated with a significantly reduced incidence of mild diarrhea (RR 1.11, CI 0.78-1.59; p=0.55). Enterotoxigenic E. coli was the main cause of diarrhea and mild diarrhea, with no significant differences seen between rifaximin and placebo. Clinically significant or serious adverse events were not reported between treatments. The authors concluded that rifaximin was effective for preventing TD caused by non-invasive enteric pathogens.

After a careful review of the literature, the articles included in this therapeutic class review are not all inclusive. Key and pivotal studies that suggest one therapy is superior to another or a place in therapy of a specific product are included. Studies of low levels of evidence may not have been included in the review. Studies deemed of little relevance may also be excluded.

Study & Level of Evidence	Design & Comparators	Sample Size & Duration	Patient Characteristics	Assessed Outcomes	Results	Author's Conclusions & GHS Comments
Zar et al[12] 2007 **LOE-1a**	Prospective, randomized, double-blind, placebo-controlled trial metronidazole PO 250mg QID PLUS placebo Vs vancomycin PO 12mg QID PLUS placebo	N=172 10 days, with 21 days follow-up	-Inpatients of St. Francis Hospital in IL with diarrhea actively recruited for trial that had stool assays performed for *C. difficile* toxin. Criteria for inclusion included diarrhea (defined as ≥3 non-formed stools in 24 hrs) and *C. difficile* toxin. CDAD-*Clostridium difficile* associated diarrhea	-To compare between treatments outcomes of cure, treatment failure, and relapse (Cure defined as resolution of diarrhea by day 6 of treatment and neg results of a *C. difficile* toxin. Treatment failure defined as a persistence of diarrhea and/or positive result of a *C. difficile* toxin. Relapse defined as recurrence of *C. difficile* toxin A-positive diarrhea by day 21 after initial cure.)	-The overall cure rate was 84% (N=66/79) in the metronidazole (MET) group vs 97% (N=69/71) of the vancomycin (VAN) group, which was statistically significantly different (p=0.006). -Of those with mild disease, there was not a statistically significant difference between treatments with clinical cure (90% MET vs 98% VAN; p=0.36). Of those with severe disease, clinical cure was 76% with MET vs 97% with VAN, which was statistically significantly different (p=0.02). -After initial cure, relapse of disease occurred in 7% (N=5/76) in those with mild disease and in 15% (N=9/59) in those with severe disease (p=0.15). -After initial cure, relapse occurred in 14% (N=9/66) of those treated with MET vs 7% (N=5/69) of those treated with VAN. This was not statistically significantly different (p=0.27).	-Although vancomycin was more effective and superior to metronidazole for those with severe CDAD, these products were equally effective for those with mild CDAD.

Study & Level of Evidence	Design & Comparators	Sample Size & Duration	Patient Characteristics	Assessed Outcomes	Results	Author's Conclusions & GHS Comments
					-Discontinuation from treatment of active study drug occurred with one patient in each treatment group.	
Al-Nassir et al[13] 2008 **LOE-2**	Prospective, observational study vancomycin PO Vs metronidazole PO	N=90 Monitored for duration of stay in acute-care hospital and for 3 weeks after completion of CDAD therapy	-Patients with *Clostridium difficile*-associated diarrhea (CDAD) from the acute-care and long-term care facilities of a Veterans Affairs medical center that had a high rate of VRE colonization. Patients were diagnosed with CDAD based on symptoms of diarrhea and positive stool toxin assay. Choice of	-Effect of treatment on concentration of VRE in those with pre-existing colonization	-The presence and concentration of vancomycin-resistant enterococci (VRE) were monitored in stool before, during, and after therapy of CDAD. -There were 56 CDAD treatment courses where there was prior VRE colonization. Of these, 66% were treated with metronidazole (MET) and 34% were treated with vancomycin (VAN). -Differences in the mean duration between treatments was not significantly different (11.2 MET vs 12.1 VAN; p=0.088). -Significant differences in concentrations of VRE between treatments were not seen prior to beginning of CDAD therapy, during therapy, or for up to 2	-Results suggest that metronidazole and vancomycin promote the overgrowth of VRE during CDAD treatment. **GHS Comments:** Limitations of the study are the small sample size and observational design.

Study & Level of Evidence	Design & Comparators	Sample Size & Duration	Patient Characteristics	Assessed Outcomes	Results	Author's Conclusions & GHS Comments
			therapy made by provider caring for patient.		weeks after completion of therapy (p>0.350). -The density of VRE significantly decreased by days 21 to 25 (p<0.049). -Of the 34 treatment courses where baseline cultures were negative for VRE, new detection of VRE stool colonization occurred during 14% (N=3/22) of MET and 8% (N=1/12) of VAN, which was not significantly different (p=1.0).	
Al-Nassir et al[14] 2008 **LOE-2**	Prospective, observational study metronidazole (MET) Vs vancomycin (VAN)	N=52 9 months	-Subjects with *Clostridium difficile*-associated disease at the Cleveland Veterans Affairs Medical center (OH), with diagnosis based on presence of diarrhea and *C. difficile* toxin in stool	-To compare treatment response, as assessed by time to resolution of diarrhea and time to suppression of *C. difficile* to undetectable levels in the stool	-34 subjects began treatment with oral metronidazole; however, 29% (N=10) had treatment changed to oral vancomycin after 3-10 days of therapy due to persistent symptoms. 18 subjects began treatment with oral vancomycin; however, none had treatment changed from vancomycin. -Those in the VAN were more likely to obtain undetectable levels of *C. difficile* than MET between days 1 and 5; however, this was not statistically	-While both metronidazole and vancomycin were effective treatments for *C. difficile*, those taking metronidazole had a slower clinical and microbiological response, as well as more treatment failures. **GHS Comments:** Limitations of the

Study & Level of Evidence	Design & Comparators	Sample Size & Duration	Patient Characteristics	Assessed Outcomes	Results	Author's Conclusions & GHS Comments
					significantly different. -Those in the VAN group were significantly more likely to have resolution of diarrhea within 5 days of treatment vs those in the MET group (p=0.033). -Nearly all who continued treatment obtained undetectable levels of *C. difficile* and resolution of diarrhea between 5-10 days of treatment. -The presence of detectable *C. difficile* in stool was significantly associated with higher odds of continued diarrhea (Odds Ratio 2.23; p<0.001). -10 subjects had treatment changed to oral VAN due to persistent diarrhea, with the mean duration of MET treatment before changing to VAN being 6.3 days. -When compared with day of initial MET therapy, the mean concentration of *C. difficile* on the day of treatment change was not	study are the small sample size and observational design.

Study & Level of Evidence	Design & Comparators	Sample Size & Duration	Patient Characteristics	Assessed Outcomes	Results	Author's Conclusions & GHS Comments
					significantly reduced (5.23 vs 4.23; p=0.119). Also, the mean # of bowl movements per day was not significantly reduced (5.4 vs 4.8; p=0.517).	
Musher et al[15] 2009 **LOE-1a**	Multicenter, randomized, prospective, double-blind, double-dummy, controlled trial vancomycin 125mg Q6H Vs nitazoxanide 500mg Q12H	N=50 10 days	-Adult subjects with *Clostridium difficile* infection (CDI) as assessed by a fecal sample positive for *C. difficile* toxin. Patients also needed to have ≥3 loose stools within 24 hrs and ≥1 of the following additional findings: fever, abdominal pain, and/or leukocytosis.	-The clinical response at the end of treatment. Response defined as resolution of all findings of CDI -Time to resolution of symptoms and sustained response rate at day 31 (end-of-treatment response with no recurrence)	-74% (N=20/27) of the vancomycin group had a response to treatment, as compared with 77% (N=17/22) of the nitazoxanide group. -Of those who completed therapy, there was an 87% (N=20/23) response rate with the vancomycin group vs 94% (N=17/18) in the nitazoxanide group by the intent-to-treat analysis. -Overall, there was no statistically significant difference in time to complete resolution of all symptoms of CDI between treatments (p=0.55). -After the initial response, relapse within 31 days after the start of treatment was reported by 2	-The authors suggest that the small sample size of the study precludes any conclusions regarding the non-inferiority of nitazoxanide to vancomycin; however, the results do suggest that nitazoxanide may be as effective as vancomycin for CDI treatment.

Study & Level of Evidence	Design & Comparators	Sample Size & Duration	Patient Characteristics	Assessed Outcomes	Results	Author's Conclusions & GHS Comments
					from the vancomycin group and 1 from the nitazoxanide group. -The sustained response rate was 67% (N=18/27) for the vancomycin group and 73% (N=16/22) for the nitazoxanide group by the intent-to-treat analysis. -Of those who completed therapy, there was a 78% (N=18/23) response rate for the vancomycin group and an 89% (N=16/18) response rate for the nitazoxanide group. -The initial and sustained responses were similar in both groups when patients were divided based on the severity of CDI. -4 serious adverse reactions were reported with vancomycin and 2 with nitazoxanide; however, these were judged to be unrelated to treatment. -Mild-to-moderate GI symptoms (such as nausea, abdominal pain,	

Study & Level of Evidence	Design & Comparators	Sample Size & Duration	Patient Characteristics	Assessed Outcomes	Results	Author's Conclusions & GHS Comments
					and worsening of GI reflux) was reported by 5 vancomycin-treated patients and none by nitazoxanide-treated patients.	
Livengood et al[16] 2007 **LOE-1a**	Multicenter, prospective, randomized, double-blind, placebo-controlled trial tinidazole 1gm PO QD X5days Vs tinidazole 2gm QD X2 days Vs placebo	N=235 2-5 days	-Adult women seen in clinics given a diagnosis of bacterial vaginosis, and who had a negative pregnancy test on day of enrollment	-To compare the therapeutic cure at the end of treatment in the modified intent-to-treat population -Safety	-Compared with placebo, both tinidazole groups had significantly greater rates of cure. 36.8% vs 5.1% with tinidazole 1mg QD vs placebo ($p<0.001$) and 27.4% tinidazole 2gm vs 5.1% placebo ($p<0.001$) were the rates. -These results are based on US FDA guideline recommendation of resolution of all 4 Amsel criteria and Gram stain score <4. -Per the authors, the NNT calculated was 3.2 for the tinidazole 1gm and 4.5 for the tinidazole 2gm. -Reported adverse events were similar between treatments and placebo except for dysgeusia and nausea. Dysgeusia was significantly more common with	-Effective treatment control of bacterial vaginosis was seen with both tinidazole regimens.

Study & Level of Evidence	Design & Comparators	Sample Size & Duration	Patient Characteristics	Assessed Outcomes	Results	Author's Conclusions & GHS Comments
					tinidazole & nausea was significantly more common in the tinidazole 2gm group.	
Dupont et al[17] 2007 **LOE-1a**	Randomized, double-blind, double-dummy study rifaximin 200mg TID X3D Vs loperamide 4mg initially, then 2mg after each unformed stool (max 8mg/day X2D) Vs combination of rifaximin & loperamide	N=310 2-3 days	-US adults attending school in Mexico for 2-5 weeks and suffering from Travelers Diarrhea (TD), defined as ≥3 unformed stools in 24 hours with ≥1 symptom of enteric infection	-The duration of diarrhea after initiation of treatment, as measured by the median time from the administration of the 1st dose until passage of the last unformed stool (TLUS)	-A significant decrease in the median duration of post-enrollment diarrhea (TLUS) was seen with the combo group vs loperamide (32.5 hrs for rifaximin, 27.3 hrs for combo, and 69 hrs for loperamide; p=0.0019 for combo vs loperamide). -Clinical cure was obtained more with rifaximin (77%) or the combo (75%) as compared with loperamide (58%; odds ratio 1.76). -A lower mean number of unformed stools passed during the 1st 24hrs of treatment was seen with the loperamide-containing groups (1.85 for loperamide, 1.77 for combo, and 2.76 for rifaximin alone; p=0.0024). -However, the rifaximin-containing groups significantly lowered the mean # of unformed stools passed during days 2 and 3	-A rapid and effective improvement was seen with the combination of rifaximin and loperamide for the treatment of TD, as well as providing a greater overall wellness when compared with the individual agents.

Study & Level of Evidence	Design & Comparators	Sample Size & Duration	Patient Characteristics	Assessed Outcomes	Results	Author's Conclusions & GHS Comments
					(day 2: 1.62 for loperamide, 1.36 for rifaximin, and 0.74 for combo; p=0.0076. day 3: 1.14 for loperamide, 0.94 for rifaximin, and 0.36 for combo; p=0.0011). -A greater overall achievement of wellness was seen with the rifaximin-containing groups vs loperamide, and this was seen at day 1. By day 4, the two rifaximin-treated groups showed similar rates of wellness but both were significantly greater than that with loperamide (odds ratio 3.99). -All treatments were well tolerated, and with a low incidence of adverse events. -Although nausea was reported more in the loperamide group, it was not a significant difference; however, vomiting was reported significantly more during treatment with loperamide (12%) as compared with rifaximin (3%) or the combo (4%).	
Louie et al[18] 2011	Multicenter, prospective,	N=629	-Adults (≥16 years) with	-The clinical cure, defined as a	-The criteria for non-inferiority with respect to clinical cure were	-Results suggest that fidaxomicin

Study & Level of Evidence	Design & Comparators	Sample Size & Duration	Patient Characteristics	Assessed Outcomes	Results	Author's Conclusions & GHS Comments
LOE-1a	randomized, double-blind, parallel-group trial fidaxomicin 200mg PO BID (FID) Vs vancomycin 12mg PO QID (VAN)	10 days	acute symptoms and diagnosis of *C. difficile* infection and a positive result on a stool toxin test	resolution of symptoms and no need for further therapy for *C. difficile* infection as of the 2nd day after the end of course of therapy -Recurrence of *C. difficile* infection and global cure (ie cure with no recurrence) -Safety	met. -88.2% (N=253/287) of the modified intent-to-treat population in the fidaxomicin and 85.8% (N=265/309) met criteria for clinical cure. This was a - 3.1% difference in cure rates between treatments. -A significantly lower rate of recurrence was associated with the fidaxomicin group (15.4%; N=39/253) vs vancomycin (25.3%; N=67/265; p=0.005). -Significantly higher rates of resolution of diarrhea without recurrence was seen with fidaxomicin (74.6%) vs vancomycin (64.1%; p=0.006). -A shorter median time to resolution of diarrhea was seen in the fidaxomicin group (58 hrs) vs the vancomycin group (78 hrs). -Significant differences in rates of adverse events were not seen between treatment groups.	was non-inferior to vancomycin for obtaining a clinical cure of *C. difficile* infection; however, a more sustained or durable resolution of disease was seen with fidaxomicin.

Study & Level of Evidence	Design & Comparators	Sample Size & Duration	Patient Characteristics	Assessed Outcomes	Results	Author's Conclusions & GHS Comments
Escobedo et al[19] 2008 **LOE-2**	Randomized, open-label nitazoxanide 7.5mg/kg BID X3 days Vs tinidazole 50mg/kg single dose	N=166 Up to 3 days	-Pediatric subjects aged 5-15 years seeking treatment for symptomatic proven infection with *Giardia lamblia* by microscopic exam of a fecal sample	-To compare response to treatment as assessed by cure rate -Safety	-Fecal samples were to be obtained by parents of treated children between 5 and 10 days after completion of treatment for parasitological follow-up. -A significantly higher parasitological cure was seen in those given a single-dose of tinidazole vs those receiving 3 days of nitazoxanide (90.5% vs 78.4% respectively; $p<0.05$). -Of those who had diarrhea at enrollment, diarrhea had stopped in all children in the nitazoxanide group within 6 days of completing therapy and in 19 of 20 children in the tinidazole group. -The median time for resolution of diarrhea (among those in whom diarrhea cleared during the study period) were 4 days after completing nitazoxanide treatment and 3 days after completing tinidazole treatment. -Both treatments were well tolerated.	-Nitazoxanide is not as efficacious as tinidazole for treatment of *G. lamblia*; however, it still remains a good candidate for treatment in this population (78.4% cure rate). **GHS Comments**: The open-label design is a limitation of this study. Furthermore, only 46 of the children completed the study.

Study & Level of Evidence	Design & Comparators	Sample Size & Duration	Patient Characteristics	Assessed Outcomes	Results	Author's Conclusions & GHS Comments
					-A significantly greater amount in the tinidazole group reported bitter taste vs nitazoxanide (17.5% vs 0%, respectively; p<0.05). -A significantly greater amount in the nitazoxanide group reported unusually yellowish urine vs tinidazole (36.5% vs 0%, respectively; p<0.05). -Other reported adverse events were not statistically significantly different between treatments.	
Mullane et al[20] 2011 **LOE-1a**	Pooled data from 2 prospective, double-blind, randomized, parallel-group, non-inferiority studies	N=999 10 days	-Adult subjects ≥16 years with diagnosis of a first episode of *Clostridium difficile* infection (CDI) or a first recurrence of CDI within the	-To compare rates of cure, recurrence, and global cure (cure without recurrence) in subgroups defined by CA use and treatment use	-In the combined treatment population, the clinical cure rate was achieved by 92.57% of those who did not received CA as compared with 84.38% of those who received CAs with study drug, which was statistically significantly more (8.2% difference between treatments; p<0.001).	-Although concomitant antibiotic use is often needed to treat concurrent infections in those being treated for CDI, the use of fidaxomicin was significantly more

Study & Level of Evidence	Design & Comparators	Sample Size & Duration	Patient Characteristics	Assessed Outcomes	Results	Author's Conclusions & GHS Comments
	fidaxomicin 200mg Q12H Vs vancomycin 125mg Q6H		previous 3 months, and had received no more than 24 hrs of pre-treatment. Subjects were considered to have taken concomitant antibiotics (CA) if they received ≥1 oral or IV doses of antibiotic (s) during treatment or follow-up periods		-Global cure was seen in 74.72% of those who did not receive CA vs 65.82% of those receiving a CA during the study, which was statistically significantly different (8.9% difference; p=0.005). -Within 28 days of completing treatment, the recurrence rate was higher in those who used CA during following-up vs those who did not; however, the difference was not statistically significantly different (24.81% vs 17.74%, respectively; p=0.06). -In those who did not use CA, the clinical cure achieved was equivalent between fidaxomicin and vancomycin at the end of treatment (92.3% vs 92.8%, respectively; p=0.80); however, when subjects received ≥1 CA with study drug, fidaxomicin was superior to vancomycin for achieving clinical cure (90.0% vs 79.4%, respectively; p=0.04). -In those who did not use CA, the global cure rate was 80.8% for	effective for obtaining clinical cure in presence of CA and for preventing recurrence as compared with vancomycin.

Study & Level of Evidence	Design & Comparators	Sample Size & Duration	Patient Characteristics	Assessed Outcomes	Results	Author's Conclusions & GHS Comments
					fidaxomicin group vs 69.1% for vancomycin group, which was significantly different (p<0.001); however, although similar results were seen in those receiving a CA with study drug, the global cure rates were substantially reduced (72.7% for fidaxomicin vs 59.4% for vancomycin; p=0.02).	
Schwebke et al[21] 2011 **LOE-1a**	Randomized, double-blind study metronidazole 500mg BID (MET) Vs tinidazole 500mg BID (TIN500) Vs tinidazole 1gm BID (TIN1000)	N=593 7 days	-Adult female subjects with symptomatic bacterial vaginosis (BV) and no evidence of sexually transmitted disease (STD)	-To compare cure rates of BV at day 14 follow-up. (Microbiologic cure was defined as a Nugent score of <7). -Safety	-Significant differences in cure rates, based on Nugent criteria, were not seen between treatments at the 14-day follow-up visit, or any of the follow-up visits. -The cure rates at 14-day follow-up visit were 82.3% for the MET group (failure rate of 17.7%), 73% for the TIN1000 group (27% failure rate), and 75.3% for the TIN500 group (24.7% failure rate; p=0.16 for comparison of all 3 groups, p=0.19 for MET vs TIN500, p=0.08 for MET vs TIN1000). -The overall cure rate was 76.8% at day 14 follow-up and 64.5% at the 1-month follow-up visit.	-Differences in cure rates between metronidazole and two different doses of tinidazole were not seen, and all therapies were well tolerated.

Study & Level of Evidence	Design & Comparators	Sample Size & Duration	Patient Characteristics	Assessed Outcomes	Results	Author's Conclusions & GHS Comments
					-Significant differences in short-term recurrence rates of the 3 treatment groups were not seen. Recurrence rates at 1 month were 33.3% for MET, 22.5% for TIN1000, and 30.2% for TIN500. -Significant differences in reported adverse events were not seen between treatments, except for bad taste. This was significantly greater in the TIN1000 group (41.8%) vs the TIN500 (15.2%) or MET group (11.0; p<0.001). -Other reported adverse events included yeast infection, nausea/vomiting, diarrhea, anorexia, and headache.	
Ortiz et al[22] 2001 **LOE-1a**	Randomized, active-controlled trial nitazoxanide 100-200mg BID X3 days Vs metronidazole	N=110 3-5 days	-Pediatric subjects aged 2-11 years with acute or chronic diarrhea and cysts of *G. intestinalis* in a stool sample obtained within 7 days prior to	-The proportion whose diarrhea resolved before the day 7 follow-up exam. Clinical response was assigned as either: 'well' (no symptoms, no watery stools, and no more than 2	-85% of the nitazoxanide group had a 'well' clinical response to diarrhea as compared with 80% of the metronidazole group. This was not a statistically significant difference (p=0.6148). -All children who were not assigned into the 'well' clinical response group were assigned to the 'continuing illness' response	-In children with giardiasis, a 3-day treatment with nitazoxanide was as effective as a 5-day treatment with metronidazole.

Study & Level of Evidence	Design & Comparators	Sample Size & Duration	Patient Characteristics	Assessed Outcomes	Results	Author's Conclusions & GHS Comments
	125-250mg BID X5 days		inclusion. Diarrhea was defined as >3 unformed stools/day or unformed stools without increased stool frequency for >4 weeks.	soft stools, and no symptoms and no unformed stools within past 48hrs), or 'continuing illness' (any # of watery stools, >2 soft stools/24hrs or enteric symptoms plus passage of any # of soft or water stools during past 48hrs), or 'clinical treatment failure' (clinical deterioration or worsening of symptoms after at least 24hrs of treatment, resulting in being removed from study) -Proportion with no cysts of *G. intestinalis* -Safety	group, except for one child in the metronidazole treatment group. This one child was assigned a response of 'clinical treatment failure'. -In either of two stool samples collected 7-10 days after treatment began, 71% of the nitazoxanide group had no cysts of *G. intestinalis* as compared with 75% of the metronidazole group. This difference was not statistically significantly different (p=0.8307). -All reported adverse events were mild and transient in nature. No reported adverse events resulted in discontinuation of treatment. -Abdominal pain was reported in both groups. Vomiting and headache was reported in the metronidazole group and diarrhea was reported in the nitazoxanide group.	

Study & Level of Evidence	Design & Comparators	Sample Size & Duration	Patient Characteristics	Assessed Outcomes	Results	Author's Conclusions & GHS Comments
Garey et al[23] 2011 **LOE-1a**	Single-center, randomized, double-blind, placebo-controlled pilot study rifaximin 400mg TID Vs placebo	N=68 20 days	-Adult subjects hospitalized from 2008-2010 with a Horn's index of moderate or above and had diarrhea associated with a positive stool test for *C. difficile* toxin. (Diarrhea was defined as ≥3 unformed stools/day for ≥2 days or more than 6 unformed stools in 1 day.) -Patients were treated with vancomycin or metronidazole PO X10-14 days	-To compare recurrent diarrhea, which included recurrent *C. difficile* infection (CDI; defined as a return of diarrhea with a positive toxin test after resolution of initial CDI diarrheal episode and after study meds had been started) AND patient self-reported return of non-CDI diarrhea (defined as diarrhea without a positive toxin test). -Safety	-35% (N=34/68) of the patients in the study had recurrent diarrhea either due to recurrent CDI (23.5%) or self-reported diarrhea (11.5%). -Recurrent diarrhea occurred in 49% (N=17/35) of the placebo group as compared with 21% (N=7/33) of the rifaximin group, which was statistically significantly different (p=0.018). -CDI occurrence was reported in 31% (N=11/35) of the placebo group vs 15% (N=5/33) of the rifaximin (p=0.11). -Self-reported diarrhea was reported in 17% (N=6/35) of the placebo group vs 6% (N=2/33) given rifaximin (p=0.15). -A significant difference in the time to recurrent diarrhea in those with CDI was seen. -3 subjects reported adverse-events, which were mild to moderate in nature. One in the placebo group reported a rash,	-Results suggest that those with CDI given rifaximin as a 'chaser' regimen (after antibiotic treatment) had a decreased rate of recurrence of diarrhea as compared with placebo. **GHS Comments:** The small sample size is a limitation of this study.

Study & Level of Evidence	Design & Comparators	Sample Size & Duration	Patient Characteristics	Assessed Outcomes	Results	Author's Conclusions & GHS Comments
					while one in the rifaximin group reported nausea and one reported pruritus.	
Bass et al[24] 2010 **LOE-1a**	Multicenter, randomized, double-blind, placebo-controlled trial rifaximin 550mg BID Vs placebo	N=299 6 months	-Adult subjects with at least 2 episodes of overt hepatic encephalopathy (HE, Conn score≥2) associated with hepatic cirrhosis during previous 6 months, remission at enrollment, and score of ≤25 on the Model for End-Stage Liver Disease (MELD) scale	-The time to the first breakthrough episode of HE. -The time to the 1st hospitalization involving HE	-Concomitant administration of lactulose was permitted throughout the study. -22.1% (N=31/140) of the rifaximin group reported breakthrough episodes of HE as compared with 45.9% (N=73/159) of the placebo group. -The hazard ratio (HR) for risk of breakthrough episode of HE in rifaximin group vs placebo was 0.42 (p<0.001) and a relative reduction by 58%. -13.6% (N=19/140) of the rifaximin group were hospitalized involving HE as compared with 22.6% (N=36/159) of the placebo group. -The HR for risk of such hospitalization in the rifaximin group vs placebo was 0.50 (p=0.01), which is a relative risk reduction of 50%	-Maintenance of remission from HE was done more effectively with rifaximin vs placebo, as well as it significantly reducing the risk of hospitalization involving HE. **GHS Comments:** While the authors noted that the relative risk reduction for breakthrough episodes for rifaximin vs placebo was 58%, the absolute risk reduction (ABR) is 23.8%. The NNT is 5. The ARR for hospitalization involving HE with rifaximin vs placebo

Study & Level of Evidence	Design & Comparators	Sample Size & Duration	Patient Characteristics	Assessed Outcomes	Results	Author's Conclusions & GHS Comments
					-Reported incidence of adverse events was similar between treatments. -Nausea, diarrhea, fatigue, peripheral edema, ascites, dizziness, headache, muscle spasm, abdominal pain, abdominal distentions, anemia, insomnia, cough, urinary tract infection, and asthenia were all reported at an incidence of greater than 10% by at least one therapy.	is 9%. The NNT is 11.
Simjee et al[25] 2011 **LOE-2**	Randomized, single-blind (patient) study metronidazole 2gm/day Vs tinidazole 2gm/day	N=48 5 days	-Black inpatient subjects with clinical diagnosis of uncomplicated amoebic liver abscess (ALA), as confirmed by percutaneous aspiration of the abscess cavity	-To compare response to treatment	-If no clinical improvement was seen after 5 days or if symptoms recurred thereafter, a second course of the same drug treatment was given. -4 subjects in the tinidazole group and 2 in the metronidazole group required a second course of treatment. All responded to the second course of treatment. -Significant differences between the two groups in respect of the duration between the onset of treatment and cessation of hepatic pain and tenderness were	-Both metronidazole and tinidazole are effective and safe for the treatment of ALA. **GHS Comments:** The small sample size and open-label design are limitations of the study.

Study & Level of Evidence	Design & Comparators	Sample Size & Duration	Patient Characteristics	Assessed Outcomes	Results	Author's Conclusions & GHS Comments
					not seen. -The time for pain to disappear was 4.24 days for metronidazole vs 5.24 for tinidazole. The time for tenderness to disappear was 7.96 days for metronidazole and 7.94 for tinidazole. The time for temperature to return to normal was 5.20 days for metronidazole vs 5.23 days for tinidazole. -Sore throat was the only reported adverse event, and was found to be due to oral candidiasis. It was reported in 2 patients from each group.	
Buranawardo-domkul et al[26] 1990 **LOE- See GHS Comments**	Randomized study metronidazole 500mg BID X7D (and a single dose for their sexual partners) Vs tinidazole	N=171 Up to 7 days	-Reproductive females aged 15-45 years attending the sexually transmitted diseases (STD) clinic and diagnosed with having nonspecific vaginitis (NSV)	-To assess cure, as defined by the absence of symptoms and the presence of less than 3 criteria in the exam of vaginal discharge	-71 patients were excluded from the results due to the loss of follow-up and had incomplete doses of medication. -*G. vaginalis* was the most prevalent organism identified by culture before beginning treatment. -Major symptoms before treatment included vaginal	-As the cure rates between metronidazole and tinidazole were not statistically significantly different, the authors concluded that tinidazole is another effective treatment of nonspecific

Study & Level of Evidence	Design & Comparators	Sample Size & Duration	Patient Characteristics	Assessed Outcomes	Results	Author's Conclusions & GHS Comments
	2gm dose (same for sexual partner)		and confirmation of urogenital symptoms and signs characteristic of vaginitis (such as abnormal or malodorous vaginal discharge, vulvar irritation, pelvic discomfort, and painful urination		discharge, offensive odor, and pruritus. After treatment, each symptom statistically significantly improved or disappeared in each treatment group ($p<0.05$). -Pelvic discomfort and dysuria were less frequent reported symptoms; however, pelvic discomfort was statistically significantly improved or disappeared after treatment in both groups ($p<0.05$). Dysuria was statistically significantly improved or disappeared in the tinidazole group ($p<0.05$) but was not in the metronidazole group ($p=0.086$). -Post-treatment results in both groups suggest that the difference in each symptom is not statistically significant ($p>0.05$). -Both treatments show statistically significantly greater improvement in vaginal secretion ($p<0.001$); however, there was not a statistically significant difference seen between treatments ($p>0.1$).	vaginitis. **GHS Comments:** Due to the lack of information found in the study, the LOE was not able to be determined.

Study & Level of Evidence	Design & Comparators	Sample Size & Duration	Patient Characteristics	Assessed Outcomes	Results	Author's Conclusions & GHS Comments
					-92% (N=46/50) of the metronidazole group were considered improved or cured as compared with 86% (N=43/50) of the tinidazole group. This difference was not considered to be statistically significant (p=0.1688). -Adverse events of nausea, vomiting, and dizziness were reported by 22% of the metronidazole group vs 8% of the tinidazole group.	
Lauritano et al[27] 2009 **LOE-1b**	Prospective, randomized, parallel-group study rifaximin 1200mg/day Vs metronidazole 750mg/day	N=142 7 days	-Consecutive patients with GI symptoms (including bloating, abdominal pain, flatulence, and diarrhea) for ≥6 months, and confirmed diagnosis of small intestinal bacterial overgrowth (SIBO), based on clinical	-The GBT normalization rate between treatments -Patient compliance -Safety	-A significantly higher GBT normalization rate was seen with rifaximin vs metronidazole (63.4% (N=45/71) vs 43.75 (N=37/71); p<0.05). -Overall compliance was high. The metronidazole group had a higher drop-out rate as compared with rifaximin (5 subjects vs 1 subject, respectively). -There was a 15.5% overall incidence of adverse events, and it was significantly higher in the metronidazole group vs the	-Rifaximin was seen to be an effective treatment for the management of those with SIBO, and had a significantly higher normalization rate on the GBT than metronidazole.

Study & Level of Evidence	Design & Comparators	Sample Size & Duration	Patient Characteristics	Assessed Outcomes	Results	Author's Conclusions & GHS Comments
			history and positive glucose breath test (GBT)		rifaximin group (22.5% vs 8.5%). -Bloating, nausea/vomiting, and constipation were reported by 3 groups.	
Pedretti et al[28] 1991 **LOE-1b**	Randomized, double-blind, double-dummy study rifaximin 400mg Q8H Vs neomycin 1gm Q8H	N=30 21 days	-Adult subjects with liver cirrhosis diagnosed on clinical and lab data and proved in all cases by laparoscopy and needle liver biopsy, also had grade I to III portal systemic encephalopathy (PSE) according to the West Haven criteria, no clinical or lab data suggesting hepatocellular carcinoma, and no GI bleeding on study admission	-To compare the efficacy, as assessed by decrease in blood ammonia levels.	-At the end of the treatment period, both groups resulted in a significant decrease in blood ammonia levels. -When the blood ammonia levels between the two groups were compared, results suggest significantly lower levels in the rifaximin group vs the neomycin group ($p<0.005$). -During the observation period, a significant decrease in blood ammonia levels were seen on the 3rd day of treatment for both groups as compared with baseline values ($p<0.001$ for rifaximin vs baseline; $p<0.005$ for neomycin vs baseline). -Significant differences seen between treatments in blood ammonia levels were observed on days 14 and 21 ($p<0.005$ for both days of treatment).	-While rifaximin was as at least as effective as neomycin for short term treatment of PSE, it was more effective for maintaining lower blood ammonia levels. **GHS Comments:** The small sample size is a limitation of the study.

Study & Level of Evidence	Design & Comparators	Sample Size & Duration	Patient Characteristics	Assessed Outcomes	Results	Author's Conclusions & GHS Comments
					-Both neomycin and rifaximin resulted in statistically significant improvements in psychometric tests and EEGs; however, significant differences were not seen between treatments. -No adverse events were seen with rifaximin; however, 5 patients reported nausea, abdominal pain, and vomiting during treatment with neomycin. Additionally, 4 patients had an increase in blood urea and plasma creatinine levels during treatment with neomycin.	
Cornely et al[34] 2012 **LOE-1a**	Multicenter, randomized, double-blind, non-inferiority trial fidaxomicin 200mg BID Vs vancomycin 125mg Q6H	N=535 10 days	-Adult subjects ≥16 years of age with acute, toxin-positive *C. difficile* infection, defined by >3 unformed bowel movements (UBM) in the 24hrs before randomization	-To compare the clinical cure between treatments, defined as the resolution of diarrhea and no further treatment needed -Those who obtained clinical cure were assessed for	-At the end of treatment, non-inferiority of treatments was established. 87.7% of the fidaxomicin group had clinical cure vs 86.8% of the vancomycin group. This was not a statistically significant difference (p=0.754), thus leading to non-inferiority. -Statistically significantly more in the vancomycin group had recurrence of infection vs the fidaxomicin group (26.9% vs 12.7%; p=0.0002).	-Fidaxomicin was non-inferior to vancomycin for initial clinical response; however, of those with initial clinical response, fidaxomicin use was associated with a lower recurrence rate than those treated with vancomycin.

Study & Level of Evidence	Design & Comparators	Sample Size & Duration	Patient Characteristics	Assessed Outcomes	Results	Author's Conclusions & GHS Comments
				recurrence and then sustained clinical response, with recurrence being defined as the return of >3 UBM in 24hrs, a positive stool toxin test, and the need for retreatment within 30 days of treatment completion -Safety	-Thus, a significantly higher sustained clinical response was seen for the fidaxomicin group vs the vancomycin group (76.6% vs 63.4%; p=0.001). -The time to resolution of diarrhea was not significantly different between treatment groups. -Significant differences in treatment emergent adverse events were not seen. -The most commonly reported adverse events in both groups included gastrointestinal symptoms (including nausea, vomiting, diarrhea, and abdominal pain). -7.6% (N=20/264) of those who had at least one dose of fidaxomicin died as compared with 6.5% (N=17/260) of the vancomycin group.	
Rossignol et al[35] 2012	Double-blind, placebo-controlled	N=100	-Outpatient children aged 12 months to	-The median time from the 1st dose to the resolution	-The median time from the first dose to the resolution of illness was 23 hrs with nitazoxanide vs	-Nitazoxanide may be a treatment option for the

Study & Level of Evidence	Design & Comparators	Sample Size & Duration	Patient Characteristics	Assessed Outcomes	Results	Author's Conclusions & GHS Comments
LOE-1a	trial nitazoxanide 100-200mg BID Vs placebo	3 days	11 years reporting diarrhea (≥3 liquid stools per day) for ≥3 days and <30 days in duration	of symptoms -Safety	103.5 hrs for placebo, which was statistically significantly different (p<0.001). -90% (N=45/50) of the nitazoxanide group had resolution of symptoms within 7 days of the start of treatment vs 54% (N=27/50) of the placebo group, which was statistically significantly different (p<0.001). -When analysis was done based on disease subset, results suggested that when compared with placebo, the nitazoxanide group had statistically shorter durations of diarrheal illness associated with *Giardia lamblia* (p<0.001), as well as in the disease subset of those with no identified enteropathogen (p=0.008). -The most commonly reported adverse event was mild yellowish discoloration of urine in 22 of the nitazoxanide group vs 6 in the placebo group, which was statistically significantly greater (p<0.001).	treatment of diarrheal illness when the cause of diarrhea is not known or is presumed to be infectious. **GHS Comments:** The NNT for having resolution of symptoms within 7 days of start of therapy with using nitazoxanide was 3.

Study & Level of Evidence	Design & Comparators	Sample Size & Duration	Patient Characteristics	Assessed Outcomes	Results	Author's Conclusions & GHS Comments
					-Significant differences in the frequency or nature of other reported adverse events were not seen between treatments.	
Irimia et al[42] 2012 **LOE- See GHS Comments**	Prospective randomized study rifaximin intermittently 14 days/month (RI) Vs rifaximin 400mg TID (RD) Vs lactulose 30-60ml in 2-3 divided doses (LD)	N=78 6 months, with a 12 month follow-up period	-Adult subjects with a definite diagnosis of cirrhosis, ≥1 episode of overt hepatic encephalopathy (HE) in the history and remission at baseline. There were different levels of hepatic failure	-Recurrence of overt HE -To compare the frequencies of HE-related hospitalizations -Safety	-Overt HE episodes occurred in 26.92% of the total population during the 12 month period. There were 10/38 cases in the RI group, 7/28 in the RD group, and 4/12 in the LD group. The probability of developing recurrent HE was not statistically significantly different between treatments groups (26.31% with RI and 25% with RD vs 33.33% with LD). -More severe episodes of overt HE (grade 3.4) were seen in the LD group. -There were no reports of serious adverse events during the study, and overall patient compliance was not significantly different between treatments (100% rifaximin vs 92% lactulose). -During the follow-up, there were 26 HE-related hospitalizations.	-While rifaximin and lactulose were equally effective for maintaining remission from overt-HE, rifaximin was superior to lactulose for reducing the risk of HE-related hospitalizations. **GHS Comments**: The LOE could not be determined due to a lack of information regarding the blinding process.

Study & Level of Evidence	Design & Comparators	Sample Size & Duration	Patient Characteristics	Assessed Outcomes	Results	Author's Conclusions & GHS Comments
					Ten in the RI group needed 12 hospitalizations. Seven in the RD group required 8 hospitalizations, and 4 in the LD group needed 10 hospitalizations. -The frequency of HE-related hospitalizations was comparable between the RI and RD group (31.57% vs 28.75%); however, these were significantly lower than when compared to the LD group (50%).	
Sharma et al[43] 2013 **LOE-1a**	Prospective, randomized, double-blind, controlled trial rifaximin 400mg TID PLUS lactulose 30-60ml TID (RL) Vs lactulose 30-60ml TID PLUS placebo capsules TID (LP)	N=120 Continued until complete recovery or a max of 10 days	-Adult subjects aged 18-80 years with liver cirrhosis and overt HE	-The complete reversal of HE -Mortality and hospital stay were also assessed -Safety	-Within 10 days, significantly more taking RL had complete reversal of HE as compared with the LP group (76% vs 44%; p=0.004). -A significantly shorter hospital stay was seen with those taking RL as compared with LP (5.8 days vs 8.2 days; p=0.001). -There was a significant decrease in mortality after treatment with RL vs LP (25% vs 49.1%; p<0.05). -There were significantly more deaths in the LP vs the RL group due to sepsis (7 vs 17; p=0.01),	-The combination of rifaximin and lactulose was significantly more effective for the treatment of overt HE as compared with lactulose alone.

Study & Level of Evidence	Design & Comparators	Sample Size & Duration	Patient Characteristics	Assessed Outcomes	Results	Author's Conclusions & GHS Comments
					but there were no differences of GI bleed (4 vs 4; p=NS), and hepatorenal syndrome (4 vs 7; p=NS). -Significantly more died in the LP vs the RL group (23 vs 13; p=0.03). -There were no reports of serious adverse events (AEs).	
Cornely et al[44] 2012 **LOE-1a**	Subgroup analysis of Louie et al[18], a Multicenter, prospective, randomized, double-blind, parallel-group trial fidaxomicin 200mg PO BID (FID) Vs vancomycin 12mg PO QID (VAN)	N=128 10 days	-Adults (≥16 years) with acute symptoms and diagnosis of *C. difficile* infection (CDI) and a positive result on a stool toxin test	-To compare recurrence (diarrhea and positive stool toxin test) within 28 days after completing treatment -Safety	-This subgroup from the per-protocol (PP) population in the original phase 3 trial had another episode of CDI prior to the CDI diagnosis at study enrollment. -There were 178 who were randomized to treatment, and 74 from the FID group were cured vs 76 from the VAN group. 22 were excluded from the analysis of recurrence for various reasons, and the remaining 128 were monitored for recurrence. -The initial outcome of clinical cure was 93.7% for the FID group vs 91.6% of the VAN group in the PP population with a prior	-In this population with a first recurrence of CDI, fidaxomicin was comparable to vancomycin for obtaining an initial clinical response at the end of therapy but was superior for preventing a second recurrence within 28 days. **GHS Comments**: These results were obtained from the per protocol population, which

Study & Level of Evidence	Design & Comparators	Sample Size & Duration	Patient Characteristics	Assessed Outcomes	Results	Author's Conclusions & GHS Comments
					episode of CDI. -Those with a prior episode of CDI were more likely to have a second recurrence within a month of completing either therapy. -In the PP population with a prior episode, 19.7% of the FID group had CDI recurrence as compared with 35.5% of the VAN group. This was a statistically significant difference (p=0.045). Recurrence rates of those with no prior episode (N=666) were 11.7% in the FID group vs 22.6% in the VAN group (p<0.001). Rates were higher in those with 1 prior episode. -In the ITT population (N=159), 20.3% had a CID recurrence in the FID group vs 32.3% of the VAN group, which was not statistically significantly different (p=0.08). Recurrence rates for those with no prior episode (N=803) were 12.9% with FID vs 24.8% with VAN (p<0.001).	can cause a risk of bias; however, when the ITT population was assessed, recurrence rates were not significantly different between treatments in the population with 1 prior episode of CDI.

Study & Level of Evidence	Design & Comparators	Sample Size & Duration	Patient Characteristics	Assessed Outcomes	Results	Author's Conclusions & GHS Comments
					-GI and infectious conditions were the most frequently reported adverse events.	
Thulkar et al[46] 2012 **LOE-2**	Prospective, comparative, randomized, subject-blinded but investigator open study metronidazole 2gm (MET) Vs tinidazole 2gm (TIN) Vs secnidazole (SEC) Vs ornidazole (ORN)	N=344 Single dose	-Adult female subjects aged 18-45 years with regular cycles and diagnosed with bacterial vaginosis (BV) who attended the gynecology Outpatient department with complains of abnormal vaginal discharge or detected to have abnormal vaginal discharge	-To compare cure rate between treatments	-At week 1, cure rates were 88.4% (N=76/86) with MET, 100% (N=86/86) with TIN, 90.7% with SEC (N=78/86) and 100% with ORN (N=86/86). Using MET as the gold standard, significant differences were seen between MET and TIN ($p<0.001$) and between MET and ORN ($p<0.001$), but not between MET and SEC ($p=0.62$). -At week 4, the cure rates were 77.9% with MET, 97.7% with TIN, 80.2% with SEC, and 97.7% with ORN. Statistically significant differences were seen between MET and TIN ($p<0.001$) and between MET and ORN ($p<0.001$), but not between MET and SEC ($p=0.71$).	-As compared with metronidazole, statistically significantly greater cure rates were seen with tinidazole and ornidazole in this population with BV. **GHS Comments:** The open-label design is a limitation of this study.

CONTRAINDICATIONS1-8

All medications in this therapeutic class carry a contraindication of hypersensitivity to their active ingredient or to any component of the compound.

The table below lists additional contraindications unique to each medication.

Drug	Contraindication
metronidazole (Flagyl®, Flagyl® ER)	Use during the first trimester of pregnancy; Prior hypersensitivity to other nitroimidazole derivatives.
neomycin	In the presence of intestinal obstruction; Hypersensitivity to other aminoglycosides may have cross-sensitivity to neomycin; In those with inflammatory/ulcerative GI disease.
rifaximin (Xifaxan®)	Hypersensitivity to any of the rifamycin antimicrobial agents.
tinidazole (Tindamax®)	Hypersensitivity to other nitroimidazole derivatives; Use during first trimester of pregnancy; Recommend interrupt breast-feeding during therapy & 3 days after last dose.

SPECIAL POPULATIONS1-8

There have been reports of nephrotoxicity with vancomycin (Vancocin®) use. Risk factors include pre-existing renal impairment, the use of concomitant nephrotoxic medications, elderly, and dehydration. Treatment should be discontinued if signs of nephrotoxicity occur.

Drug	Pediatrics	Pregnancy Category	Dosage change with Renal impairment	Dosage change with Hepatic impairment
fidaxomicin (Dificid®)	No	B	Not required	Use not studied
metronidazole (Flagyl®)	Yes[1]	B	Not required	Use with caution; Severe: ↓ dose, use with caution
metronidazole ER (Flagyl® ER)	No	B	Not required	Use with caution; Severe: ↓ dose & use with caution
neomycin	No	D	Use with caution↓ dose prn due to risk of nephrotoxicity	Not required

Drug	Pediatrics	Pregnancy Category	Dosage change with Renal impairment	Dosage change with Hepatic impairment
nitazoxanide (Alinia®)	≥12 yrs	B	Use not studied	Use not studied
rifaximin (Xifaxan®)	≥12 yrs	C	Not studied	Not required; Severe: Use with caution
tinidazole (Tindamax®)	>3 yrs[2]	C	Not required	Use with caution
vancomycin (Vancocin®)	No[3]	B	Use with caution due to risk of nephrotoxicity	Not reported

[1] Only for the treatment of amebiasis [2] Only for the treatment of giardiasis and amebiasis
[3] But doses are provided for the pediatric population based upon weight

ADVERSE DRUG REACTIONS1-8

Metronidazole (Flagyl®, Flagyl® ER) has a boxed warning as it has been shown to be carcinogenic in mice and rats. Unwarranted use of this product should be avoided, and use should be reserved for approved indications. Additionally, although there have not been these same reports with tinidazole (Tindamax®), the two drugs are structurally related have similar biologic effects; therefore, the same risk for carcinogenicity boxed warning exists for tinidazole (Tindamax®).

Placebo data was not available for metronidazole (Flagyl®). The most frequently reported adverse events were gastrointestinal (GI) in nature, particularly nausea. Nausea was often accompanied by headache, anorexia, and vomiting. Other GI events include diarrhea, epigastric distress, abdominal cramping, and constipation.

Other adverse events reported during metronidazole (Flagyl®) therapy included a sharp, unpleasant metallic taste, reversible neutropenia (leukopenia), flattening of the T-wave, encephalopathy, urticaria, dysuria, and proliferation of Candida in the vagina. As there have been reports of mild leukopenia, total and differential leukocyte counts are recommended before and after therapy. Additionally, abdominal distress, nausea, vomiting, flushing, and headache may occur in those who drink alcoholic beverages concurrently while on metronidazole (Flagyl®). There have been reports of psychotic reactions in alcoholic patients using metronidazole and disulfiram concomitantly.

Neomycin carries a box warning regarding the potential for systemic absorption after oral administration and thus toxic reactions that may occur. Due to this potential, those being treated with neomycin should be watched with close observation. Neurotoxicity (including ototoxicity) and nephrotoxicity have been reported, even when used at recommended doses. Furthermore, the potential for nephrotoxicity, permanent bilateral auditory ototoxicity and sometimes vestibular toxicity is at hand in those with normal renal function when high doses of

neomycin are used and/or when neomycin is used for longer periods than recommended. The risk of nephrotoxicity and ototoxicity is also greater in those with impaired renal function.

The box warning also indicates there have been reports of neuromuscular blockage and respiratory paralysis after using oral neomycin. Concurrent and/or sequential systemic oral or topical use of other aminoglycosides should be avoided as the toxicity may be additive. Additionally, the potential for neuromuscular blockage and respiratory paralysis have also been reported with vancomycin (Vancocin®) use.

Other reported adverse events reported with neomycin use include nausea, vomiting, and diarrhea. With prolonged neomycin use, there have been reports of 'malabsorption syndrome', which was characterized by increased fecal fat, decreased serum carotene, and fall in xylose absorption.

Placebo data was not available for nitazoxanide (Alinia®); however, there are reported incidences for some adverse events in those 12 years of age and older and they did not differ significantly from those of placebo in placebo-controlled trials. These include abdominal pain (6.6%), diarrhea (4.2%), headache (3.1%), and nausea (3.0%). Reported adverse events that occurred in less than 1% included asthenia, dizziness, vomiting, discolored urine, increased SGPT, anemia, rash, pruritus, epistaxis, tachycardia, and myalgia.

Placebo data was not available for tinidazole (Tindamax®); however, there are reported incidences for some adverse events from pooled studies. These include metallic/bitter taste (6.3%), nausea (4.5%), anorexia (2.5%), dyspepsia/cramps/epigastric discomfort (1.4%), vomiting (0.9%), constipation (1.4%), weakness/fatigue/malaise (1.1%), dizziness (0.5%), and headache (0.7%). Other reported adverse events include convulsions and transient peripheral neuropathy, urticaria, vertigo, insomnia, darkened urine, transient neutropenia/leukopenia, palpitations, and Candida overgrowth.

There have been reports of neurotoxicity with vancomycin (Vancocin®) use. Although rare, the risk of ototoxicity is proportional to the dose given and duration of treatment. Treatment should be discontinued if this occurs. There is a potential of bacterial or fungal superinfections occurring with prolonged use, including CDAD and pseudomembranous colitis. Reversible neutropenia has also been reported with use; however, it is reversible once vancomycin (Vancocin®) treatment has been discontinued.

Other reports of adverse events with vancomycin (Vancocin®) use include anaphylaxis, drug fever, chills, nausea, rash, toxic epidermal necrolysis, and rare cases of vasculitis.

The following table lists additional adverse reactions reported with the medications in this class.

The occurrence of side effects for the drugs listed in the tables below have been adjusted so that they reflect only the extent that they exceed placebo, except for fidaxomicin (Dificid®). The comparator for fidaxomicin (Dificid®) was vancomycin

Miscellaneous Adverse Reaction	fidaxomicin (Dificid®)	metronidazole ER (Flagyl® ER)	rifaximin (Xifaxan®)
Abdominal distension	-	-	0%
Abdominal Pain	2%	0%	1%
Anemia	1%	-	4%
Arthralgia	-	-	3%
Ascites	-	-	2%
Back pain	-	-	0%
Constipation	-	-	0%
Cough	-	-	0%
Depression	-	-	2%
Diarrhea	-	3%	-
Dizziness	-	3%	5%
Dry Mouth	-	1%	-
Dysmenorrhea	-	1%	-
Dyspnea	-	-	2%
Edema, peripheral	-	-	7%
Fatigue	-	-	1%
Gastrointestinal Hemorrhage	2%	-	-
Headache	-	3%	-
Infection-Bacterial	-	1%	-
Influenza-like symptoms	-	0%	-

Miscellaneous Adverse Reaction	fidaxomicin (Dificid®)	metronidazole ER (Flagyl® ER)	rifaximin (Xifaxan®)
Insomnia	-	-	0%
Moniliasis	-	0%	-
Muscle Spasms	-	-	2%
Nasopharyngitis	-	-	1%
Nausea	0%	7%	1%
Neutropenia	1%	-	-
Pharyngitis	-	2%	-
Pruritus Genital	-	0%	-
Pruritus	-	-	3%
Pyrexia	-	-	3%
Rash	-	-	1%
Rhinitis	-	0%	-
Sinusitis	-	1%	-
Taste Perversion	-	9%	-
Upper Respiratory Tract Infection	-	0%	-
Urinary Tract Infections	-	0%	-
Urine Abnormal	-	2%	-
Vaginitis	-	3%	-
Vomiting	1%	-	-

DRUG-DRUG INTERACTIONS1-8

fidaxomicin (Dificid®): Fidaxomicin is a substrate of P-glycoprotein. Although studies suggest the combination with cyclosporine may result in significant increased concentrations of fidaxomicin, dose adjustment is not required.

neomycin :

Drug/Class	Mechanism of Drug Interaction	Clinical Recommendations
Aminoglycosides	Additive effects	↑ nephro-, ototoxicity, neuromuscular blocking effects; Use combination with caution
Anesthetics	Additive effects	↑ risk neuromuscular blockage/respiratory paralysis; Use combination with caution
Anticoagulants	↓ vitamin K availability	↑ effects of coumarin; Monitor and use with caution
Digoxin	Inhibition of GI absorption	↓ levels of digoxin; Monitor combination
Neuromuscular Blocking Agents	Additive effects	↑ risk neuromuscular blockage/respiratory paralysis; Use combination with caution
Nephrotoxic/Neurotoxic Drugs	Additive effects	↑risk for toxicity; Avoid concomitant use
Polymyxins		↑ nephrotoxicity and/or ototoxicity effects; Use combination with caution
Potent diuretics	Additive effects	Concurrent use may cause ↑ effect of ototoxicity; Avoid concomitant use

[1] e.g. ethacrynic acid and furosemide
[2] e.g. bacitracin, cisplatin, vancomycin, amphotericin B, polymyxin B, colistin, and viomycin

nitazoxanide (Alinia®): There were no reported drug-drug interactions with nitazoxanide (Alinia®).

rifaximin (Xifaxan®): In vitro studies suggested that rifaximin (Xifaxan®) induces CYP3A4; however, it is not expected to induce CYP3A4 in those with normal liver function when used at the recommended dose. Also, an in vitro study suggested that rifaximin (Xifaxan®) is a substrate of P-glycoprotein (P-gp). It is not known if concomitant use of a P-gp inhibitor will increase systemic levels of rifaximin (Xifaxan®).

metronidazole (Flagyl®, Flagyl® ER)/tinidazole (Tindamax®): Specific drug-drug interactions have not been studied with tinidazole; however, tinidazole and metronidazole are chemically-related nitroimidazoles. Therefore, the manufacturer suggests that the drug interactions reported with metronidazole may occur with tinidazole.

Drug/Class	Mechanism of Drug Interaction	Clinical Recommendations
Alcohol		Avoid concomitant use and use for at least one day after due to adverse effects
Anticoagulants	Prolongation of PT	Potentiation of anticoagulation may occur; Use combination with caution and monitor
Cimetidine	CYP450 enzyme system	↑ Levels of metronidazole; Monitor and use with caution
Cholestyramine		↓ oral bioavailability; Separate dosing to minimize potential effects
Cyclosporine/Tacrolimus		↑ levels of cyclosporine/tacrolimus; Monitor for signs of calcineurin-inhibitor toxicities
Disulfiram		Do not administer metronidazole to those who have taken disulfiram within last 2 weeks
Fluorouracil		↓ clearance of fluorouracil; Monitor for fluorouracil toxicities if need combo.
Lithium (↑ doses)		↑ Levels of lithium or reports of lithium toxicity; Monitor lithium and creatinine levels and monitor
Phenobarbital	CYP450 enzyme system	↓ Levels of metronidazole; Monitor and use with caution
Phenytoin	CYP450 enzyme system	↓ Levels of metronidazole; Monitor and use with caution

vancomycin (Vancocin): There were no reported drug-drug interactions with vancomycin.

SUMMARY

Clostridium difficile infection (CDI) is one of the most common hospital-acquired infections. Antibiotic treatment is the most common cause of CDI. CDI has been an increasingly problematic infection in the hospital setting where both the severity and prevalence are increasing.40

Numerous treatments exist for CDI, including metronidazole and vancomycin which have been available for many years. One comparator study by Zar et al12 suggests that vancomycin is more effective than metronidazole for those with severe CDAD, but is as effective as metronidazole for those with mild CDAD. Fidaxomicin (Dificid®) is also FDA approved for the

treatment of CDI. A study by Louie et al18 suggested that fidaxomicin (Dificid®) was as effective as vancomycin; however, fidaxomicin (Dificid®) had a greater sustained clinical effect in those who had an initial cure as compared with vancomycin for certain subtypes of Clostridium difficile.

A 2009 treatment guideline by the European Society of Clinical Microbiology and Infectious Diseases (ESCMID) for CDI and a guideline updated in 2010 by the Infectious Disease Society of America (IDSA), continue to recommend using metronidazole for 10 days in those with a non-severe form and vancomycin for 10-14 days in those with a severe form of disease.37,39 Please note that fidaxomicin (Dificid®) was not available at the time the ESCMID or IDSA guidelines were released, and therefore recommendations were not made regarding this drug's place in therapy.

Practice guidelines for the diagnosis, treatment, and prevention of CDI by Surawicz et al50 published in 2013 in the American Journal of Gastroenterology suggest (with a strong recommendation from high-quality evidence) that those with mild to moderate CDI be treated with metronidazole (500mg TID X10days) and that those with severe CDI be treated with vancomycin (125mg QID X10 days, a conditional recommendation with moderate-quality evidence). If there is a failure to respond to metronidazole within 5-7 days, then it is suggested to consider changing therapy to vancomycin (strong recommendation with moderate-quality evidence). With recurrent CDI, it is recommended to repeat metronidazole or vancomycin pulse regimen. Fidaxomicin is listed as an alternate antibiotic for the treatment of mild-to-moderate CDI. Furthermore, it was recommended that fidaxomicin be used with caution, only given to the fact of the limited available data, its higher cost, and the need for more definitive evidence of superiority.

Two treatments from this class are approved for management of hepatic encephalopathy (HE), including neomycin and rifaximin (Xifaxan®). One double-blind study by Pedretti et al28 suggested that rifaximin (Xifaxan®) was at least as effective as neomycin; however, it was more effective for obtaining and sustaining lower blood ammonia levels. Additionally, a 2011 meta-analysis by Eltawil et al32 included randomized studies comparing rifaximin (Xifaxan®) with other treatments, including neomycin and lactulose, for the treatment of HE. The authors also concluded that rifaximin (Xifaxan®) was at least as effective as the other treatments, but had a better safety profile.
Additional comparator studies did not suggest differences between various treatments for other diagnoses, except for one open label study by Escobedo et al19, which suggested that nitazoxanide (Alinia®) was not as effective as tinidazole (Tindamax®) for the treatment of G. lamblia.
In conclusion, other than the caveats discussed above, there is no evidence to support that one product is more efficacious than another within a given class and indication.

ADDENDUM

Goold Health Systems Levels of Evidence	
Level of Evidence	**Criteria**
1a	• Systematic review or meta-analysis of high quality studies o Patient-oriented outcomes (mortality, morbidity, symptom improvement, quality of life) • High quality randomized controlled trial o Patient-oriented outcomes (mortality, morbidity, symptom improvement, quality of life) o Double-Blinded o Clearly defined appropriate endpoints o Intent-to-treat analysis in primary group, appropriate use of per protocol population if utilized o Appropriate handling of drop-outs (e.g. LOCF, MMRM)
1b	• Systematic review or meta-analysis of high quality studies o Disease-oriented outcomes (physiologic or surrogate end points) • High quality randomized controlled trial o Disease-oriented outcomes (physiologic or surrogate end points) o Double-Blinded o Clearly Defined appropriate endpoints o Intent-to-Treat analysis in primary group, appropriate use of per protocol population if utilized o Appropriate handling of drop-outs (e.g. LOCF, MMRM)
2	• Low quality randomized controlled trial o Clearly defined primary outcome o Open-label (non-blinded) o Appropriate handling of drop-outs (e.g. LOCF, MMRM) • Non-randomized controlled trial • Cohort study
3	• Case control study/Case series/expert opinion

Definitions:

Intent-to-Treat: Inclusion of all subjects who received at least one dose of study medication or placebo

Last Observation Carried Forward (LOCF): Method of handling drop-outs wherein the last measurement is utilized as the final outcome data point at study conclusion.

Mixed Model Repeated Measures (MMRM): A statistical model to handle drop outs. Uses repeated measures to define data point outcome trends.

Observed Cases: Method of handling drop-outs, which only includes study completers.

Per-Protocol population: A sub-group of intention to treat population often used to enrich for compliance.

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THERAPEUTIC CLASS REVIEW

OCTOBER 22, 2013

[Last Review Update: June 27, 2013]

ANTINEOPLASTICS, SELECTED SYSTEMIC ENZYME INHIBITORS

This publication is a result of the collaboration of the Goold Health Systems Clinical Workgroup and represents the opinion of these authors based on a review of the literature available at the time it was written. It is intended for the sole purpose of providing information to committee members in order to compare medications within a specified subset of clinical parameters. It is not intended to provide specific clinical advice for any condition, or to be an exhaustive review of all potential aspects of pharmacotherapies for any given condition. Medical evidence is rapidly changing, and no representation is made regarding the use of this material beyond the stated purpose. The literature for this review was last searched through the date listed above. Please note that it may take time for published articles to be available via medical literature search engines.

SYNOPSIS12, 23

Cancer is a general term used to describe a group of diseases where abnormal cell growth and division occur without control, along with potential invasion into other tissues. There are currently more than 100 different types of cancer, with a majority of them being named after the organ or type of cell in which they originate. There has been an estimate of approximately 1.5 million new cases of cancer in the United States in 2010, along with an estimated 569, 500 deaths.[1] Additionally, cancer will arise in half of all men and one-third of all women in the US throughout their lifetime.[2]

Cancer can be sorted into distinct categories based upon the type. The main groups of cancer include: (1) carcinoma- a cancer that begins in the skin or in tissues that line or cover internal organs; (2) sarcoma- cancer that begins in bone, cartilage, fat, muscle, blood vessels, or other connective or supportive tissue; (3) leukemia- cancer that starts in blood-forming tissues such as the bone marrow, and causes large numbers of abnormal blood cells to be produced and enter the blood; (4) lymphoma and myeloma- cancers that begin in the cells of the immune system; and (5) central nervous system cancers- cancers that begin in the tissues of the brain and spinal cord.1

Regardless of the type of cancer, the origin of disease is from within the body's cells. Numerous types of cells make up the human body. To keep the body healthy, cells grow and divide to yield more cells, and when the cells become injured or old, the cells die (apoptosis) and are exchanged for new ones. However, during cancer, this process of normal cell growth is disturbed. Abnormal cells, where DNA has changed or become damaged, grow out of control in a certain part of the body. These abnormal cells, or cancer cells, bypass apoptosis, and continue to grow and proliferate more abnormal cells.[1-2]

In most cases, these extra cells form into a mass of tissue, called a tumor. Tumors are categorized as being either benign or malignant. Benign tumors are not considered cancerous and typically can be removed from the body. The cells in benign tumors do not move to other parts of the body. Malignant tumors are considered cancerous, and the cells from these tumors can spread into nearby tissues or other parts of the body, also known as metastasis. Nevertheless, not all cancerous cells develop into tumors. For example, leukemia is not a tumor.[1-2]

Tumor growth and progression relies mainly on the "…activity of cell surface membrane receptors that control the intracellular signal transduction pathways regulating proliferation, apoptosis, angiogenesis, adhesion, and motility." [3] Cancers are typically the result of an imbalance between the rate of cell progression and growth (division and mass) with programmed cell death. It is now thought that cellular signal transduction pathways are a critical element for this imbalance to occur.

The kinases are one of the key groups of signaling molecules that are involved in both normal and abnormal cell control. Receptor tyrosine kinases are considered proto-oncogenes, which are normal genes that can become oncogenic due to mutations or increased expression. Receptor tyrosine kinases are one type of cell surface receptor that is considered a family of transmembrane proteins. They engage in different aspects of cell growth and survival, but have also been associated with the starting of and advancement of numerous malignancies.4 Mutations causing the receptors to be constitutively active or overexpressed may be factors that drive the growth of certain cancers, such as with non-small cell lung cancer (EGFR activation) and breast cancer (HER2 overexpression). The development of numerous hematologic malignancies has also been linked to dysregulated tyrosine kinases.3 In recent years, a number of additional receptors and kinases have been implicated in the development of cancer. Examples include: BCR-ABL, EML4-ALK, c-Kit, VEGFR, HER2, EGFR, and RET. Intracellular pathways such as Ras/Raf/MEK/ERK have also been targeted and is a viable strategy for treating melanoma and colon cancer.5 Additionally, the Phosphoinositide 3-Kinase (PI3K) signaling pathway (which includes mTOR and Akt) has emerged as a favorable target due to its effects on cellular proliferation, inflammation, and on the immune system.6 There are currently drugs available to inhibit this pathway; they are the mTOR inhibitors everolimus (Afinitor®)and temsirolimus (Torisel®). Please see Addendum 2 for list of abbreviations and definitions.

This review includes information on current FDA labeled uses for these drugs. It is beyond the scope of this review to include off label uses that may be considered based on credible medical evidence, generally indicated by being described in established drug compendia or nationally recognized sources such as the National Comprehensive Cancer Network Guidelines and Compendia. These evidence based off label uses are rapidly changing and sources such as these should be consulted regarding the appropriateness of therapies beyond the FDA labelled uses.

The drugs included in this therapeutic class review include those that are involved in the inhibition of the aforementioned receptors or pathways (plus others): axitinib (Inlyta®), bortezomib (Velcade®), bosutinib (Bosulif®), cabozantinib (Cometriq®), carfilzomib (Kyprolis®), crizotinib (Xalkori®), dasatinib (Sprycel®), erlotinib (Tarceva®), everolimus (Afinitor®), gefitinib (Iressa®), imatinib (Gleevec®), lapatinib (Tykerb®), nilotinib (Tasigna®), pazopanib (Votrient®), ponatinib (Iclusig®), regorafenib (Stivarga®), ruxolitinib (Jakafi®), sorafenib (Nexavar®), sunitinib (Sutent®), temsirolimus (Torisel®), vandetanib (Caprelsa®), and vemurafenib (Zelboraf®).

FDA APPROVED INDICATIONS 7-27

Drug	FDA Approved Indications	Breast	Lung	Colon	Thyroid	Kidney	GIST	CML
axitinib (Inlyta®)	Advanced renal cell carcinoma after failure of one prior systemic therapy					X		

Drug	FDA Approved Indications	Breast	Lung	Colon	Thyroid	Kidney	GIST	CML
bortezomib (Velcade®)	Patients with multiple myeloma; patients with mantle cell lymphoma who have received at least 1 prior therapy							
bosutinib (Bosulif®)	Adult patients with chronic, accelerated, or blast phase Ph+ chronic myelogenous leukemia (CML) with resistance or intolerance to prior therapy							X
cabozantinib (Cometriq®)	Patients with progressive, metastatic medullary thyroid cancer				X			
carfilzomib (Kyprolis®)	Patients with multiple myeloma who have received at least two prior therapies including bortezomib and an immunomodulatory agent, have demonstrated disease progression on or within 60 days of completing last therapy¥							
crizotinib (Xalkori®)	Patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) that is anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test¥		X					
dasatinib (Sprycel®)	Newly diagnosed adults with Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase. The trial is ongoing and further data will be required to determine long-term outcome; adults with chronic, accelerated, or myeloid or lymphoid blast phase Ph+ CML with resistance or intolerance to prior therapy including imatinib; adults with Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) with resistance or intolerance to prior therapy							X
erlotinib (Tarceva®)	First-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test; maintenance treatment of patients with locally advanced or metastatic NSCLC whose disease has not progressed after four cycles of		X					

Drug	FDA Approved Indications	Breast	Lung	Colon	Thyroid	Kidney	GIST	CML
	platinum-based first-line chemotherapy; treatment of locally advanced or metastatic NSCLC after failure of at least one prior chemotherapy regimen; first-line treatment of patients with locally advanced, unresectable or metastatic pancreatic cancer, in combination with gemcitabine. -Limitations of use: not recommended for use in combination with platinum-based chemotherapy; safety and efficacy of TARCEVA have not been evaluated as first-line treatment in patients with metastatic NSCLC whose tumors have EGFR mutations other than exon 19 deletions or exon 21 (L858R) substitution							
everolimus (Afinitor®)	Postmenopausal women with advanced hormone receptor-positive, HER2-negative breast cancer (advanced HR+ BC) in combination with exemestane after failure of treatment with letrozole or anastrozole; adults with progressive neuroendocrine tumors of pancreatic origin (PNET) that are unresectable, locally advanced or metastatic; adults with advanced renal cell carcinoma (RCC) after failure of treatment with sunitinib or sorafenib; adults with renal angiomyolipoma and tuberous sclerosis complex (TSC), not requiring immediate surgery¥	X				X		
gefitinib (Iressa®)	Monotherapy for the continued treatment of patients with locally advanced or metastatic non-small cell lung cancer after failure of both platinum-based and docetaxel chemotherapies who are/have benefited from IRESSA.†		X					
imatinib (Gleevec®)	Newly diagnosed adult and pediatric patients with Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase; Patients with Philadelphia chromosome positive						X	X

Drug	FDA Approved Indications	Breast	Lung	Colon	Thyroid	Kidney	GIST	CML
	chronic myeloid leukemia (Ph+ CML) in blast crisis (BC), accelerated phase (AP), or in chronic phase (CP) after failure of interferon-alpha therapy; Adult patients with relapsed or refractory Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL); Adult patients with myelodysplastic/ myeloproliferative diseases (MDS/MPD) associated with PDGFR (platelet-derived growth factor receptor) gene re-arrangements; Adult patients with aggressive systemic mastocytosis (ASM) without the D816V c-Kit mutation or with c-Kit mutational status unknown; Adult patients with hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukemia (CEL) who have the FIP1L1-PDGFRα fusion kinase (mutational analysis or FISH demonstration of CHIC2 allele deletion) and for patients with HES and/or CEL who are FIP1L1-PDGFRα fusion kinase negative or unknown; Adult patients with unresectable, recurrent and/or metastatic dermato-fibrosarcoma protuberans (DFSP); Patients with Kit (CD117) positive unresectable and/or metastatic malignant gastrointestinal stromal tumors (GIST); Adjuvant treatment of adult patients following resection of Kit (CD117) positive GIST							
lapatinib (Tykerb®)	In combination with capecitabine, for the treatment of patients with advanced or metastatic breast cancer whose tumors overexpress HER2 and who have received prior therapy including an anthracycline, a taxane, and trastuzumab; in combination with letrozole for the treatment of postmenopausal women with hormone receptor positive metastatic breast cancer that over expresses the HER2 receptor for whom hormonal therapy is indicated	X						

Drug	FDA Approved Indications	Breast	Lung	Colon	Thyroid	Kidney	GIST	CML
nilotinib (Tasigna®)	Newly diagnosed adult patients with Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase; chronic phase (CP) and accelerated phase (AP) Ph+ CML in adult patients resistant to or intolerant to prior therapy that included imatinib							X
pazopanib (Votrient®)	Advanced renal cell carcinoma; advanced soft tissue sarcoma who have received prior chemotherapy					X		
ponatinib (Iclusig®)	Adult patients with chronic phase, accelerated phase, or blast phase chronic myeloid leukemia (CML) that is resistant or intolerant to prior tyrosine kinase inhibitor therapy or Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ALL) that is resistant or intolerant to prior tyrosine kinase inhibitor therapy¥							X
regorafenib (Stivarga®)	Metastatic colorectal cancer (CRC) who have been previously treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF therapy, and, if KRAS wild type, an anti-EGFR therapy; locally advanced, unresectable or metastatic gastrointestinal stromal tumor (GIST) who have been previously treated with imatinib mesylate and sunitinib malate			X			X	
ruxolitinib (Jakafi®)	Intermediate or high-risk myelofibrosis, including primary myelofibrosis, post- polycythemia vera myelofibrosis and post-essential thrombocytopenia myelofibrosis							
Sorafenib (Nexavar®)	Unresectable hepatocellular carcinoma; advanced renal cell carcinoma					X		
sunitinib (Sutent®)	Gastrointestinal stromal tumor (GIST) after disease progression on or intolerance to imatinib mesylate; advanced renal cell carcinoma (RCC); progressive, well-differentiated pancreatic neuroendocrine tumors (pNET) in patients with unresectable locally advanced or metastatic disease					X	X	

Drug	FDA Approved Indications	Breast	Lung	Colon	Thyroid	Kidney	GIST	CML
temsirolimus (Torisel®)	Advanced renal cell carcinoma					X		
vandetanib (Caprelsa®)	Symptomatic or progressive medullary thyroid cancer in patients with unresectable locally advanced or metastatic disease‡				X			
vemurafenib (Zelboraf®)	Unresectable or metastatic melanoma with BRAFV600E mutation detected by an FDA-approved test -Limitation of Use: ZELBORAF is not recommended for use in patients with wild-type BRAF melanoma							

¥Approval based on response rate; currently no data informing survival and/or patient-reported outcomes.
†In light of positive survival data with other agents including another oral EGFR inhibitor, physicians should use other treatment options in advanced non-small cell lung cancer patient populations who have received one or two prior chemotherapy regimens and are refractory or intolerant to their most recent regimen.
‡Use in patients with indolent, asymptomatic or slowly progressing disease should be carefully considered because of the treatment related risks

The following table includes the Pediatric approvals.

Drug	FDA-Approved Pediatric Indication(s)
Imatinib	Philadelphia chromosome+ chronic myeloid leukemia (Ph+ CML)- In chronic phase; pediatric patients with newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) in combination with chemotherapy

DOSAGE FORMS, DOSE, AND MANUFACTURER7-27

There are currently no generic equivalents available for any product within this class.

The products listed in the table below that indicate they should be taken on an empty stomach should be taken at least one hour before or two hours after ingestion of food. All medications can be taken with or without food, unless specified.

Drug	Dosage Forms	Usual Dose	Manufacturer
axitinib (Inlyta®)	Tablets: 1mg, 5mg	5 mg BID	Pfizer
bortezomib (Velcade®)	Single-use vial: 3.5mg	1.3mg/m2 day 1, 4, 8, 11	Millennium

Drug	Dosage Forms	Usual Dose	Manufacturer
bosutinib (Bosulif®)	Tablets: 100mg, 500mg	500-600mg daily	Pfizer
cabozantinib (Cometriq®)	Capsules: 20mg, 80mg	140mg daily on empty stomach	Exelixis
carfilzomib (Kyprolis®)	Single-use vial: 60mg	20-27mg/m2 days 1, 2, 8, 9, 15, 16	Onyx
crizotinib (Xalkori®)	Capsules: 200mg, 250mg	250mg twice daily	Pfizer
dasatinib (Sprycel®)	Tablets: 20mg, 50mg, 70mg, 100mg	100-140mg daily	Bristol-Myers Squibb
erlotinib (Tarceva®)	Tablets: 25mg, 100mg, 150mg	100-150mg daily on empty stomach[1]	Genentech
everolimus (Afinitor®)	Tablets: 2.5mg, 5mg, 7.5mg, 10mg	10 mg daily	Novartis
gefitinib (Iressa®)	Tablets: 250mg	250mg daily	AstraZeneca
imatinib (Gleevec®)	Tablets: 100mg, 400mg	*Adults:* 400-600mg daily, or 400mg twice daily *Children:* 260-340mg/m^2/day	Novartis
lapatinib (Tykerb®)	Tablets: 250mg	*HER2+*: 1250mg daily, days 1-21[2] *Hormone receptor +*: 1500mg daily[3]	GlaxoSmithKline
nilotinib (Tasigna®)	Capsules: 150mg, 200mg	300-400mg twice daily on empty stomach	Novartis
pazopanib (Votrient®)	Tablets: 200mg	800mg daily on empty stomach	GlaxoSmithKline
ponatinib (Iclusig®)	Tablets: 15mg, 45mg	45mg daily	Ariad
regorafenib (Stivarga®)	Tablets: 40mg	160mg daily, 3 weeks on/1 off with a low-fat breakfast	Bayer
ruxolitinib (Jakafi®)	Tablets: 5mg, 10mg, 15mg, 20mg, 25mg	15-20mg twice daily	Incyte
sorafenib (Nexavar®)	Tablets: 200mg	400mg twice daily on empty stomach	Bayer
sunitinib (Sutent®)	Capsules: 12.5mg, 25mg, 50mg	50mg daily, 4 weeks on/2 weeks off	Pfizer

Drug	Dosage Forms	Usual Dose	Manufacturer
temsirolimus (Torisel®)	Single-use vial: 25mg	25mg weekly	Pfizer
vandetanib (Caprelsa®)	Tablets: 100mg, 300mg	300mg daily	AstraZeneca
vemurafenib (Zelboraf®)	Tablets: 240mg	960mg every 12 hours	Genentech

1 To be taken concurrently with gemcitabine (Gemzar®)
2 Taken on an empty stomach, in combination with 2000mg/m2/day of capecitabine on days 1-14 in a repeating 21 day cycle
3 Taken on an empty stomach in combination with letrozole 2.5mg QD

PHARMACOLOGY1-9, 12, 15

All of the products in this class are small molecules that are considered targeted therapy, and they all have a similar mechanism of action. The tyrosine kinase inhibitors work by competitive adenosine-5'-triphosphate (ATP) inhibition at the catalytic binding site of tyrosine kinase (TK).29 With inhibition, access of ATP to the substrate is prevented, which thus inhibits phosphorylation. Downstream mechanisms from tyrosine kinase receptors that can be inhibited include proliferation and maturation, decreased apoptosis, angiogenesis, and metastasis.

Receptor TKIs have an extracellular ligand-binding domain. These tyrosine kinase domains have a binding site for ATP and a cleft to which the substrate binds. Without the appropriate ligand, the receptor TKIs are in an un-phosphorylated state. Once a ligand binds to the domain, the substrate is activated by phosphorylation of the terminal phosphate from the ATP, and there is subsequent increased catalytic activity of the kinase. They intercede in several extra- and intracellular signals, to help in cell growth and differentiation. Non-receptor TKs remain inactive through several mechanisms, and are also activated by various intracellular signals, including phosphorylation. 3

Numerous malignancies are caused by an altered kinase. Oncogenes are genes that are mutated and help turn normal cells into tumor cells. Oncogenic transformation by kinases may occur in 4 different fashions. With any of these transformations, the kinase activity eludes the normal cell mechanisms and generates altered cell downstream signaling.[30]

Kinase inhibitors bind close to the ATP binding site and do not allow this phosphorylation. Thus, there is an ultimate inhibition of the proliferation of these abnormal tyrosine kinase enzymes. Some affect tumor growth, pathologic angiogenesis, and metastatic progression of cancer.

DRUG-DRUG INTERACTION [7-27]

TKI's are commonly substrates for the CYP enzymes in the liver during metabolism. The most common CYP enzymes utilized by TKI's are CYP3A4 and CYP2D6. CYP1A2, CYP2C8, and CY2C9 are also part of the metabolism of TKI's, but to a lower extent. Patients who are on TKI's should have full drug-drug interaction review completed when prescribed a medication known to be an inhibitor and/or inducer of the CYP enzymes. Other non-CYP interactions include pH-dependent absorption of medications in the stomach, which limits oral absorption and P-glycoprotein inhibition. It is hard to include all possible drug interactions in this review. As a rule of thumb, all TKI's that are metabolized by the CYP enzymes in the liver are subject to drug interactions that either induce or inhibit the CYP enzymes. Recommendations for specific dose adjustments, when used in combination with CYP inducers or inhibitors, can be found in the prescribing information.

The non-TKI's in this review, everolimus, temsirolimus, bortezomib and carfilzomib, are also primarily metabolized by CYP3A4. Medications that are known to either induce or inhibit this enzyme should be used with caution due to possible over- and under-exposure of the chemotherapy agent. Recommendations for specific dose adjustments, when used in combination with CYP inducers or inhibitors, can be found in the prescribing information.

DISEASE STATE SUMMARIES

Breast Cancer:

Breast cancer is a major problem in the United States; it is the leading cause of cancer in women and the second-leading cause of cancer-related mortality in the USA. It accounts for over 200,000 new cases and approximately 40,000 deaths annually.31 The treatment and management of early breast tumors typically involves surgery and adjuvant chemotherapy, radiation, and endocrine therapy (e.g., tamoxifen or aromatase inhibitors) if the tumor is hormone-receptor positive for goal of cure. The determination of HER2 status in patients with breast cancer is also important, as this will determine whether or not patients should receive anti-HER2 agents, such as trastuzumab, pertuzumab, or lapatinib. The treatment and management strategy of metastatic (or advanced) breast cancer is different than early-stage tumors; in this situation, the cancer is deemed to be incurable. Thus, the management strategy typically includes sequencing or combining endocrine therapy, anti-HER2 agents, and chemotherapy. In the context of this review, the agents indicated for breast cancer (via FDA-approval and NCCN recommended use) are everolimus and lapatinib. The evidence currently suggests that they are useful in the metastatic setting, in combination with chemotherapy (lapatinib) or endocrine therapy (everolimus).32-33 These agents represent options that could be used in the overall sequence of therapies designed to control the metastatic breast cancer. Based on the differing mechanisms of action of these agents and the current data, both of these agents should be made available to patients with metastatic breast cancer.

Colorectal Cancer:

Colorectal cancer is the fourth most common cancer in the United States, but the second leading cause of cancer death. Colorectal cancer is curable with surgery only for early stage patients but is incurable for patients with metastatic disease. Front-line treatment of colorectal

cancer is generally a combination of surgery plus or minus chemotherapy or chemotherapy alone for advanced disease. The only TKI available for the treatment of colon cancer is regorafenib (Stivarga). Regorafenib is listed as a category 2A recommendation by the NCCN as a single-agent after first progression in patients, KRAS mutant only, receiving the FOLFOXIRI (fluorouracil, leucovorin, oxaliplatin, and irinotecan); as a single-agent after second progression in patients with the KRAS mutation or in patients previously receiving cetuximab or panitumumab; or as a single-agent following third progression. 34

Chronic Myelogenous Leukemia (CML):
CML is a disease characterized by the translocation of the oncogene ABL from chromosome 9 and the breakpoint cluster region (BCR) on chromosome 22, which results in the BCR/ABL mutation, also called the Philadelphia chromosome. This translocation produces an over-activation of the downstream tyrosine kinase, which leads to cell overproduction and proliferation. CML is further broken down into chronic-phase, accelerated-phase, and blast-phase. There are currently five TKI's indicated for CML, which are imatinib, dasatinib, nilotinib, bosutinib, and ponatinib. Imatinib, dasatinib, and nilotinib are all listed as category 1 in the NCCN guidelines for primary treatment of patients with newly diagnosed CML. If a patient is intolerant and Bosutinib and ponatinib are listed as category 2A in the NCCN guidelines for the treatment of patients who are intolerant- or resistant to front-line therapy. Bosutinib, dasatinib, nilotinib, and ponatinib are all recommended as a single-agent in patients with accelerated-phase CML or in combination with chemotherapy for patients with blast-crisis CML. All five medications can be used, NCCN category 2A recommendation, for patients post-transplant with a molecular relapse following complete cytogenetic remission or cytogenetic relapse or those who are not in cytogenetic remission.35

Gastrointestinal Stromal Tumors:
Gastrointestinal stromal tumors or GIST are rare tumors that most commonly occur in the stomach and small intestine. Surgery, radiation and medications are the current options for the treatment of GIST. Imatinib is a category 1 recommendation as adjuvant treatment for patients with completely resected tumors or in patients with persistent gross residual disease after surgery. Imatinib is also a category 2A recommendation by the NCCN for the treatment of primary/preoperative GIST that is deemed unresectable, metastatic, or patients with recurrent disease or patients with resectable disease but significant morbidity.36

Kidney Cancer:
In the last decade, there has been much progress in the treatment of renal cell carcinoma (RCC). Immunotherapy with agents such as interleukin-2 and interferon used to be the standard of care until agents targeting vascular endothelial growth factor (VEGF) were developed. After bevacizumab demonstrated that inhibiting this pathway could result in robust clinical outcomes, many other oral agents that inhibit this pathway were FDA-approved for this indication.37 In the context of this class review, the NCCN Guideline-recommended first-line therapy for relapsed, metastatic, or unresectable clear-cell RCC includes sunitinib, temsirolimus, pazopanib, or sorafenib (for select patients).38 After progression on first-line therapy, in the

context of this review, subsequent therapy consists of any of the available oral therapies (i.e., axitinib, everolimus, pazopanib, sorafenib, sunitinib, temsirolimus). Everolimus and axitinib have the most data in the setting of progression after first-line TKI therapy, and thus are category 1 recommendations by the NCCN.38 Pazopanib does not have supporting data in this subsequent therapy (the recommendation is extrapolated from patients who failed cytokine therapy), and thus it is a category 3 recommendation.38 Sunitinib and sorafenib represent the first oral agents FDA-approved for this indication, and therefore may see higher utilization rates.39

Melanoma:
Melanoma is a disease of the melanocytes in the skin. Melanoma is generally curable with surgery but some patients can develop disease that is unresectable and affects other organ systems other than the skin. Chemotherapy and biotherapy was the mainstay for advanced melanoma until newer treatments became available. Two oral TKIs that are available for the treatment of metastatic melanoma are imatinib and vemurafenib. Vemurafenib is listed as a category 1 recommendation and preferred agent by the NCCN in patients with V600 mutation of the BRAF gene for unresectable state III in-transit metastases; local/satellite and/or in-transit unresectable recurred; and recurrent or metastatic disease in patients with good performance status. Ipilumumab is preferred in patients who do not carry the V600 BRAF mutation. Imatinib is a NCCN category 2A recommendation as a single-agent in patients with C-KIT mutated melanoma with local, unresectable recurrence and/or distant metastases. 40

Multiple Myeloma:
Multiple myeloma (MM) is a cancer of the plasma cells that results in recurrent infections, bleeding, and renal failure. Over the last decade, a number of new medications have become available and have changed the treatment of the disease. The class of medications called the protesome inhibitors is a very important class in the treatment of MM. Agents in this class include bortezomib and carfilzomib. Bortezomib was first approved in 2003 and carfilzomib was just approved in 2012. Bortezomib is incorporated into many first-line preferred NCCN regimens and can also be used as a single-agent in 2nd-line and beyond. It can also be utilized in patients who are both transplant eligible and transplant ineligible. Carfilzomib is a NCCN preferred agent in the treatment of MM in patients who have received at least 2 prior therapies, including bortezomib and an immunomodulating agent, like thalidomide or lenalidomide.41

Non-Small Cell Lung Cancer:
Lung cancer is the leading cause of cancer-related death in the United States.31 Non-small cell lung cancer (NSCLC) represents the majority of these lung tumor histologies, and include adenocarcinoma, squamous cell carcinoma, and large cell. The management of early-stage NSCLC (i.e., stage I-II) typically includes surgery and adjuvant chemotherapy. In the metastatic setting, the treatment strategy is genetically driven.42 Patients with EML4-ALK mutations and EGFR mutations will derive benefit from crizotinib and erlotinib, respectively, and should receive them as first-line therapy. The NCCN Guidelines state that erlotinib may be added to

chemotherapy if the EGFR mutation status was discovered during the initiation of first-line therapy, although there is limited data to support this strategy.43 Additionally, erlotinib may be used as maintenance therapy in patients who do not progress after 4-6 cycles of chemotherapy for first-line treatment of NSCLC (irrespective of EGFR mutation status).44 Lastly, erlotinib was first FDA-approved for the treatment of metastatic NSCLC in patients who progress after chemotherapy therapy (irrespective of EGFR mutation status) and this is still an option for use in the NCCN Guidelines.[43]

Thyroid Cancer:
The treatment of metastatic, recurrent or unresectable thyroid cancer requires management with systemic chemotherapy. From a historical perspective, these relatively indolent tumors do not typically respond to traditional cytotoxic chemotherapy agents. Recent understanding about the influence of mutations in the RET protooncogene on the development of thyroid cancer have led to novel tyrosine kinase inhibitors that specifically target RET (among other receptors).45 Cabozantinib and vandetanib are two examples of TKIs that target RET and have data demonstrating clinical benefit in this disease (although studies evaluating overall survival have not yet been published and are ongoing) and are recommended by the NCCN Guidelines for various types of thyroid cancer. Other agents in this class review: sunitinib, sorafenib, and pazopanib, also inhibit RET and are listed as options for the treatment of thyroid cancer in the NCCN Guidelines.[46]

SUMMARY

TKI's are small molecules that block the phosphorylation of intracellular components of various receptors. The first TKI FDA-approved in the United States was imatinib (Gleevec®), which was approved in 2001 for CML.17 Oral chemotherapy and in particular TKI's are the fastest area of growth of medications in cancer treatment.[3-4]

Many of the TKI's block a number of different receptors.[7-27] Using imatinib as the example, this medication not only blocks the BCR-ABL tyrosine kinase as it was first developed, but it also blocks C-KIT, PDGR-α, and stem cell factor.[17] This makes the medication not only useful in treating CML, but also GIST, melanoma, graft-versus-host disease, and a variety of other conditions. This seems to be the trend for almost all the TKI's coming onto the market. They are developed for a particular mutation and disease state, but as we learn more about the genetics of the tumors, different treatment options are becoming available.

The NCCN guidelines provide the most up-to-date information on the appropriate use of oral chemotherapy agents in cancer. Guidelines are updated yearly if not more often, when new information is published and discovered.

In summary, the indications for these agents are evolving. For some types of cancer, the clinical utility of these expensive oral medications is marginal. It is reasonable to clinically authorize these drugs only for those indications for which there is a proven, clinically significant benefit.

ADDENDUM-1

NCCN Guidelines Category Definitions:

Category 1: Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.

Category 2A: Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.

Category 2B: Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate.

Category 3: Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate.

ADDENDUM-2

Acronym	Meaning
EGFR	Epidermal Growth Factor Receptor
HER2	Human Epidermal Growth Factor Receptor Type 2
BCR-ABL	Breakpoint cluster region (BCR) and Abelson murine leukemia (ABL) genes; a translocation between chromosomes 9 and 22 result in the formation of the Philadelphia Chromosome (BCR-ABL fusion gene), resulting in a protein that is critical for the development of chronic myelogenous leukemia (CML)
EML4-ALK	Echinoderm microtubule-associated protein-like 4 (EML4) and Anaplastic lymphoma kinase (ALK); a fusion between the ALK and EML4 genes has been identified in a subset of non-small cell lung cancer patients
c-Kit or **KIT**	v-kit Hardy-Zuckerman 4 feline sarcoma viral oncogene homolog; mutations in this gene result in a constitutively active receptor protein tyrosine kinase (occurs in 95% of Gastrointestinal stromal tumors)
VEGFR	Vascular endothelial growth factor receptor; involved with neovascularization of tumors and angiogenesis

Acronym	Meaning
RET	Rearranged during transfection gene; this is a proto-oncogene where specific mutations result in the formation of an activated tyrosine kinase and is associated with poorer outcomes
Ras	Rat sarcoma; a family of guanosine nucleotide-binding proteins ("G-proteins") responsible for signal transduction and is part of the mitogen-activated protein kinase (MAPK) cascade
Raf	Rapidly accelerated fibrosarcoma; a family of serine/threonine-specific protein kinases and is part of the mitogen-activated protein kinase (MAPK) cascade
MEK	mitogen-activated protein kinase/extracellular-signal-regulated kinase kinase; a protein kinase that is part of the mitogen-activated protein kinase (MAPK) cascade
ERK	Extracellular signal-regulated kinases; a protein kinase that is part of the mitogen-activated protein kinase (MAPK) cascade

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THERAPEUTIC CLASS REVIEW

INSERT DATE HERE

[Last Literature Review: January 2, 2014]
[Last Review Update: January 10, 2014]

COLONY STIMULATING FACTORS

This publication is a result of the collaboration of the Goold Health Systems Clinical Workgroup and represents the opinion of these authors based on a review of the literature available at the time it was written. It is intended for the sole purpose of providing information to committee members in order to compare medications within a specified subset of clinical parameters. It is not intended to provide specific clinical advice for any condition, or to be an exhaustive review of all potential aspects of pharmacotherapies for any given condition. Medical evidence is rapidly changing, and no representation is made regarding the use of this material beyond the stated purpose. The literature for this review was last searched through the date listed above. Please note that it may take time for published articles to be available via medical literature search engines.

SYNOPSIS

Neutrophils, which are produced from hematopoietic stem cells (HSCs) in the bone marrow, are a type of white blood cell that are released into the bloodstream and circulate to where they are needed.4 Neutropenia is an abnormally low number of circulating neutrophils in the peripheral blood, considered as an absolute neutrophil count (ANC) of <1500 cells/mm3. Neutropenia can be described based on the disease grade and type. It can be graded as mild (1,000-1,500 cells/mm3), moderate (500-1,000 cells/mm3), severe (<500 cells/mm3), and very severe (<200 cells/mm3). Types of neutropenia may include acquired or congenital neutropenia.[5]

There are numerous causes associated with acquired neutropenia. One associated cause is by an infection, whether it is viral (which is the most common agent), bacterial, rickettsial, or parasitic. Other causes may include HIV infection, drug-induced, chronic idiopathic, chemotherapy-induced, nutrition-related, or immune-associated. Primary causes associated with congenital neutropenia include cyclic neutropenia and severe congenital neutropenia (static neutropenia). Febrile neutropenia is neutropenia with an associated temperature and has varying definitions based upon ones temperature and ANC level.[5]

If neutropenia develops secondary to another condition, the underlying condition should be treated. Prophylactic antimicrobials may be part of the treatment regimen for those with neutropenia. Other treatment options include neutrophil transfusions and colony stimulating factors (CSFs).[5]

Per Mandell, Douglas, and Bennett's Principles and Practice of Infectious Disease, 7th ed, CSFs are "...a group of naturally occurring glycoprotein cytokines that regulate the production, differentiation, survival, and activation of hematopoietic cells." Specifically, granulocyte-CSFs (G-CSF) act on neutrophils and neutrophilic precursors to promote cell growth, differentiation, and function.6 These products have various indications with little concern for drug interactions. Tbo-filgrastim (Granix®) was just recently approved and the first approved in numerous years.

The CSFs in this therapeutic class review include filgrastim (Neupogen®), pegfilgrastim (Neulasta®), sargramostim (Leukine®), and tbo-filgrastim (Granix®).

FDA APPROVED INDICATIONS1-[3, 24]

FDA-Approved Indications	filgrastim (Neupogen®)	pegfilgrastim (Neulasta®)	sargramostim (Leukine®)	tbo-filgrastim (Granix®)
To ↓ incidence of infection in cancer patients receiving myelosuppressive chemotherapy[1]	X	X[2]		X

FDA-Approved Indications	filgrastim (Neupogen®)	pegfilgrastim (Neulasta®)	sargramostim (Leukine®)	tbo-filgrastim (Granix®)
Patients with Acute Myeloid Leukemia (AML) following induction or consolidation chemotherapy[4]	X		X[3]	
Cancer patients receiving Bone Marrow Transplant[5]	X			
Patients undergoing peripheral blood Progenitor Cell collection and therapy[6]	X		X	
Severe Chronic Neutropenia[7]	X			
In Bone Marrow Transplantation Failure or Engraftment Delay			X[8]	
Use in Myeloid Reconstitution after Autologous or Allogeneic Bone Marrow Transplantation (BMT)			X[9, 10]	

1 In those with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of severe neutropenia with fever
2 Not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.
3 Following induction chemotherapy only; to shorten time to neutrophil recovery and reduce the incidence of severe and life-threatening infections and infections resulting in death. The safety/efficacy of use in patients with AML <55 years of age has not been established.
4 For reducing the time to neutrophil recovery and the duration of fever
5 To reduce the duration of neutropenia and neutropenia-related clinical sequelae (e.g. febrile neutropenia) in patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by marrow transplantation. It is recommended to monitor and obtain CBCs and platelet counts at least 3 times per week after marrow infusion.
6 For the mobilization of hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis.
7 For chronic administration to reduce the incidence and duration of sequelae of neutropenia (e.g. fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia.
8 Has been found to be safe/effective in prolonging survival of patients who experience graft failure or engraftment delay.
9 Allogenic BMT: In those undergoing allogeneic BMT from human leukocyte antigen (HLA)-matched related donors. Autologous BMT: In patients with non-Hodgkin's lymphoma (NHL), acute lymphoblastic leukemia (ALL), and Hodgkin's disease undergoing autologous BMT. Hematologic response can be found by CBC with differential cell counts performed twice per week.
10 It is safe/effective in accelerating myeloid engraftment, reducing the incidence of bacteremia and other culture positive infections, and shortening the median duration of hospitalization.

DOSAGE FORMS, DOSE, AND MANUFACTURER1-[3, 24]

There are currently no generic formulations available in this class. Tbo-filgrastim (Granix®) is not considered a generic or biosimilar medication to filgrastim by the FDA.

Dosage forms and specific dosages vary significantly by product and indication, and the information provided in the dose table is general information regarding doses. The route of administration (IV or SC) and duration of treatment may also vary dependent upon indication.

Drug	Dosage Forms	Dose	Manufacturer

Drug	Dosage Forms	Dose	Manufacturer
filgrastim (Neupogen®)	Single-dose vials, PF: 300mcg/ml, 480mcg/1.6ml Prefilled Syringes, single-dose: 300mcg/0.5ml, 480mcg/0.8ml	5-10mcg/kg/day given as SC or IV	Amgen
pegfilgrastim (Neulasta®)	Prefilled syringe: 6mg/0.6ml	6mg SC once per chemo cycle; not to be given between 14 days before & 24 hrs after chemo	Amgen
sargramostim (Leukine®)	Multiple-use Vials[1]: 500mcg/ml Lyophilized Powder for Injection: 250mcg	250mcg/m^2/day IV or SC	Sanofi-Aventis
tbo-filgrastim (Granix®)	Prefilled Syringes, single-dose: 300mcg/0.5ml, 480mcg/0.8ml	5mcg/kg/day SC	Teva Oncology

PF- Preservative Free [1] Contains 1.1% benzyl alcohol in a 1ml solution.

PHARMACOLOGY 1-[3, 24]

Products in this class are either a human granulocyte-macrophage colony stimulating factor (GM-CSF) or a human granulocyte colony-stimulating factor (G-CSF) produced by recombinant DNA technology. Colony stimulating factors (CSFs) are glycoproteins that bind to specific cell surface receptors on hematopoietic cells to stimulate proliferation, differentiation commitment, and some end-cell functional activation. Endogenous G-CSF controls the production of neutrophils in the bone marrow and affects neutrophil progenitor proliferation, differentiation, and selected end-cell functional activation.

Filgrastim (Neupogen®) is a 175 amino acid protein manufactured by recombinant DNA technology. It is produced by Escherichia coli (E coli) bacteria, into which has been inserted the human granulocyte colony-stimulating factor gene.

Pegfilgrastim (Neulasta®) is a conjugate of filgrastim (recombinant methionyl human G-CSF) and mono-methoxypolyethylene glycol.

Sargramostim (Leukine®) is also produced by recombinant DNA technology, but in a yeast system (S. cerevisiae). It is a glycoprotein of 127 amino acids, but with an amino acid sequence that differs from the natural human GM-CSF with a substitution of leucine.

Tbo-filgrastim (Granix®) is a non-glycosylated recombinant human G-CSF manufactured by recombinant DNA technology using bacterium strain E coli K802. Tbo-filgrastim (Granix®) is not considered a biosimilar to filgrastim in the US. This medication was FDA-approved through an original biologic license application.

The table below summarizes the mechanism of action for each medication in this therapeutic category.

Drug	Granulocyte-macrophage colony stimulating factor (GM-CSF)	Granulocyte colony stimulating factor (G-CSF)
filgrastim (Neupogen®)		X
pegfilgrastim (Neulasta®)		X
sargramostim (Leukine®)	X	
tbo-filgrastim (Granix®)		X

PHARMACOKINETICS1-[3, 24]

All products should be stored in the refrigerator in the original carton to protect from light.

The following table discusses pharmacokinetic information for each medication.

Drug	Peak Plasma Concentration	Half-Life	Elimination	Other
filgrastim (Neupogen®)	SC: 2-8 hours	3.5 hours	Not reported	One dose per vial, discard if unused; Max 24 hrs at room temperature
pegfilgrastim (Neulasta®)	Not reported	SC: 15-80 hours	Renal: minimal	Discard if at room temperature for >48 hrs
sargramostim (Leukine®)	1-4 hours	IV: 60 minutes SC: 162 minutes	Renal: <0.2%	Liquid may be stored up to 20 days refrigerated once vial has been entered
tbo-filgrastim (Granix®)	4-6 hours	3.2-3.8 hours	Not reported	Max 5 days at room temperature

CLINICAL TRIALS

Clinical trials performed to obtain FDA approval confirmed all the medications in this therapeutic class to be superior in efficacy, as well as showing safety of the drug, when compared to placebo.

A 2013 retrospective claims analysis by Naeim et al7 included US claims data from 2004-2009 to assess for the effect of pegfilgrastim versus filgrastim on the risk of hospitalization in adults receiving chemotherapy for non-Hodgkin's lymphoma (NHL) or breast, lung, ovarian, or colorectal cancer. Outcomes including neutropenia-related and all-cause hospitalization rates were assessed. There were 3,535 patients eligible for inclusion, representing 12,056 cycles

when G-CSF was given prophylactically (383 filgrastim cycles and 11,683 pegfilgrastim cycles). Filgrastim was used for a mean of 4.8 injections per cycle as compared to 1.0 injection per cycle with pegfilgrastim. Note that neutropenia-related hospitalization were defined with a 'narrow' criterion for claims with an ICD-9 code for neutropenia as well as with a broad criterion for claims with an ICD-9 code for neutropenia, fever, or infection.

Results suggested that there was not a significant difference in the incidence of neutropenia-related hospitalization (narrow definition) per cycle (1.3% with filgrastim vs 0.6% with pegfilgrastim (p=0.063); however, significant differences were seen between treatments for neutropenia-related hospitalization (broad definition) per cycle, with a higher incidence occurring with filgrastim vs pegfilgrastim (6.7% vs 2.4%; p<0.001). Additionally, a higher incidence in all-cause hospitalization per cycle was seen with filgrastim vs pegfilgrastim (10.2% vs 5%; p<0.001). The adjusted odds ratio (OR) for risk of hospitalization with pegfilgrastim vs filgrastim was 0.43 for neutropenia-related narrow, 0.38 for neutropenia-related broad definition, and all-cause hospitalization (0.50). The authors concluded that there was an associated reduced risk of neutropenia-related or all-cause hospitalization with pegfilgrastim prophylaxis relative to filgrastim prophylaxis.

A 2009 retrospective matched-cohort study by Heaney et al8 included US health insurance claims data from 2000 to 2007 to assess for the infection-related hospitalization rates between the CSFs in adults with chemotherapy-induced neutropenia. Included in the cohorts were those taking chemotherapy and one CSF, either sargramostim, filgrastim, or pegfilgrastim. Cohorts were sargramostim-filgrastim (N=990) and sargramostim-pegfilgrastim (N=982) matched pairs. A matched-cohort was chosen because sargramostim was used less frequently than filgrastim or pegfilgrastim.

Results suggested that the sargramostim group had a lower risk of infection-related hospitalization as compared to filgrastim (incidence rate ratio [IRR] 0.46; p=0.0422) and as compared to pegfilgrastim (IRR 0.52; p=0.0628). After adjusting for confounding factors, results suggested an adjusted IRR of 0.44 (p=0.0333) for sargramostim vs filgrastim and an adjusted IRR of 0.44 (p=0.0256) for sargramostim vs pegfilgrastim. This suggests a 56% lower risk of infection-related hospitalization with sargramostim as compared with filgrastim and pegfilgrastim. There were <10 febrile neutropenia-related hospitalizations in each group, but the sargramostim group tended to have a lower rate than filgrastim or pegfilgrastim. The authors concluded that the use of sargramostim was associated with a reduced risk of infection-related hospitalization as compared with filgrastim or pegfilgrastim. (GHS Comments: Please note the limitations of this study, including the less frequent use of sargramostim vs the other comparators.)

A 2007 meta-analysis by Pinto et al14 included 5 randomized controlled trials (N=617) to assess for the safety and efficacy of pegfilgrastim as compared to filgrastim for the incidence of febrile neutropenia (FN) in adults with solid tumors and malignant lymphomas receiving myelosuppressive chemotherapy. A single dose of pegfilgrastim was administered versus daily

filgrastim injections (median of 10-14 days) at approved doses. The primary outcomes were the rates of grade IV neutropenia, FN, the time to absolute neutrophil count (ANC) recovery, and bone pain. FN was defined as an ANC <0.5 X109/L and temperatures >38.2°C in all studies except for one which defined FN as an ANC <0.5 X109/L and temperatures ≥38.2°C. Results suggested that in 4 studies, the relative risk (RR) for FN was lower for pegfilgrastim (PEG) as compared to filgrastim (FIL). In the fifth study, FIL had a higher reduction rate as compared with PEG (RR 1.1; p=0.846). The pooled RR of FN was 0.64 and statistically significantly in favor of PEG. The pooled RR for grade IV neutropenia was not statistically significantly different between treatments, suggesting that PEG was comparable to FIL for reducing the incidence of grade IV neutropenia. The pooled standardized mean difference (SMD) for the time to ANC recovery was also not statistically significantly different between treatments (SMD 0.11; p=0.63). The rates of reported bone pain were not statistically significantly different between treatments, with a pooled RR of 0.95. The authors concluded that pegfilgrastim use was better for reducing FN rates as compared with filgrastim.

A 2011 retrospective cohort study by Tan et al[15] included data from US commercial administrative claims regarding adults with Non-Hodgkin's lymphoma, breast, or lung cancer, who were treated with chemotherapy and granulocyte-colony stimulating factors (G-CSFs) for febrile neutropenia. The primary outcome was to assess the risk of neutropenia-related and all-cause hospitalization between pegfilgrastim and filgrastim prophylaxis.

Results suggested that 88.9% of the population used pegfilgrastim and 11.1% used filgrastim. The rate of neutropenic hospitalization was significantly lower for pegfilgrastim vs filgrastim (1.1% vs 3.5%; p=0.001). All-cause hospitalization occurred in 5.5% of pegfilgrastim cycles vs 9.5% of filgrastim cycles (p=0.02). The odds of neutropenia-related hospitalization was 62% lower with pegfilgrastim prophylaxis vs filgrastim (adjusted odds ratio [OR] 0.38). The neutropenic hospitalization rate was 1.2% for G-CSF prophylactic initiation vs 3.7% for delayed G-CSF initiation (p<0.001). The authors concluded that pegfilgrastim prophylaxis resulted in a lower risk of neutropenia-related and all-cause hospitalization as compared to filgrastim prophylaxis.

A 2011 systematic review and meta-analysis by Cooper et al16 included 25 studies to assess the efficacy of G-CSFs (pegfilgrastim, filgrastim, or lenograstim) for reducing the incidence of febrile neutropenia (FN) when used in adults undergoing chemotherapy for solid tumors or lymphoma. The primary outcome was the incidence of FN over all cycles of chemotherapy, comparing the effectiveness of G-CSFs vs no prophylaxis and vs each other. Of the included studies, there were 5 that compared pegfilgrastim with filgrastim, 5 that compared pegfilgrastim with no treatment, 10 that compared filgrastim with no treatment, and 5 that compared lenograstim with no treatment.

Results suggested that all 3 G-CSFs significantly reduced the incidence of FN as compared with no treatment. The relative risk (RR) was 0.3 for pegfilgrastim (p=0.002), 0.57 for filgrastim (p<0.00001), and 0.62 for lenograstim (p=0.007). Overall, the RR of FN for any G-CSF

prophylaxis vs no prophylaxis was 0.51 (p<0.00001). Of the comparator studies, results suggested that pegfilgrastim significantly lowered the incidence of FN as compared with filgrastim (p=0.04), with a RR of 0.66. The authors concluded that primary G-CSF prophylaxis was effective for reducing the risk of FN in this population, and that pegfilgrastim reduced the risk to a greater extent than filgrastim.

A 2013 retrospective cohort study by Henk et al17 included US claims data from 2 different databases between 2001 to 2010 to assess the incidence of febrile neutropenia (FN) and all-cause hospitalizations associated with filgrastim, pegfilgrastim, and sargramostim prophylaxis for adults receiving myelosuppressive chemotherapy (M-CT) for non-Hodgkin lymphoma, Hodgkin lymphoma, or solid tumors. In the HIRD® database analysis, sargramostim (odds ratio [OR] 3.48) and filgrastim (OR 1.78) had a higher risk of neutropenia-related hospitalization as compared with pegfilgrastim. This was also the case in the OptumInsight® analysis, with sargramostim (OR 2.81) and filgrastim (OR 2.36) having a higher risk of neutropenia-related hospitalization as compared with pegfilgrastim. The risk of all-cause hospitalization was higher in both database analyses for sargramostim (OR 2.18/2.41) and filgrastim (1.57/1.95) as compared with pegfilgrastim. The authors concluded that the use of pegfilgrastim was associated with a lower risk of neutropenia-related and all-cause hospitalizations as compared to filgrastim or sargramostim prophylaxis.

A 2012 retrospective cohort study by Weycker et al18 included US healthcare claims data to assess the efficacy of filgrastim, pegfilgrastim, and sargramostim for the prevention of hospitalization for febrile neutropenia (FN) during myelosuppressive chemotherapy. Using the narrow definition (ie principal or secondary diagnosis of neutropenia), results suggested that the risk of hospitalization for neutropenic complications was higher during cycles with filgrastim (odds ratio [OR] 1.93; p<0.001) or sargramostim (OR 2.39; p<0.001) as compared with pegfilgrastim. Using the broader definition of hospitalization for neutropenic complications (ie principal or secondary diagnosis of neutropenia, fever, or infection), the risk was higher with filgrastim (OR 1.53; p<0.001) and sargramostim (OR 2.39; p<0.001) as compared with pegfilgrastim. The risk of all-cause hospitalization was higher for filgrastim (OR 1.55; p<0.001) and sargramostim (OR 1.91; p<0.001) as compared with pegfilgrastim. The authors concluded that the risk of hospitalization due to neutropenic complications was reduced more with pegfilgrastim prophylaxis as compared with filgrastim or sargramostim prophylaxis in this population receiving cancer chemotherapy.

A 2000 retrospective cohort study by Milkovich et al19 included data from 10 US outpatient chemotherapy centers to assess the rates of adverse events with filgrastim as compared with sargramostim when used in adults (N=490) receiving myelosuppressive chemotherapy for lung, breast, lymphatic system, or ovarian tumors. Records of all patients who received at least one dose of either treatment were assessed. Results suggested that febrile episodes occurred significantly more with sargramostim vs filgrastim (9% vs 4%; p<0.001), but differences in fever duration or maximum temperature recorded were not seen. Fever not explained by infection was significantly more common with sargramostim vs filgrastim (7% vs 1%; p<0.001). Skeletal

pain occurred more but not significantly more with filgrastim vs sargramostim (11% vs 8; p=0.06). Adverse events that occurred significantly more with sargramostim vs filgrastim included fatigue (4% vs 2%; p<0.05), diarrhea (3% vs 2%; p<0.05), injection site reaction (6% vs 1%; p<0.01), other dermatologic disorders (3% vs 1%; p<0.01), and edema (2% vs 1%; p<0.01). The authors concluded that adverse events were less common with filgrastim as compared with sargramostim, thus quality of life may also differ.

A 2008 cohort study by Ballestrero et al[23] included adults (N=44) with solid tumors and lymphomas receiving pegfilgrastim starting day 5 after autologous peripheral blood stem cell transplantation to assess the incidence and duration of neutropenic fever as compared to a historical control group of adults (N=25) who received filgrastim. Results suggested that there were not significant differences in hematological recovery between the two treatment groups. The median times to obtain an absolute neutrophil count (ANC) of 0.5X109/l and 1X109/l were 9.5 and 10 days, respectively for the pegfilgrastim group vs 10 and 11 days in the filgrastim group. Significant differences in the median duration of severe neutropenia and thrombocytopenia were not seen between groups. The median duration of grade 4 neutropenia was 7 days with the pegfilgrastim group vs 6 days with the filgrastim group, while for thrombocytopenia the median duration was 2 days vs 3 days, respectively.

For adverse events, bone pain was reported during neutrophil recovery, being reported in 20% (N=9) of the pegfilgrastim group as compared with 40% (N=10) of the filgrastim group. The incidence of grade III-IV mucositis was significantly lower in the pegfilgrastim group (20%) as compared with the filgrastim group (56%; p=0.00). The authors concluded that a single injection of pegfilgrastim had comparable safety and efficacy to daily injections of filgrastim. (GHS Comments: Please note a limitation is the small sample size.)

The following table represents data from additional trials of interest.

After a careful review of the literature, the articles included in this therapeutic class review are not all inclusive. Key and pivotal studies that suggest one therapy is superior to another or a place in therapy of a specific product are included. Studies of low levels of evidence may not have been included in the review. Studies deemed of little relevance may also be excluded.

Study & Level of Evidence*	Design & Comparators	Sample Size & Duration	Patient characteristics	Assessed Outcomes	Results	Author's Conclusions & GHS Comments
Sierra et al[9] 2008 **LOE-1a**	Multicenter, randomized, double-blind, phase 2 study pegfilgrastim 6mg single-dose Vs filgrastim 5mcg/kg QD	N=84	-Adult subject's ≥18 years of age with histologically confirmed *de novo* low to intermediate risk acute myeloid leukemia (AML), and Eastern Cooperative Oncology Group (ECOG) performance status ≤2, and life expectancy ≥3 months.	-To compare the time to recovery from severe neutropenia -To compare the rate of complete remission following induction chemo, ANC, and the incidence and duration of hospitalization/ fever -Adverse events	-Patients were administered 1-2 courses of standard induction chemotherapy (idarubicin plus cytarabine), followed by 1 course of consolidation therapy (high-dose cytarabine) if complete remission was achieved. Treatment with pegfilgrastim (peg) and filgrastim (fil) began 24 hours after induction and consolidation of chemotherapy. -In Induction 1 (1st course of chemo), all patients had severe neutropenia, and ANC recovered in most patients. -The estimated median time to ANC recovery was 22 days for each treatment (difference between groups 0.0). -During consolidation, most all had severe neutropenia. The median time to ANC recovery was 17 days for peg vs 16.5 days for fil. -Febrile neutropenia (FN)	-Clinically meaningful differences were not seen between treatments for shortening the duration of severe neutropenia following chemo in this population with AML.

Study & Level of Evidence*	Design & Comparators	Sample Size & Duration	Patient characteristics	Assessed Outcomes	Results	Author's Conclusions & GHS Comments
					developed in 81% of the peg group vs 88% of the fil group. The median duration of FN during Induction 1 was 15 days for peg vs 14 for fil. The incidence/median number of days with fever was comparable between treatments during Induction 1 (90%/ 5 days for peg vs 93%/6 days for fil). During the Consolidation phase, fever was reported more in the peg group (77%) vs the fil group (58%); however the median duration was the same for each group (2 days). -At the end of Induction 1, 79% of the peg group achieved complete remission (CR) vs 63% of the fil group. Two additional achieved CR during Induction 2, which results in an overall CR of 79% peg vs 68% fil. Overall, CR was not significantly different between treatment groups. -Treatment-related adverse events were reported in 26% of the peg group vs 22% of the fil group.	

Study & Level of Evidence*	Design & Comparators	Sample Size & Duration	Patient characteristics	Assessed Outcomes	Results	Author's Conclusions & GHS Comments
Weaver et al[10] 2001 **LOE-2**	Multicenter, randomized, open-label, phase III study filgrastim 6mcg/kg/day SC Vs sargramostim 250mcg/m^2/day SC Vs sargramostim X6days followed by filgrastim until completion of stem cell harvest	N=156	-Adult subjects on myelosuppressive mobilization chemotherapy with multiple myeloma, breast cancer, or lymphoma (received either paclitaxel or etoposide and then randomized to treatment with a CSF).	-Primary outcome not clear -Time to recovery of absolute neutrophil count (ANC) -Fevers, hospitalizations, CD34+ cell yields	-The median days to ANC ≥0.5X10^9 was 11 days with filgrastim (fil) vs 14 days with sargramostim (sar), which was significantly different (p=0.0001). -There were significantly less with no temp >38.5°C in the fil vs the sar group (18% vs 52%; p=0.001), but no significant differences in the number of febrile days (1 vs 1). -There were significantly less in the fil vs the sar group with no admission to the hospital (20% vs 42%; p=0.013), but comparable amount of days in the hospital between treatment groups (4.5 vs 5, respectively). Significantly less in the fil group needed IV antibiotics vs the sar group (24% vs 69%; p=0.001). -The fil group yielded significantly more CD34 cells than the sar group (median 7.1 vs 2.0 X10^6 kg per apheresis; p=0.0001).	-Filgrastim alone is superior to sargramostim for the mobilization of CD34+ cells and the time to recovery of ANC.

Study & Level of Evidence*	Design & Comparators	Sample Size & Duration	Patient characteristics	Assessed Outcomes	Results	Author's Conclusions & GHS Comments
					-Significant differences in outcomes were not seen between the fil group as compared with the sequential regimen of sar followed by fil.	
Cesaro et al[11] 2013 **LOE-2**	Multicenter, randomized, prospective, open-label, phase III, non-inferiority study pegfilgrastim 100mcg/kg (max 6mg) single dose Vs filgrastim 5mcg/kg/day (max 300mcg/day), up to 9 doses	N=61 Median of 9 days with filgrastim, one dose for peg-filgrastim	-Pediatric subjects were randomized to treatment in the period between admission for transplant and the day of autologous peripheral blood stem cell (PBSC) infusion. 28% had lymphoma/leukemia and 80% had solid tumors	-To assess the speed in recovery of polymorphonuclear cells (PMN) -The incidence of febrile neutropenia and proven infection, the duration of hospitalization, and overall survival were other assessments	-The mean time to PMN engraftment was 10.48 days with filgrastim (FIL) as compared with 10.48 days (p=0.3) with pegfilgrastim (PEG), which suggested non-inferiority of PEG was established. -Differences were not seen between treatments in the number of episodes of fever of unknown origin (1 FIL vs 1 PEG; p=0.6), proven infectious (19 No/10 Yes with FIL vs 23 No/9 Yes with PEG; p=0.6), antibiotic therapy needed (No/Yes response was 2/27 with FIL vs 3/29 with PEG; p=1), and days of hospitalization (15 FIL vs 15.5 PEG; p=0.7). -The time from stem cell transplant (SCT) to death was 614 days with FIL vs 317 days with PEG (p=0.6).	-In this pediatric population who underwent PBSC, pegfilgrastim was non-inferior to filgrastim. **GHS Comments**: A limitation of this study is the small sample size.

Study & Level of Evidence*	Design & Comparators	Sample Size & Duration	Patient characteristics	Assessed Outcomes	Results	Author's Conclusions & GHS Comments
Sebban et al[12] 2012 **LOE-2**	Multicenter, randomized, open-label, phase II study filgrastim (FIL) 5mcg/kg/day Vs pegfilgrastim (PEG) 6mg single dose	N=151 Single dose for PEG daily dose of FIL starting on day 5 and given until the recovery of ANC	-Adult subjects ≥18 years of age with a diagnosis of myeloma or lymphoma requiring high-dose chemotherapy followed by autologous peripheral blood stem cell transplantation (HDC-SCT). Had to have an absolute neutrophil count (ANC) ≥1.5 $X10^9$, a platelet count ≥100 X 10^9/L, and at least 2 X 10^6 cryo-preserved CD34 cells/kg	-Duration of febrile neutropenia (FN), defined as an ANC <0.5G/L and a temperature >38°C at least once a day -Neutrophilic and platelet recovery, transfusion and antibiotic requirements were also assessed -Adverse events	-In the PEG group, FN occurred in 97.4% of those with lymphoma (N=38/39) with a mean duration of 3.49 days. In the FIL group, FN occurred in 90% of those with lymphoma (N=36/40) with a mean duration of 4.15 days. -Of those with myeloma: 88.6% of the PEG group had FN (N=31/35), with a mean duration of 2.6 days; 83.3% of the FIL group had FN (N=30/36), with a mean duration of 2.33 days. -The mean duration of FN was 3.07 in the PEG group vs 3.29 in the FIL group. -The mean duration of days with platelets <20g/l was 3.19 with the PEG group vs 3.61 with the FIL group. -The mean duration of days of antibiotic therapy was 5.42 with PEG and 9.86 with FIL. -There were no grade 3 or 4 adverse events related to PEG or	-When compared with filgrastim, pegfilgrastim was as safe and effective in this population with myeloma or lymphoma needing SCT.

Study & Level of Evidence*	Design & Comparators	Sample Size & Duration	Patient characteristics	Assessed Outcomes	Results	Author's Conclusions & GHS Comments
					FIL that were reported.	
Gerds et al[13] 2010 **LOE-1b**	Randomized, prospective, double-blind, placebo-control, double-dummy study pegfilgrastim (PEG) 6mg single dose Vs filgrastim (FIL) 5mcg/kg daily until sustained engraftment	N=78	-Adult subjects ≥18 years of age undergoing an autologous peripheral blood stem cell transplantation (APBSCT) for multiple myeloma (MM), lymphoma, testicular, or ovarian carcinoma	-To compare the time to a neutrophil engraftment of ≥1.5 X 10^9/L x3 days or 5 X 10^9/L x1 day -The time to resolution of severe neutropenia, length of hospital stay, and incidence of infections were some other assessments	-The median time to an ANC of 1.5 X 10^9/L x3 days or 5 X 10^9/L x1 day was 12 days for each treatment group. -The median time to resolution of severe neutropenia (ANC ≥0.5 X 10^9/L x3 days) was 9 days for the PEG group vs 10 days for the FIL group, which was not statistically significantly different (p=0.15). -The median duration of hospital stay was the same for both treatment groups, which was 19 days. -Significant differences in survival were not seen between treatments at day +100 (p=0.67) or at 1 year (p=0.97). -There were no grade III or IV toxicities reported with either drug.	-A difference in time to neutrophil engraftment was not seen between treatment groups in this population.

Study & Level of Evidence*	Design & Comparators	Sample Size & Duration	Patient characteristics	Assessed Outcomes	Results	Author's Conclusions & GHS Comments
Shi et al[20] 2013 **LOE-2**	Multicenter, randomized, open-label, crossover, non-inferiority study pegfilgrastim 100mcg/kg single dose Vs filgrastim 5mcg/kg/day	N=337 1 of 2 cycles	-Adult subjects 18-70 years of age diagnosed with malignant solid tumors but were chemo-naïve. Had a Karnofsky performance status ≥70 and a normal WBC count, platelet count, and bone marrow function	-The rate of protection against grade 4 neutropenia after chemo (defined as the rate at which the absolute neutrophil count [ANC] remained >0.5 X 10^9/l) -Safety	-94% of those taking either medication did not develop grade 4 neutropenia. In cycle 1, the rates of protection were 89.7% with pegfilgrastim vs 89.5% with filgrastim. There were no episodes of grade 4 neutropenia in cycle 2. -Rates of grade 3/4 neutropenia and the incidence of febrile neutropenia were comparable between treatment groups. -The time to recovery of ANC was quicker with pegfilgrastim vs filgrastim (8.99 days vs 9.67 days; p=0.001). -The safety profile between the two treatments were comparable, with adverse events (AEs) being reported in 41.1% of those treated with pegfilgrastim and 46.3% of those being treated with filgrastim.	-A single dose of pegfilgrastim resulted in effective and safe neutrophil support that was comparable to once daily injections of filgrastim.
Weaver et al[21] 2000	Multicenter, randomized, open-label study	N=156	-Adult subjects <66 yrs of age with breast cancer, malignant lymphoma, or	-Primary outcome not clear, but median days to recovery of absolute neutrophil count (ANC)	-The median number of days to recovery of an ANC >0.5 X10^9/L was 3 days shorter for the filgrastim group vs the	-Filgrastim monotherapy or sequential sargramostim

Study & Level of Evidence*	Design & Comparators	Sample Size & Duration	Patient characteristics	Assessed Outcomes	Results	Author's Conclusions & GHS Comments
LOE-2	filgrastim QD Vs sargramostim QD Vs sargramostim X5 days followed by filgrastim after chemotherapy (sequential therapy)	3 schedules of mobil-ization chemo (MC)	multiple myeloma with an Eastern Cooperative Oncology Group performance status of 0-2 and evidence of adequate hepatic, renal, and cardiac function		sargramostim group (day 11 vs day 14; p=0.0001). -35% of the filgrastim group had a Hb nadir of 8mg/dl as compared with 54% of the sargramostim group, which was not statistically significantly different (p=0.058). -Significantly more in the filgrastim group had a temp ≥38.5°C for ≥1 days as compared with the sargramostim group (p=0.001). -20% of the filgrastim group were admitted to the hospital vs 42% of the sargramostim group (p=0.001). -The median number of days to recovery of ANC of >0.5 $X10^9$/L was 2 days shorter for the sequential group vs the sargramostim group (day 12 vs day 14) , which was statistically significantly different (p=0.0001). -54% of the sargramostim group	followed by filgrastim was superior to sargramostim monotherapy for recovery of ANC and other toxicities after MC.

Study & Level of Evidence*	Design & Comparators	Sample Size & Duration	Patient characteristics	Assessed Outcomes	Results	Author's Conclusions & GHS Comments
					had an Hb nadir of 8.0mg/dl as compared with 35% of the sequential therapy group, which was significantly different (p=0.040). -52% of the sargramostim group had a temp 38.5°C as compared with 15% of the sequential treatment (p=0.001). -42% of the sargramostim group were hospitalized as compared with 21% of the sequential therapy (p=0.017). -There was a significant difference in the median day of recovery of ANC with sequential therapy vs filgrastim (day 12 vs day 11; p=0.001). -Other outcomes were not statistically significant between sequential vs filgrastim treatment.	
Castagna et al[22] 2010	Multicenter, randomized, open-label study	N=80	-Adult subjects >18 years of age with hematological malignancies and solid	-The duration of neutropenia in terms of absolute neutrophil count (ANC)<0.5 X 10^9/l	-The mean number of days with an ANC <0.5 X 10^9/l was 5.97 days with filgrastim vs 6.20 with pegfilgrastim.	-Pegfilgrastim was seen to be as effective as filgrastim for

Study & Level of Evidence*	Design & Comparators	Sample Size & Duration	Patient characteristics	Assessed Outcomes	Results	Author's Conclusions & GHS Comments
LOE-2	filgrastim 5mcg/kg/day Vs pegfilgrastim 6mg single dose		tumors with an adequate harvest of CD34+ cells	and days to reach an ANC >0.5 X 10^9/l	-The time to reach ANC>0.5 X 10^9/l was 11.53 days (mean) with filgrastim vs 10.75 days with pegfilgrastim. -Differences were not seen between treatments in the mean time to reach an ANC >1 X 10^9/l (12.2 days vs 12 days, respectively). -Differences in the incidence of fever were also not seen between treatments (62% vs 56%).	accelerating hematopoietic recovery.
del Giglio et al[27] 2008 **LOE-2**	Multicenter, randomized, Phase 3 controlled, investigator blinded study tbo-filgrastim 5mcg/kg/day Vs Neupogen®	N=348 5-14 days in each cycle	-Adult patients with high risk breast cancer stage II-IV and receiving docetaxel/doxorubicin as routine chemotherapy; ECOG ≤2; chemotherapy-naïve	-The duration of severe neutropenia (DSN) in cycle 1, defined as the number of days with grade 4 neutropenia with an ANC <0.5 x 10^9/L -The incidence of observed febrile neutropenia.	-The mean number of DSN in cycle 1 with tbo-filgrastim, Neupogen®, and placebo were 1.1, 1.1 and 3.9 days, respectively (p<0.0001 vs placebo). There was superiority of tbo-filgrastim over placebo but no difference between tbo-filgrastim and Neupogen®. -The incidence of observed or	-Treatment with tbo-filgrastim is beneficial in ameliorating severe neutropenia and febrile neutropenia in breast cancer patients receiving myelosuppressive chemotherapy.

Study & Level of Evidence*	Design & Comparators	Sample Size & Duration	Patient characteristics	Assessed Outcomes	Results	Author's Conclusions & GHS Comments
	5mcg/kg/day Vs placebo (2:2:1)			-Safety	protocol defined febrile neutropenia was distinctly lower in the tbo-filgrastim and Neupogen® arms (12.1% and 12.5% respectively) compared to the placebo group (36.1%). There was no statistical difference between tbo-filgrastim and Neupogen® in terms of febrile neutropenia. -The most common reported drug-related adverse events were bone pain (10.3%), asthenia (7.8%), myalgia (6.3%), and diarrhea (5.2%).	

CONTRAINDICATIONS [1-3, 24]

All medications in this therapeutic class carry a contraindication of hypersensitivity to their active ingredient or to any component of the compound.

Unique contraindications listed for an individual agent are listed in the table below.

Drug	Contraindication
filgrastim (Neupogen®)	In those with hypersensitivity to *E coli*-derived proteins
pegfilgrastim (Neulasta®)	In those with hypersensitivity to filgrastim
sargramostim (Leukine®)	In those with excessive leukemic myeloid blasts in the bone marrow or peripheral blood (≥10%) Concomitant use with chemotherapy and radiotherapy

SPECIAL POPULATIONS [1-3, 24]

As sargramostim (Leukine®) contains benzyl alcohol, which has been reported to be associated with a fatal 'Gasping Syndrome' in premature infants, it should not be administered to neonates.

Drug	Pediatrics	Pregnancy category	Dosage change for Renal insufficiency	Dosage change for Hepatic insufficiency
filgrastim (Neupogen®)	Yes[2]	C	No information found	No information found
pegfilgrastim (Neulasta®)	No	C	Not required	Not studied
sargramostim (Leukine®)	No[1]	C	Monitor function QOW	Monitor function QOW
tbo-filgrastim (Granix®)	No	C	Mild: Not required Moderate/Severe: Not studied	Not studied

1 However, available safety data indicates that it does not have any greater toxicity in pediatric patients than in adults. Liquid solutions containing benzyl alcohol (including liquid Leukine®) or lyophilized Leukine reconstituted with bacteriostatic water for injection should not be given to neonates.
2 The safety and efficacy in neonates and patients with autoimmune neutropenia of infancy have not been established.

ADVERSE DRUG REACTIONS [1-3, 24]

Acute respiratory distress syndrome (ARDS) has been reported in patients receiving human G-CSF. Those who develop fever, lung infiltrates, or respiratory distress should be assessed for ARDS. If ARDS is diagnosed, treatment should be withheld until resolution of ARDS or discontinued. With sargramostim (Leukine®), there have been occasional reports of dyspnea during treatment. In those reporting dyspnea during Leukine® treatment, the rate of infusion

should be reduced by one-half. If respiratory symptoms worsen even with a reduction in the infusion rate, treatment should be discontinued.

Splenic rupture, including fatal cases, has been reported after the use of human G-CSF treatment. In those who report left upper abdominal pain or shoulder pain during treatment, it is recommended to assess for an enlarged spleen or splenic rupture.

Severe sickle cell crises, in some cases resulting in death, have been associated with human G-CSF treatment. It is recommended that only qualified physicians with specialized training or experience in treating those with sickle cell disorders prescribe human G-CSF for such patients.

Transient supraventricular arrhythmia has been reported during sargramostim (Leukine®) treatment in uncontrolled trials, especially in those with a previous history of cardiac arrhythmia. These arrhythmias were reversible upon discontinuation of treatment. Nevertheless, it is recommended to use sargramostim (Leukine®) treatment with caution in those with preexisting cardiac disease.

Severe allergic reactions, including anaphylaxis, can occur in patients receiving human G-CSF. Reactions can occur on the initial exposure and the medication should be permanently discontinued in patients with a serious allergic reaction. Patients with a history of serious allergic reaction with a human G-CSF should not be re-challenged with a different human G-CSF product.

The G-CSF receptor through which tbo-filgrastim (Granix®) acts has been found on tumor cell lines. The possibility that Granix® acts as a growth factor for any tumor type, including myeloid malignancies and myelodysplasia, diseases for which tbo-filgrastim (Granix®) is not approved, cannot be excluded.

***In the following tables, the results are adjusted so that they reflect only the extent that they exceed placebo. ***

Adverse Reaction	filgrastim (Neupogen®)	pegfilgrastim (Neulasta®)	sargramostim[3] (Leukine®)	tbo-filgrastim (Granix®)
Asthenia	-	-	15%	-
Bone pain	-	5%	-	3.4%
Diarrhea	-	-	7%	-
Fever	1%	-	-	-
Hypertension	4%[1]	-	-	-
Malaise	-	-	6%	-
Nausea	6%[1]	-	-	-

Adverse Reaction	filgrastim (Neupogen®)	pegfilgrastim (Neulasta®)	sargramostim[3] (Leukine®)	tbo-filgrastim (Granix®)
Pain in extremity	-	5%	-	-
Peripheral edema	-	-	4%	-
Peritonitis	2%[1]	-	-	-
Rash	2%[1]	-	6%	-
Skeletal Pain	11%[2]	-	-	-
Urinary tract disorder	-	-	1%	-
Vomiting	4%[1]	-	-	-

1 In studies of cancer patients receiving bone marrow transplant
2 In studies of cancer patients receiving myelosuppressive chemotherapy. Additional adverse events were reported but the reported incidence was greater with placebo than with Neupogen®.
3 In studies of patients with autologous and allogeneic bone marrow transplantation. Additional adverse events were reported but the reported incidence was greater with placebo than with Leukine®.

DRUG-DRUG INTERACTIONS 1-3

Drug interactions have not been fully evaluated for the products in this class; however, it has been recommended that drugs which may potentiate the myeloproliferative effects of G-CSF agents, such as lithium and corticosteroids, should be used with caution.

GUIDELINES

The National Comprehensive Cancer Network (NCCN) has a set of guidelines on the use of myeloid growth factors in patients with cancer. Category 1 recommendations are the highest recommendation by the NCCN and are defined as recommendations based on the high-level evidence and uniform NCCN consensus that the intervention is appropriate. Category 2A recommendations are based on lower-level evidence, but there is uniform NCCN consensus that the intervention is appropriate.

The NCCN considers tbo-filgrastim, filgrastim, pegfilgrastim, and sargramostim to be myeloid growth factors. The NCCN considers both filgrastim and tbo-filgrastim to be category 1 agents for primary and secondary prophylaxis and also when used in the therapeutic setting. Pegfilgrastim is a category 1 medication in the primary and secondary prophylaxis setting, but should be avoided in the therapeutic setting. Sargramostim is considered a category 2B G-CSF by the NCCN.

Prophylactic use of G-CSF: For patients undergoing chemotherapy, in which the regimen has a >20% risk in the rate of febrile neutropenia, the NCCN recommends the use of G-CSF agents as a category 1 recommendation to reduce the risk of febrile neutropenia, hospitalization, and the use of intravenous antibiotics. The category 1 recommendation only applies to patients undergoing chemotherapy for either curative/adjuvant treatment or prolonging survival/quality of life. Growth factors can be considered in regimens with a 10-20% risk of febrile neutropenia, but G-CSF's should not be used in regimens where the risk of febrile neutropenia is <10%.

Secondary use of G-CSF: For second and subsequent cycles of chemotherapy, G-CSF's should be used in patients who experienced a febrile neutropenia event (category 2A recommendation). Dose adjustments and changing treatment plans are also considerations. The decision to use G-CSF's in this setting should be decided by the goal of care, with curative and adjuvant versus palliative treatment.

Therapeutic use of G-CSF: The therapeutic use of G-CSF is defined as the administration of G-CSF during a febrile neutropenia episode. The NCCN recommends (category 2A) that G-CSF's should be considered in patients who present with febrile neutropenia and are currently receiving G-CSF as part of primary prophylaxis. The NCCN also recommends (category 2A) that G-CSF's should be considered in patients who did not receive primary prophylaxis but have certain risk factors. These risk factors include: sepsis syndrome, age >65, severe neutropenia, neutropenia expected to be >10 days duration, pneumonia, invasive fungal infection, other clinically documented infection, hospitalization at the time of fever, and prior episode of febrile neutropenia.

Mobilization of stem cells and post-transplant: Filgrastim and tbo-filgrastim are listed as category 2A recommendations for: mobilization of hematopoietic progenitor cells in the autologous setting, in combination with plerixafor (for patients with non-Hodgkin's lymphoma or multiple myeloma), mobilization of allogeneic donors, and post-autologous stem cell or cord blood transplant. There is limited data that pegfilgrastim may be equivalent to filgrastim or tbo-filgrastim for mobilization and in the post-transplant setting (category 2A recommendation). Sargramostim may be considered in mobilization, post autologous transplant, and in delayed hematopoietic recovery (category 2A recommendation).25

The European Organization for Research and Treatment of Cancer (EORTC) guidelines from 2006 are similar to the version 2.2013 NCCN guidelines. The EORTC recommends (category A) the use of G-CSF support as primary prophylaxis in patients undergoing chemotherapy regimens where there is a >20% risk of febrile neutropenia. The therapeutic use of G-CSF is considered a category B recommendation and should be limited to patients with septic shock/sepsis syndrome. Also, the EORTC does not recommend one G-CSF product over the other and considers filgrastim and pegfilgrastim to be category A recommended medications. Tbo-filgrastim is not included in these guidelines because it was unavailable at the time of these guidelines were written.

SUMMARY

Neutropenia and febrile neutropenia are serious complications from myelosuppressive chemotherapy. Febrile neutropenia can lead to hospitalization, use of parenteral antibiotics, and possibly death. The use of colony stimulating factors (CSFs) can decrease the severity of neutropenia following myelosuppressive chemotherapy and subsequently decrease the rate of febrile neutropenia.

There are currently four FDA-approved medications that are considered CSFs. Filgrastim (Neupogen®) and tbo-filgrastim (Granix®) are both short-acting G-CSF agents that require daily dosing. Pegfilgrastim (Neulasta®) is the pegylated, long-acting formulation of filgrastim that can be given once per cycle. Sargramostim (Leukine®) is the only FDA-approved GM-CSF product that requires daily dosing. These agents should not be given with 24 hours after receiving chemotherapy but need to be administered within 96 hours of receiving chemotherapy. The preferred route of administration is subcutaneous.24

The NCCN and EOTRC have both published guidelines on the use of G-CSF and GM-CSF medications. Both organizations give their highest recommendation for the use of filgrastim (Neupogen®), pegfilgrastim (Neulasta®), and tbo-filgrastim (Granix®; NCCN guideline only) as primary prophylaxis in patients receiving chemotherapy in which the risk of febrile neutropenia is higher than 20%. Another use of CSFs is the therapeutic use during febrile neutropenia. The NCCN gives the use of these products a category 2A recommendation and the EORTC a category 2 recommendation when used during a febrile neutropenia episode, and should be restricted to patients with serious, life-threatening, documented infections.

While there is limited evidence on the newest product tbo-filgrastim (Granix®), a study by del Giglio et al27 suggests it is superior to placebo and comparable to filgrastim (Neupogen®). Tbo-filgrastim obtained its own FDA-approval and is not labeled a biosimilar to filgrastim (Neupogen®).

ADDENDUM

Adverse Reaction	filgrastim (Neupogen®)	pegfilgrastim (Neulasta®)	sargramostim[3] (Leukine®)	tbo-filgrastim (Granix®)
Asthenia	-	-	15%	-
Bone pain	-	5%	-	3.4%
Diarrhea	-	-	7%	-
Fever	1%	-	-	-
Hypertension	4%[1]	-	-	-
Malaise	-	-	6%	-
Nausea	6%[1]	-	-	-
Pain in extremity	-	5%	-	-
Peripheral edema	-	-	4%	-
Peritonitis	2%[1]	-	-	-
Rash	2%[1]	-	6%	-
Skeletal Pain	11%[2]	-	-	-
Urinary tract disorder	-	-	1%	-
Vomiting	4%[1]	-	-	-

Definitions

Intent-to-Treat: Inclusion of all subjects who received at least one dose of study medication or placebo

Last Observation Carried Forward (LOCF): Method of handling drop-outs wherein the last measurement is utilized as the final outcome data point at study conclusion.

Mixed Model Repeated Measures (MMRM): A statistical model to handle drop outs. Uses repeated measures to define data point outcome trends.

Observed Cases: Method of handling drop-outs, which only includes study completers.

Per-Protocol population: A sub-group of intention to treat population often used to enrich for compliance.

Number Needed to Treat (NNT): The number of subjects required to bring about one response on the primary outcome.

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Exhibit C – Implementation Plan

The following Implementation Plan describes the major task assignments which need to be considered in order to meet PDL, PPL and SMAC program requirements. Goold will comply with all of the requirements outlined above in the RFQ Specification document.

The Implementation Plan begins on the following page.

ID	Task Name	Duration	Start	Finish	Predecessors
0	**WV PDL Prof Serv Project Plan**	**720 days**	**Mon 2/9/15**	**Fri 11/10/17**	
1	Estimated Contract Start Date	0 days	Mon 2/9/15	Mon 2/9/15	
2	Confirm vendor registration status	1 day	Mon 2/9/15	Mon 2/9/15	1
3	Confirm proof of coverage of liability insurance for loss, damage, or injury	1 day	Mon 2/9/15	Mon 2/9/15	1
4	Confirm good standing with the State Agency of Employment Programs	1 day	Mon 2/9/15	Mon 2/9/15	1
5	Provide proof of licensure as requested	1 day	Mon 2/9/15	Mon 2/9/15	1
6	Joint Application Design (JAD) Sessions	2 days	Mon 2/9/15	Tue 2/10/15	1
7	**Implementation**	**32 days**	**Wed 2/11/15**	**Thu 3/26/15**	
8	Review regular meeting schedule	1 day	Wed 2/11/15	Wed 2/11/15	6
9	Review current business rules document	1 day	Wed 2/11/15	Wed 2/11/15	6
10	Submit updated implementation plan for approval	1 day	Wed 2/11/15	Wed 2/11/15	6
11	Submit weekly implementation status reports (recurring throughout Implementation Phase)	5 days	Thu 2/12/15	Wed 2/18/15	10
12	**Pharmaceutical & Therapeutics Committee**	**13 days**	**Wed 2/11/15**	**Fri 2/27/15**	
13	Review theraputic class review/monograph/new drug review templates	2 days	Wed 2/11/15	Thu 2/12/15	6
14	State approves P&T templates	5 days	Fri 2/13/15	Thu 2/19/15	13
15	Plan P&T meeting	2 days	Fri 2/20/15	Mon 2/23/15	14
16	Provide financial information for the P & T Committee for each therapeutic class at least annually	1 day	Tue 2/24/15	Tue 2/24/15	15
17	Provide financial information for the P & T Committee for each new drugs as they are reviewed by the P & T Committee at least quarterly	1 day	Wed 2/25/15	Wed 2/25/15	16
18	Confirm no additional monograph updates are needed	1 day	Thu 2/26/15	Thu 2/26/15	17
19	Review new drugs or drug formulations using a schedule agreed to by the Vendor and BMS, at a minimum quarterly.	1 day	Fri 2/27/15	Fri 2/27/15	18
20	P&T Functions Ready for Operations	0 days	Fri 2/27/15	Fri 2/27/15	19
21	**Preferred Drug List (PDL)**	**32 days**	**Wed 2/11/15**	**Thu 3/26/15**	
22	Meet with fiscal agent to review file requirements for PDL changes and updates	1 day	Wed 2/11/15	Wed 2/11/15	6
23	Review formatting, maintenance needs, file formats, and schedule for all PDL documents, including those publicly posted on website	1 day	Thu 2/12/15	Thu 2/12/15	22
24	Perform PDL data layout and content updates	10 days	Fri 2/13/15	Thu 2/26/15	23
25	State approves PDL	5 days	Fri 2/27/15	Thu 3/5/15	24
26	State/fiscal agent approves updated file feed/layout	5 days	Fri 3/6/15	Thu 3/12/15	25
27	Develop newsletter layouot and initial content	5 days	Fri 3/13/15	Thu 3/19/15	26
28	State approves newsletter	5 days	Fri 3/20/15	Thu 3/26/15	27
29	Ready for PDL Operations	0 days	Thu 3/26/15	Thu 3/26/15	28
30	**State Maximum Allowable Cost (SMAC) Program**	**12 days**	**Thu 2/12/15**	**Fri 2/27/15**	
31	Meet with fiscal agent to review file requirements for SMAC changes and updates	1 day	Thu 2/12/15	Thu 2/12/15	6,22
32	Review formatting, maintenance needs, file formats, and schedule for all SMAC documents, including those publicly posted on website	1 day	Fri 2/13/15	Fri 2/13/15	31

ID	Task Name	Duration	Start	Finish	Predecessors
33	Review current Help Desk operations	1 day	Mon 2/16/15	Mon 2/16/15	32
34	Perform SMAC layout and content updates	3 days	Tue 2/17/15	Thu 2/19/15	33
35	State/vendor approves updated file feed/layout	3 days	Fri 2/20/15	Tue 2/24/15	34
36	Documentation and system review finalized	2 days	Wed 2/25/15	Thu 2/26/15	35
37	State approves final documentation/layouts	1 day	Fri 2/27/15	Fri 2/27/15	36
38	Ready for SMAC Operations	0 days	Fri 2/27/15	Fri 2/27/15	37
39	**Supplemental Rebate Program**	**11 days**	**Wed 2/11/15**	**Wed 2/25/15**	
40	Review SR/OBRA rebate collection with with the State and fiscal agent	1 day	Wed 2/11/15	Wed 2/11/15	6
41	Review formatting, SR agreements, maintenance needs, file formats, and schedule for all SR documents, including those publicly posted on website	1 day	Thu 2/12/15	Thu 2/12/15	40
42	GHS review of layout & signoff	1 day	Fri 2/13/15	Fri 2/13/15	41
43	Documentation and system review finalized	5 days	Mon 2/16/15	Fri 2/20/15	42
44	State and Fiscal Agent approves final documentation and/or file layouts	3 days	Mon 2/23/15	Wed 2/25/15	43
45	Ready for Supplemental Rebate Operations	0 days	Wed 2/25/15	Wed 2/25/15	44
46	**Reporting**	**13 days**	**Wed 2/11/15**	**Fri 2/27/15**	
47	Review and refine current reports, develop and define new standard reports including initial release notes with calculation methodologies, and prototype.	3 days	Wed 2/11/15	Fri 2/13/15	6
48	Update current templates, build new reports	5 days	Mon 2/16/15	Fri 2/20/15	47
49	State approves updates/new reports	5 days	Mon 2/23/15	Fri 2/27/15	48
50	Ready for Reporting Operations	0 days	Fri 2/27/15	Fri 2/27/15	49
51	**Ongoing Operations (The activities and durations below reflect the first cycle of each activity or deliverable. Upon request, GHS can include all recurring operational activities in the final plan)**	**83 days**	**Mon 2/9/15**	**Wed 6/3/15**	
52	Provide access by telephone and/or email to a Board certified psychiatrist physician for clinical advice	1 day	Mon 2/9/15	Mon 2/9/15	1
53	**Pharmaceutical & Therapeutics Committee**	**79 days**	**Fri 2/13/15**	**Wed 6/3/15**	
54	Provide P&T agenda at least thirty-five (35) calendar days prior to meetings	2 days	Mon 3/2/15	Tue 3/3/15	20
55	State approves P&T agenda	5 days	Wed 4/8/15	Tue 4/14/15	54FS+35 edays
56	GHS sends final agenda in PDF format	1 day	Wed 4/15/15	Wed 4/15/15	55
57	State posts final agenda on website	1 day	Thu 4/16/15	Thu 4/16/15	56
58	Develop/update therapeutic class reviews, new drug reviews, and monographs	60 days	Fri 2/13/15	Thu 5/7/15	13
59	Update reporting	2 days	Fri 5/8/15	Mon 5/11/15	58
60	Create clinical packet binder build (tabs, Account Manager letter, CDs, RSVP, etc.)	0.25 days	Tue 5/12/15	Tue 5/12/15	59
61	Prepare clinical packets for Committee members and BMS staff	5 days	Tue 5/12/15	Tue 5/19/15	60
62	Develop, format, and print financial analysis reports for P&T Executive Session	7 days	Tue 5/19/15	Thu 5/28/15	61

ID	Task Name	Duration	Start	Finish	Predecessors
63	State approves financial reports	0.5 days	Thu 5/28/15	Thu 5/28/15	62
64	Deliver the monographs and any other information needed for the P&T Committee meeting via UPS fourteen (14) calendar days prior to meetings.	2 days	Tue 5/19/15	Thu 5/21/15	61
65	**P&T Meeting**	**0.5 days**	**Thu 5/21/15**	**Thu 5/21/15**	**64**
66	Present therapeutic class findings and recommendations to the P&T Committee and BMS	0.25 days	Thu 5/21/15	Thu 5/21/15	64
67	Present SSDC-negotiated supplemental rebates and financial analysis information for each therapeutic class or specific drugs during Executive Session	0.25 days	Thu 5/21/15	Thu 5/21/15	66
68	Submit meeting minutes for approval (delivered within 10 days maximum)	2 days	Thu 5/21/15	Mon 5/25/15	67
69	State approves meeting minutes	5 days	Mon 5/25/15	Mon 6/1/15	68
70	GHS provides minutes in PDF format	0.25 days	Mon 6/1/15	Mon 6/1/15	69
71	State posts meeting minutes	2 days	Tue 6/2/15	Wed 6/3/15	70
72	**Maintain Preferred Drug List**	**19 days**	**Fri 3/13/15**	**Wed 4/8/15**	
73	Update the PDL after each P&T meeting and when major changes are made to the PDL, at a minimum of monthly.	3 days	Fri 3/27/15	Tue 3/31/15	29
74	Assure that the PDL is in compliance with all applicable Federal and State statutes and regulations and the State Plan approved by CMS.	1 day	Wed 4/1/15	Wed 4/1/15	73
75	Apply an effective date and a unique version number for each PDL.	0.25 days	Wed 4/1/15	Wed 4/1/15	73
76	Assist in development of step-care therapy and prior authorization (PA) criteria	2 days	Fri 3/27/15	Mon 3/30/15	29
77	Update the PDL document when PA criteria is changed or updated by the DUR Board and issue an updated version for web posting, at a minimum of monthly.	5 days	Fri 3/27/15	Thu 4/2/15	29
78	Provide written evaluations of Value Added Programs offered in lieu of supplemental rebates, such as disease management programs.	5 days	Fri 3/27/15	Thu 4/2/15	29
79	**PDL Data Files**	**7 days**	**Fri 3/13/15**	**Mon 3/23/15**	
80	Provide the PDL data files for exportation to external sources, including but not limited to the Bureau's Fiscal Agent.	1 day	Fri 3/13/15	Fri 3/13/15	26
81	Provide the PDL data files in accordance with a schedule agreed upon by the Bureau and Vendor, at a minimum of weekly.	7 days	Fri 3/13/15	Mon 3/23/15	26
82	**PDL Communication and Documentation**	**9 days**	**Fri 3/27/15**	**Wed 4/8/15**	
83	Draft letters and/or make telephone calls that respond to inquiries from providers and other interested parties concerning the PDL within five (5) business days of the receipt of the inquiry.	5 days	Wed 4/1/15	Tue 4/7/15	29,73
84	Assist the Bureau with State Plan Amendments related to the PDL.	5 days	Thu 4/2/15	Wed 4/8/15	1,74
85	Fold, stuff, and mail first newsletter	2 days	Fri 3/27/15	Mon 3/30/15	28
86	**Supplemental Rebate Administration**	**60 days**	**Thu 2/26/15**	**Wed 5/20/15**	
87	**Supplemental Rebate Contract Administration**	**33 days**	**Thu 2/26/15**	**Mon 4/13/15**	
88	Work with SSDC partners to accurately determine supplemental rebate contract data	3 days	Thu 2/26/15	Mon 3/2/15	45

ID	Task Name	Duration	Start	Finish	Predecessors
89	Produce and facilitate the signing of supplemental rebate contracts with pharmaceutical manufacturers, the Bureau, and the Secretary of DHHR.	30 days	Tue 3/3/15	Mon 4/13/15	88
90	Track contracts and documents at all points from origin to completion.	30 days	Tue 3/3/15	Mon 4/13/15	88
91	Assure that both BMS and manufacturers receive an original signed agreement/contact.	30 days	Tue 3/3/15	Mon 4/13/15	88
92	**Supplemental Unit Rebate Amounts (SURA) File**	**60 days**	**Thu 2/26/15**	**Wed 5/20/15**	
93	Provide SURA files to the Bureau and its Fiscal Agent within sixty (60) calendar days of the end of a quarter	60 days	Thu 2/26/15	Wed 5/20/15	45
94	Provide data, including but not limited to current and prior quarter adjustment data necessary for BMS to invoice manufacturers on a quarterly basis for supplemental rebates	1 day	Thu 2/26/15	Thu 2/26/15	45
95	Coordinate supplemental rebate submission with submission of traditional Federal rebates.	5 days	Thu 2/26/15	Wed 3/4/15	45
96	Provide necessary documentation to the Bureau and/or its designee to support supplemental rebate invoicing at the NDC level	5 days	Thu 2/26/15	Wed 3/4/15	45
97	**Dispute Resolution Services**	**5 days**	**Thu 2/26/15**	**Wed 3/4/15**	
98	Communicate directly with manufacturers to resolve disputes arising from supplemental rebate calculations or contract issues within five (5) business days of receipt of the dispute.	5 days	Thu 2/26/15	Wed 3/4/15	45
99	Communicate directly with manufacturers regarding unpaid supplemental rebates upon request by BMS.	3 days	Thu 2/26/15	Mon 3/2/15	45
100	Communicate the resolution of disputes in a written document to BMS, within one (1) business day of resolution.	1 day	Thu 2/26/15	Thu 2/26/15	45
101	**State Maximum Allowable Cost Program**	**69 days**	**Tue 2/17/15**	**Fri 5/22/15**	
102	**State Maximum Allowable Cost (SMAC) List**	**60 days**	**Mon 3/2/15**	**Fri 5/22/15**	
103	Update the SMAC list no less than quarterly, and as modifications occur.	60 days	Mon 3/2/15	Fri 5/22/15	38
104	Ensure that each SMAC list submitted has an effective date and a unique version number.	0.25 days	Mon 3/2/15	Mon 3/2/15	38
105	Update the Fiscal Agent with SMAC changes approved by the Bureau.	1 day	Mon 3/2/15	Mon 3/2/15	38
106	Coordinate activities with the Fiscal Agent to support the implementation and updates of the SMAC list.	1 day	Mon 3/2/15	Mon 3/2/15	38
107	Review opportunities for expansion of the SMAC pricing list and regularly report the Vendor's SMAC activities monthly	1 day	Mon 3/2/15	Mon 3/2/15	38
108	Collect acquisition cost data and other required source information to support SMAC pricing.	1 day	Mon 3/2/15	Mon 3/2/15	38
109	Prepare for, attend in person and facilitate the meetings with the provider industry, interested parties, and internal work groups in regard to the SMAC program, at a minimum of quarterly.	1 day	Mon 3/2/15	Mon 3/2/15	38
110	Develop alternative SMAC reimbursement models for the Bureau's consideration when requested by BMS, at a minimum annually.	5 days	Mon 3/2/15	Fri 3/6/15	38

ID	Task Name	Duration	Start	Finish	Predecessors
111	Coordinate the addition of drugs for SMAC pricing with drugs in the same therapeutic category on the PDL to ensure that the PDL and SMAC activities result in the most cost effective results.	1 day	Fri 3/6/15	Fri 3/6/15	
112	**WV Provider Pricing Support and Dispute Resolution**	**20 days**	**Tue 2/17/15**	**Mon 3/16/15**	
113	Acknowledge disputes within one (1) business day of receipt	1 day	Tue 2/17/15	Tue 2/17/15	33
114	Submit pricing disputes within fourteen (14) calendar days of the date of the complaint	14 days	Wed 2/18/15	Mon 3/9/15	113
115	State approves disputes	5 days	Tue 3/10/15	Mon 3/16/15	114
116	**Reports**	**60.75 days**	**Mon 3/2/15**	**Mon 5/25/15**	
117	Update BMS Pharmacy Monthly Utilization (required every 30 days)	2 days	Tue 5/12/15	Wed 5/13/15	50,59
118	Update BMS Pharmacy Annual Utilization	5 days	Tue 5/12/15	Mon 5/18/15	50,59
119	Update BMS Summary Monthly Report (required every 30 days)	2 days	Tue 5/12/15	Wed 5/13/15	50,59
120	Update BMS Summary Annual Report	5 days	Tue 5/12/15	Mon 5/18/15	50,59
121	Update Marketshare Summary Report (required every 90 days)	2 days	Tue 5/12/15	Wed 5/13/15	50,59
122	Update Therapeutic Class Marketshare Report (required every 90 days)	2 days	Tue 5/12/15	Wed 5/13/15	50,59
123	Update Generic Compliance Report (required every 90 days)	2 days	Tue 5/12/15	Wed 5/13/15	50,59
124	Update PDL Compliance Report (required every 90 days)	2 days	Tue 5/12/15	Wed 5/13/15	50,59
125	Update PDL Savings Report (required every 90 days)	2 days	Tue 5/12/15	Wed 5/13/15	50,59
126	Update WV Provider Pricing Support and Dispute Resolution Report (required every 30 days)	2 days	Mon 3/2/15	Tue 3/3/15	50,45
127	Update PDL Changes Report (required 14 days after P & T)	2 days	Thu 5/21/15	Mon 5/25/15	50,65
128	Update Rebate Dispute Status Report (required every 30 days)	2 days	Mon 3/2/15	Tue 3/3/15	50,45
129	Update Supplemental Rebate Contract Tracking Report (required every 30 days)	2 days	Mon 3/2/15	Tue 3/3/15	50,45
130	Update Supplemental Rebate Contract Details Report (required every 30 days)	2 days	Mon 3/2/15	Tue 3/3/15	50,45
131	Update Supplemental Rebate Pricing File Quality Assurance Checklist (required every 30 days)	2 days	Mon 3/2/15	Tue 3/3/15	50,45
132	Update Supplemental Rebate Pricing File Additions and Corrections Report (required every 30 days)	2 days	Mon 3/2/15	Tue 3/3/15	50,45
133	Update Supplemental Rebate Pricing File Spreadsheet (required every 90 days)	2 days	Mon 3/2/15	Tue 3/3/15	50,45
134	Update SMAC Savings Beyond Aggregate FUL Cap (required every 90 days)	2 days	Mon 3/2/15	Tue 3/3/15	50,38
135	Update SMAC Savings Report (required every 30 days)	2 days	Mon 3/2/15	Tue 3/3/15	50,38
136	Update SMAC Dispute Report (required every 7 days)	2 days	Mon 3/2/15	Tue 3/3/15	50,38
137	**Ad Hoc Reports**	**9 days**	**Mon 3/2/15**	**Thu 3/12/15**	
138	Provide to the Bureau ad hoc reports when requested and shall include the report methodology and parameters used in developing the report.	2 days	Mon 3/2/15	Tue 3/3/15	50
139	Deliver the ad hoc reports desired by the Bureau in accordance with the schedule and delivery method approved by the Bureau.	2 days	Wed 3/4/15	Thu 3/5/15	138

ID	Task Name	Duration	Start	Finish	Predecessors
140	State approves ad hoc reports	5 days	Fri 3/6/15	Thu 3/12/15	139
141	**Turnover and Contract Closeout Services**	**30 days**	**Mon 10/2/17**	**Fri 11/10/17**	
142	Receive notification to initiate Close-Out and Turnover	0 days	Mon 10/2/17	Mon 10/2/17	
143	Submit Training Handbook	1 day	Mon 10/2/17	Mon 10/2/17	142
144	Provide the Close-Out and Turnover Plan within thirty (30) calendar days of receiving BMS notification to initiate the Close-out and Turnover Phase.	30 days	Mon 10/2/17	Fri 11/10/17	142
145	Submit data, deliverables, and reports no later than thirty (30) days prior to the end of the contract.	30 days	Mon 10/2/17	Fri 11/10/17	142
146	Submit Turnover Results Report no later than thirty (30) days prior to the end of the contract.	30 days	Mon 10/2/17	Fri 11/10/17	142
147	**Additional Services**	**12.5 days**	**Mon 2/9/15**	**Wed 2/25/15**	
148	The Vendor shall provide a pool of hours annually that can be used by BMS for assistance, advice and consultation for Medicaid pharmacy activities.	12.5 days	Mon 2/9/15	Wed 2/25/15	1
149	**PROJECT MANAGEMENT - ONGOING**	**1 day**	**Wed 10/4/17**	**Wed 10/4/17**	
150	GHS will be available for appearances before the West Virginia Legislature or other interested parties as requested by BMS at a minimum of four (4) and maximum of six (6) times per calendar year.	1 day	Wed 10/4/17	Wed 10/4/17	
151	Provide notice of changes in staff regarding the account manager, clinical pharmacist, physician, rebate manager and SMAC pricing manager	1 day	Wed 10/4/17	Wed 10/4/17	
152	Facilitate status meetings with BMS including providing meeting agendas and minutes	1 day	Wed 10/4/17	Wed 10/4/17	

Exhibit D – Proof of Insurance

Goold holds the appropriate levels of insurance required by West Virginia for performance of the services under this RFQ. Upon contract award, Goold will work with the necessary State officials to finalize the required documentation. The following is proof of insurance held by Goold as of December 2014.

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 11/17/2014

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER	CONTACT NAME:	
MARSH USA, INC. TWO ALLIANCE CENTER 3560 LENOX ROAD, SUITE 2400 ATLANTA, GA 30326 Attn: Atlanta.CertRequest@marsh.com Fax: 212-948-4321 38472 -EMDEO-E&O-14-15	PHONE (A/C, No, Ext):	FAX (A/C, No):
	E-MAIL ADDRESS:	
	INSURER(S) AFFORDING COVERAGE	NAIC #
	INSURER A : National Union Fire Ins Co Pittsburgh PA	19445
INSURED EMDEON, INC. 3055 LEBANON ROAD NASHVILLE, TN 37214	INSURER B :	
	INSURER C :	
	INSURER D :	
	INSURER E :	
	INSURER F :	

COVERAGES **CERTIFICATE NUMBER:** ATL-003041898-14 **REVISION NUMBER:** 1

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSR	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
	GENERAL LIABILITY						EACH OCCURRENCE	$
	☐ COMMERCIAL GENERAL LIABILITY						DAMAGE TO RENTED PREMISES (Ea occurrence)	$
	☐ CLAIMS-MADE ☐ OCCUR						MED EXP (Any one person)	$
							PERSONAL & ADV INJURY	$
							GENERAL AGGREGATE	$
	GEN'L AGGREGATE LIMIT APPLIES PER:						PRODUCTS - COMP/OP AGG	$
	☐ POLICY ☐ PRO-JECT ☐ LOC							$
	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident)	$
	☐ ANY AUTO						BODILY INJURY (Per person)	$
	☐ ALL OWNED AUTOS ☐ SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	☐ HIRED AUTOS ☐ NON-OWNED AUTOS						PROPERTY DAMAGE (Per accident)	$
								$
	☐ UMBRELLA LIAB ☐ OCCUR						EACH OCCURRENCE	$
	☐ EXCESS LIAB ☐ CLAIMS-MADE						AGGREGATE	$
	☐ DED ☐ RETENTION $							$
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y / N						☐ WC STATU-TORY LIMITS ☐ OTH-ER	
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? N (Mandatory in NH)	N / A					E.L. EACH ACCIDENT	$
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$
							E.L. DISEASE - POLICY LIMIT	$
A	PROFESSIONAL LIABILITY			01-842-26-12	11/16/2014	11/16/2015	LIMIT	1,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (Attach ACORD 101, Additional Remarks Schedule, If more space is required)

CERTIFICATE HOLDER	CANCELLATION
EMDEON, INC. 3055 LEBANON PIKE NASHVILLE, TN 37214	SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.
	AUTHORIZED REPRESENTATIVE of Marsh USA Inc. Stephen R. Earp

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CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 11/17/2014

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER MARSH, INC. 1801 WEST END AVE., SUITE 1500 NASHVILLE, TN 37203 Attn: Tammy.A.Adcock@marsh.com 38472 -EMDEO-GAWU-14-15	CONTACT NAME: PHONE (A/C, No, Ext): FAX (A/C, No): E-MAIL ADDRESS:
INSURED EMDEON BUSINESS SERVICES, LLC, EMDEON, INC. 3055 LEBANON PIKE NASHVILLE, TN 37214	INSURER(S) AFFORDING COVERAGE — NAIC # INSURER A : Charter Oak Fire Insurance Company — 25615 INSURER B : N/A — N/A INSURER C : N/A — N/A INSURER D : N/A — N/A INSURER E : — INSURER F : —

COVERAGES **CERTIFICATE NUMBER:** ATL-003036707-16 **REVISION NUMBER:** 3

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSR	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	GENERAL LIABILITY			HO-GLSA- 157D3875-COF-14	11/16/2014	11/16/2015	EACH OCCURRENCE	$ 1,000,000
	X COMMERCIAL GENERAL LIABILITY						DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 1,000,000
	CLAIMS-MADE X OCCUR						MED EXP (Any one person)	$ 10,000
							PERSONAL & ADV INJURY	$ 1,000,000
							GENERAL AGGREGATE	$ 2,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						PRODUCTS - COMP/OP AGG	$ 2,000,000
	X POLICY PRO-JECT LOC							$
	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident)	$
	ANY AUTO						BODILY INJURY (Per person)	$
	ALL OWNED AUTOS / SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	HIRED AUTOS / NON-OWNED AUTOS						PROPERTY DAMAGE (Per accident)	$
								$
	UMBRELLA LIAB OCCUR						EACH OCCURRENCE	$
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	$
	DED RETENTION $							$
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY						WC STATU-TORY LIMITS / OTH-ER	
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? Y / N (Mandatory in NH)	N / A					E.L. EACH ACCIDENT	$
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$
							E.L. DISEASE - POLICY LIMIT	$

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (Attach ACORD 101, Additional Remarks Schedule, if more space is required)

CERTIFICATE HOLDER	CANCELLATION
Emdeon Inc. 3055 Lebanon Road Nashville, TN 37214	SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS. AUTHORIZED REPRESENTATIVE of Marsh USA Inc. Stephen R. Earp

ACORD 25 (2010/05) The ACORD name and logo are registered marks of ACORD

RESPONSE TO REQUEST FOR QUOTATION
Preferred Drug, Product List, and State Allowable Cost Services

TECHNICAL AND COST PROPOSAL
ORIGINAL

Submitted December 22, 2014

Prepared for:
Health and Human Resources
Bureau of Medical Services
350 Capitol Street, Rm 251
Charleston, WV 25301-3709

Prepared by:
Goold Health Systems,
an Emdeon company
45 Commerce Drive, Suite 5
P.O. Box 1090
Augusta, Maine 04332-1090
Phone: 800-832-9672
Fax: 207-623-5125
www.ghsinc.com

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PO Box 1090
Augusta, Maine, 04332-1090
www.ghsinc.com

Tel: 207.622.7153
800.832.9672
Fax: 207.623.5125

Transmittal Letter

December 8, 2014

Mr. Robert Kilpatrick
Department of Administration, Purchasing Division
2019 Washington Street East
Charleston, West Virginia 25305-0130

Dear Mr. Kilpatrick:

On behalf of Goold Health Systems ("GHS" or "Goold"), an Emdeon company, I am pleased to present the State of West Virginia's Bureau of Medical Services, hereinafter referred to as "BMS" or "the State", with our response to the Request for Quotation ("RFQ") for Preferred Drug/Product List and State Maximum Allowable Cost Services.

As Vice President, I am authorized to bind Goold to all statements, including services and prices contained in the proposal and to lead negotiations on behalf of the company in conjunction with our legal team. I shall be responsible for the overall management of any potential contract as a result of this RFQ, including any requests for clarification or other communication needed between the State staff and Goold. My contact information is as follows:

James A. Clair
Vice President
Goold Health Systems, an Emdeon company
45 Commerce Drive, Suite 5
P.O. Box 1090
Augusta, Maine 04332-1090

P: 800.832.9672
C: 207.242.2715
F: 207.623.5125
E: jclair@ghsinc.com

As required by the RFQ, Goold is submitted our response through the wvOasis online procurement system. All signed documents, Goold's response to the technical proposal, attachments, and price proposal have been submitted electronically.

Per the RFQ Specification document, Goold makes the following certifications to the best of its information, knowledge and belief:

(1) Goold's bid has been made without prior understanding, agreement, or connection with any corporation, firm, limited liability company, partnership, person or entity submitting a bid or offer for the same material, supplies, equipment or services;
(2) Goold's bid is in all respects fair and without collusion or fraud;
(3) A Contract as a result of this bid will be accepted or entered into without any prior understanding, agreement, or connection to any other entity that could be considered a violation of law;

PO Box 1090
Augusta, Maine, 04332-1090
www.ghsinc.com

Tel: 207.622.7153
800.832.9672
Fax: 207.623.5125

(4) The Solicitation has been reviewed in its entirety and Goold understands the requirements, terms and conditions, and other information contained herein;
(5) By signing this bid, Goold also affirms that neither it nor its representatives have any interest, nor shall acquire any interest, direct or indirect, which would compromise the performance of its services hereunder. Any such interests will be promptly presented in detail to the Agency; and
(6) To the best of our knowledge, Goold has properly registered with any State agency that may require registration.

Goold Health Systems has a long history of effective collaboration with our State Medicaid Agency partners to deliver projects on-time and on-budget. We would be honored to serve as the vendor for BMS' Preferred Drug/Product List and State Maximum Allowable Cost Services once again. It is our objective to bring the State of West Virginia a solution with excellent customer service and cost-effective pharmacy services that will improve clinical outcomes, and increase savings for tax payers with a focus on the future of Medicaid for West Virginia. We have built our pharmacy support systems and services to be accountable, flexible, scalable, and transparent.

GHS will carry out all contract responsibilities in the same highly professional and successful manner to which you were accustomed. Our commitment is to establish a transparent, quality partnership that will allow West Virginia's Bureau for Medical Services to meet its operational and financial objectives.

We thank you for your time and consideration of our proposal. We look forward to answering any questions you might have, providing any other information you might request, and working with the West Virginia staff again in the near future.

Sincerely,

James A. Clair
Vice President

Table of Contents

Figures and Tables:

Figures:

Tables:

Signed Documents

RFQ Signature Page

Purchasing Divison
2019 Washington Street East
Post Office Box 50130
Charleston, WV 25305-0130

State of West Virginia
Request for Quotation

Proc Folder: 26403
Doc Description: Addendum 2: PDL/PPL/SMAC Services
Proc Type: Central Master Agreement

Date Issued	Solicitation Closes	Solicitation No	Version
2014-12-10	2014-12-23 13:30:00	CRFQ 0511 BMS1500000003	3

BID RECEIVING LOCATION

BID CLERK
DEPARTMENT OF ADMINISTRATION
PURCHASING DIVISION
2019 WASHINGTON ST E
CHARLESTON WV 25305
US

VENDOR

Vendor Name, Address and Telephone Number:

FOR INFORMATION CONTACT THE BUYER

Robert Kilpatrick
(304) 558-0067
robert.p.kilpatrick@wv.gov

Signature X  FEIN # 01-0475134 DATE December 19, 2014

All offers subject to all terms and conditions contained in this solicitation

Page : 1 FORM ID : WV-PRC-CRFQ-001

Certification and Signature Page

CERTIFICATIONAND SIGNATURE PAGE

By signing below, or submitting documentation through wvOASIS, I certify that I have reviewed this Solicitation in its entirety; understand the requirements, terms and conditions, and other information contained herein; that I am submitting this bid, offer or proposal for review and consideration; that I am authorized by the vendor to execute and submit this bid, offer, or proposal, or any documents related thereto on vendor's behalf; that I am authorized to bind the vendor in a contractual relationship; and that to the best of my knowledge, the vendor has properly registered with any State agency that may require registration.

Goold Health Systems, an Emdeon company
(Company)

James A. Clair, Vice President
(Authorized Signature) (Representative Name, Title)

P: (800) 832-9672 F: (207) 623-5125 December 8, 2014
(Phone Number) (Fax Number) (Date)

Revised 08/08/2014

Purchasing Affidavit

CRFQ 0511
RFQ No. BMS15000000003

STATE OF WEST VIRGINIA
Purchasing Division

PURCHASING AFFIDAVIT

MANDATE: Under W. Va. Code §5A-3-10a, no contract or renewal of any contract may be awarded by the state or any of its political subdivisions to any vendor or prospective vendor when the vendor or prospective vendor or a related party to the vendor or prospective vendor is a debtor and: (1) the debt owed is an amount greater than one thousand dollars in the aggregate; or (2) the debtor is in employer default.

EXCEPTION: The prohibition listed above does not apply where a vendor has contested any tax administered pursuant to chapter eleven of the W. Va. Code, workers' compensation premium, permit fee or environmental fee or assessment and the matter has not become final or where the vendor has entered into a payment plan or agreement and the vendor is not in default of any of the provisions of such plan or agreement.

DEFINITIONS:

"Debt" means any assessment, premium, penalty, fine, tax or other amount of money owed to the state or any of its political subdivisions because of a judgment, fine, permit violation, license assessment, defaulted workers' compensation premium, penalty or other assessment presently delinquent or due and required to be paid to the state or any of its political subdivisions, including any interest or additional penalties accrued thereon.

"Employer default" means having an outstanding balance or liability to the old fund or to the uninsured employers' fund or being in policy default, as defined in W. Va. Code § 23-2c-2, failure to maintain mandatory workers' compensation coverage, or failure to fully meet its obligations as a workers' compensation self-insured employer. An employer is not in employer default if it has entered into a repayment agreement with the Insurance Commissioner and remains in compliance with the obligations under the repayment agreement.

"Related party" means a party, whether an individual, corporation, partnership, association, limited liability company or any other form or business association or other entity whatsoever, related to any vendor by blood, marriage, ownership or contract through which the party has a relationship of ownership or other interest with the vendor so that the party will actually or by effect receive or control a portion of the benefit, profit or other consideration from performance of a vendor contract with the party receiving an amount that meets or exceed five percent of the total contract amount.

AFFIRMATION: By signing this form, the vendor's authorized signer affirms and acknowledges under penalty of law for false swearing (*W. Va. Code* §61-5-3) that neither vendor nor any related party owe a debt as defined above and that neither vendor nor any related party are in employer default as defined above, unless the debt or employer default is permitted under the exception above.

WITNESS THE FOLLOWING SIGNATURE:

Vendor's Name: Goold Health Systems, an Emdeon company

Authorized Signature: _____ Date: 12/16/2014

State of Tennessee

County of Davidson, to-wit:

Taken, subscribed, and sworn to before me this 15th day of December, 2014

My Commission expires July 6, 2015

AFFIX SEAL HERE

ROBIN R. NICHOLSON
STATE OF TENNESSEE NOTARY PUBLIC
DAVIDSON COUNTY

MY COMMISSION EXPIRES:
July 6, 2015

NOTARY PUBLIC Robin R. Nicholson

Purchasing Affidavit (Revised 07/01/2012)

Addendum Acknowledgement #1

ADDENDUM ACKNOWLEDGEMENT FORM
SOLICITATION NO.: HHR1500000003

Instructions: Please acknowledge receipt of all addenda issued with this solicitation by completing this addendum acknowledgment form. Check the box next to each addendum received and sign below. Failure to acknowledge addenda may result in bid disqualification.

Acknowledgment: I hereby acknowledge receipt of the following addenda and have made the necessary revisions to my proposal, plans and/or specification, etc.

Addendum Numbers Received:
(Check the box next to each addendum received)

[X]	Addendum No. 1	[ ]	Addendum No. 6
[ ]	Addendum No. 2	[ ]	Addendum No. 7
[ ]	Addendum No. 3	[ ]	Addendum No. 8
[ ]	Addendum No. 4	[ ]	Addendum No. 9
[ ]	Addendum No. 5	[ ]	Addendum No. 10

I understand that failure to confirm the receipt of addenda may be cause for rejection of this bid. I further understand that any verbal representation made or assumed to be made during any oral discussion held between Vendor's representatives and any state personnel is not binding. Only the information issued in writing and added to the specifications by an official addendum is binding.

Goold Health Systems, an Emdeon company
Company

Authorized Signature

December 19, 2014
Date

NOTE: This addendum acknowledgement should be submitted with the bid to expedite document processing.
Revised 6/8/2012

Addendum Acknowledgement #2

ADDENDUM ACKNOWLEDGEMENT FORM
SOLICITATION NO.: HHR1500000003

Instructions: Please acknowledge receipt of all addenda issued with this solicitation by completing this addendum acknowledgment form. Check the box next to each addendum received and sign below. Failure to acknowledge addenda may result in bid disqualification.

Acknowledgment: I hereby acknowledge receipt of the following addenda and have made the necessary revisions to my proposal, plans and/or specification, etc.

Addendum Numbers Received:
(Check the box next to each addendum received)

[ ]	Addendum No. 1	[ ]	Addendum No. 6
[X]	Addendum No. 2	[ ]	Addendum No. 7
[ ]	Addendum No. 3	[ ]	Addendum No. 8
[ ]	Addendum No. 4	[ ]	Addendum No. 9
[ ]	Addendum No. 5	[ ]	Addendum No. 10

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Goold Health Systems, an Emdeon company
Company

Authorized Signature

December 19, 2014
Date

NOTE: This addendum acknowledgement should be submitted with the bid to expedite document processing.
Revised 6/8/2012

Executive Summary

Goold Health Systems (Goold), *an Emdeon company*, is pleased to present to the State of West Virginia Bureau of Medical Services (BMS or Bureau) with our proposal for Preferred Drug/ Product List and State Maximum Allowable Cost Services, CRFQ# 0511 BMS1500000003.

Goold has ***40 years of experience in providing Pharmacy Benefit Management (PBM) services and solutions to state Medicaid programs***. We presently provide a wide range of value-driven Medicaid pharmacy services in **sixteen (16) states**. Our expertise includes robust clinical management, account management, analytics, cost management, claims processing, Preferred Drug List (PDL)/ formulary management, and rebate negotiations, contracting and processing. Goold prides itself on building ongoing personal relationships, producing consistent and reliable deliverables and being responsive to our clients – **customer service and satisfaction are our priority.**

The Goold-West Virginia Advantage

- Qualified, Account Manager, staffing, and partners;
- Experience with large healthcare payers;
- Innovative clinical results;
- Trusted partnerships;
- Long history of providing quality customer service; and
- Full transparency with our State clients.

Goold welcomes the opportunity to once again provide the State of West Virginia with excellent customer service and cost-effective pharmacy services that will maintain and improve the quality of life to the citizens that rely on Medicaid. We have built our pharmacy support systems and services to be ACCOUNTABLE, FLEXIBLE, SCALABLE, AND TRANSPARENT. Our solution will meet or exceed the Bureau's requirements.

Experienced - Goold is well positioned to provide cost-effective PDL, PPL and SMAC services for the West Virginia's program as we have serviced this contract for the State before. Goold's current and historical PDL design experience includes West Virginia, as well as Iowa, Maine, Mississippi, and Wyoming. In 2015, Vermont will be included to make a total of six states for which we provide, or have provided, PDL design services. These services are provided for the nearly 2.5 million recipients for the six listed states. Goold has experience working with Medicaid programs of different sizes and with varying program and benefit designs.

Goold currently negotiates with pharmaceutical and DME manufacturers for rebates on behalf of nine state Medicaid pharmacy programs. We have acted as the vendor to the Sovereign States Drug Consortium (SSDC) since its origination and recently re-secured the contract for another four years. In addition to the eight states in the SSDC multistate pool, we also negotiate and contract for these rebates for Georgia Medicaid as a single state program. As an SSDC Member State, West Virginian recognizes the many benefits of the SSDC negotiation process that Goold has been dedicated to and has worked hard to tailored to the Member States.

In addition to our rebate negotiation services, Goold also provides the following states with other programs and services related to rebate and PDL management:

- Preferred Drug List (PDL) and Supplemental Rebate (SR) invoicing for the State of Mississippi;
- Full CMS, supplemental, J-code, managed care organization (MCO) pharmacy and MCO J-code rebate services for the State of Georgia;
- CMS, supplemental, J-code, and DME (including diabetic supply) rebate services for the State of Iowa;
- CMS, SR, DME, Prescription Drug Assistance Program (PDAP) and Aids Drug Assistance Program (ADAP) services for the State of Wyoming;
- Management of the Supplemental Rebate contracts process for Georgia, Iowa, Maine, Mississippi, and Wyoming; and
- Previously provided Preferred Drug List (PDL), Pharmacy & Therapeutic (P&T) Committee support and Supplemental Rebate (SR) contract management and State Maximum Allowable Cost services to the State of West Virginia.

Qualified Staff - Goold will be providing qualified staff to BMS with our pharmacy PDL/PPL and SMAC services team, allowing the State to maintain its commitment to members and providers, and avoid any unnecessary disruption of services. This qualified team has previously worked with BMS and achieved excellent results during our tenure. ***Goold's services are an orchestrated combination of technology and professional services. It is our people that make the difference.***

We've named experienced account manager, [redacted] clinical subject matter expert, has in-depth PDL and SMAC experience, as well as P&T committee presentation expertise. Goold will provide a highly skilled team of physicians, pharmacists, project managers, data analysts, rebate contract specialists, and others to the State. Our West Virginia team, collectively, has decades of experience in Medicaid PDL and SMAC operations that will be shared with BMS staff in order to further the agency's goals.

Partnership - Goold will partner with West Virginia to assure access to safe, efficacious, and clinically appropriate drug therapies at the lowest possible cost. During our partnership as the West Virginia contractor for these services in the past, Goold created a professional and trusting relationship with the involved parties. ***We will, once again, work with the Bureau to build a relationship that is based on trust and is reinforced by our commitment to BMS. Unlike companies that might have conflicts such as ownership of a commercial PBM, Goold has no such outside arrangements – our goals and visions are, by definition, the goals and visions of our customer and partner, the State of West Virginia.***

Our overall process will help reduce the administrative burdens that impact the State, providers, and beneficiaries. We will approach this project as a collaborative effort between all

stakeholders at Goold, BMS, the State, and other vendors. Goold is committed and well positioned to deliver an innovative Preferred Drug/Product List and SMAC Program that will help the State administer a highly effective and fiscally accountable Medicaid pharmacy benefit.

The Goold / West Virginia PDL/PPL and SMAC Solution

PREFERRED DRUG/PRODUCT LIST (PDL/PPL):

Goold Preferred Drug List Administration

- **Eleven (+)** years of experience in PDL services;
- PDL compliance currently **exceeds 96%;**
- Current and historical PDL design and management for **five states**, including Iowa, Maine, Mississippi, West Virginia and Wyoming, and beginning in 2015 for Vermont as the sixth state; and
- Recently, added **thirteen new PDL categories** for the Mississippi PDL program with much success.

Efficient and effective management of Medicaid PDLs is an area of excellence for Goold. Our PDL/PPL solution and supporting tools have been built to offer the maximum amount of rule capabilities as possible. Our PDL/PPL programs are aimed to optimize net savings for clients with minimal burden on clients, providers and members. ***Goold considers a clinically and financially sound PDL to be a key component to an effective pharmacy program.*** A carefully designed and closely monitored PDL will allow state Medicaid Programs to realize significant savings while maintaining or improving clinical outcomes. We have achieved this goal for each state Medicaid program that we have worked with, and will do the same for West Virginia.

STATE MAXIMUM ALLOWABLE COST (SMAC) SERVICES:

Goold's philosophy regarding SMAC rate schedules is based on the belief that chemically equivalent drug products in the same strength, dosage form, and package size available from multiple sources should be reimbursed similarly. SMACs are designed to maximize the cost-effectiveness of pharmacy services by setting reimbursement amounts for brand name and therapeutically equivalent drug products at the same price, based on the cost of the products to pharmacies. The SMAC rate usually applies to both the brand and generic drug products. The Centers for Medicare and Medicaid Services (CMS) uses the same rationale to establish Federal Upper Limits (FULs) for drug products – Effectively, SMAC rates are State Medicaid program equivalents of CMS FULs.

Goold has used its wealth of knowledge and experience in the Pharmacy Benefit Services Administration (PBSA) industry to accomplish the objectives for our clients, achievements that have been recognized nationwide as leading edge and extremely cost effective. In addition to 11 years of SMAC management experience, Goold has more than 20 years of electronic Pharmacy Point-of-Sale (POS) pharmacy claims processing, 15 years of drug rebate management, 11 years of Preferred Drug List (PDL) maintenance, and 10 years of Prior Authorization (PA) experience. Goold also helped form, and currently manages, the Sovereign States Drug Consortium (SSDC), a multi-state rebate pooling program. This collective, related

experience provides our clinical and management teams with insights into the many other aspects of pharmacy benefit management that influence SMAC rate management.

We presently support the Medicaid SMAC programs for the States of Illinois, Maine, Minnesota, New Jersey, North Dakota, South Dakota, Utah, Vermont and Wyoming. This collection of diverse state clients helps Goold realize the challenges and opportunities for MAC programs in both rural and urban settings.

REPORT MANAGEMENT:

Goold will leverage our Goold Analytics solution to support the ongoing reporting and analysis needs of the State and those who support the scope of work presented in this RFQ. Goold has a team of experienced healthcare data analysts in-house who manage and support the Goold Analytics solution. This team is also responsible for preparing customized and standard (recurring) reporting and analysis for our clients. They too are a key component of the overall Goold Analytics solution, providing knowledge, guidance, and consultation related to Medicaid pharmacy reference data and the construction of complex ad-hoc reports and long-term analysis. ***Analytics rely on quality data and knowledgeable staff that work with our analysts to create a clear, concise scope based on the needs of the client.***

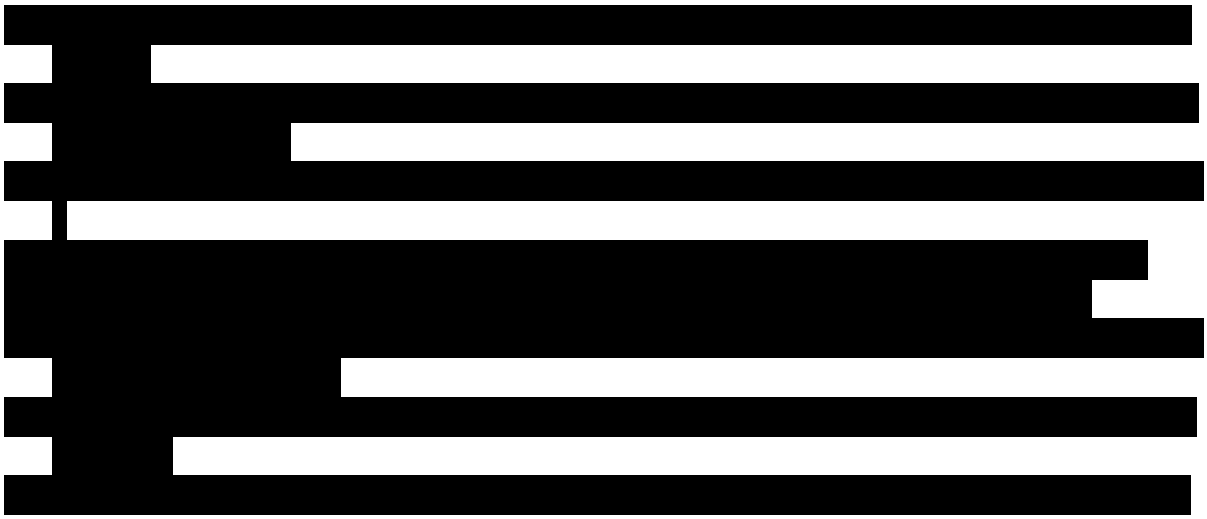
The West Virginia / Goold Team

Goold has assembled a well-qualified team of professionals that will be carrying out the duties required for operation of the West Virginia Preferred Drug/Product List and State Maximum Allowable Cost Services. Our experienced team has worked with the West Virginia pharmacy team and will allow BMS to maintain its commitment to its members, providers and taxpayers through an effectively managed Medicaid PDL, PPL and SMAC program

Our team has centuries of collective experience in pharmacy benefit administration, PDL design, SR negotiations and contracting, drug rebate management, healthcare data analytics, SMAC management, participation in clinical drug trials, drug literature evaluation, and, importantly, direct patient care. This team, supported by a strong corporate management team, enables Goold to provide effective and leading-edge Medicaid pharmacy solutions.

The West Virginia / Goold team includes a core set of key personnel, supported by a dedicated support and operations team:

[redacted]



The West Virginia / Goold team, as well as the Goold / Emdeon corporate management, pledges our commitment to provide the proper resources to effectively manage the program and operate the systems described in this proposal.

Project Timeframe

With years of experience as a Medicaid Pharmacy Benefits Administration vendor, Goold is familiar with a number of different approaches used by states transitioning to a new vendor, including those used in West Virginia. We have been working with State Medicaid programs to improve efficiency and apply cost effective management practices to pharmacy benefits since the days of paper claims and continue to do so in today's technologically and clinically sophisticated environment. The Goold team has implemented numerous and varied complex pharmacy services on time and on budget. **After carefully examining the scope of services included in this RFQ, we are confident it is possible to implement these services within a timeframe that is satisfactory to BMS.** Goold will work with the Bureau to achieve the desired timeline for this project, taking into consideration the current vendor and/or any other project constraints.

Summary and Closing

Goold is distinctive in our approach to working in a collaborative, customer-centric fashion with State Medicaid Programs. Goold builds ongoing personal relationships, produces consistent and reliable deliverables, and places a priority on being responsive to our clients. The Goold approach is built upon client partnerships, fiduciary responsibility, transparency, technology adoption, and project stakeholder outreach.

We are a company focused on providing the high quality, cost-effective pharmacy solutions for public health benefits administration in partnership with our State clients. We maintain high standards of integrity, cooperation, and insight for all services we provide. Our decades of

clinically-focused, cost-effective State Medicaid Pharmacy experience make us the right choice for the West Virginia Preferred Drug/Product List and State Maximum Allowable Cost Services.

Mandatory Requirements (RFP Section 4)

4.1 Mandatory Contract Services Requirements and Deliverables: Contract Services must meet or exceed the mandatory requirements listed below.

4.1.1 Vendor shall provide program management and coordination of PDL, PPL, and SMAC activities with the Bureau, the state's Medicaid Fiscal Agent, the Medicaid MCOs, the Pharmaceutical and Therapeutics (P & T) Committee, the SSDC and its vendor, the prior authorization vendor, and any other business partner associated with PDL, PPL, and SMAC programs.

Goold has worked effectively with BMS in the past, the State's Medicaid Fiscal Agent, the Medicaid MCOs, the P&T Committee, the prior authorization vendor, and other business partners within the State to coordinate updates and changes to the PDL, PPL and the SMAC list. We look forward to the opportunity to resume those relationships in West Virginia. There is a longstanding tradition of our staff and systems collaborating and integrating with other Medicaid business entities to ensure the overall success of the program. Goold intends to continue these positive relationships going forward.

As the current vendor for SSDC, Goold will continue using our collaborative approach to ensure successful outcomes for BMS. Goold will provide program management and coordination of PDL, PPL and SMAC activities with BMS, the State's Medicaid Fiscal Agent, the Medicaid MCOs, the P&T Committee, the prior authorization vendor, and other business partners.

4.1.2 Vendor shall comply with all federal regulations, including confidentiality of rebate related data, and the State Plan filed and approved by the Centers for Medicare and Medicaid Services (CMS) as stated in Attachment A and B of this RFQ.

Goold operates a fully compliant drug rebate management program and will continue to comply with all current state and federal regulations, including the Omnibus Budget Reconciliation Act (OBRA), the State Plan (RFP Attachments A and B) filed and approved by CMS and the Health Insurance Portability and Accountability Act provisions. Goold provides transparent, full disclosure of all information involved in negotiation.

Goold is acutely aware of the confidential nature of the rebate-related data and maintains strict security standards to ensure that confidential information is kept secure.

4.1.2.1 Vendor shall assist the Bureau with writing State Plan Amendments related to the PDL, PPL, and SMAC programs.

Goold has experience assisting the Bureau in development of its State Plan Amendments related to the PDL, PPL and SMAC. Our staff has many years of experience with communications and interactions with CMS. This experience includes the drafting and

submission of State Plan Amendments. Our experience in multiple states will help ensure that West Virginia is always aware of the current best practices of other Medicaid programs.

4.1.3 Vendor shall be available for appearances before the West Virginia Legislature or other interested parties as requested by the Bureau at a minimum for four (4) and maximum of six (6) times per calendar year.

Goold staff will be available on an as needed basis for appearances before the West Virginia Legislature or other interested parties as requested by BMS at a minimum of four (4) and a maximum of six (6) times per calendar year. In addition, Goold is available to assist with the preparation of reports and/or presentations for use by BMS when requested.

4.1.4 Vendor shall facilitate status meetings with the Bureau including meeting agendas and minutes. Meeting minutes must be provided to the Bureau within ten (10) working days of each meeting, including the Pharmacy and Therapeutics Committee meetings. Status meetings will be held on an agreed upon schedule by the Bureau and the Vendor, at a minimum of weekly via conference call.

Goold recognizes that the success to any endeavor is close communication with the client, the ability and willingness to think outside the box and provide comprehensive, cost savings solutions that meet the needs of the client. ***Identifying the customer's needs and accommodating them is an area where Goold excels.***

Frequent communication is the KEY TO A STRONG PARTNERSHIP and Goold will be available on a scheduled and as needed basis to work on issues in a timely manner with the State.

Goold will to comply with all of the requirements outlined in RFP Section 4.1, and will facilitate weekly conference calls (or more frequently if necessary), and provide meeting agendas and minutes within 10 working days of each meeting, including P&T meetings.

4.1.5 Staff

4.1.5 Vendor shall provide staff to work cooperatively with the Bureau and its partner vendors to assist in managing the PDL, PPL, and SMAC programs.

For West Virginia, Goold will provide experienced staff with extensive Medicaid experience to work cooperatively with BMS and its partner vendors to assist in managing the State's PDL, PPL and SMAC services. The combined Medicaid experience of our proposed staff is unparalleled and their broad Medicaid experience, combined with their specific knowledge of West Virginia's unique needs and vendor relationships will bring many benefits to the State.

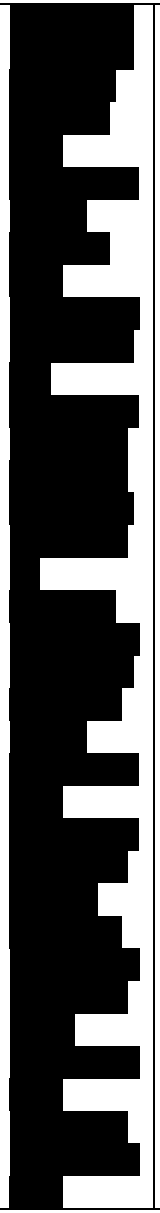
Goold's Experienced Staff for West Virginia:

[redacted]

4.1.5.1 Vendor shall submit references from three (3) state Medicaid fee-for-service programs other than West Virginia that demonstrate experience as required in this RFQ.

Goold has provided similar and more extensive set of services in multiple states. The references provided in the table on the following page will validate the scope of work and quality of services that have been provided.

	[redacted]	



	[redacted]	

Table 1: Goold Business References

4.1.5.2 Vendor shall submit with their quotation the names and resumes for staff assigned to this contract including account manager, clinical pharmacist, physician, rebate manager, and SMAC pricing manager.

Goold is proposing key staff that are* FAMILIAR AND EXPERIENCED *with the West Virginia PDL, PPL and SMAC services. Additional staff are named as part of this response. As Goold has provided these services to West Virginia is the past, our key staff and support personnel are familiar with the project specifications and will provide the State with the same highly professional service as they have in years past. In addition to the information below, resumes for key staff, including the Account Manager, Clinical Pharmacist, Physicians, Rebate Manager, and SMAC Pricing Manager are included in Exhibit A – Staff Resumes. Resumes for other staff that are part of the Goold West Virginia project team are also provided.

WEST VIRGINIA ACCOUNT MANAGER – [redacted]

WEST VIRGINIA CLINICAL PHARMACIST – [redacted]

WEST VIRGINIA PHYSICIANS – [redacted]

WEST VIRGINIA REBATE MANAGER – [redacted]

WEST VIRGINIA SMAC PRICING MANAGER – [redacted]

4.1.5.3 Vendor shall provide an account manager that will be available during business hours of 8am to 5pm Eastern Time, Monday through Friday. This person is responsible for the overall operations of the contracted deliverables.

[redacted]

[redacted]

4.1.5.4 Vendor shall provide a clinical pharmacist as stated in section 3.2.2 of this RFQ who shall attend, in person, P & T Committee and Drug Utilization Review (DUR} Board Meetings to offer advice to the Bureau on clinical issues relating to the PDL and PPL, and be available by telephone and email to the Bureau during business hours of 8:00am and 5:00pm Eastern Time, Monday through Friday. The P & T Committee meets three (3) times annually, with two (2) meetings being held in the DHHR Building at 350 Capitol Street and one (1) meeting being held at the Charleston Civic Center. The DUR Board shall meet quarterly and meetings are held at the DHHR Building.

[redacted]

[redacted]

4.1.5.5 Vendor shall provide for the services of a physician, actively licensed with the Board of Medicine or Osteopathic Medicine for the state in which they are employed. This physician shall attend P & T Committee meetings three (3) times annually and quarterly DUR Board meeting in person to offer advice to the Bureau on clinical issues relating to the PDL and PPL, and be available by telephone and/or email to the Bureau during business hours of 8am to 5pm Eastern Time, Monday through Friday. P & T and DUR Board meetings are held in the DHHR Building or the Charleston Civic Center.

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

4.1.5.6 Vendor shall provide for the services of a rebate manager. This individual shall be available to the Bureau by telephone and email during the business hours of 8am to 5pm Eastern Time, Monday through Friday. This individual is responsible for, at a minimum, completion and management of rebate contracts, contract tracking, contract status, contract disputes, and pricing and contract data files and reports for rebate invoicing.

[redacted]

[redacted]

4.1.5.7 Vendor shall provide for the services of a SMAC pricing manager. This individual shall be available to the Bureau by ·telephone and email during business hours of 8am to 5pm Eastern Time, Monday through Friday. This individual is responsible, at a minimum, for management of the SMAC program, oversight of the selection of generic, other drugs, and products to which SMAC prices will be applied, calculation and tracking SMAC pricing, providing documentation for price posting, and advising the Bureau when pricing disputes occur.

[redacted]

[redacted]

4.1.5.8 Vendor shall complete background checks for current and potential employees to ensure that staff meets the minimum requirement under state and federal statute and/or regulations. See Attachment A and B. Vendor shall not employ persons who are excluded from Medicare or Medicaid participation by the Federal Office of the Inspector General or any state Medicaid program.

Goold conducts background checks internally on all prospective employees and will comply with State checks for current and potential employees as a result of this contract. The scope of the background check includes employment and education verification, criminal record screen/social security trace, and professional employment reference checks. All employees have completed HIPAA privacy training. Additionally, all employees must sign confidentiality agreements.

4.1.5.9 Changes in staff positions of account manager, clinical pharmacist, physician, rebate manager and SMAC pricing manager shall be approved by the Bureau.

Goold and Emdeon's company vision is to make healthcare more efficient. We are always seeking talented people who work together as a team and are committed to Emdeon's Values of INTEGRITY, HONESTY, TRUST, ACCOUNTABILITY, CUSTOMER FOCUS, QUALITY, INNOVATION, TEAMWORK, and COMMUNICATION. These values and our commitment to quality staffing will directly benefit the quality of the West Virginia project.

Goold and Emdeon are guided by industry expertise, innovation, and foresight. New product development, high quality of service, an advanced technology infrastructure, a great company culture, and engaging employee programs are just some of the positive by-products. Our employees work hard, generously giving their passion and dedication in pursuit of our shared vision with our clients and making this a great place to work.

As our business continues to grow and develop, we realize the need to attract and retain our most valuable asset, our employees. ***Emdeon is committed to equipping employees with the training, tools and opportunities needed to advance not only the business, but themselves.*** Goold and Emdeon have a comprehensive employee retention program consisting of employee recognition, awards, and career advancement opportunities. We monitor our employee retention, attrition, and satisfaction on a continuous basis.

Goold pays competitive salaries relative to the location of work and the employees' experience. We make all efforts to ensure that staff are not over-allocated and that project and operational teams are sufficiently staffed.

Staff turnover is typically the result of an employee pursuing other career opportunities. There are any number of reasons that may trigger this type of move, and they are completely unique to each individual. As a testament to the quality of our work environment, however, we have experienced key employees returning to Goold after one to two years with another organization.

Should Goold experience changes in key staff position for the BMS project, all changes will be approved by the State prior to implementing the new personnel. Goold realizes our commitment to provide the proper resources to operate the applications, program and services described in this RFQ. Goold has assembled a staff of extremely talented, competent, and

capable employees who collectively bring decades of experience in Medicaid PDL, supplemental rebate negotiation and contracting, clinical, and SMAC operations. These staff members are familiar with West Virginia, having worked on the project with the State in the past. See Project Organizational Chart in the figure below.

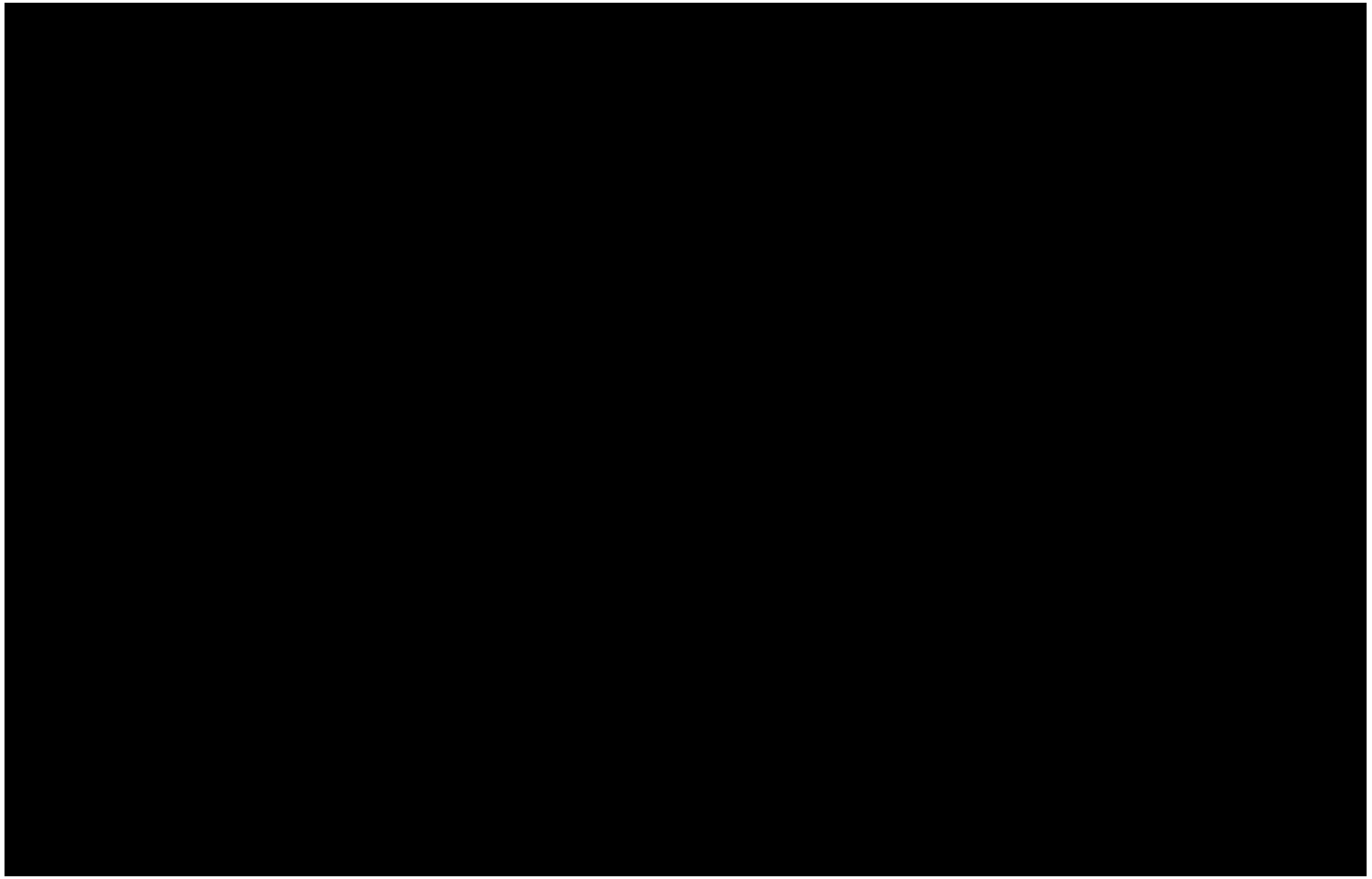


Figure 1: Goold-West Virginia Team - Organizational Chart

Our expert staff members are available at a moment's notice to answer questions, provide technical support, address concerns and assist with legislative requests. Named staff are available to attend meetings via teleconference or online, and are also able to travel in order to attend meetings in person, as appropriate. Goold has named the following key staff:

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

4.1.5.10 Vendor attendants at meetings shall be consistent. Attendant changes for any given meeting shall be approved by the Bureau at least five (5) business days prior to the scheduled meeting date.

Goold will provide consistent, experienced staff to the State of West Virginia in order to carry out all services related to this RFQ. Goold agrees to inform and receive approval from BMS for any Goold attendee changes five (5) days prior to P&T Committee meetings. We are pleased to be able to provide BMS with an experienced team that has provided these services for many of our client States.

4.1.6 Cooperation with Bureau and its Partners

4.1.6 Vendor shall agree that any and all data provided to the Vendor by the Bureau or the Bureau's partners, and any and all data collected, created, summarized, and/or aggregated, deliverables submitted to the Bureau or the Bureau's partners, and reports created under the contract awarded pursuant to this RFQ, are the sole property of the State of West Virginia, intended for the purposes of supporting the Medicaid and Pharmacy programs in any manner deemed appropriate by the State. None of these materials may be used by the Vendor at any time or in any manner without the express approval of the State.

Goold agrees with West Virginia that the following information is the sole property of the State, intended for the purposes of supporting the Medicaid and Pharmacy programs. None of the following materials will be used by Goold, at any time or in any manner, without the express approval of the State:

- Any, and all, data provided to the Vendor by the Bureau or its partners; and
- Any and all data:
    - Collected;
    - Created;
    - Summarized and/or aggregated;
    - Deliverables submitted to the Bureau or its partners and reports; and
    - Reports created under the contract awarded pursuant to this RFQ.

Information that will remain proprietary to Goold includes our methodologies, as well as our applications used in servicing the West Virginia project.

It is Goold's goal to work collaboratively with a State and its Vendors during all phases of the project. We've done this in the past during transitions to and from our Systems in West Virginia and will continue to provide this same level of professionalism moving forward with BMS.

4.1.7 Support of P&T Committee

4.1.7 Vendor shall develop and provide support for clinically sound and cost effective recommendations to the Bureau and the West Virginia Medicaid P & T Committee to refine and manage the PDL and PPL.

As with our other clients, Goold will provide innovative, clinically sound and cost-effective recommendations to the West Virginia Medicaid P&T Committee in ongoing efforts to refine and manage the PDL and PPL.

4.1.7.1 Vendor shall facilitate meetings, present clinical and cost information, develop print, copy, collate, and distribute meeting materials such as, but not limited to, agendas, minutes, reports, and handouts for all P & T Committee meetings, and provide ad hoc reports or other requested clinical and/or financial information for the DUR Board meetings throughout the year as approved by the Bureau.

Goold prides itself on the expert management of all facets of PDL administration, including P&T Committee support. Our proposed staff is experienced at providing these very specialized services and will provide West Virginia with the same level of professionalism that West Virginia experienced and that our other clients have come to rely upon. We will facilitate the presentation of clinical and cost information and develop, print, collate, and distribute meeting

materials such as, but not limited to, agendas, minutes, reports and handouts for all P&T Committee meetings throughout the year, as approved by BMS. Furthermore, Goold will provide ad hoc reports or other requested clinical and/or financial information for the DUR Board meetings throughout the year as approved by BMS.

4.1.7.1.1 Vendor shall develop and provide P & T Committee meeting agendas for each P & T Committee meeting at a minimum of thirty-five (35) calendar days prior to meetings. Content shall be approved by the Bureau for release.

Goold's experienced, trained administrative staff will provide any and all required administrative support for meetings, including preparation of P&T Committee meeting agendas and transcription of meeting minutes. Our staff has performed this function for the State in the past and continues to do so for our other State clients. We are knowledgeable and practiced at providing the necessary support to ensure the ongoing success and effective operation of the P&T Committee.

All draft meeting agendas will be sent to BMS for approval no less than thirty-five (35) days prior to the meeting and will be approved by BMS prior to release.

4.1.7.1.2 Vendor physician(s) and clinical pharmacist(s) shall review therapeutic classes including new medications or indications as approved by the Food and Drug Administration (FDA) and present in person recommendations to the P & T Committee and the Bureau for appropriate revisions to the PDL.

Goold will provide our physicians and clinical pharmacists to review therapeutic classes, including new medications and/or indications approved by the Food and Drug Administration. These updates to the therapeutic class reviews and monographs will be presented in person to the P&T Committee and BMS along with recommendations for revisions to the PDL.

Goold has over seven years of experience in conducting comprehensive drug class reviews. This knowledge base and experience will be available to West Virginia.

Goold is an industry leader in providing evidence-based clinical information for our clients. Our experienced staff includes pharmacists, physicians, analysts and statisticians. Goold will apply this expertise and our proven processes and procedures to therapeutic class reviews, in the form of clinical monographs. **Goold currently has a library of over 85 active therapeutic class reviews.** We will partner with the Bureau to propose content and classes to be reviewed, with final determinations to be made by BMS. Classes will include groups of drugs that are therapeutically similar and will be approved by the Bureau for inclusion via a mutually agreeable process. Drugs will be assessed, at a minimum, for comparative efficacy and the other key attributes listed on at least an annual basis. The format developed by Goold is presented in an attractive, user-friendly format with new information from the last review highlighted for the Committee's convenience. Additional details regarding the therapeutic class reviews are discussed in sections 4.1.8.1, 4.1.8.2 and 4.1.8.3 that follow.

In summary, Goold will provide in-person, timely reviews and recommendations by physicians and pharmacist to the State and the Committee regarding new drugs, new indications, new safety issues, and positive or negative studies, both for the scheduled Committee meetings and for any interim drug decisions.

4.1.7.1.3 Vendor shall provide meeting documents to the Bureau and Committee members fourteen (14) calendar days prior to meetings.

As stated previously, Goold's experienced administrative staff will provide any and all required administrative support for meetings, including preparation of agendas and transcribing meeting minutes. Our staff has provided this function for the State in the past and continues to do so for our other State clients. Our staff is knowledgeable and practiced at providing the necessary support to ensure the ongoing success and effective operation of the P&T Committee. All draft meeting documents will be sent to BMS and Committee members at least fourteen (14) calendar days prior to the meeting.

4.1.7.1.4 Vendor shall provide meeting minutes for all P & T Committee meetings. Meeting minutes will follow the current format as found on the Bureaus' website. Minutes are due no later than ten (10) business days after each P & T Committee meeting.

Goold will provide comprehensive meeting minutes in a format specified by the State for all P&T Committee meetings. All minutes will be provided to the State no later than 10 business days after each P&T Committee meeting.

4.1.8 Therapeutic Class Reviews/Monographs

4.1.8 Vendor shall provide the Bureau and the P & T Committee with therapeutic class reviews that compare drugs and products, at a minimum, for efficacy, safety, side effects, dosing, indications, prescribing trends, and cost efficiencies of each drug or product within the therapeutic drug or product class. These reviews will be delivered as monographs. Vendor shall submit a monograph example with their quotation.

Goold has experience in providing West Virginia with Therapeutic Class Reviews, which will be delivered as monographs for the life of the existing contract, updating each class at least annually. In these class reviews, all medications available in a therapeutic class are reviewed, at a minimum, for comparative efficacy, safety, side effects, dosing, prescribing trends, indications, and cost efficiencies. Sample Therapeutic Class Review Monographs have been included in Exhibit B- Sample Therapeutic Class Reviews.

4.1.8.1 Vendor shall provide to the Bureau and the P & T Committee members concise and systematic reviews of each therapeutic drug or product class or specific drugs or products to be presented for review by the Bureau or P & T Committee, including monographs, pricing information, and other pertinent information, no later than fourteen (14) calendar days prior to each P & T Committee meeting.

Goold produces high quality, evidence based therapeutic class reviews. Goold will provide BMS and West Virginia's P&T Committee members with concise and systematic reviews of each therapeutic class and/or specific drugs or products to be presented to the Committee for

review. Goold will be responsible for all delivery costs of these monographs and associated materials. The materials will be distributed no later than fourteen (14) calendar days prior to each P&T Committee meeting. Goold has a history of providing these materials early to our clients and will strive to exceed deadlines set forth by BMS.

[redacted]

[redacted]

The [redacted] will also receive additional support from Goold's staff of pharmacists and physicians. Our extensive experience regarding best practices from multiple states will benefit West Virginia and allow insight into various approaches to PDL issues. We will create and provide customized drug monographs and savings analyses to the Committee, according to the State's specifications.

Although West Virginia has a mature PDL, it is essential to continue analyzing relevant, timely clinical trial data, including updates on efficacy, safety and added indications or patient populations. The Committee needs to focus on the most important essentials of a drug to maintain PDL therapeutic classes, including the following elements:

- Significant, clinically positive drug characteristics, especially if unique to class;
- Significant, clinically negative drug characteristics, especially if unique to class; and
- What financial effect a drug will have on a PDL class if it is preferred or non-preferred or if the drug undergoes a significant price change or becomes available generically or in another form (XR or ODT, for example).

Going forward, the primary operational concerns for a mature PDL such as West Virginia's are the annual negotiations and the interim drug considerations between Committee meetings. Goold will proactively make recommendations to BMS on how to make adjustments to the PDL and PPL based on timely clinical and net pricing information.

4.1.8.2 Vendor shall designate to the Bureau and the P & T Committee the Vendor's recommendation as to preferred or non-preferred status for each drug or product within each class based on current clinical and cost data.

All of our reviews and cost models are thoroughly researched by experienced pharmacists, with oversight by our Medical Directors, with multiple sources referenced and based on full text

article review and net cost information. Articles are rated for the quality of the study based on a specified set of parameters and the type of outcome measured.

Our current therapeutic class review process can easily be modified if the Bureau has aspects they would like tailored to meet their specific needs. [redacted]

[redacted]

The Goold class review template is a format that was created and developed by the Goold clinical team specifically for the purpose of P&T Committee review for PDL determinations. [redacted]

[redacted]

When the clinical information is combined with our financial analysis, along with our recommended preferred/non-preferred status for each drug, P&T Committee members will have all the necessary information presented to them to make an informed decision on the PDL placement of a new drug. This approach has worked well with the West Virginia P&T

Committee; we look forward to working with the State once again on this process and refining it as needed to meet the Committee's needs.

4.1.8.3 Vendor shall update and keep current all therapeutic drug and product class monographs using peer reviewed referenced materials and must grade the strength of evidence used. Monographs shall be updated no less than annually.

It is Goold's overall belief that a PDL needs to provide a selection of preferred drugs that allows primary care physicians to care for the majority of their patients without prior authorization requests being necessary on a daily basis. The driving force for or against recommending PDL placement is the drug's unique clinical contribution. Our clinical reviews are thoroughly researched; using peer reviewed reference materials, and uniquely edited to provide the P&T Committee with enough information to decipher differences in drugs, without overwhelming the Committee members with irrelevant details. Goold will update and keep current all therapeutic drug and product class reviews using peer referenced materials and grading the strength of the evidence used no less than annually.

[redacted]

[redacted]

[redacted]

[redacted]

Once the entire review has been written, the entire review is edited by the writer, along with a final edit by one or both of the medical directors.

This process is used for both new class reviews and when updating older class reviews. When new drug products come onto the market, they are added to the class review, along with any additional studies found after a repeated search of the literature. When new information is added to the class review, the date of the latest change is added to the title page along with the date of the last literature search for the review. Any new text is highlighted in yellow to allow

the Department and Committee members to easily recognize new information since their last review of the class.

[redacted]

In summary, Goold's class reviews are designed and written for the purpose of supporting Preferred Drug List determinations. They are written in an unbiased fashion by experienced pharmacists using extensive information resources including full text journal articles, textbooks, and multiple, respected sources of medical and drug information. New information is always reviewed by the Medical Directors prior to being presented and the updates are done at least annually or as needed to incorporate new drugs or new information. [redacted]

Please see Exhibit B for a Sample of our Therapeutic Class Monograph.

4.1.8.4 Vendor shall review new drugs or drug formulations or products using a schedule agreed upon by the Vendor and the Bureau, at a minimum quarterly.

Goold has over seven years of experience conducting comprehensive annual drug class reviews. Our review schedule allows for off-cycle reviews of new products on an as needed basis. New drugs and new indications are routinely assessed weekly as part of normal PDL maintenance activities. New drug monographs are created promptly and net pricing is immediately calculated so that interim PDL determinations can be made. New indications are assessed relative to other products with similar indications so that PDL status can be reconsidered and/or PA criteria adjusted. In advance of each quarter's P&T Committee meeting, Goold's clinical staff will review with BMS a proposed list of new monographs, which will be presented for consideration at the next scheduled meeting.

In summary, Goold will work with BMS to develop a schedule for review of new drugs or drug formulations which will, at a minimum, be quarterly.

4.1.8.5 Vendor shall advise the Bureau monthly and the P & T Committee at regularly scheduled meetings on comparative value of new drugs or drug formulations or products that fall into categories already established on the PDL and PPL.

In cases where a new drug or formulation enters a category that is already established on the Preferred Drug List or Product List, Goold will prepare a new drug monograph and provide a recommendation based on the comparative clinical efficacy of other drugs in the category, in addition to cost comparisons. As part of the routine SSDC process, supplemental rebates will be sought as appropriate and included in pricing considerations. We will prepare cost analyses for consideration of the Bureau at least monthly and for distribution to the Committee members at regularly scheduled meetings. Other brand name drugs will be included if an appropriate supplemental rebate (SR) is obtained from the manufacturer. We will include in these analyses considerations regarding current contract requirements within the category and upcoming changes in the category such as predicted new generic or branded entrants. These analyses will enable informed recommendations that balance clinical and cost considerations, based on current and forecasted conditions in the category.

At a detailed level, all cost analyses are performed comparing net costs within PDL classes to help decide best values. Most drugs, especially the one unit per day drugs, are easily compared. Other drugs require adjustments in order to arrive at fair comparisons. We determine the most frequently prescribed courses of therapy and model out net costs to arrive at net cost per course of therapy.

The last major component of the cost analysis relates to market share. The Committee needs to know how many people are using (tentatively) preferred and non-preferred drugs. They also need to know if any data exists that would help predict the probability of success if drug A was made preferred and drug B non-preferred. This data assists the Committee in making sound, well-informed decisions.

4.1.8.6 Vendor shall incorporate multisource drugs into the PDL, maximizing the use of the most cost-effective drugs for inclusion on the PDL.

Goold routinely assesses the relative cost and availability of multi-source drugs. We review pricing on a continuing basis to make sure our client states are aware of savings opportunities when new multisource drugs become available or, as we have seen more recently, have significant price increases that warrant reconsideration of a PDL categories preferred choices. Many PDL drug categories are well suited to generic-first design requirements and Goold is experienced at leveraging multisource drugs when it is clinically appropriate and fiscally prudent. However, there have been recent examples of rising generic drug prices, such as the erythromycins, that emphasize the need for proactive monitoring of relative prices within PDL categories. West Virginia will benefit from our industry-leading, proven practices and procedures that will actively monitor for opportunities to take advantage of net price differences between similar drugs both based on actual drug price changes, but also based on predictions regarding upcoming multisource entries to the PDL categories.

Although the flurry of patent expirations of major drugs has abated somewhat over the last year, closely tracking patent expirations and applications for new generic approvals allows prediction of the entry of lower cost generics to the market. It is essential that these upcoming generics be tracked and planned for. The entry of a lower cost generic to the market in the following year may actually affect PDL decisions in the current year, as the Bureau may want more people to be using the drug scheduled to become generic in the near future, rather than accepting a more generous supplemental rebate offer for a drug that has no generic on the horizon.

It is also critical that net costs after all rebates be tracked closely, and for PDL determinations to include this information. It has become common for many new generics to be produced with an exclusive license or by a very limited number of labelers. These generics are often *higher* priced on a net basis than the existing brand formulations for a period of time. It is critical that this pricing be followed, and the PDL switch to the generic not be made unless, and until, it is cost effective to do so. It is appropriate to prefer the generic formulation only when it is priced like a generic. Goold will continue to incorporate multisource drugs into the PDL, maximizing the use of the most cost-effective drugs for inclusion on the PDL.

4.1.8.7 Vendor shall advise the Bureau of new drugs appearing on the weekly reference drug data file including, but not limited to, the drug name, PDL category, its indication, the overall value of the drug and its impact to the Medicaid pharmacy program.

Goold provides preferred drug list services to multiple Medicaid clients and West Virginia will benefit from our established tools, procedures and experienced account staff in providing information about new drugs appearing on the weekly reference drug data file. This will include important details including, but not limited to the drug name, its PDL category,

indication, the overall value of the drug and considerations regarding the drug's potential impact on the Medicaid pharmacy program. Information regarding potential supplemental rebate considerations is often included as appropriate. The format and method of delivery of this information will be proposed and approved by BMS in advance. A sample format for this report is provided below.

Reference Drug Data File				
Drug Name	***PDL Category***	***Indication***	***Overall Value***	***Impact on Program***
[Example]	[Example]	[Example]	[Example]	[Example]
[Example]	[Example]	[Example]	[Example]	[Example]
[Example]	[Example]	[Example]	[Example]	[Example]

Table 2: Sample Drug Data File Table

SSDC-Negotiated Supplemental Rebates and Financial Analysis

4.1.8.8 Vendor will provide to the Bureau and the members of the P & T Committee SSDC-negotiated supplemental rebates and financial analysis information for each therapeutic class or specific drugs or products under review by the Bureau and P & T Committee. Drug and product rebate information shall be kept confidential as required by 42 USC 1396r-8(b) (3) (D) or future update(s).

Goold is the current vendor for the SSDC and has been for the past nine years, having recently re-procured this contract. We will continue to provide to all members of the P&T Committee and BMS staff, as appropriate, SSDC-negotiated supplemental rebates and financial analysis information for each therapeutic class or specific drug under review by the P&T Committee. Goold acknowledges that all drug rebate information must be kept confidential as required by 42 USC 1396r-8(b) (3) (D).

4.1.8.8.1 Vendor will provide financial information for the P & T Committee for each therapeutic drug or product class at least annually, and new drugs or products as they are reviewed by the Bureau or P & T Committee at least quarterly, in a format that contains at a minimum, drug or product class, drug or product name, brand or generic status, current PDL or PPL status, average quantity dispensed per prescription, net cost after all rebates per prescription.

Goold will comply with all of the requirements outlined in Section 4.1.8.8. Goold will perform and provide to all members of the P&T Committee and BMS staff, as appropriate, SSDC-negotiated supplemental rebates and financial analyses, in the form of cost sheets, for each therapeutic class and specific drug under review by the P&T Committee. This information will be provided for each therapeutic class at least annually and financial information on new drugs will be prepared for review by the P&T Committee at least quarterly. The format will, at a minimum, include the drug class, drug name, brand/generic status, current PDL/PPL status, and utilization information, including average quantity dispensed per prescription, and net cost (after all rebates) per prescription. Recommendations will be made in all therapeutic classes for inclusion or exclusion of each drug, based upon clinical factors, net cost, past utilization, forecasted utilization and expenditures. Goold recognizes the confidentially of rebate information and will continue to be vigilant with regard to keeping this information confidential as required by 42 USC 1396r-8(b)(3)(D).

Most often, Goold's cost sheets are designed to follow the PDL so that one can easily transition from the cost sheets to the PDL when reviewing recommendations. While this is the typical approach, our cost sheets can be developed in any way necessary. In states that use First Data Bank as their drug reference, the cost sheets are most frequently designed using the Enhanced Therapeutic Classification (ETC) to identify the drug categories and include all Generic Sequence Numbers (GSNs) and/or NDCs that are managed and fall under that ETC on the PDL. The cost sheets could also use Hierarchical Ingredient Codes (HIC) or the Ingredient List Identifier (HICL) if the need arises.

Rebates (CMS and supplemental), offset amounts, FULs, MACs and West Virginia's utilization will be pulled in and reported on the cost sheets and modeling analyses. In cases where there is

no historical rebate data that will allow net cost computations, we will use estimations based on our understanding of WAC and its relationship to AMP, especially for newly released brand drugs. A draft form of the cost sheets will be provided, along with a discussion with Goold's clinical staff, as part of the overall process to gain approval for the list of drugs to be included in the cost modeling.

Goold will be able to present various cost sheets and models that will show what the net cost and projected utilization based on how the drug will be placed on the PDL depending on which rebate offer is selected. Cost sheets will be prepared showing the various offers submitted and how we anticipate the net spend and utilization will flow based on various factors. These factors include variables such as anticipated PDL compliance, percent of population using drugs, use by age groups, location, eligibility category and medical conditions/diagnoses. This way, the State will have all the information needed to make an informed decision as to whether or not to take the larger supplemental rebate offer that is available only if multiple states accept.

Results of supplemental rebate negotiations and savings analyses of specific drugs/drug categories will be provided by Goold on a mutually acceptable schedule. At a minimum, they will be prepared before each P&T Committee meeting. We will present estimated savings in a manner agreeable to the Bureau. This will involve estimations based on both current and projected utilization.

Of course, pharmacoeconomic information is not the only factor that must be considered when making PDL decisions. As the provider of a full scope of pharmacy benefit management services, Goold also has the capability to bring to light relevant clinical ramifications that must be considered as well. For example, medical claims data (if made available to Goold) and clinical information will be presented and reviewed prior to making recommendations on the PDL placement of a drug. It does little good to make a recommendation that saves money in one category but increases expenditures in another. That is why Goold takes a holistic approach to guiding clients through new SR offers and PDL changes.

An important distinction of Goold's financial models is that they do not represent a report of what has happened in a previous quarter (there are reports for that as well, of course) but rather, a projection of what will happen in subsequent quarters. While recent utilization and rebate data forms the foundation of our models, future changes that are likely to affect drug costs/utilization are factored into the models. One example of such a change is the provision of the Affordable Care Act (ACA) that applies higher Federal rebates that are fully offset to line extension drugs. CMS has not yet specifically identified what drug products are line extensions, but has published the proposed methodology for the implementation of this provision. Goold incorporates this methodology into the financial models so that the net cost of drugs affected by the provision can more accurately be projected. Goold also closely monitors the brand and generic drug pipeline, trends and anomalies in the Federal rebates so that those factors can be incorporated into our financial projections.

Our financial models are “live” and can be generated on an ad hoc basis when the need arises, such as when there are changes in the market (new brand drugs, new generics, etc.) or significant changes in drug prices or rebate amounts. They provide the ability to determine the financial impact of supplemental rebate offers, including positioned/tiered offers (such as 1 of 1 preferred brands, etc.). They also incorporate the critical component of likely shifts in market share resulting from various PDL decisions. ***Our clinical staff leverages their experience, over a decade in modeling and monitoring state Medicaid PDLs, to estimate market shifts and the resulting financial impact.***

An example of the Cost Sheets that Goold can provide is included on the following page. These reports demonstrate [redacted]

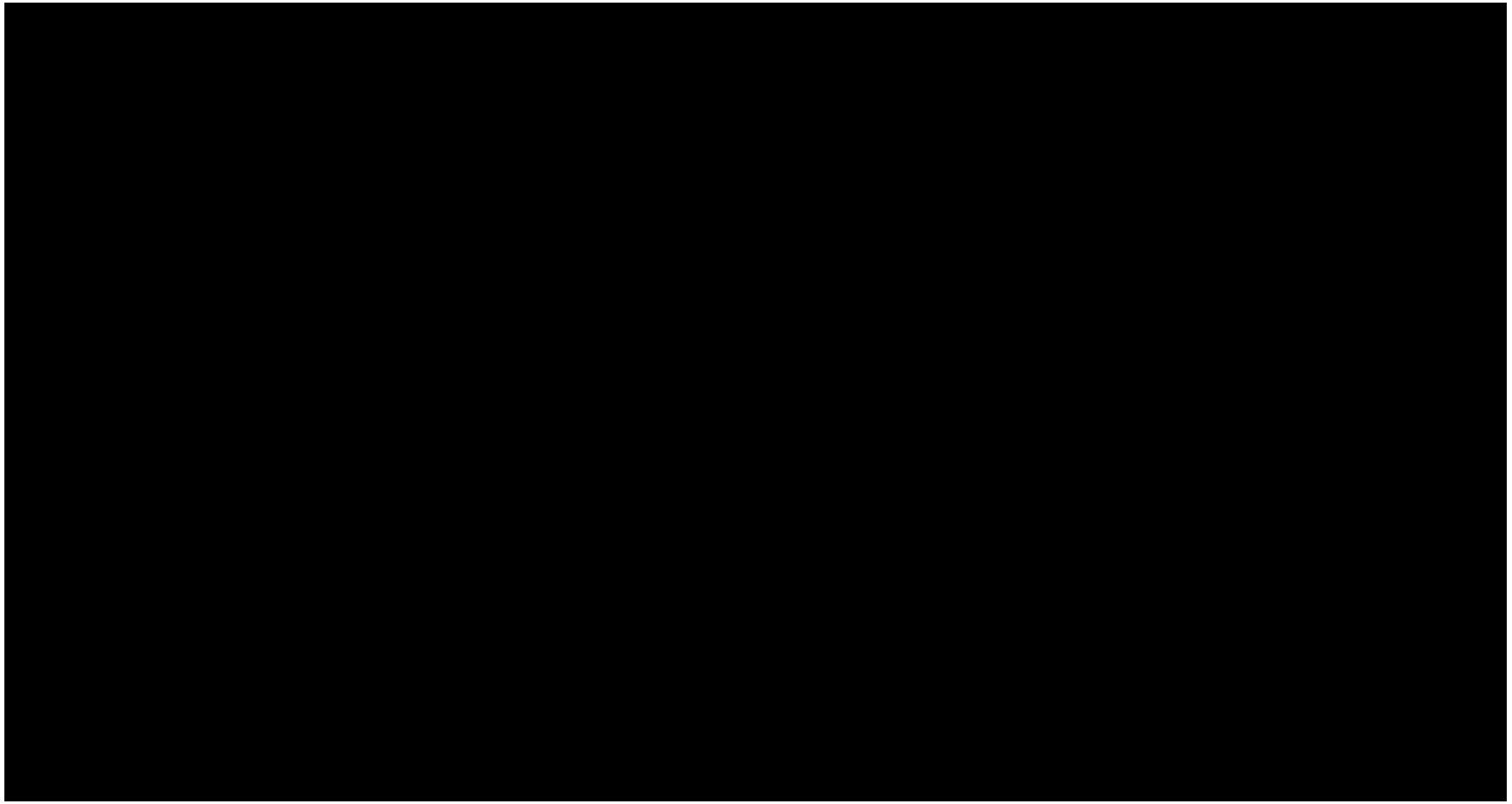


Figure 2: Excerpt from Cost Sheets

Figure 3: Excerpt from Cost Sheets, continued

Figure 4: Excerpt from Cost Sheet, continued

4.1.8.8.2 Vendor shall incorporate SSDC negotiated pricing into its PDL and PPL business models, analyze SSDC pricing, and produce recommendations for a PDL and PPL using SSDC negotiated pricing on an annual basis for review of the entire PDL and daily as information becomes available.

As the vendor for the SSDC, Goold has access to and is completely knowledgeable about the details of SSDC pricing. Goold will incorporate SSDC-negotiated pricing into its PDL/PPL business model, pricing analyses, and all financial models provided to BMS to produce PDL and PPL recommendations. There are many synergies that can be realized for West Virginia to have the same vendor negotiate supplemental rebates and also design the Preferred Drug List.

Goold is the Experienced SSDC Vendor:

- Goold negotiates rebates for Iowa, Maine, Mississippi, Oregon, Utah, Vermont, West Virginia, and Wyoming
- Representing approximately 3,000,000 covered lives;
- Full PDL autonomy;
- Total drug spend $1,550,555,930;
- Diabetic supply negotiations;
- Terms of pool participation are set by the member states; and
- Goold has negotiated nine annual pool negotiations to date.

If selected as the successful bidder for West Virginia, Goold will provide supplemental rebate negotiations and saving analyses of specific drugs/drug categories to the State. We will present estimated savings in a manner agreeable to the State on at least an annual basis and, as frequently as daily, if requested by the State. This will involve estimations based on both current and projected utilization. Depending on the Bureau's preference, we can present a simple summary version of estimated savings within each class, reflecting shifts in market share utilization, average blended net cost per unit, and supplemental rebates. These summaries can accompany the more complex analysis that incorporates all utilization, including that of minor drugs.

4.1.8.8.3 Vendor shall keep confidential SSDC pricing information and keep SSDC pricing information separate from the Vendor's other lines of business.

As an experienced vendor to the SSDC, Goold is familiar with the need to keep all confidential SSDC pricing information separate from other lines of business. Our System is specifically designed to the SSDC confidential needs and we will continue to provide this service successfully.

Goold agrees to maintain manufacturer price and rebate information as strictly confidential in accordance with State and Federal statutes and requirements. Goold will maintain the Bureau's supplemental rebate agreements/contracts separately from our other clients. Goold is committed to protecting the confidentiality, integrity, privacy and physical security of Protected Health Information (PHI), confidential information, data information, personnel, and supporting technological information resources created, obtained by, and provided to the organization. Goold will execute all appropriate business associate agreements as required by the Health Insurance Portability and Accountability Act (HIPAA).

Preferred Drug List

4.1.8.9 Vendor shall manage the Bureau's PDL and PPL, including but not limited to, the production of documents and data needed for claims processing, and PDL updates as recommended by the P & T Committee that are approved by the Bureau and the Secretary of the West Virginia Department of Health and Human Resources (DHHR) or PPL updates as approved by the Bureau.

Goold considers the PDL to be one of the most important aspects of a high quality pharmacy solution. We take great pride in the PDL's we have helped to create and maintain.

Efficient application of the PDL and PPL is an area of excellence for Goold. Our interface system, used by our clinicians to help track, appropriately report on, and send PDL/PPL status to the POS vendor, has been built to offer the maximum amount of functionality possible. ***We have learned that a highly intelligent and flexible system reduces both administrative costs and provider burdens, while optimizing net savings for clients.*** A carefully designed PDL/PPL, in combination with PA's and supplemental drug rebates, allow state Medicaid Programs to realize significant savings without sacrificing clinical outcomes. We have done this successfully in the States of Maine, Iowa and for the State of West Virginia.

Goold will produce documents and data files required for claims processing, as well as PDL updates from P&T Committee meetings, which have been approved by the Bureau and the Secretary of DHHR.

4.1.8.10 Vendor must ensure that the PDL and PPL are in compliance with all applicable Federal and State statues and regulation and the State Plan approved by CMS.

As stated previously, it is Goold's overall belief that a PDL should provide a selection of preferred drugs and products that allows primary care physicians to care for the majority of their patients without prior authorization requests being necessary on a daily basis. The driving force for or against recommending PDL/PPL placement is the drug's unique clinical contribution. Goold will assist the State of West Virginia in refining and managing a PDL and PPL so that it is CLINICALLY SOUND, COST-EFFECTIVE AND MINIMALLY DISRUPTIVE to West Virginia Medicaid members and their providers. In addition, Goold will ensure that the PDL/ PPL is in compliance with all Federal and State statutes and regulations, and the CMS-approved State Plan.

4.1.8.11 Vendor shall prepare the PDL and PPL documents electronically in a file format that is compatible with the West Virginia Office of Technology's currently supported versions of Microsoft Office® Suite to be displayed on the Bureau's website for interested parties.

Goold is experienced and familiar with providing necessary PDL/PPL documents to our client States and will prepare all PDL documents in a file format compatible with the WV Office of Technology, currently supported in versions of Microsoft™ Office Suite, for display on the BMS website for interested parties.

4.1.8.12 Vendor shall comply with the standards of the Bureau and the Bureau's business partners for drug and product data-file maintenance including, but not limited to, the use of therapeutic class codes, enhanced therapeutic class codes, generic sequence numbers, prior authorization requirements, injectable or other dosage form indicators, replacement or change files as desired, catch-up files, or any other drug and product data file standards required by the Bureau and the Bureau's business partners.

Goold agrees to comply with the standards of the Bureau and its business partners for all drug and product data-file maintenance including, but not limited to:

- The use of therapeutic class codes;
- Enhanced therapeutic class codes;
- Generic sequence numbers;
- Prior authorization requirements;
- Injectable or other dosage form indicators;
- Replacement or change files (as desired);
- Catch up files; and
- Any other drug or product data file standards required by BMS.

4.1.8.13 Vendor shall comply with the requirements of the Bureau and the Bureau's business partners for weekly, monthly, and quarterly file deliveries.

Goold continually works with our client States and is familiar with requirements to provide frequent file deliveries. We will utilize our Secure File Transfer Protocol (SFTP) site which we have used in the past to transmit files on behalf of West Virginia. We will work with the Bureau and its partners to provide weekly, monthly and quarterly file deliveries in a method that is requested by the State.

4.1.8.14 Vendor shall establish and maintain an interface with the Bureau's fiscal agent for secure document and file exchanges on a weekly basis.

Goold works cooperatively with various Fiscal Agents in order to provide secure document and file exchanges on a schedule decided by the State. We currently do this with Molina in Maine, Noridian in Iowa, HP in Georgia, the State in Utah, Xerox in Wyoming and Mississippi and have done so for West Virginia in the past as well. We will provide the PDL/PPL data files for exportation to external sources, including, but not limited to, the Bureau’s Fiscal Agent.

Our highly trained network services staff has experience establishing and maintaining data interfaces with external third parties. This includes network infrastructure for all internal and external connectivity and the Secure File Transfer Protocol (SFTP) processes employed at Goold for operating data interfaces. In addition they automate data feeds, create automated subroutines to drive file processes, conduct file transfer quality control, support Data Warehouse and development staff for code deployments, and provide ongoing network support for internal staff, server and network maintenance and monitor systems operations and up-time. These resources will be available and used for the West Virginia project.

The following tables demonstrate Goold's experience with integrating with various vendors, both currently and in the past.

Vendor	Services	State
Molina	MIHMS	Maine, West Virginia
Noridian	MMIS	Iowa
Xerox	MMIS	Iowa
State administered legacy system	MMIS	Utah
CNSI	MMIS	Utah *(currently developing interface)*
HP Enterprise Services	MMIS	Georgia
HP Enterprise Services	MMIS	Alabama

Table 3: Goold's List of MMIS Integrations

In the past, Goold was integrated with the following MMIS implementations:

Vendor	Services	State
State administered mainframe	MMIS	Maine
CNSI-built system	MECMS	Maine
ACS (now Xerox)	MMIS	Iowa

Table 4: Goold's List of Past Integrations

Goold integrated with the following PBM/POS Systems to support Rebate services contracts:

Vendor	Services	State
Molina (Unisys)	POS	West Virginia
Catamaran (SXC)	POS	Georgia
Xerox	POS	Mississippi

Table 5: Goold's List of PBM/POS Rebate Service Integrations

Goold was one of the first PBMS vendors to successfully integrate and invoice rebates for Managed Care Organization (MCO) encounter claims. Goold is currently interfacing with over 30 MCO vendors.

Goold is currently working on deployment of a complete PBMS solution for Illinois and Vermont Medicaid. The vendors for integration under these contracts are:

Vendor	Services	State
State administered mainframe	MMIS	Illinois
HP Enterprise Services	MMIS	Vermont
Catamaran (SXC)	POS	Vermont

Table 6: Goold's List of MMIS Integrations In-Progress

4.1.8.15 Vendor shall comply with the requirements of the Bureau and the Bureau's business partners relating to the method of file exchanges, i.e., "pushing" or "pulling" data.

Goold can provide file exchanges in the method requested of the State. We are experienced in both “pushing” and “pulling” data and will comply with the Bureau’s requirement to provide file exchanges to BMS and its partners in such a manner.

4.1.8.16 Vendor shall apply an effective date and a unique version number for each PDL, PPL, and other business documents.

Goold is familiar with the State’s document identification system and will ensure that each PDL, PPL and other business document submitted has an effective date and a unique version number.

4.1.8.17 Vendor shall ensure that the quality of all files delivered to the Bureau and the Bureau's business partners contain error-free data.

Goold’s staff is meticulous in providing detailed documents and reports to our clients and making every effort to ensure that they are error-free. For example, our dedicated personnel have worked collaboratively with the Member States of the SSDC to create reports that are held to very high formatting and data standards.

We strive to provide all of our client States and their business partners with documents that are error-free and will work with the State of West Virginia to provide the same high-level of service.

4.1.8.18 Vendor shall update the PDL document after each P & T Committee meeting and when changes are made to the PDL, at a minimum monthly. The PPL document shall be updated weekly if requested by the Bureau.

Goold agrees to update the PDL after each P&T Committee meeting, as well as when major changes are made to the PDL, at a minimum of monthly, and provide the list to the State. The PPL may be updated as often as weekly, if requested, and when these updates occur, Goold will supply the updated version to the State.

4.1.8.19 Vendor shall assist in development of step-care therapy and prior authorization (P A) criteria to promote appropriate utilization and to enhance PDL compliance and achieve optimal savings.

Pharmacy prior authorization (PA) is a successful cost saving strategy for Medicaid programs. Our approach to Prior Authorization criteria development allows Medicaid pharmacy program managers to reduce costs by requiring physicians to receive authorization before prescribing cost restrictive and/or clinically questionable drugs to patients. This process allows our customers to limit expensive pharmaceuticals to those patients for whom the drug is therapeutically necessary. At the same time, we ensure that the majority of primary care

providers can prescribe the majority of the drugs they need to treat their patients without requiring prior authorizations. Goold will serve in an advisory role in developing and maintaining PA criteria and step-care therapy to promote appropriate drug utilization, enhance PDL compliance and achieve optimal savings. We have often had success in discussing potential step-care therapy and PA criteria with the Bureau in advance of signing a supplemental rebate offer, such that approved criteria can be incorporated into the supplemental rebate offer.

4.1.8.20 Vendor will update the PDL document when PA criteria is changed or updated by the Bureau and/or the DUR Board and issue an updated version for web posting, at a minimum monthly.

When updates are necessary to the PDL document due to PA criteria that has been changed or updated by the DUR Board, Goold will provide an updated version to the Bureau, at least monthly, for web posting.

PDL Data Files

4.1.8.21 Vendor shall provide the PDL and PPL data files in an electronic file format that is compatible with the WV Office of Technology's currently supported versions of Microsoft Office® Suite.

Goold will provide the PDL and PPL data files to external sources, including, but not limited to the Bureau's Fiscal Agent, in a format that is compatible with the WV Office of Technology currently supported versions of Microsoft Office™ Suite.

4.1.8.22 Vendor will provide PDL and PPL data files in accordance with a schedule agreed upon by the Bureau and the Vendor, at a minimum of weekly.

Goold will provide PDL and PPL data files in accordance with a schedule agreed upon by BMS and Goold, at a minimum of weekly.

PDL Communication and Documentation

4.1.8.23 Vendor shall assist the Bureau in developing documents and responding to inquiries regarding the PDL and PPL.

Goold will work with the Bureau to assist with developing documents and responses to inquiries regarding the PDL and PPL in addition to assisting with any State Plan Amendments required by changes to the PDL and PPL. Our staff has experience in doing this, not only for our other client States, but for West Virginia as well. We will use this past experience to provide excellent collaboration with BMS during this contract.

4.1.8.24 Vendor will draft letters and/or make telephone calls that respond to inquiries from providers and other interested parties concerning the PDL and PPL within five (5) business days of the receipt of the inquiry.

Goold will draft letters and/or make telephone calls in response to inquiries from providers and other interested parties concerning the PDL and PPL within five (5) business days of the receipt

of the inquiry. Our staff is experienced at providing timely, helpful responses to inquiries from any interested stakeholders.

4.1.9 Supplemental Rebate Administration

4.1.9 Vendor shall work cooperatively with the Bureau, its SSDC partners, and the Bureau's fiscal agent to assist the State in drug supplemental and product rebate contract administration.

Goold excels at working cooperatively with numerous vendors and stakeholders in multiple states. We will work cooperatively with BMS, the SSDC partners, and the Bureau's Fiscal Agent to assist the State in supplemental rebate contract administration. As the current SSDC vendor, we are ideally positioned and uniquely qualified to provide coordinated services.

4.1.9.1 All rebate agreements or contracts shall be made between the West Virginia Department of Health and Human Resources (DHHR), Bureau for Medical Services, and manufacturers using the Bureau and/or CMS approved templates.

Our approach to rebate negotiation on behalf of the SSDC is completely transparent. Goold is not party to the rebate agreements we negotiate, and as such, all supplemental rebate agreements/contracts will be made between the West Virginia Department of Health and Human Resources (DHHR), Bureau for Medical Services, and the pharmaceutical manufacturers using the CMS approved template.

4.1.9.2 Rebate contracts must be in an electronic file format that is compatible with the WV Office of Technology's currently supported version of Microsoft Office® Suite.

Goold is exclusively familiar with providing the rebate contracts to the State, and other client States, and will make these documents available in a file format that is compatible with the WV Office of Technology currently supported versions of Microsoft™ Office Suite.

4.1.9.3 Vendor shall work cooperatively with SSDC partners to accurately determine supplemental drug or product rebate contract data.

As the SSDC vendor, Goold has experience working with SSDC partners to accurately determine supplemental rebate contract data; West Virginia will continue to benefit from this relationship

4.1.9.4 Vendor shall produce and facilitate the signing of supplemental drug rebate or product rebate contracts with manufacturers, the Bureau, and the West Virginia DHHR.

It can be surprisingly complex to track dozens of contracts and amendments as they move through the process requiring multiple signatures. Goold will produce and facilitate the signing of supplemental rebate contracts with pharmaceutical manufacturers, the Bureau and the DHHR. We will use our experience to provide a focused resource that will attend weekly status meetings and update the status of all contracts and amendments currently in process.

4.1.9.5 Vendor shall track contracts and documents at all points from origin to completion.

Goold Rebate Administration (Rebate Admin) is the web-based secure tool that is used to create, process, and track all Supplemental Rebate Agreements/contracts/and amendment documents from start to completion. Tracking begins as soon as the document is sent to the manufacturer and continues until the fully executed documents are mailed back to the manufacturer. Rebate Admin includes a log of the shipping tracking number for a full audit trail of delivery recipient and delivery date. A monthly Contract Status report (shown in the example below) will be provided to BMS to report the current year's contract activity.

Figure 5: Contract Status Report

The following screenshot is an example of the Contract Dashboard with displays [redacted] information.

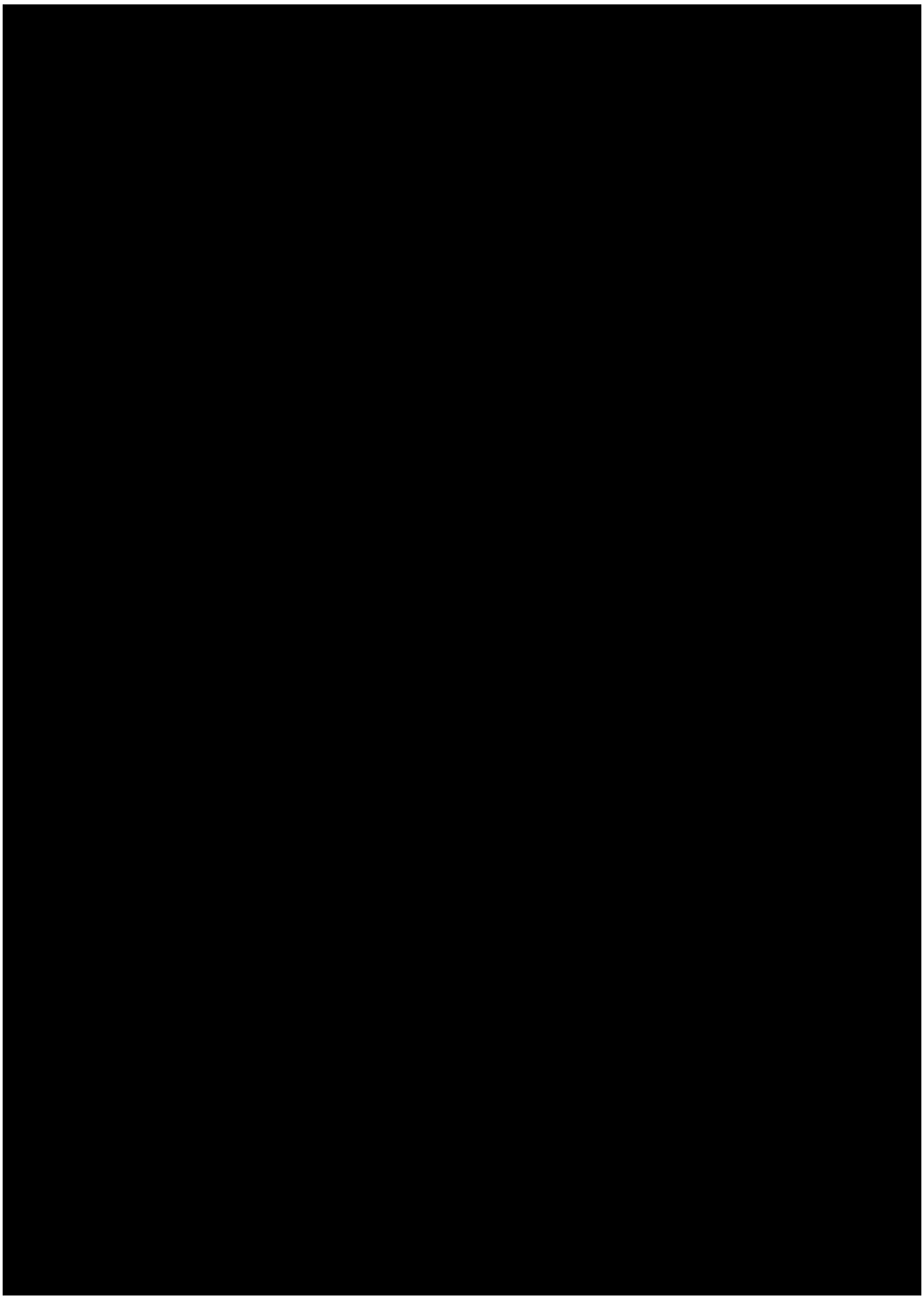


Figure 6: Rebate Administration Contract Management Screen Shot

As outlined above, Goold recognizes the importance of contract tracking and does a complete and thorough job at it. We will track contracts and documents from origin to completion.

4.1.9.6 Vendor shall assume administration of existing supplemental drug and product rebate agreements and/or contracts.

Goold is experienced in the migration of existing contracts. Documents will be scanned and data files will be integrated and stored in the Goold data warehouse for use in the invoicing and SR management process.

Goold will draw upon our past experience to administer existing supplemental rebate agreements and contracts. We have an entire process and dedicated staff whose main concentration is on the proper administration of rebate agreement and contracts. Our process includes working collaboratively with States to define the Contract Management Business Rules document used for contract processing, as demonstrated in the example below. This process has proven successful for many of our States and will be provided to West Virginia as well.

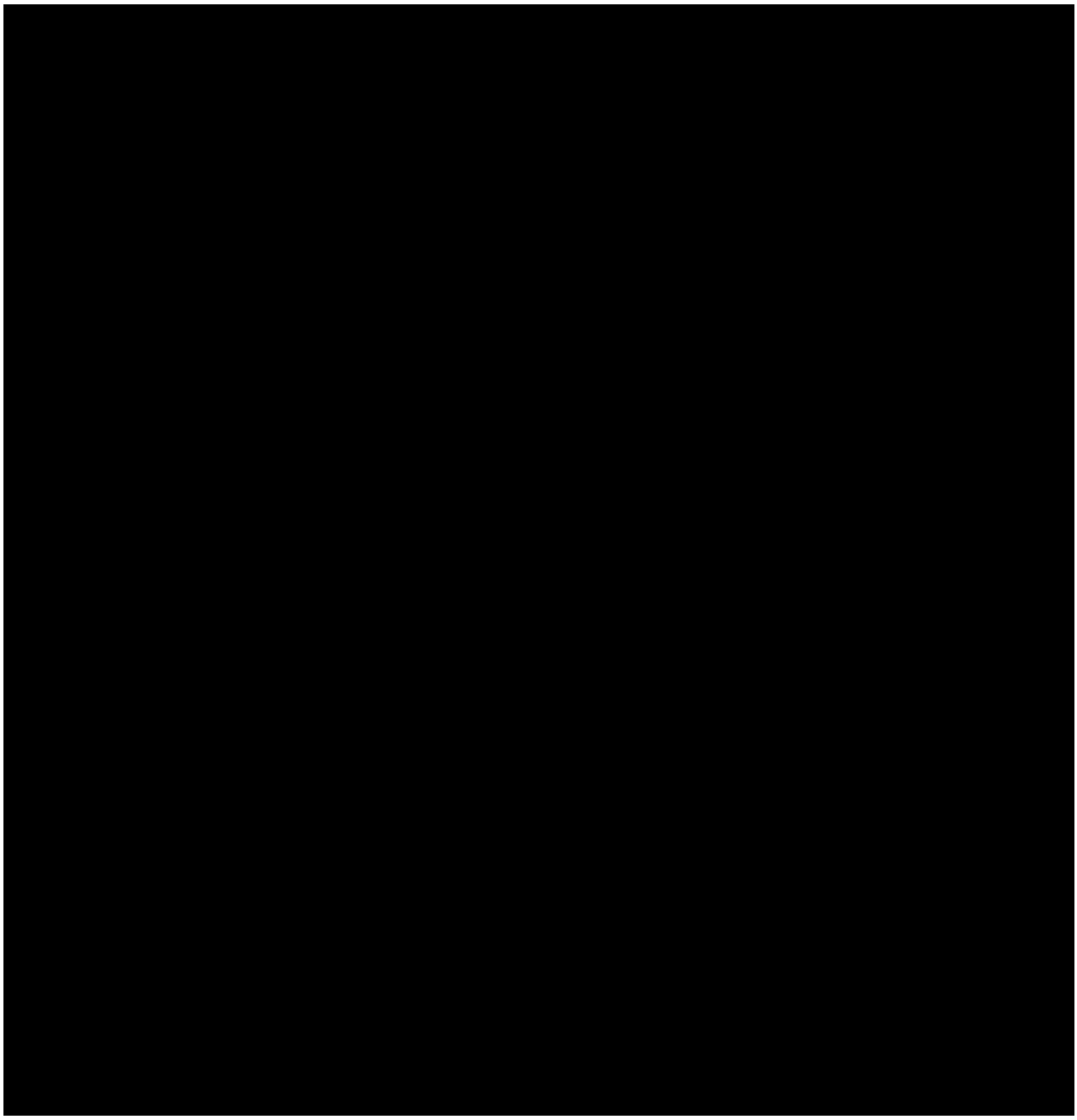


Figure 7: Sample Contract Management Business Rules

4.1.9.7 Vendor shall maintain the Bureau's supplemental drug or product rebate agreements and/or contracts separately from its other clients, ensuring strict confidentiality and controls that meet Federal and State requirements.

Goold agrees to maintain manufacturer price and rebate information as strictly confidential in accordance with State and Federal statutes and requirements in accordance with Section 1927(b) (3) (D) of the Social Security Act. Goold will maintain the Bureau's supplemental rebate agreements/contracts separately from our other clients, as we have done in the past and

continue to do for our other client States. The pertinent data from the SRAs (specific NDCs and their respective rebate amounts) are maintained using our eROMS application, which is secured from unauthorized access according to our internal security plan job roles within our rebate services department.

Goold is committed to protecting the confidentiality, integrity, privacy and physical security of Protected Health Information (PHI), confidential information, data information, personnel, and supporting technological information resources created, obtained by, and provided to the organization. Goold will execute all appropriate business associate agreements as required by the Health Insurance Portability and Accountability Act (HIPAA).

Through user roles and permissions, access is managed to ensure only approved users can view the contract information stored in Rebate Admin, as demonstrated in the image below.

Figure 8: Rebate Admin User Roles

4.1.9.8 Vendor shall ensure that both the Bureau and manufacturers receive original signed agreements or contracts.

Goold assures that both BMS and manufacturers will receive an original signed agreement/ contract.

SURA and NDURA Files

4.1.9.9 Vendor shall provide electronic files containing calculated drug supplemental unit rebate amounts (SURA) and non-drug unit rebate amounts (NDURA), along with additional specified information to the Bureau and to the Bureau's fiscal agent. See Attachment C.

Goold has provided this service to BMS in the past. After referring to RFQ Attachment C-Supplemental Rebate Rate File, Goold agrees to provide a quarterly electronic file containing the calculated supplemental unit rebate amounts (SURA) and non-drug unit rebate amounts (NDURA), along with additional specified information to BMS and its Fiscal Agent.

Upon receipt of historical SR pricing, Goold will merge the pricing into the Goold SR Pricing file for use in invoice and collecting past rebates.

4.1.9.10 Vendor shall provide electronic files containing specific supplemental drug or product rebate contract and amendment data to the Bureau and to the Bureau's fiscal agent. See Attachment D.

Per RFQ Attachment D- Supplemental Rebate Contract File, Goold has reviewed the criteria and agrees to provide the Bureau and its fiscal agent with electronic files with specific supplemental drug or product rebate contract and amendment data.

4.1.9.11 Vendor shall provide SURA and NDURA files, and contract files, to the Bureau and its fiscal agent within fifty (50) calendar days of the end of a quarter, in an electronic file format that is compatible with the WV Office of Technology's currently supported versions of Microsoft Office® Suite. See Attachments C and D. Specific reports shall accompany these files and be due within the same timeframe. Vendor shall provide data, including but not limited to, current and prior quarter adjustment data; historical data; and contract and contract amendment data necessary for the Bureau to invoice manufacturers on a quarterly basis for supplemental drug rebates and product rebates in a file format that is compatible with the WV Office of Technology's currently supported versions of Microsoft Office® Suite.

Goold has previous experience in providing the State with the SURA files within a timeframe defined by the State. We agree to provide electronic files containing calculated SURA, as well as NDURA files, and contract files to the Bureau and its Fiscal Agent within fifty (50) calendar days of the end of the quarter in a file format compatible with the WV Office of Technology currently supported versions of Microsoft Office™ Suite. Upon referring the RFQ Attachment C and D, Goold agrees that the specific reports will comply with these files and will be supplied within the same timeframe to the State and is Fiscal Agent.

Data to be provided will include, but is not limited to:

- Current and prior quarter adjustment data;
- Historical data; and
- Contract and contract amendment data necessary for BMS to invoice manufacturers on a quarterly basis.

Product rebates will be provided in a file format that is compatible with the WV Office of Technology currently supported versions of Microsoft Office™ Suite.

4.1.9.12 Vendor must coordinate supplemental drug rebate and product rebate submissions with submission of traditional federal drug rebates.

Upon availability of the CMS DDR quarterly file, Goold agrees to coordinate submission of the supplemental / non drug rebate pricing file to the State within a timeframe designated by the State. In addition to the data file, BMS will receive the SR Pricing file Report and a QA Document that outlines changes processed for current and historical files, as demonstrated in the example below.

Figure 9: Example of the QA document Additions and Corrections tab

4.1.9.13 Vendor shall provide documentation to the Bureau and/or its designee to support supplemental drug rebate and product rebate invoicing at the NDC level in an electronic file format that is compatible with the WV Office of Technology's currently supported versions of Microsoft® Suite.

Goold agrees to provide necessary documentation to the Bureau and/or its designee to support supplemental rebate invoicing at the NDC level in a file format that is compatible with the WV Office of Technology currently supported versions of Microsoft™ Office Suite.

4.1.9.14 Vendor shall ensure that the quality of all rebate files delivered to the Bureau and the Bureau's business partners contain error-free data.

As previously discussed, Goold's staff is experienced and careful to make every effort to provide detailed documents and reports to our clients that are error-free. For example, our dedicated personnel have worked collaboratively with the Member States of the SSDC to create reports that are held to very high formatting and data standards.

We strive to provide all of our client States and their business partners with documents that are error-free and will work with the State of West Virginia to provide the same high-level of service.

Dispute Resolution Services

4.1.9.15 Vendor shall assist the Bureau and/or its designee in dispute resolution activities with manufacturers as they pertain to supplemental drug rebate or product rebate calculations and contracts.

Goold works diligently to minimize the occurrence of disputes related to supplemental rebates. For one of our clients, we have worked with the State in an aggressive approach to dispute avoidance which resulted in a 55% decrease in disputes reported by labelers.

We will assist the Bureau and/or its designee in dispute resolution activities that pertain to supplemental rebate calculations, negotiated rates, PDL conditions, contract dates and contract status.

4.1.9.16 Vendor shall communicate directly with manufacturers to resolve disputes arising from supplemental drug rebate or product rebate calculations or contract issues within five (5) business days of receipt of the dispute.

As demonstrated above, Goold is experienced in resolving disputes that arise. We will assist the Bureau and/or its designee in dispute resolution activities with pharmaceutical manufacturers

as they pertain to supplemental rebate calculations and contacts. All contracts undergo a quality assurance (QA) process before they are sent out. This ensures that what was agreed to during the bidding process is accurately represented on the contracts, minimizing disputes. Contracts tracked throughout the signatory process data is collected and used for QA of the pricing file, which prevents contracting issues that may cause disputes.

Goold Rebate Specialist staff will reach out directly to manufacturers to open discussions within five (5) business days of the receipt of the dispute. Designated staff will continue working with the manufacturer to resolve disputes through completion for issues arising from supplemental rebate calculations negotiated rates, PDL conditions, contract dates and /or contract status issues.

Rebate specialists are trained in supplemental dispute resolution and work closely with rebate supervisors on more complex disputes. The integrity of the data throughout the process allows rebate specialists to make determinations rapidly and provides a complete audit trail from the initial bid onward.

4.1.9.17 Vendor shall communicate directly with manufacturers regarding unpaid supplemental drug rebates or product rebates upon request by the Bureau.

In our many years of experience in the Medicaid industry, Goold has established close working relationships with manufacturers. We agree to communicate directly with manufactures regarding unpaid supplemental rebates upon request by BMS. Non-payment of invoiced SR amounts is treated very seriously and is rapidly elevated until a satisfactory resolution is reached.

The designated Rebate Specialist will log conversations, emails and resolution responses. This information will be made available to the State for review and intervention in cases when the Labeler is uncooperative or an agreement cannot be reach. In rare cases where a resolution cannot be reached, a customized Notice of Dispute Decision, shown in the example below, will be completed and submitted to BMS.

Figure 10: Example Notice of Dispute Decision

4.1.9.18 Vendor shall communicate the resolution of disputes in a written document to the Bureau within one (1) business day of resolution.

Goold will communicate the resolution of disputes in a written document to BMS within one (1) business day of resolution. A customized Dispute Resolution Notification (demonstrated below) will be used to communicate dispute resolution agreements to BMS and to the labeler using an agreed upon process.

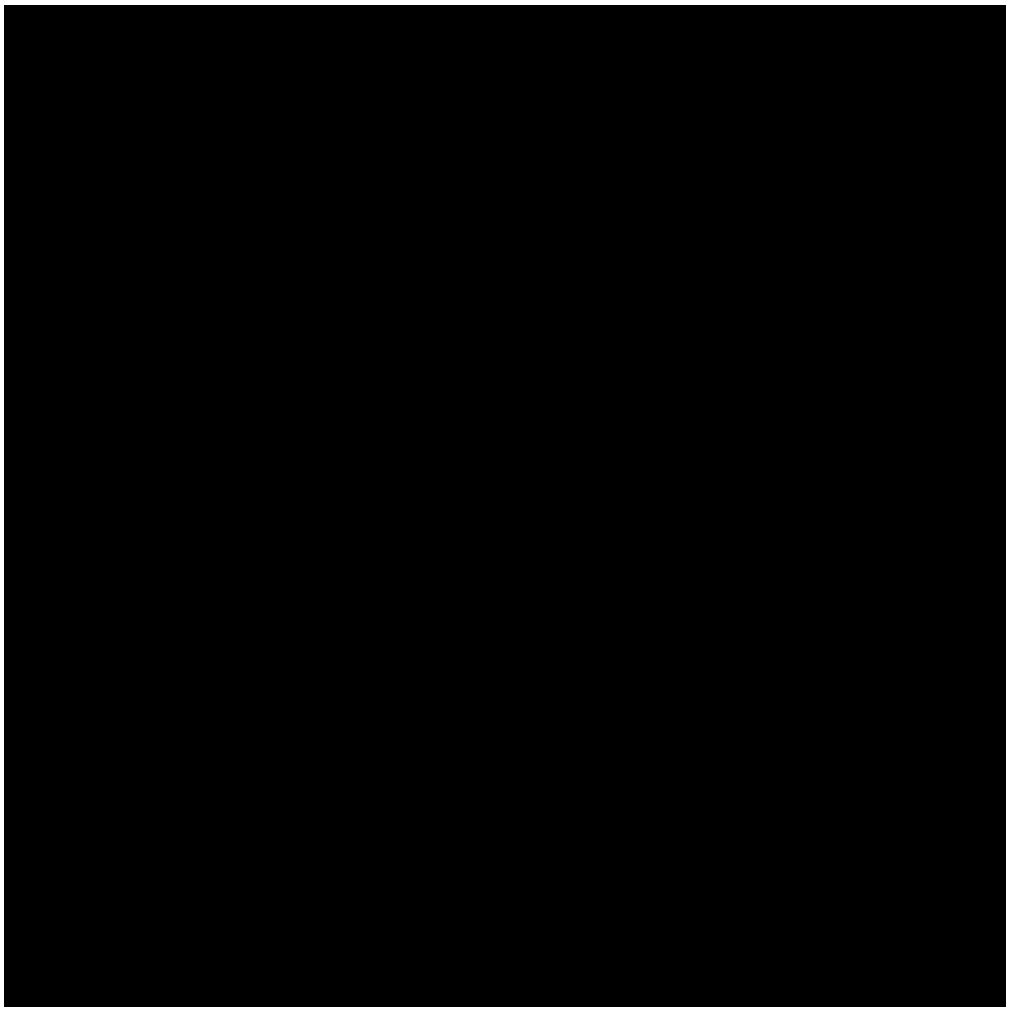


Figure 11: Example Dispute Resolution Notification

4.1.10 State Maximum Allowable Cost Program

4.1.10 Vendor shall assume administration of the current State Maximum Allowable Cost (SMAC) program.

Goold has a successful track record of bringing down Medicaid drug costs through the effective implementation and management of a carefully crafted Maximum Allowable Cost (MAC) program. ***Goold's philosophy regarding MAC rate schedules is based on the belief that chemically equivalent drug products in the same strength, dosage form, and package size available from multiple sources should be reimbursed similarly.***

Goold's Success as a SMAC Program Administrator:

West Virginia's Vendor:

- The SMAC Program saved over $150 million during our tenure; and
- Monthly SMAC savings consistently averaged $4 million.

Illinois:

- As one of our largest SMAC clients, we save the State approximately $25 million per quarter.

Vermont:

- Goold will be taking over the Vermont SMAC Program in 2015.
- Goold has evaluated just 5% of the Vermont's drugs eligible for a MAC and estimates savings, so far, to be over $9 million per year.

MACs are designed to maximize the cost-effectiveness of pharmacy services by setting reimbursement amounts for brand name and therapeutically equivalent drug products at the same price, based on the cost of the products. The MAC rate usually applies to both the brand and generic drug products, unless overridden as permitted with DAW1 or prior authorization. CMS uses the same rationale to establish Federal Upper Limits (FULs) for drug products. MAC rates are state Medicaid program versions of CMS FULs.

Goold has the experience to provide West Virginia with a SMAC program that is best in its class. As was the case in Wyoming where Goold took an aggressive approach to their SMAC pricing formula and inclusion criteria and produced a significant savings for the State. Our work was recognized by CMS as a benefit to the State and the program itself.

Goold has an established SMAC management solution in place, including tools, techniques, processes, procedures, and expert staff to facilitate ongoing operation. This comprehensive solution is already implemented and currently operated by Goold in nine states:

- Illinois;
- Maine;
- Minnesota;
- New Jersey;
- Wyoming.
- North Dakota;
- South Dakota;
- Utah;
- Vermont; and

For each of our SMAC clients, Goold provides the specialized expertise, capabilities, methodologies, and technical competence necessary to meet their requirements and achieve their long-term goals.

In general, Goold applies an approach and methodology to SMAC rate setting that seeks to establish reimbursement rates with the greatest savings and to promote cost-effective utilization of prescription drugs. As the SMAC provider for the West Virginia, Goold will evaluate, as we have in the past, the existing MAC prices, make recommendations for enhancements and maintain the State's SMAC pricing at the direction of State administrators.

Goold also conducts drug acquisition cost surveys on a quarterly basis for three States in order to get current drug pricing, as well as maintains a J-Code SMAC list for another State. Our staff is experienced in SMAC lists for factor products for several of our clients, along with specialty SMAC lists.

4.1.10.1 Vendor shall create, refine and maintain the SMAC program for multiple source drug products or other drug products such as specialty drugs, and non-drug products tailored to the marketplace in West Virginia.

As West Virginia's SMAC vendor, we will create, refine and maintain the SMAC program for multiple source drug products, specialty drugs, and supplies tailored to the marketplace. We can assure that West Virginia will see significant savings each month through the MAC program and all associated services (reporting, Help Desk, etc.), as we have in the past. Ongoing maintenance of the SMAC list not only calls for the addition of new generics that have come onto the market and adjusting the prices of existing products on the SMAC list in response to market conditions, but also to always look for new ways of achieving savings, such as with adding specialty drugs and supplies. Goold has experience in bringing new-found savings with the addition of such specialty products to an existing SMAC list.

SMAC List

4.1.10.2 Vendor shall submit the SMAC data in a file format that is compatible with the WV Office of Technology's currently supported versions of Microsoft Office® Suite.

Goold will submit the SMAC list in a file format that is compatible with the WV Office of Technology currently supported versions of Microsoft Office™ Suite.

4.1.10.3 Vendor shall collaborate with the Bureau to create business rules that comply with the Bureau's business rules relating to file formats (i.e., NDC level data), schedules of delivery, type of files (i.e., change only, full files) for the SMAC program.

Goold is experienced in collaborating with our client States to create business rules that comply with each State's specification. For West Virginia, Goold will work with the Bureau to create business rules that will comply with the Bureau's rules relating to the SMAC program including:

- File formats;
- Schedule of delivery; and
- Type of files.

4.1.10.4 Vendor shall ensure that the quality of all SMAC files delivered to the Bureau and the Bureau's business partners contain error-free data.

As mentioned previously, Goold's staff is meticulous in providing detailed documents and reports to our clients and makes every effort to provide materials that are error-free.

We strive to provide all of our client States and their business partners with documents that are error-free and will work with the State of West Virginia to provide the same high-level of service for the SMAC files that are delivered to the State.

4.1.10.5 Vendor shall provide SMAC lists for public viewing on the Bureau's website and maintain archived versions that are available to the Bureau upon request.

Goold will prepare all SMAC lists in a file format compatible with the WV Office of Technology, currently supported in versions of Microsoft™ Office Suite, for display on the BMS website for interested parties. Goold will maintain archived versions of the SMAC list for the Bureau.

4.1.10.6 Vendor shall ensure that each SMAC list submitted has an effective date and a unique version number.

Goold will ensure that each SMAC list submitted has an effective date and a unique version number. We have worked collaboratively with the State in the past to name these documents in a way that best suites the Bureau and we will do so based on specifications from the State.

4.1.10.7 Vendor shall update the SMAC list no less than weekly, and as SMAC changes are approved by the Bureau.

Goold will update the SMAC list as frequently as weekly, when the State requests, and/or when modifications occur, usually as a result in changes in the market place leading to disputes.

4.1.10.8 Vendor shall coordinate activities with the Bureau's fiscal agent to support the implementation and updates of the SMAC list.

Goold will coordinate all activities with the Fiscal Agent to support the implementation and updates of the SMAC list.

4.1.10.9 Vendor shall actively pursue opportunities for expansion of the SMAC pricing list and regularly report the Vendor's SMAC activities in a schedule to be determined by the Bureau, at a minimum of monthly.

Goold is knowledgeable of this process and will actively pursue opportunities for expansion of the SMAC pricing list and regularly report on our SMAC activities on a schedule approved by BMS, at a minimum of monthly. The chart below demonstrates the trend of the total dollars paid for brand, generic and total drug spend between November 2012 and August 2014.

Goold is constantly looking for innovative ways to continue to control the prices paid for drugs. We have assisted other State MAC clients with implementing a specialty drug SMAC list to include products such as hemophilia factor drugs and Synagis®. These are just some of the ideas we would be prepared to discuss with the Bureau to expand the existing SMAC pricing list.

Figure 12: Total Drug Spend Example Chart

4.1.10.10 Vendor shall collect acquisition cost data and other source information to support SMAC pricing.

For West Virginia, Goold agrees to collect acquisition cost data and other required source information to support SMAC pricing. We constantly collect fresh acquisition cost data from a variety of sources, including State provider pharmacies via disputes, and surveys performed on behalf of other state Medicaid programs (both stores and wholesalers).

4.1.10.11 Vendor shall prepare for, attend in person and facilitate meetings with the provider industry, interested parties, and internal work groups in regard to the SMAC program twice a year if requested by the Bureau.

Goold will prepare for and attend in person as well as facilitate meetings with the provider industry, interested parties, and internal work groups in regard to the SMAC program twice a year, if requested by BMS.

4.1.10.12 Vendor shall develop alternative SMAC reimbursement models for the Bureau's consideration when requested by the Bureau.

Goold will develop alternative SMAC reimbursement models for the Bureau's consideration when requested by BMS. Goold utilizes multiple formulas to generate SMAC prices. This allows flexibility when developing and maintaining SMAC prices. Upon request from BMS, Goold will be prepared and happy to discuss alternative reimbursement models for the SMAC program. Some of the models are variations on applying a multiplier to actual acquisition cost, while others are more customized for the state and take into account the average number of units dispensed per script and desired gross profit.

4.1.10.13 Vendor shall coordinate the addition of drugs for SMAC pricing with drugs in the same therapeutic category on the PDL to ensure that the PDL and SMAC activities result in the most cost effective results.

The critical importance of close coordination of efforts between current and planned SMAC prices and PDL changes is often a missed savings opportunity. Goold will coordinate the addition of drugs for SMAC pricing with the drugs in the same therapeutic category on the PDL to ensure that PDL and SMAC activities result in the most cost effective results.

As the SSDC vendor and experienced PDL and SMAC vendor, we have a comprehensive view on utilization trends, PDL expenditures, and current and future SMAC pricing. We use these data to carefully coordinate additions and changes to the SMAC list, taking into account the way in which supplemental rebates and PDL placement of drugs are expected to play out. As a result, West Virginia will see the savings between the PDL and the SMAC list maximized. Related issues include exiting supplemental rebate contracts with adequate notice and timing PDL changes carefully so that the change to a preferred generic does not occur until the superior SMAC pricing is in effect.

Provider Pricing Support

4.1.10.14 Vendor shall provide outreach services to the WV Medicaid providers regarding Medicaid pharmacy pricing issues and the SMAC program.

Goold will provide outreach services to WV Medicaid providers regarding Medicaid pharmacy pricing issues and the SMAC program. The type and schedule of communications will be reviewed and presented to BMS for approval prior to initiation.

4.1.10.14.1 Vendor shall establish and staff a toll-free telephone line and be responsible for logging and responding to calls from providers regarding pricing issues. The toll-free telephone line must be available, at a minimum, Monday through Friday from 9am to 5pm Eastern Time. Vendor shall be the primary contact for all drug and product pricing inquiries.

Goold agrees to provide and staff a dedicated toll-free phone line for providers to call regarding pharmacy pricing issues. The Help Desk will be available Monday through Friday from 9AM to 5PM Eastern time.

The Goold Help Desk is staffed by competent, considerate professionals who understand and adhere to Goold's rigorous standards of accuracy, courtesy, and speed. Most of these Help Desk professionals have a background in community pharmacy, so they have a deep understanding of the rigors and demands of the community pharmacy pace and business.

Along with all other Goold employees, help desk staff are well-versed in HIPAA compliance and maintain complete confidentiality and professionalism in their work, as dictated by Goold policy. Goold has developed Help Desk manuals consisting of user documentation for the software used by staff, along with all memos, policies, mailings and internal "cheat sheets" designed to provide optimum service to the communities served. Goold has also developed a customized program that provides record keeping and performance reporting for the Help Desk. This utility allows technicians to log all calls, note the type of call, the account involved, and add comments to the call log.

4.1.10.14.2 The Vendor shall answer, log, and respond to telephone calls and/or other communicated messages from pharmacy providers and resolve disputes related to pricing.

Goold will answer, log and respond to calls from pharmacy providers and will continue to resolve disputes related to pricing. Goold will summarize provider support activities including summaries, presentation, and discussion of open pricing disputes.

Figure 13: Sample Call Log

Dispute Resolution

4.1.10.14.3 Responses to providers acknowledging disputes must occur within one (1) business day of receipt.

Goold will respond to providers acknowledging disputes within one (1) business day of receipt.

4.1.10.14.4 Resolution of pricing disputes must be submitted to the Bureau and reported to the inquiring provider within fourteen (14) calendar days of the date of the complaint.

Goold will propose resolution of pricing disputes and submit them to BMS within fourteen (14) calendar days from the date of the complaint.

4.1.11 Reports

During the DDI phase, Goold will meet with State officials to discuss the specifications of the following reports, agree on report styles and formats, and, most importantly, define the purpose and parameters of the following reports. Our main interest is that the State is receiving the information that meets their requirements and our talented staff will create the reports needed. We provide robust reporting services to all of our State clients, and have for West Virginia in the past, and we do this extremely well. The samples provided are meant to serve as examples only.

In the following section we discuss our capability to meet the West Virginia specifications.

4.1.11 Vendor shall provide a suite of reports for the Bureau which reflects the components necessary to manage the PDL, PPL, and SMAC programs and to support the supplemental drug and product rebate invoicing.

Goold will produce a suite of reports for BMS which reflect the components necessary to manage the PDL, PPL, and SMAC programs. Some of these reports will include PDL savings reports, market share reports, utilization reports, and MAC savings reports. Samples have been included in the proceeding sections.

Goold will work with the Bureau during DDI to develop a regular suite of reports that will meet the needs of the Bureau staff.

4.1.11.1 Vendor shall develop standard reports desired by the Bureau. Reports requested through this contract shall include but not be limited to, those listed below. For purposes of cost estimation, vendors may assume a maximum of forty (40) standard reports. All reports shall be in an electronic file format that is compatible with the WV Office of Technology's currently supported versions of Microsoft Office® Suite.

Upon review of the RFQ sections 4.1.11.5.1.1 – 4.1.11.5.1.39, Goold is familiar with the report suite requested by the State as we have provided many of them to the State before. Goold agrees to provide the 40 reports listed in the RFQ in an electronic format that is compatible with the WV Office of Technology's currently supported versions of Microsoft Office® Suite.

4.1.11.2 Vendor shall work with the Bureau using a standardized process to define and develop standard reports including initial release notes with calculation methodologies and prototypes.

Goold will work with the Bureau using a standardized process to define and develop or improve standard reports, including initial release notes with calculation methodologies and prototype presentation. The same process will be applied to accepted and currently utilized reports to ensure that BMS has the information necessary to benefit maximally from the information they contain. Specifically, Goold agrees to produce monthly and quarterly progress reports in a format approved by BMS including, but not limited to, those reports listed in the following subsections.

Goold offers our clients robust, flexible and scalable reporting services that include both standard and ad hoc reports. Effective reporting is a critical function of Goold's proposed solution. Goold uses reporting to monitor performance and to assure that we are carrying out all our responsibilities effectively. Reporting allows State policymakers to evaluate the impact of decisions as well as opportunities for cost savings and quality improvement. Reporting is also critical to the State's ability to hold Goold accountable for performance of our contractual obligations.

Goold has, and will provide, the State with standard and ad hoc reporting on a pre-determined and pre-approved schedule with BMS-approved data elements. We have the experience and competence necessary to meet the reporting requirements outlined in this RFQ. Our team of data analysts, clinicians and support staff – our "integrated clinical data teams" – will work with key stakeholders upon contract award to document any new reporting requirements of BMS. Print-ready reports will be delivered electronically using Microsoft™ Word or Excel, using a format that is compatible with the WV Office of Technology's currently supported versions of Microsoft™ Office Suite, unless otherwise specified. Upon contract award, if desired, Goold will work with BMS to systematically review and improve any currently used reports and to evaluate the necessity for new reports in order to manage the PDL, PPL, SR or SMAC programs. Goold will also review the reporting schedule with BMS.

4.1.11.3 Vendor shall deliver standards reports monthly.

Goold agrees to deliver all standard reports to the State at least monthly on an agreed upon time frame.

4.1.11.4 Vendor shall provide report analyses to the Bureau that will assist the Bureau in making program adjustments to improve the cost efficiency of the pharmacy program. Vendor must host regularly scheduled meetings in order to discuss reports provided by the Vendor. These meetings will be held at a minimum of quarterly.

Goold has the experience to provide West Virginia with report analyses that will assist the State in making program adjustments to improve cost efficiency for the pharmacy program. If necessary, and at a minimum of quarterly, Goold will host meetings to discuss the provided reports and their usefulness to the State. Regular and frequent communication is encouraged by our account managers to ensure the program is running optimally.

4.1.11.5 Vendor shall submit standard reports per the terms of the contract when requested by the Bureau.

Goold will submit the standard reports as outlined in the RFQ per the terms of the contract when requested by the Bureau.

4.1.11.5.1 Monthly, Quarterly and Annual Pharmacy Utilization for PDL and PPL and/or All Drugs Categories: Based on a rolling twenty-four (24) months of pre-rebate expenditures in graph or chart format, to be delivered monthly, quarterly and annually:

4.1.11.5.1.1 Average dollars paid amount per member user;
4.1.11.5.1.2 Total dollars paid;
4.1.11.5.1.3 Total dollars paid by brand and by generic;
4.1.11.5.1.4 Average generic drug prescription cost;
4.1.11.5.1.5 Average brand drug prescription cost;
4.1.11.5.1.6 Percent of generic drugs by number of prescriptions;
4.1.11.5.1. 7Average number of prescriptions per member user;
4.1.11.5.1.8 Average paid amount per prescription.
4.1.11.5.1.9 Summary Monthly, Quarterly, and Annual Reports to be delivered monthly, quarterly, and annually.

Goold agrees to supply the Bureau with the above listed reports monthly, quarterly and annually, as requested by the State. Samples of some of these reports are included on the following pages and demonstrate Goold's capability to work with a State in order to create the reports desired. Our experienced, dedicated staff are more than qualified to provide this service for the State of West Virginia.

The following chart demonstrates to a State the Cost per User based on total pre-rebate dollars. In this example, the cost is displayed on a per month basis for dates between November 2012 and October 2014.

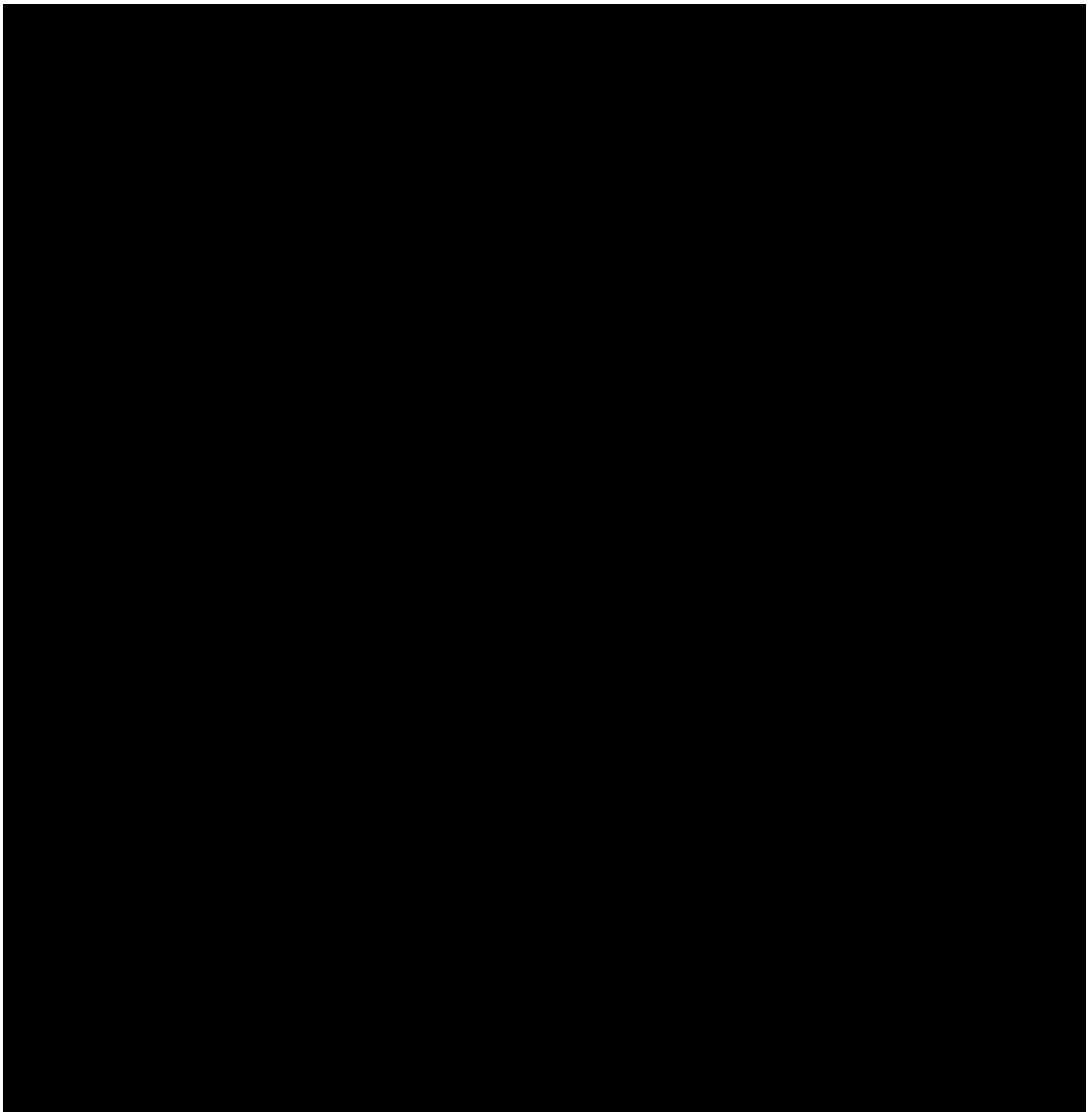


Figure 14: Monthly Cost per User Chart

The following example shows the total pre-rebate spend (state and federal dollars) for brand and generic drugs. This chart has pulled data for the months of November 2012 through October 2014 and allows for easy tracking of pre-rebate costs over time.

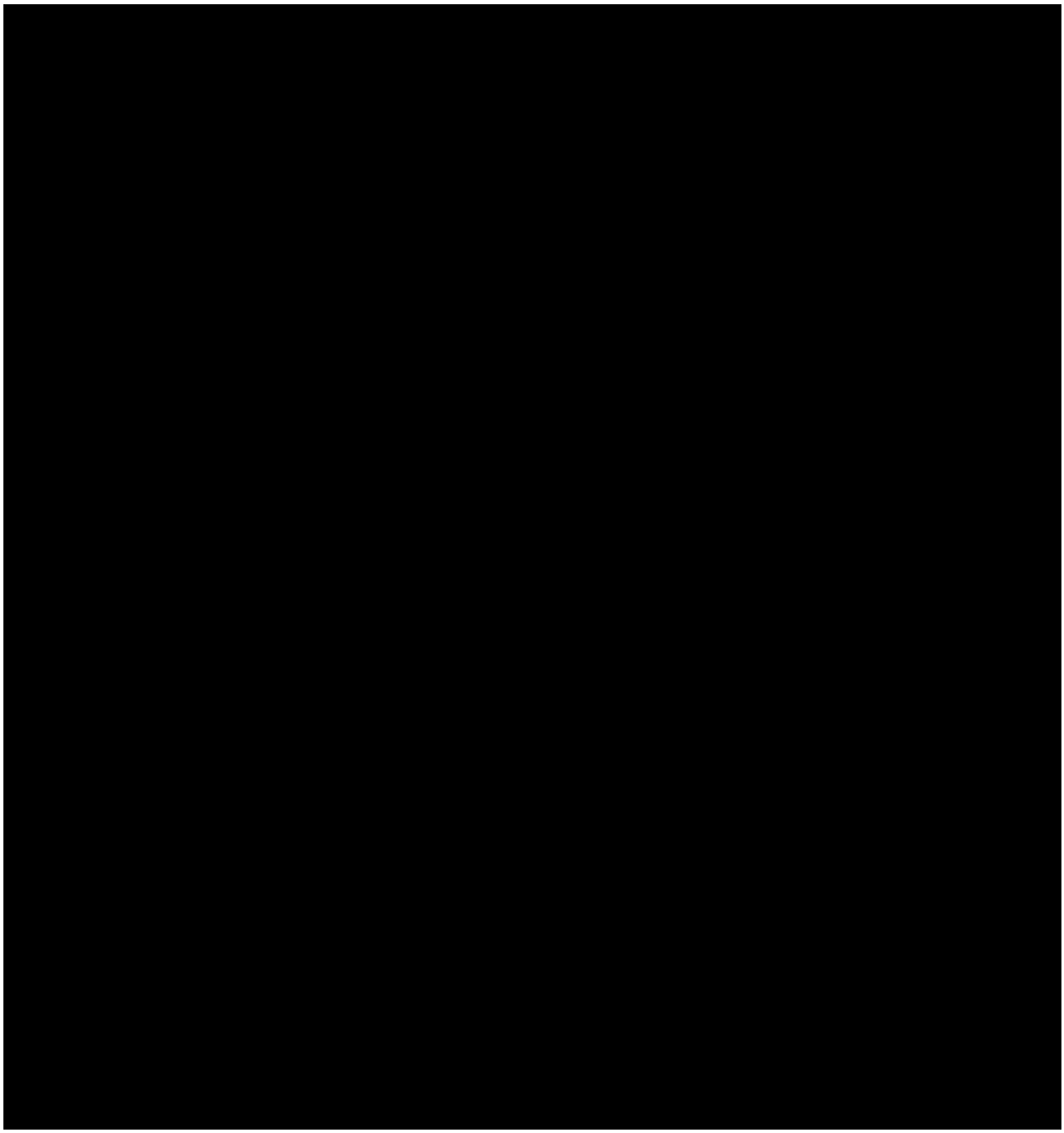


Figure 15: Total Paid (Brand and Generic) Chart

The chart below breaks out the total dollars spent (state and federal) for brand, generic and then the total dollars spent for a state on one chart. This chart shows a side-by-side comparison of the three categories. Brands and generics are broken out separately as well on other charts. The data has been compiled monthly for the date range of November 2012 through August 2014.

Figure 16: Total Dollars Paid for Brand, Generic and Total Chart

The following chart shows the State's average generic drug cost, a closely watched metric, on a monthly basis from November 2012 through October 2014.

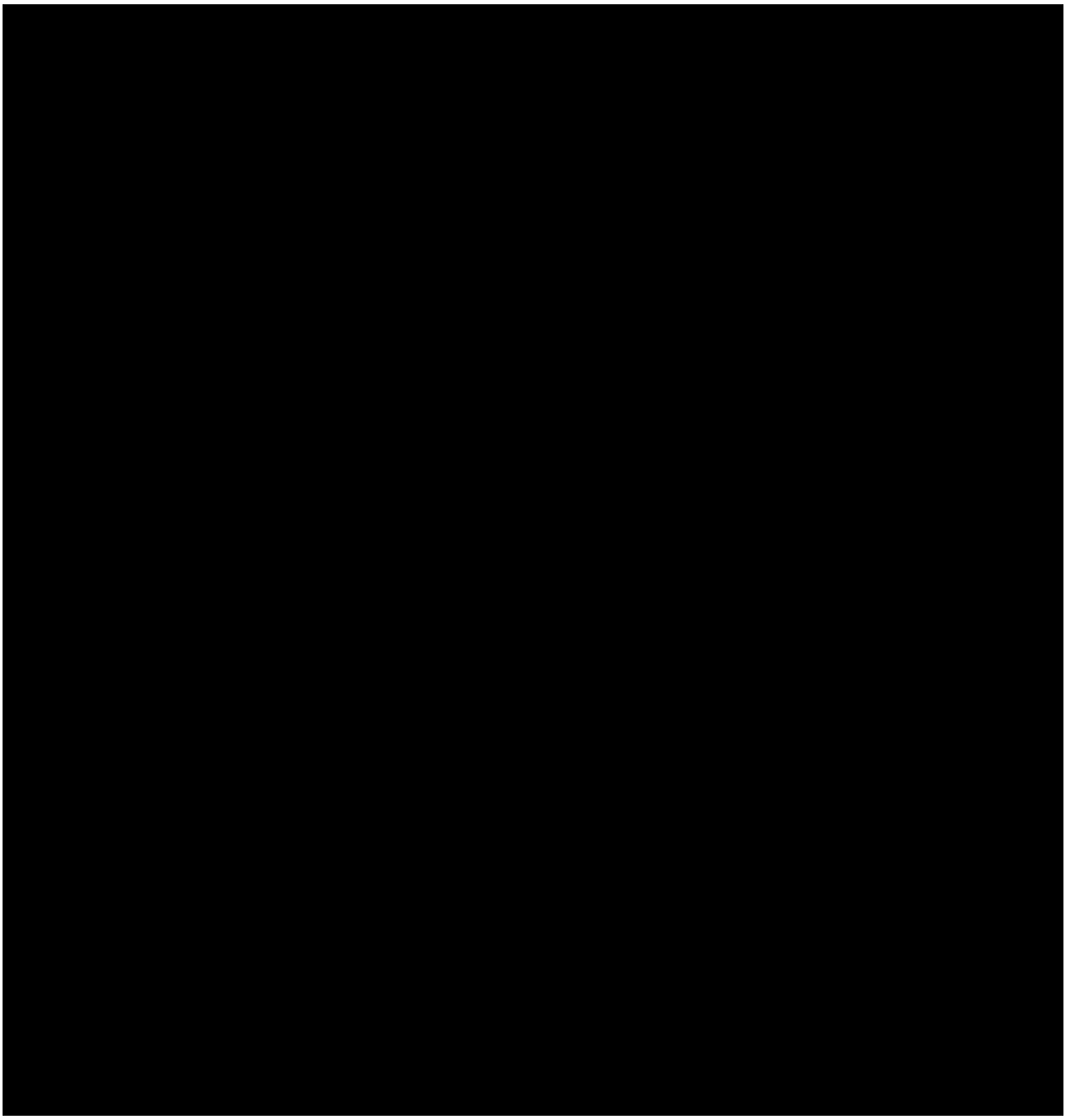


Figure 17: Average Generic Drug Cost Chart

The chart below is similar to the previous one, except that the data displayed represents average brand drug cost.

Figure 18: Average Cost of Brand Drugs Chart

The chart below demonstrates the percentage of generic drugs for a State on a monthly basis for the date range of November 2012 through October 2014.

Figure 19: Percentage of Generic Drugs Chart

The example below shows the average number of prescriptions per user for a state.

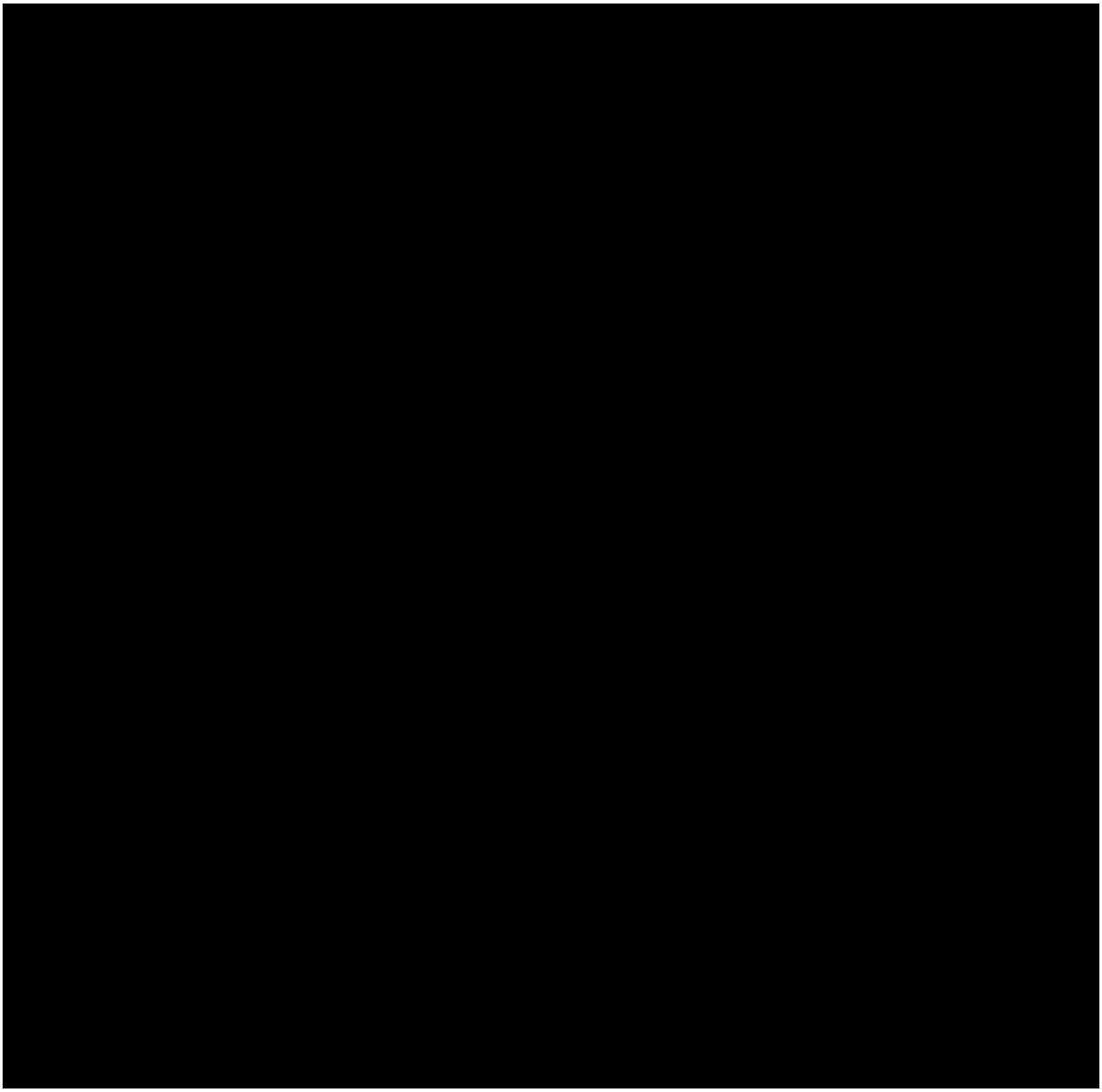


Figure 20: Average Scripts per User Chart

The following chart demonstrates the average amount paid for prescriptions on a monthly basis from November 2012 through October 2014.

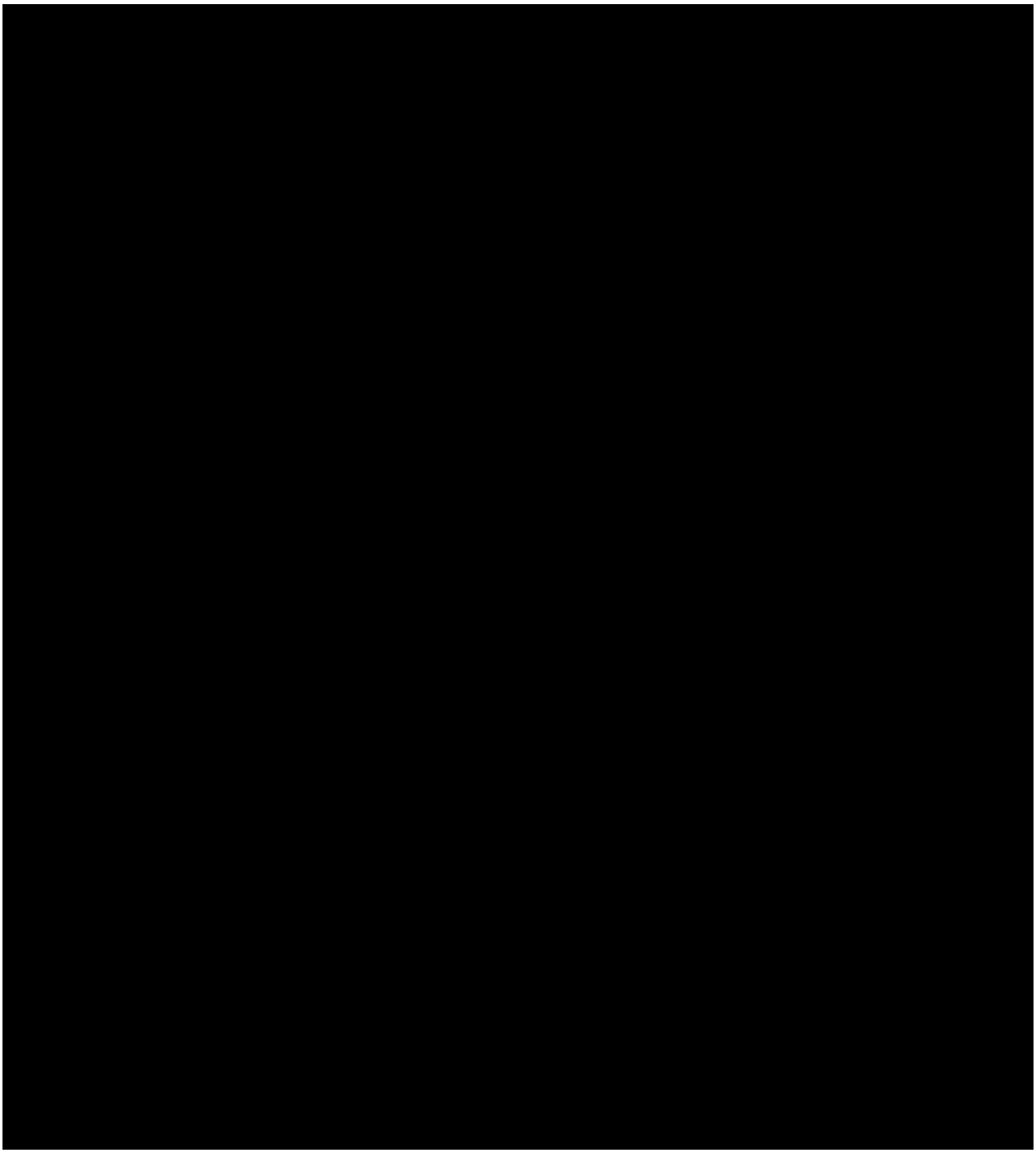


Figure 21: Average Paid Per Script Chart

4.1.11.5.1.10 Monthly and State Fiscal Year Statistics: Compares the current month to the same month for the previous year. Summarizes the calendar year-to-date for the current month and previous calendar year-to-date; shall contain the total amount paid, number of users, total number of prescriptions, average prescriptions per member user, average cost per prescription; number of generic prescriptions, percentage of generic prescriptions paid compared to the overall amount paid for all prescriptions, total amount paid for generic prescriptions, average generic prescription cost, average days' supply for generic prescriptions, number of brand prescriptions, percentage of brand prescriptions paid compared to the overall amount paid for all prescriptions, total amount paid for brand prescriptions, average brand prescription cost, average days' supply for brand prescriptions. At a minimum, this report shall be delivered monthly.

Goold will comply with the State's request for a Monthly and State Fiscal Year Statistics Report that will be supplied monthly to the Bureau. This report will summarize the calendar year-to-date for the current month to the previous calendar year-to-date and will contain all of the details as outlined in the requirement. The details of this report are commonly accompanied by the corresponding graphs shown previously.

Samples of these reports are provided on the following pages. Each can be tailored to the State's specifications.

The Fiscal Year Statistics Report below displays various data, as shown on the left column of the chart, and compares the data from a month in 2013 to the same month in 2014, as well as calendar year 2013 to calendar year 2014.

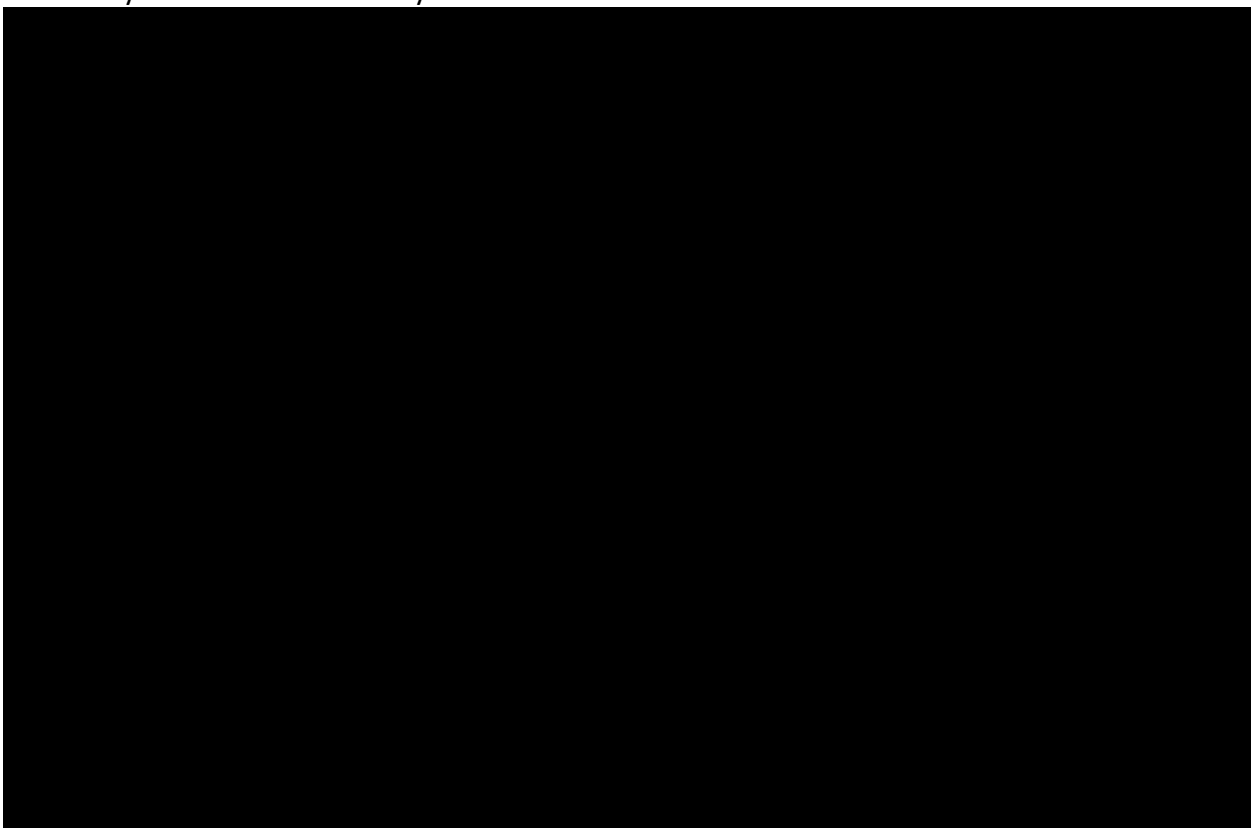


Figure 22: Sample Fiscal Year Statistics Report

4.1.11.5.1.11 Top twenty (20) Therapeutic Classes by Dollars: Lists the therapeutic class description, ranking based on amount paid, comparison from the previous year for the same period, and the percentage change from the previous year period, the percent of the overall pharmacy expenditures for the period and the percent of the overall pharmacy expenditures for the previous year period. At a minimum, this report shall be delivered quarterly and annually.

4.1.11.5.1.12 Top twenty (20) Drugs by Dollars: Lists the drug description, ranking based on amount paid, comparison from the previous year for the same period, and the percentage change from the previous year period, the percent of the overall pharmacy expenditures for the period and the percent of the overall pharmacy expenditures for the previous year period. At a minimum, this report shall be delivered quarterly and annually.

4.1.11.5.1.13 Top twenty (20) Therapeutic Classes by Utilization: Lists the therapeutic class description, ranking based on number of prescriptions, comparison from the previous year of the same period, and the percentage change from the previous year period, the percent of the overall number of prescriptions for the period and the percent of the overall number of prescriptions for the previous year period. At a minimum, this report shall be delivered quarterly and annually.

4.1.11.5.1.14 Top twenty (20) Drugs by Utilization: Lists the drug descriptions, ranking based on number of prescriptions, comparison from the previous year for the same period, and the percentage change from the previous year period, the percent of the overall number of prescriptions for the period and the percent of the overall number of prescriptions for the previous year period. At a minimum, this report shall be delivered quarterly and annually.

4.1.11.5.1.15 Top twenty (20) Prescribing Providers: Lists for both numbers of prescriptions prescribed and by amount paid for prescriptions prescribed: the prescriber NPI, prescriber name, total amount of prescription costs for prescribed drugs, total number of paid prescriptions prescribed, number of members for which prescriptions were prescribed, average price of paid prescriptions prescribed. At a minimum, this report shall be delivered quarterly and annually.

Goold is experienced at providing the above listed reports and agrees to provide BMS with the Quarterly and Annual reports with all of the data elements listed above as required by BMS. The following reports are examples of Goold's capability to provide the suite of reports requested in this RFQ.

The following report shows the top 20 therapeutic classes by amount paid. This compares from a sample month in 2013 to the same month in 2014 to easily identify shifts in spend. This type of report can be helpful in making recommendations for PDL changes and additions. We include

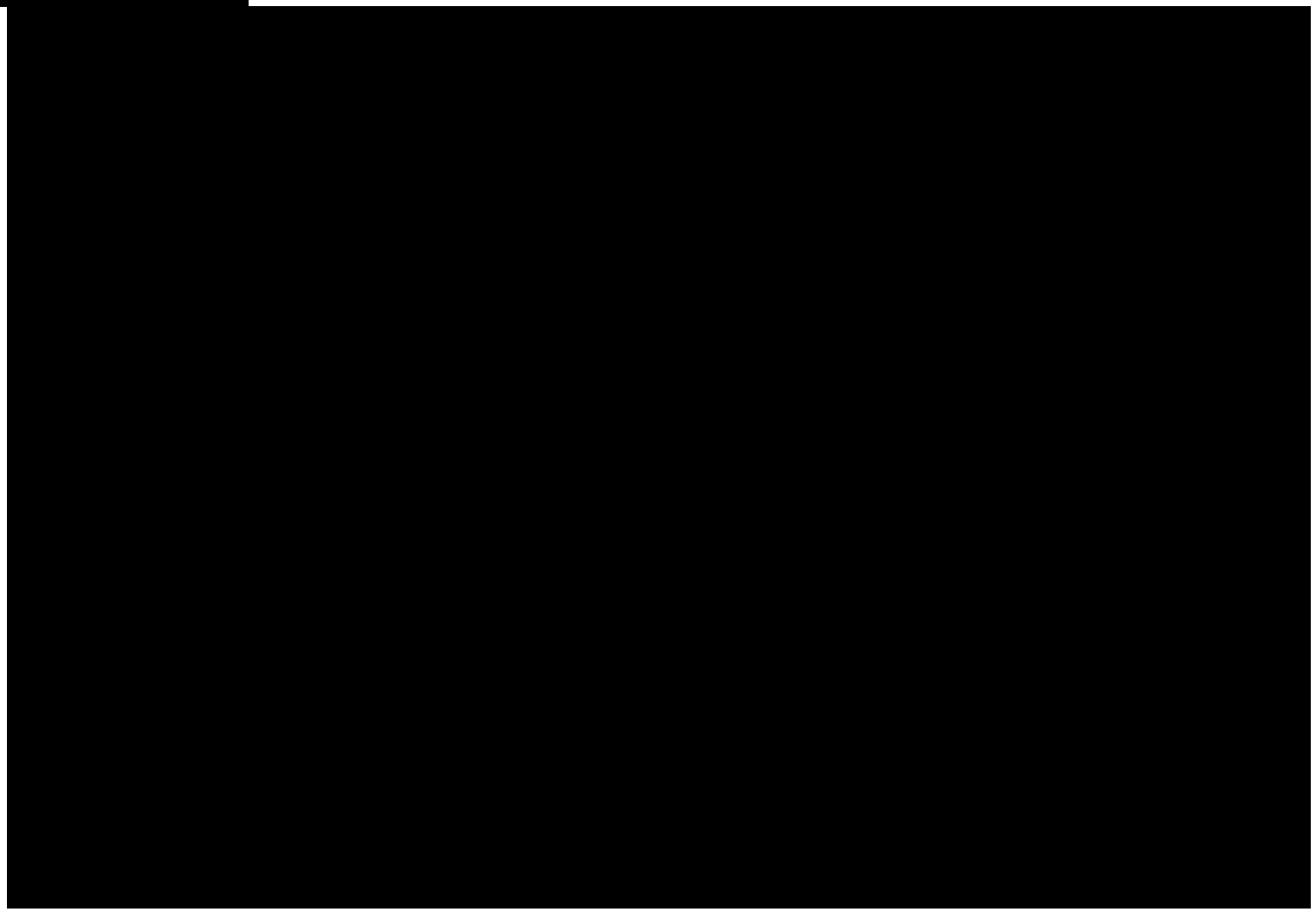


Figure 23: Top 20 Therapeutic Classes Paid by Amount

The following report shows the top 20 drugs by paid amount. This chart is designed [redacted]

Figure 24: Top 20 Drugs sorted by Paid Amount

The following report shows the top 20 therapeutic classes by utilization. This is displayed to compare from a sample month in 2013 to the same month in 2014. This report [redacted]

Figure 25: Top 20 Therapeutic Classes by Utilization

The following report shows the top 20 drugs by utilization. This chart is also designed to [redacted]

Figure 26: Top 20 Drugs by Utilization

The following report shows the top 20 pharmacy NPIs [redacted]

Figure 27: Top 20 Pharmacy NPIs by Paid Amount – 2014

Figure 28: : Top 20 Pharmacy NPIs by Paid Amount – 2014

4.1.11.5.1.16 Marketshare Summary Report: Lists the PDL and PPL therapeutic classes individually and unmanaged products collectively. This report shall provide the number of prescriptions for managed drugs and products within a therapeutic class, martketshare percentage for managed drugs and products within a therapeutic class, number of prescriptions for unmanaged drugs and products within a therapeutic class, and marketshare percentage for unmanaged drugs and products within a therapeutic class. At a minimum, this report must be provided quarterly.

Goold is familiar with the Marketshare Summary Reports and will provide the specified report to the Bureau with all of the data elements listed above quarterly, at a minimum, as required by BMS.

This report shows the market share of drug products in PDL classes in a recent quarter in each state. Using a standardized data format facilitates comparison of information across states. This better enables both Goold and the end user to identify issues or anomalies that might require additional review (such as higher than average utilization of a non-preferred drug in a particular state suggesting that a modification of PA criteria might be warranted). An excerpt of this report is provided on the following page but can be tailored to the State's specifications upon further discussions.

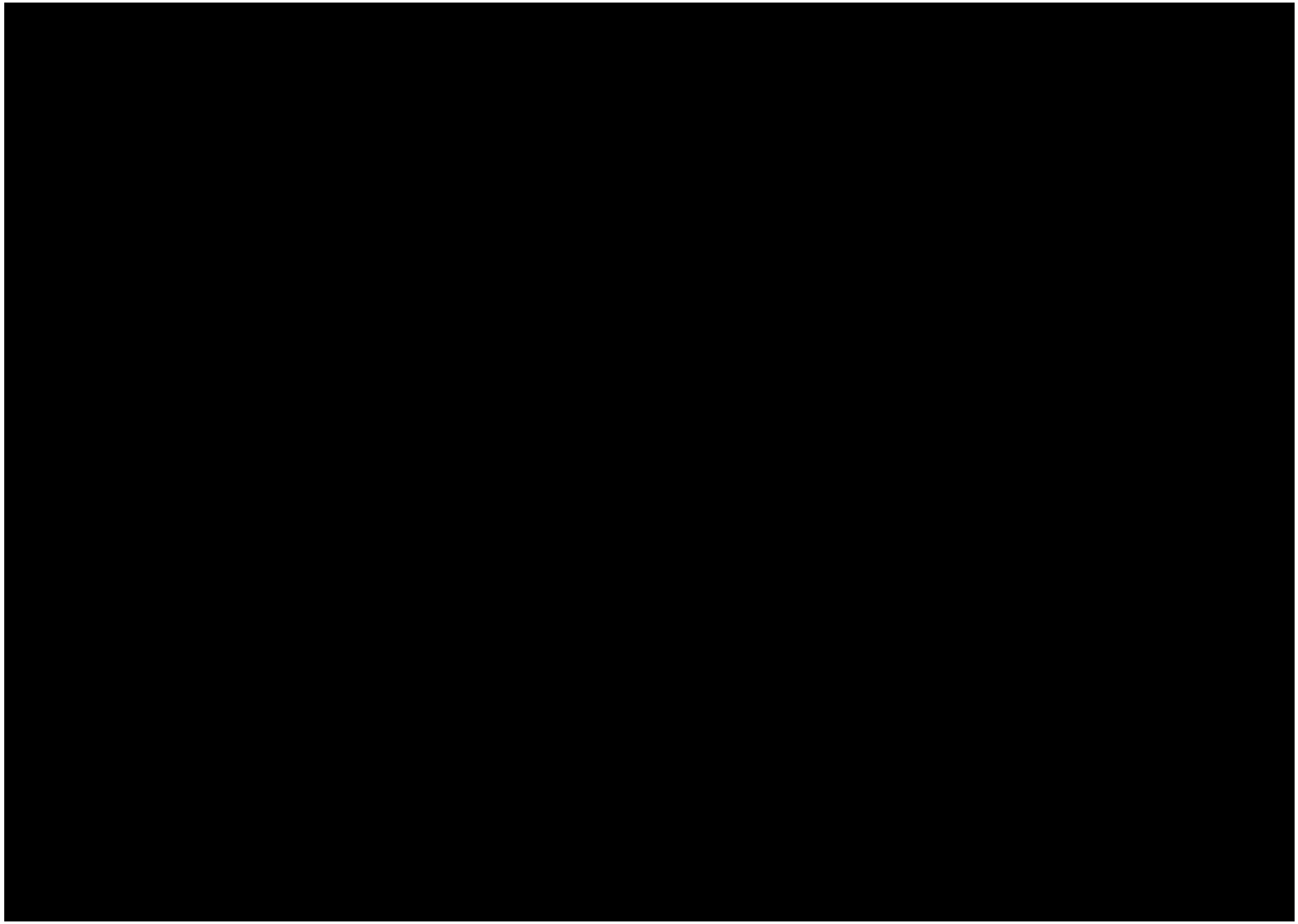


Figure 29: Marketshare Report

4.1.11.5.1.17 Therapeutic Class Marketshare Report: This report shall display within each therapeutic class, the drug or product name, brand or generic status, PDL or PPL status, number of units dispensed, number of paid prescriptions for the period, percentage of prescription marketshare within the therapeutic class, average units per prescription, pre-rebate paid amount, and average expenditures per prescription. At a minimum, this report must be provided quarterly.

Goold will provide the Therapeutic Class Marketshare Report with all of the data elements listed above quarterly, at a minimum, as required by BMS and demonstrated on the previous page.

4.1.11.5.1.18 Generic Compliance Report: This report will show the total number of prescriptions of brand versus generic drugs for a specific timeframe. This report shall display the POL managed therapeutic classes and report the number of prescriptions number of units paid total paid amount generic percentage for the therapeutic class and the generic percentage for the previous quarter. In additional this report shall report the overall generic percentage of managed and unmanaged products. At a minimum this report shall be provided quarterly.

Goold will provide the Generic Compliance Report with all of the data elements listed above quarterly, at a minimum, as required by BMS.

An example is shown on the following page.

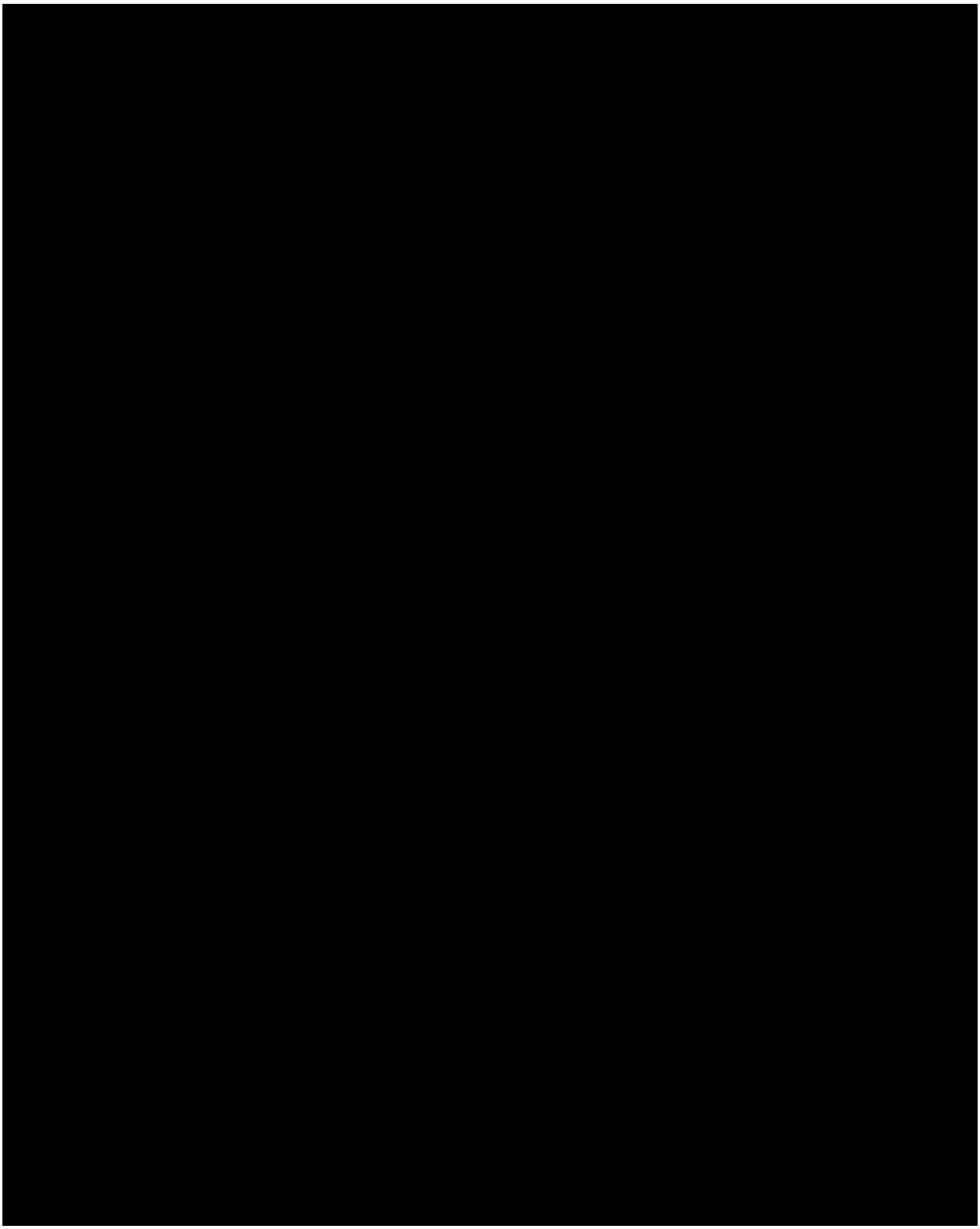


Figure 30: Sample Generic Compliance Report

4.1.11.5.1.19 PDL and PPL Compliance Report: This report will show the percent compliance with the PDL and PPL. It shall display the PDL and PPL managed therapeutic classes and report the number of prescriptions number of units paid total paid amount percentage of preferred products paid for the therapeutic class, and the percentage of preferred products paid for the previous quarter. In addition, this report shall report the overall preferred percentage of managed and unmanaged products collectively. At a minimum this report must be provided quarterly.

Goold will provide the PDL and PPL Compliance Report with all of the data elements listed above quarterly, at a minimum, as required by BMS.

An example of the PDL compliance report is shown on the following page. A report similar to this will be compiled for the State for the PPL.

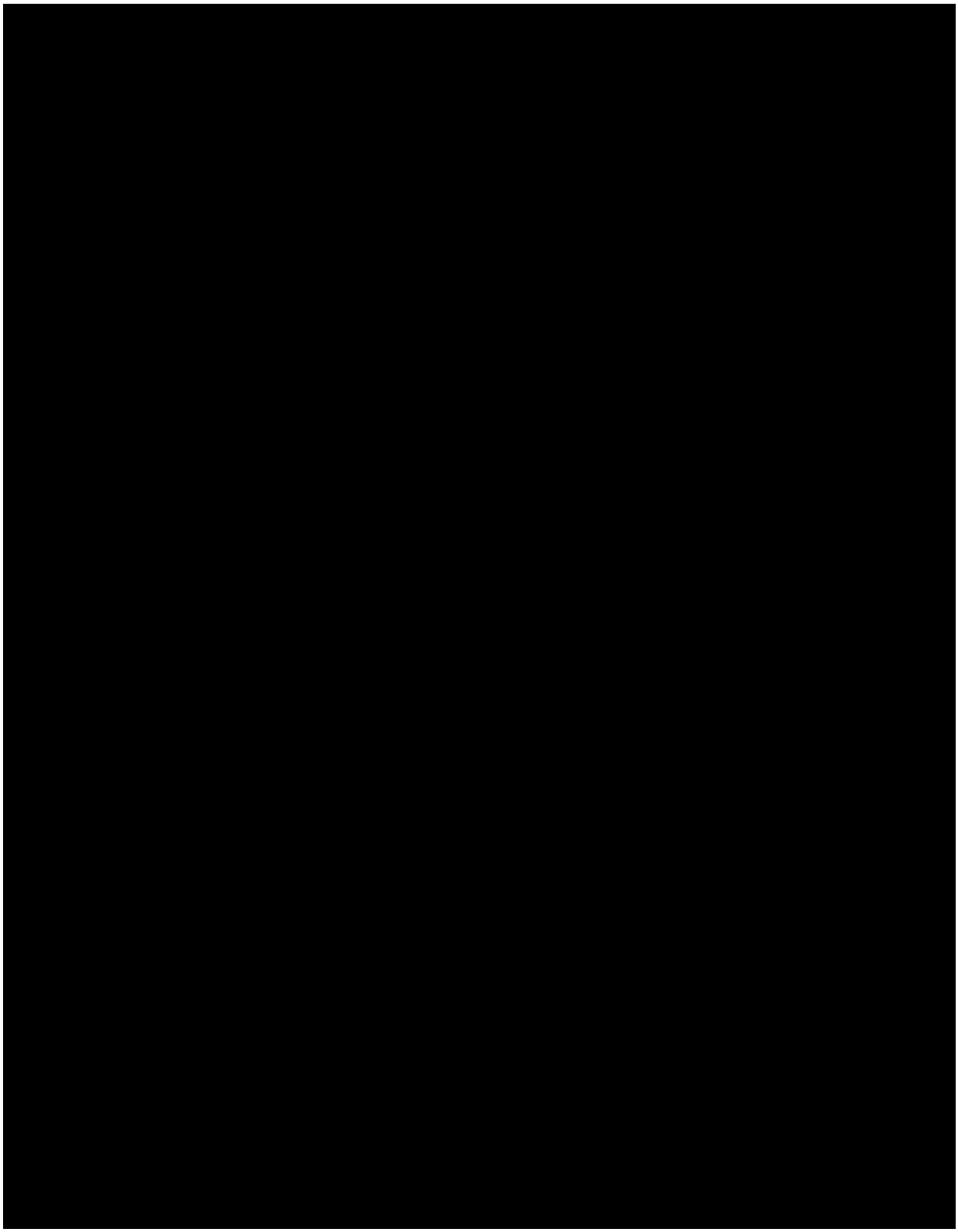


Figure 31: Sample PDL Compliance Report

4.1.11.5.1.20 Weekly NDC Update Report: This report will summarize new additions to the drug reference file. At a minimum this report shall display the PDL or PPL category drug or product name, generic name, NDC or product code date of FDA approval, date of database entry, and comments. This report shall be provided weekly.

Goold will provide the Weekly NDC Update Report with all of the data elements listed above weekly, at a minimum, as required by BMS. Goold currently produces the [redacted] A sample is included below.

Figure 32: Sample Weekly NDC Update Report

4.1.11.5.1.21 Rebate Dispute Status Report: No later than fourteen (14) calendar days after the end of each month, the Vendor will submit a written report detailing the status of any disputes that the Bureau has requested the Vendor to assist in resolving. At a minimum, this report shall be provided monthly.

All dispute activity is documented in a weekly status report. Dispute resolution is discussed, and labeler communication is documented in the weekly meeting minutes, including client comments and/or related action items. Goold will provide a Rebate Dispute Status Report monthly, at a minimum, no later than fourteen (14) calendar days after the end of each month, as required by BMS.

4.1.11.5.1.22 SMAC Savings Report: This report shall document savings generated from the SMAC pricing program. At a minimum, this report must be provided quarterly.

Goold will provide the SMAC Savings Report quarterly, at a minimum, as required by BMS. A sample of this report is provided below. This demonstrates the [redacted] sample report and can be tailored to the State's specifications upon further discussions.

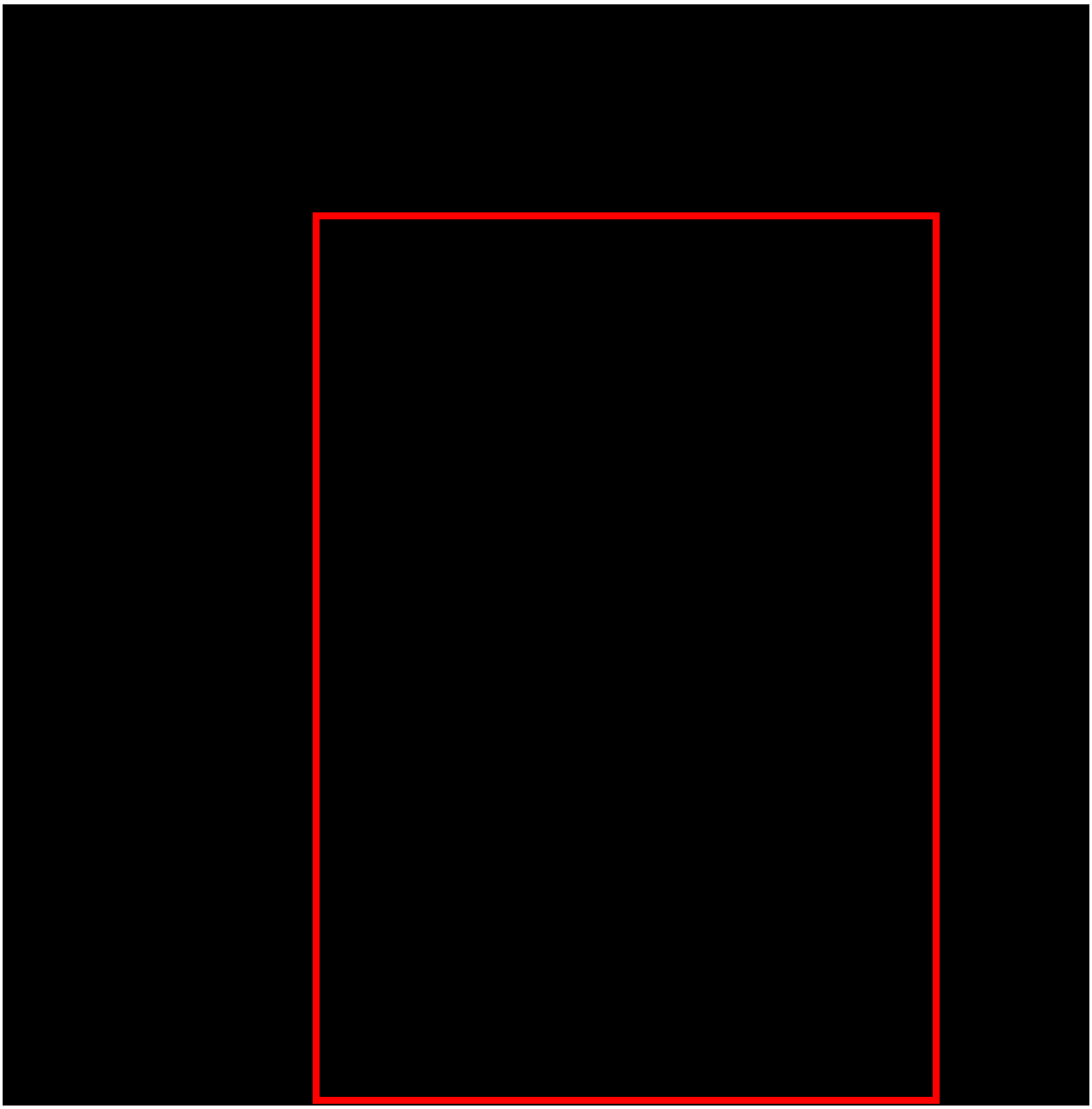


Figure 33: Actual SMAC Savings Summary Report

4.1.11.5.1.23 PDL and PPL Savings Report: This report shall document savings generated from the PDL and PPL. At a minimum, this report must be provided quarterly.

Goold will provide the PDL Savings Report quarterly, at a minimum, as required by BMS. Goold will work with the Bureau during DDI to clearly define how savings should be considered and subsequently calculated.

4.1.11.5.1.24 SMAC Savings Beyond Aggregate FUL Cap: This report will document assurances that multisource drug pricing is in compliance with federal regulations (42 CFR 447.332 or revision). At a minimum, this report shall be provided quarterly.

Goold will provide the SMAC Savings Beyond Aggregate FUL Cap Report, which assures that generic pricing is in compliance with 42 CFR 447.332, quarterly, at a minimum, as required by BMS.

The following is a sample of this report. [redacted]. This could be tailored to the State's specifications upon further discussions.

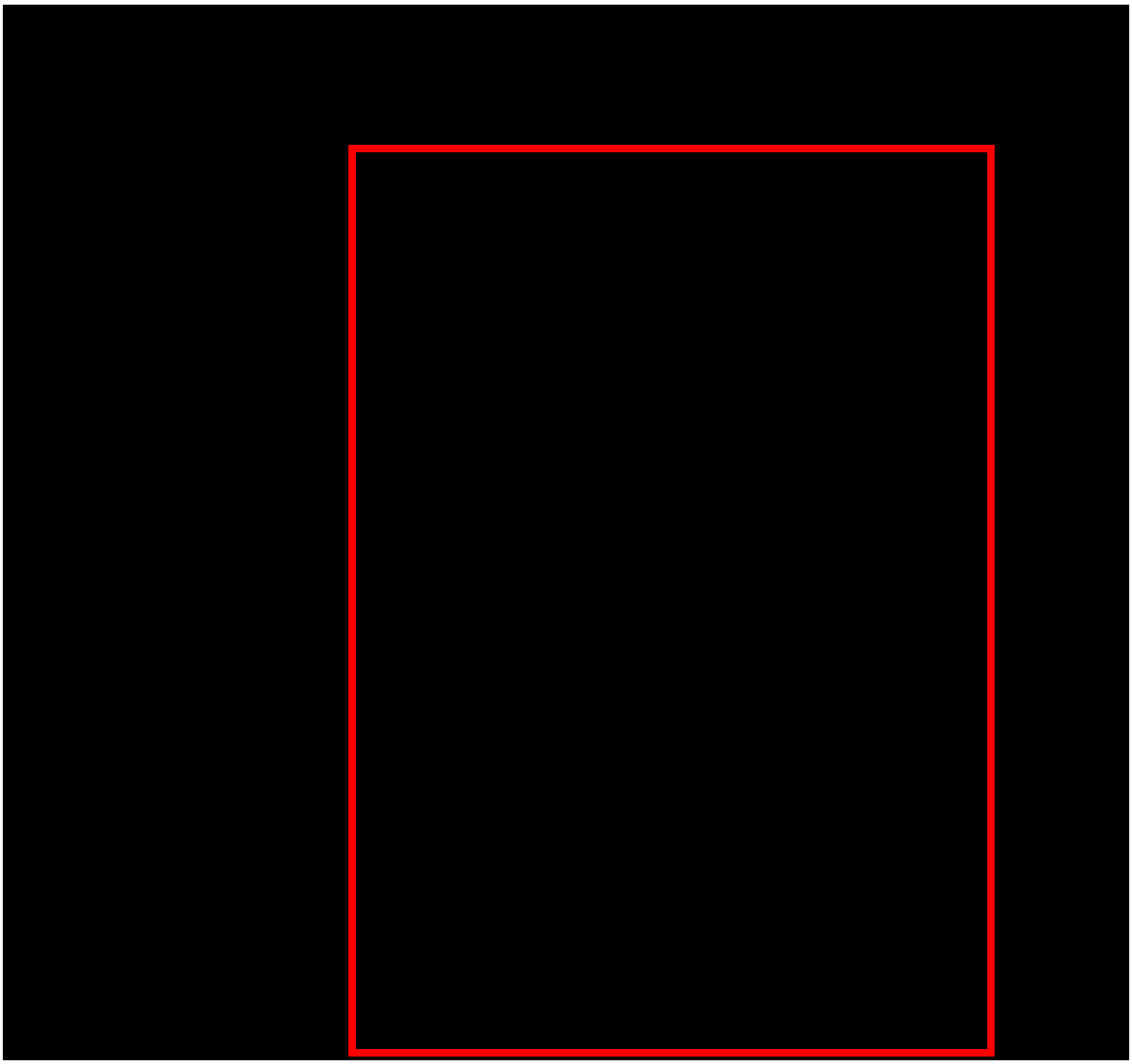


Figure 34: Sample SMAC Savings Beyond Aggregate FUL Cap

4.1.11.5.1.25 WV Provider Pricing Support and Dispute Resolution Report: This report shall log and track all pricing issues from providers and resolutions reached. This report must detail the dispute, and track both approved and resolved issues during the state fiscal year (7/1/XX-6/30/XX) as well as open disputes still being considered. This report shall include, but not be limited to: product name, NDC, prescription number, inquiry date, date of service, Average Wholesale Price (A WP), Wholesale Acquisition Cost (WAC), Federal Upper Limit (FUL), SMAC, provider acquisition cost, dispensing fee, quantity, reviewer identifier, date of outcome returned, recommendation, final outcome, comments, new SMAC, effective date, provider name, and removal of FUL effective date. At a minimum, this report must be provided weekly.

Goold will provide the WV Provider Pricing Support and Dispute Resolution Report, which will track all pricing issues from providers and resolutions reached. Detail about the dispute will be reported and both approved and resolved issues will be tracked. We currently do this for our

other SMAC clients on a weekly basis and will include this for West Virginia. All other report information outlined above will be included in the report to be provided weekly to the Bureau.

4.1.11.5.1.26 New GSN SMAC Report: Vendor shall provide a report of new products for which a SMAC is recommended. This report shall include, but not be limited to, the Generic Sequence Number (GSN), product name, SMAC, effective date, and comments. 1bis report shall be delivered weekly.

Goold will provide the New GSN SMAC Report weekly and will include the information specified by the State. We currently provide this report for our existing SMAC clients and, although changes may not occur weekly, our staff will be happy to supply this report to the State on a weekly basis or on any frequency requested. Goold regularly monitors the First Data Bank and MediSpan drug files for opportunities for savings on newly released generic drugs and drugs where WAC prices have decreased.

4.1.11.5.1.27 PDL and PPL Changes Report: This report will highlight changes to the PDL and /or PPL approved by the P & T Committee and/or Bureau, and must be provided no later than fourteen (14) calendar days after each P & T Committee meeting.

Goold will provide the PDL and PPL Changes Report which will highlight changes to the PDL approved by the P&T Committee no later than fourteen (14) calendar days after every P&T Committee meeting, as required by BMS. An excerpt of this report is included on the following page and can be tailored to the State's specifications.

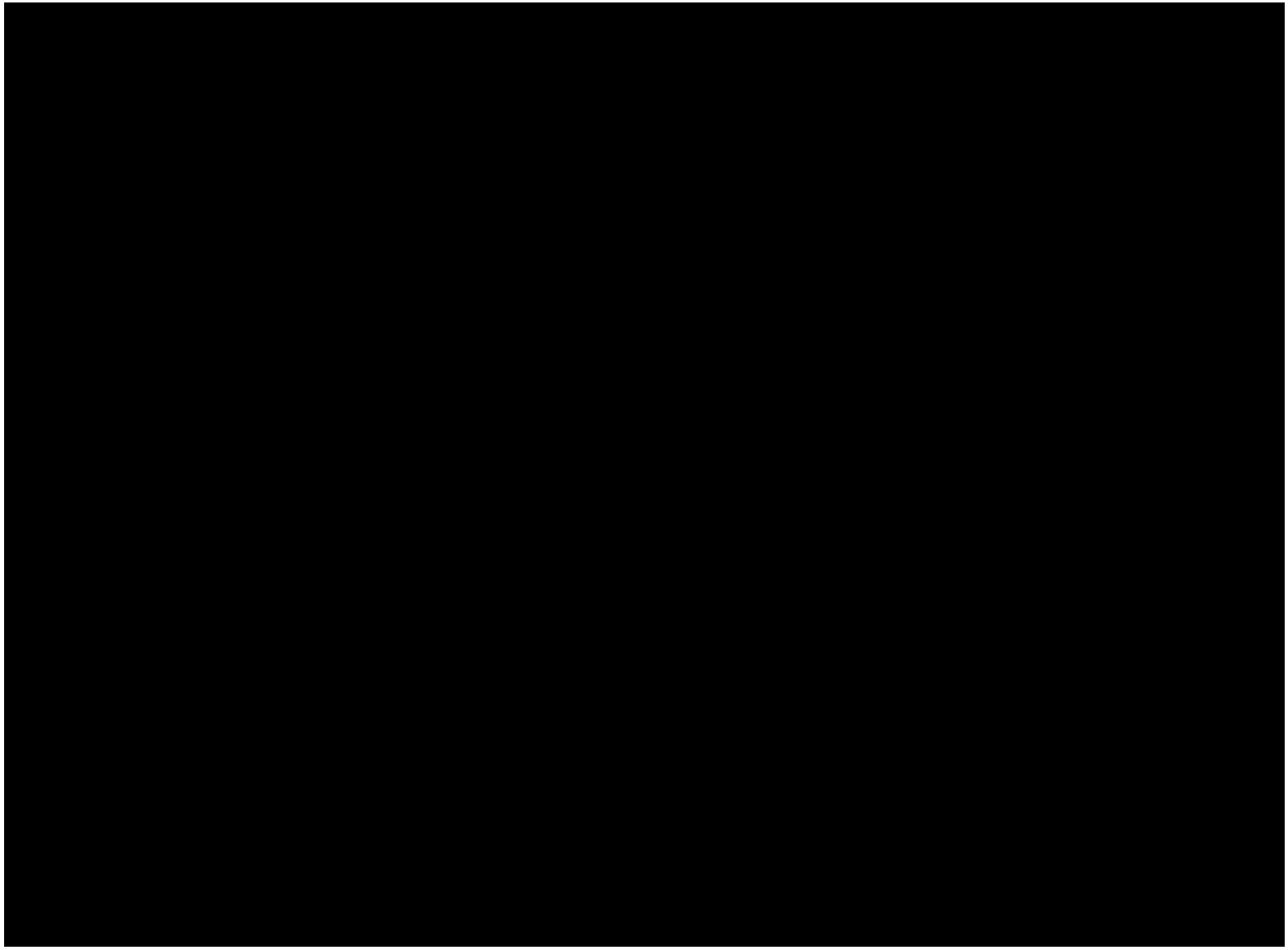
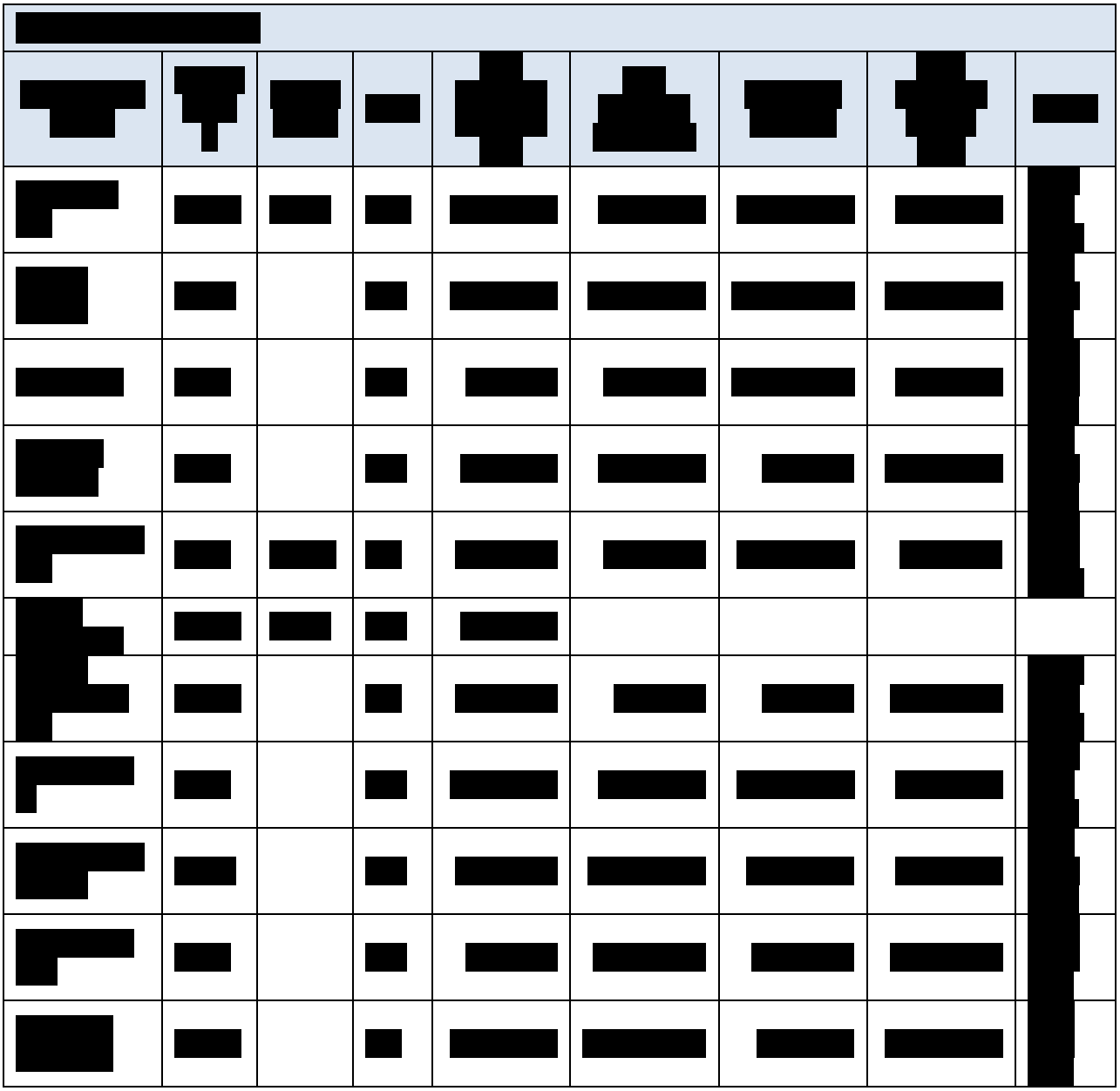


Figure 35: Excerpt of PDL Change Report

4.1.11.5.1.28 Supplemental Drug Rebate Contract and Product Rebate Contract Tracking Report: This report will track all supplemental drug rebate and product rebate contracts between the Bureau and manufacturers in the process of being finalized. This report must include the status of each contract at all points toward completion. The report shall contain, at a minimum: labeler identifier, manufacturer name, labeler number, date contract mailed, date returned form the manufacturer, date sent to state, date sent to manufacturer, contract term, contract end date, contract year. This report shall be provided monthly and more often if requested.

Goold will provide the Supplemental Rebate Contract and Product Rebate Tracking Report with all of the data elements listed above monthly, or more often if requested, as required by BMS. A sample of this report is shown below but can be tailored to the State's specifications.



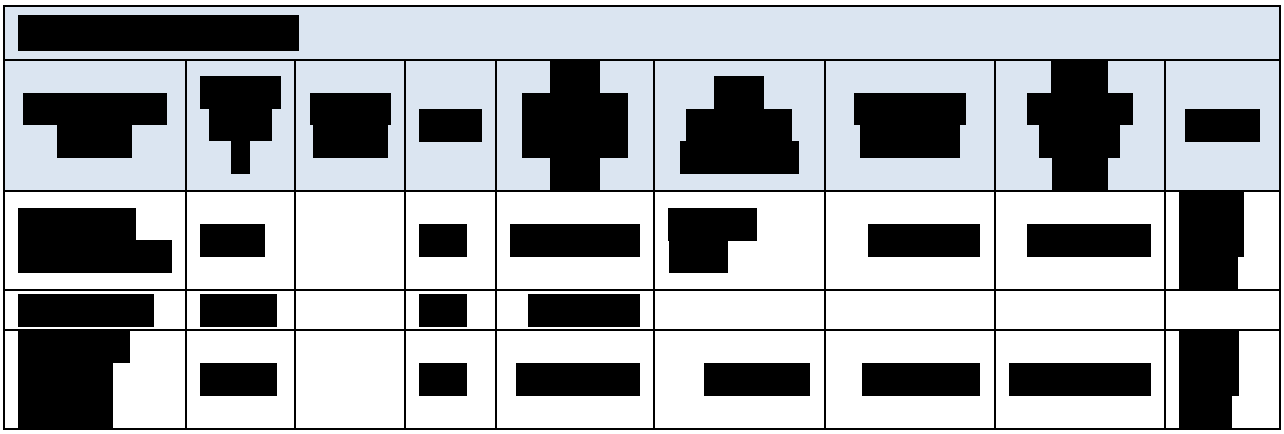


Table 7: SR Contract and Product Rebate Tracking Report

4.1.11.5.1.29 Supplemental Drug and Product Rebate Contract Details Report: This report will document all contracts finalized between the Bureau and manufacturers, and must include contract details such as, but not limited to: product description, NDC, labeler, contracted guaranteed net price (GNP), contracted percent of price, contract type. This report shall be provided monthly.

Goold will provide a Supplemental Rebate Contract Details Report with all of the data elements listed above monthly, as required by BMS.

4.1.11.5.1.30 Supplemental Drug Rebate and Product Rebate Pricing Files Quality Assurance Checklists: These reports will track the steps that are taken by the Vendor to ensure that supplemental drug rebate and product rebate pricing files are correct and accurately contain contract data. At a minimum, these reports must be provided quarterly.

Goold will provide the Supplemental Drug Rebate and Product Rebate Pricing Files Quality Assurance Checklist, which will track the steps that are taken by Goold to assure that the supplemental rebate pricing file is correct and that it accurately contains the supplemental rebate contract data quarterly, at a minimum, as required by BMS.

4.1.11.5.1.31 Supplemental Drug Rebate and Product Rebate Contract Files Quality Assurance Checklists: These reports will track the steps that are taken by the Vendor to ensure that supplemental drug rebate and product rebate contract files are correct and accurately contain contract data. At a minimum, these reports must be provided quarterly.

Goold will provide a Supplemental Drug Rebate and Product Rebate Contract Files Quality Assurance Checklist with all of the data elements listed above monthly, as required by BMS.

4.1.11.5.1.32 Supplemental Drug Rebate and Product Rebate Pricing Files -Additions and Corrections Reports: These reports will track adjustments that are included on the supplemental drug rebate and product rebate pricing files and the reasons for the adjustments. At a minimum, this report must be provided quarterly.

Goold will provide the Supplemental Drug Rebate and Product Rebate Pricing Files - Additions and Corrections Report that will track adjustments that are included on the supplemental

rebate pricing file and the reasons for the adjustments quarterly, at a minimum, as required by BMS.

4.1.11.5.1.33 Supplemental Drug Rebate and Product Rebate Contract Files -Additions and Corrections Reports: These reports will track adjustments that are included on the supplemental drug rebate and product rebate contract files and the reasons for the adjustments. At a minimum, this report must be provided quarterly.

Goold will provide the Supplemental Drug Rebate and Product Rebate Contract Files - Additions and Corrections Report that will track adjustments that are included on the supplemental rebate pricing file and the reasons for the adjustments quarterly, at a minimum, as required by BMS.

4.1.11.5.1.34 Supplemental Drug Rebate and Product Rebate Pricing Files Spreadsheets: These reports will contain all the data for each NDC included on the supplemental drug rebate and product rebate pricing files, along with any other pertinent rebate contract or pricing information. At a minimum, this report must be provided quarterly.

Goold will provide the Supplemental Drug Rebate and Product Rebate Pricing Files Spreadsheet with all of the data elements listed above quarterly, at a minimum, as required by BMS.

4.1.11.5.1.35 Supplemental Drug Rebate and Product Rebate Contract Files Spreadsheets: These reports will contain all the data for each NDC included on the supplemental drug rebate and product rebate contract files, along with any other pertinent rebate contract information. At a minimum, this report must be provided quarterly.

Goold will provide the Supplemental Drug Rebate and Product Rebate Contract Files Spreadsheet with all of the data elements listed above quarterly, at a minimum, as required by BMS.

4.1.11.5.1.36 NDC Conversion Factor Report: This report will track the drugs and products that require a unit of measure conversion factor in the rate calculation. At a minimum, this report shall be provided quarterly.

Goold will provide the NDC Conversion Factor Report with all of the data elements listed above quarterly, at a minimum, as required by BMS.

Ad Hoc Reports

4.1.11.5.1.37 Ad Hoc Reports: Vendor shall provide responses to ad hoc reporting requests by the Bureau within five (5) business days of the request throughout the duration of the contract at no additional cost to the State. For cost estimation purposes, assume fifty (50) ad hoc reports per year. Ad hoc reports shall include the report methodology and parameters used in developing the reports.

Goold will provide the Bureau with timely responses to requests for ad hoc reports when requested by the Bureau throughout the duration of the contract, at no additional cost to the State; Goold will include the methodology and parameters used to develop the reports. In addition, Goold is pleased to provide BMS with a license to use a Web Intelligence (WEBI) tool

that is loaded with West Virginia Medicaid pharmacy data. This tool will provide a desktop resource for rapid answers to utilization questions, including detail to the claim level. Goold will provide any information or ad hoc report upon request in compliance with this RFQ, and will provide this tool for use by the Bureau as well.

4.1.11.5.1.38 Additional Ad Hoc Reports: Vendor shall include in the Pricing Pages (Line I 0) the cost of each additional ad hoc report that exceed the estimated fifty (50) ad hoc reports per year that are included in the base contract.

Per the State's request, Goold has provided an hourly rate for additional services in the pricing page of the online response. For ad hoc reporting purposes, reports requested beyond the estimated 50 of this this RFQ, the State should refer to Goold's hourly rate for an additional cost estimate.

Business Rules Document

4.1.11.5.1.39 Business Rules Document: Vendor shall provide a document that details all business rules that apply to the PDL, PPL, and SMAC programs, as well as to the supplemental drug and product rebate invoicing, in an electronic format. This document shall contain at a minimum: processes, standard operational procedures, details regarding data file layouts, delivery schedules and maintenance of reports, management of NDCs, prior authorization requirements, contracting deliverables, pricing methodologies, telephone line processes, and all details of other business rules and procedures.

Goold will provide the Business Rules Document in an electronic format as required by BMS. Information to be included in the Document will include at a minimum:

- Processes;
- Standard operations procedures;
- Details regarding data file layouts;
- Delivery schedules and maintenance of reports,
- Management of NDCs;
- Prior authorization requirements;
- Contracting deliverables;
- Pricing methodologies;
- Telephone line processes;
- All other details of other business rules and procedures.

Training Handbook

4.1.11.5.1.40 Training Handbook: Vendor will develop a Training Handbook that describes all major processes being conducted by the Vendor to meet the needs of each requirement and deliverable of this contract. This handbook shall be developed at contract initiation and maintained throughout the life of the contract. Any changes will be added to the Handbook and provided to the Bureau within five (5) days after the change is made. It will be used for purposes of training new Bureau staff on what is currently being accomplished by the Vendor, as well as to help guide the transition of knowledge at the end of the contract.

Goold will develop a Training Handbook that describes all major processes being conducted by Goold to meet the needs of each requirement and deliverable of this contract. Goold

understands that this document will be developed during the contract initiation phase and is to be maintained throughout the life of the contract for training purposes for new staff as well as a to guide through the transition at the end of the contract. As changes and updates occur, Goold will provide the Bureau with an updated Handbook within five days of making the changes.

4.1.12 Data Files

4.1.12 Vendor shall create data files to be shared with the Bureau and Bureau's partners relating to the PDL, PPL, and SMAC programs.

Goold agrees to create data files relating to the PDL, PPL and SMAC programs for West Virginia to be shared with the Bureau and its partners.

4.1.12.1 Vendor shall, at a minimum, create and distribute to the Bureau or Bureau's designee the following data files in an electronic that are compatible with the WV Office of Technology's currently supported versions of Microsoft Office® Suite:

- ***4.1.12.1.1 Weekly SMAC update file;***
- ***4.1.12.1.2 Weekly SMAC web list;***
- ***4.1.12.1.3 Weekly PDL and PPL files. These files shall contain all available NDCs regardless of their rebate statues;***
- ***4.1.12.1.4 Quarterly supplemental rebate rate, product rebate rate, and contract files; See Attachment C and D;***
- ***4.1.12.1.5 PDL and PPL reconciliation files when needed;***
- ***4.1.12.1.6 Complete PDL and PPL files when needed;***
- ***4.1.12.1.7 PDL and PPL file updates or complete files to be delivered to the Medicaid MCOs, Bureau, or other Bureau designees as needed;***
- ***4.1.12.1.8 Pharmacy utilization files to be delivered to the SSDC vendor, the Bureau, or Bureau's designee quarterly;***
- ***4.1.12.1.9 Other data files when identified that support the PDL, PPL, and SMAC programs quarterly***

As outlined in the requirement above, Goold will create and distribute, at a minimum, the listed data files in electronic format. These files will be compatible with the WV Office of Technology's currently supported versions of Microsoft Office® Suite.

4.1.13 Newsletter

4.1.13 Vendor shall develop, create, and mail to 15,000 prescribers and pharmacies quarterly newsletters containing information relating to changes to the PDL, PPL and other pharmacy program matters in a file format that is compatible with the WV Office of Technology's currently supported versions of Microsoft Office® Suite. Mailing shall be via United States Postal service or other nationally recognized carrier. Vendor shall also provide an electronic final version that will be displayed on the Bureau's website. Newsletter content and schedule must be approved by the Bureau, at a maximum of quarterly.

Goold will work with the State to develop, create and mail 15,000 newsletters quarterly to prescribers and pharmacies. Content of the newsletter will include, but not be limited to, information relating to changes in the PDL, PPL and other pharmacy programs matters. The newsletter will be compatible with the WV Office of Technology's currently supported versions of Microsoft Office® Suite and Goold will use the United State Postal service or other recognized carrier to distribute the newsletters.

An electronic, final version of the newsletter will be made available to the State for use on the BMS website. All versions of the newsletter will be approved by the Bureau prior to any distribution.

4.1.14 Contract Execution and Implementation Plan

4.1.14 Vendor shall assist and fully cooperate with the Bureau in the implementation of the contract executed from this RFQ upon effective date of the contract.

As Goold has done in the past with West Virginia, we agree to assist and fully cooperate with the Bureau during the implementation of any contract that is executed as a result of this RFQ.

4.1.14.1 Vendor shall submit with their quotation an Implementation Plan that demonstrate the Vendor's ability to assume the responsibilities for the Bureau's PDL, PPL, and SMAC programs upon award of this contract.

Goold will comply with all of the requirements outlined above in the RFQ Specification document. A draft Implementation Plan can be found in Exhibit C.

4.1.14.2 Vendor's Implementation Plan must describe major task assignments considered to meet PDL, PPL, and SMAC program services, including but not limited to, project start-up, project status, project updates, and project reassignments.

The Implementation Plan included in Exhibit C describes the major task assignments which need to be considered in order to meet PDL, PPL and SMAC program requirements. Detailed information regarding the resources assigned to the major tasks is supplied, including additional information related to Goold's comprehensive approach to the project.

4.1.14.3 Vendor shall conduct face-to-face meetings with the Bureau's staff and Vendor's key staff and other support staff to initiate the contract deliverables and services. These meetings shall be conducted at the Bureau's offices in Charleston, West Virginia.

Upon project initiation, Goold's key staff will meet with BMS in person to discuss contract deliverables and services. Goold understands that these meetings will be held at the Bureau's office in Charleston, West Virginia.

4.1.15 Transition and Turnover

4.1.15 Vendor shall assist and fully cooperate with the Bureau when transitioning to a new vendor at the end of the contract executed from this RFQ.

In the event that a replacement vendor is selected as the result of a future re-procurement, Goold is prepared to assist and fully cooperate with the State, as directed. Goold will support transition planning services to enable a new PDL, PPL, SMAC vendor or the State to continue providing the pharmacy services specified in the RFQ.

4.1.15.1 Vendor shall provide a Close-Out and Turnover Plan that identifies the Vendor's approach, tasks, staffing, and schedule for turnover of contract responsibilities.

Goold will provide a Close-Out and Turnover Plan that identifies and details Goold's approach, tasks, staffing, and schedule for turnover of contract responsibilities.

4.1.15.2 Vendor will provide the Close-Out and Turnover Plan within thirty (30) calendar days of receiving Bureau notification to initiate the Close-Out and Turnover Phase.

Goold will agrees to provide a Close-Out and Turnover Plan within thirty (30) calendar days of receiving notification from BMS to initiate the Close-Out and Turnover Phase.

4.1.15.3 Vendor shall dedicate resources consistent with the approved Close-Out and Turnover Plan.

Goold will dedicate appropriate resources consistent with the approved Close-Out and Turnover Plan for the State of West Virginia.

4.1.15.4 Upon request, Vendor shall transfer to the Bureau's ownership any and all data collected, created, summarized, and/or aggregated, and any deliverables and reports created specifically for the Bureau during the contract period.

Upon request, Goold will transfer to the Bureau any and all data collected, created, summarized and/or aggregated, and any deliverables and reports created during the contract period. Data transferred will be limited to the data that belongs to the State only, as outlined in Section 4.1.6 – Cooperation with Bureau and its Partners. Goold methodologies and applications used to serve the West Virginia project are proprietary to Goold.

4.1.15.4.1 Data, deliverables, and reports shall be transferred in a file format that is compatible with the WV Office of Technology's currently supported versions of Microsoft Office® Suite.

Goold will transfer data, deliverables and reports in a file format compatible with the WV Office of Technology's currently supported versions of Microsoft Office™ Suite. As stated above, data transferred will be limited to the data that belongs to the State only, as outlined in Section 4.1.6 – Cooperation with Bureau and its Partners. Goold methodologies and applications used to serve the West Virginia project are proprietary to Goold.

4.1.15.4.2 Data, deliverables, and reports will be transferred in accordance with a schedule and in an electronic format, no longer than thirty (30) calendar days prior to the end of the contract.

Goold assures that all data, deliverables and reports will be transferred in accordance with a schedule approved by the Bureau, but no later than thirty (30) calendar days prior to the end of the contract.

4.1.15.4.3 Vendor shall provide a Turnover Results Report which documents the completion and results of each task identified in the Turnover Plan.

Goold agrees to provide the Turnover Results Report which will document the completion and results of east task identified in the Turnover Plan to the Bureau as requested.

4.1.15.4.4 The Turnover Results Report shall be submitted in a file format that is compatible with the WV Office of Technology's currently supported versions of Microsoft Office® Suite.

Goold will submit the Turnover Results Report, documenting the completion and results of each task identified in the Turnover Plan in a file format that is compatible with the WV Office of Technology's currently supported versions of Microsoft Office™ Suite.

4.1.15.4.5 The Turnover Results Report shall be submitted in accordance with a schedule approved by the Bureau, no later than thirty (30) calendar days prior to the end of the contract.

Goold will submit the Turnover Results Report in accordance with a schedule approved by the Bureau and no later than thirty (30) days prior to the end of the contract.

4.1.16 Additional Services

4.1.16 Vendor shall provide a pool of one hundred (100) hours annually that can be used by the Bureau for assistance, advice and consultation for Medicaid pharmacy activities, such as additional clinical consultation, reports related to the PDL, PPL, or pricing of a complex nature, direct contact by telephone or by other agreed upon means to prescribers regarding appropriate drug utilization. Vendor shall provide on the Pricing Pages the all-inclusive hourly rate for additional services requested by the Bureau during each of the possible Contract years. The one hundred (I 00) hour pool is an estimate only; actual quantities requested by the Bureau during the life of contract may vary.

Goold prides itself on being available and providing expertise to our client States for any and all issues related to their PDL and SMAC programs. Goold will provide an outstanding customer service experience in support of the BMS staff. In addition, Goold will provide a pool of at least 100 hours annually that can be used by BMS for assistance, advice and consultation for Medicaid pharmacy activities.

These hours will be available to BMS for additional clinical consultation, reports related to the PDL, PPL and/or pricing of a complex nature (e.g., drugs not currently managed through the PDL) or direct contact by phone or by other agreed upon mean to prescribers regarding appropriate drug utilization.

For further services beyond the 100 annual pooled hours, Goold has provided an all-inclusive hourly rate in the pricing page of the online response, as requested by the Bureau.

4.1.17 Location of Vendor Services

4.1.17 Vendor's primary business site from which the services described in this RFQ will be provided shall be located within the continental United States of America.

Goold's primary business site is located at the address below. All services for this RFQ will be provided to the State of West Virginia from within the continental United States of America.

Primary Business Site:
Goold Health Systems, an Emdeon company 45 Commerce Drive, Suite 5 PO Box 1090 Augusta, Maine 04332-1090

Contract Award (RFP Section 5)

Goold has provided a purchase price for the services outlined in the RFQ. Per the instructions in RFQ Section 5.2 – Pricing Page, we have completed the Pricing Page with an annual not-to-exceed cost for the combined program deliverables for the Preferred Drug List, Preferred Product List, and State Maximum Allowable Cost program, plus the Additional Ad Hoc Reports and Additional Services Hours for each year of the contract.

Goold understands that all mailing costs and other requirements contained in the RFQ are included in the cost; furthermore, all requirements contained in this RFQ are included in the price quotation.

Goold's Pricing Page has been submitted electronically through the wvOasis online service.

General Contract Terms

Performance (RFP Section 6)

Upon contract award, Goold will work with the Agency to come to an agreement on the schedule for performance of contract services and deliverables as a part of this RFQ.

Payment (RFP Section 7)

Goold has reviewed and understands the Agency's payment methods as outlined in RFQ Section 7.

Travel (RFP Section 8)

Goold understands that we are responsible for all mileage and travel costs, including travel time, associated with performance of this contract. Anticipated mileage and travel costs are included in the price quotation of this RFQ.

Facilities Access (RFP Section 9)

Upon contract award, Goold understands we may be required to comply with the following facility access requirements:

9.1 Identify the principle service personnel that will be issued access cards and/or keys to perform services;
9.2 Responsibility for controlling cards and keys, and will pay the replacement fee if the cards/keys are lost or stolen;
9.3 Notify the Agency immediately of lost, stolen, or missing cards or keys;
9.4 Personnel performing under the resulting contract may be subject to security protocol and procedures; and
9.5 Informing all Goold staff of the Agency's security protocol and procedures.

Vendor Default (RFP Section 10)

Goold has reviewed and understands the vendor default conditions outlined in RFQ Section 10.1.1 – 10.2.3.

Miscellaneous (RFP Section 11)

During the performance of the contract with West Virginia, Goold has designated the following as the Contract Manager. We will maintain a primary contact responsible for overseeing the vendor responsibilities under the contract as a result of this RFQ.

Contract Manager

Contract Manager: *James A. Clair*

Telephone Number: *(800) 832-9672*

Fax Number: *(207) 623-5125*

Email Address: *jclair@ghsinc.com*

General Terms and Conditions

Pursuant to Section 11 of the WV RFQ Instructions to Vendors Submitting Bids, Goold Health Systems ("GHS") submits the following exceptions to the State of West Virginia RFQ General Terms and Conditions:

Section	Exception Statement/Explanation
10. Litigation Bond	GHS requests the opportunity to negotiate the requirements of this section upon award.
19. Compliance	Because it is unclear which local laws, regulations and/or ordinances may be applicable, GHS requests the opportunity to negotiate this section upon award.
29. Confidentiality.	The documents associated with this section require detailed review by GHS information security, compliance and legal teams. Therefore, GHS requests the opportunity to negotiate this section upon award.
36. Indemnification.	This section requires detailed review by GHS' legal team and internal approvals. Therefore, GHS requests the opportunity to negotiate this section upon award.
38. Additional Agency and Local Government	GHS is uncertain at this time if any awarded contract with the State of WV can be extended to any other WV governmental agency. Therefore, GHS requests that this section be considered 'not approved' at this time.

Table 8: Terms & Conditions Exemptions and Explanation

Disclosure

Per the RFQ Instructions to Vendors document, Section 30 – Disclosure, Goold is submitting a separate response to the RFQ that contains redacted information which we consider is exempt from public disclosure. This redacted copy is suitable for public viewing and has been uploaded to the wvOasis website and is labeled with the following filename:

Filename: WV PDL SMAC CRFQ # 0511 BMS1500000003_Redacted

The following table outlines the information Goold has redacted, as well as the justification for redacting the material.

Exempt Information	Justification for Exemption
All specific descriptions of how Gold has been managing and addressing recent changes to Medicaid pharmacy programs.	Goold's executed plans for these changes were designed by Goold to support or specific client base. These plans were not / are not known by our competitors.
All names, resumes, and other identifying information regarding our proposed staffing for the project.	Goold considers the qualifications of our key staff to be a unique aspect of the solution we provide. If disclosed, the names and credentials of our named staff could be used by other vendors to align their staffing with our own, or even attempt to recruit our staff.
Any calculations of business and technical staffing resources.	These estimates were calculated using Goold proprietary methodology. This information is only known to certain people within Goold and provides us with a business advantage over competitors who do not use it.
All application screen shots and descriptions of functionality.	Goold considers the functionality of our software tools to be a trade secret.
All sample reports.	Goold considers the form and function of our proprietary reporting and analysis to be a trade secret.
Substantive descriptions of our processes for developing reports and documentation.	Goold considers these methods and procedures to be a trade secret.
Substantive descriptions of our SMAC rate setting process.	Goold considers these methods and procedures to be a trade secret.
Substantive descriptions of our preferred drug list management process.	Goold considers these methods and procedures to be a trade secret.
All system workflow diagrams.	Goold considers the internal workflow to be a trade secret.
Descriptions of internal programming practices.	Goold considers the internal workflow to be a trade secret.

Table 9: Redaction Justifications

Exhibit A – Staff Resumes

4.1.5.2 Vendor shall submit with their quotation the names and resumes for staff assigned to this contract including account manager, clinical pharmacist, physician, rebate manager, and SMAC pricing manager.

Goold has assembled an experienced staff that is familiar with West Virginia's unique PDL/PPL and SMAC needs. Our team of key personnel collectively has more than a century of collaborated knowledge and industry related experience to bring to BMS through this contract. We have provided these services to the State in the past successfully and look forward to the opportunity to bring our expertise to the State's programs once again.

The following section includes the resumes for the staff assigned to this contract. Licenses for Registered Pharmacists and Registered Physicians, per RFQ Instructions Section 8 – Required Documents, have also been included with the appropriate resumes. Criteria can be found on the following pages as follows:

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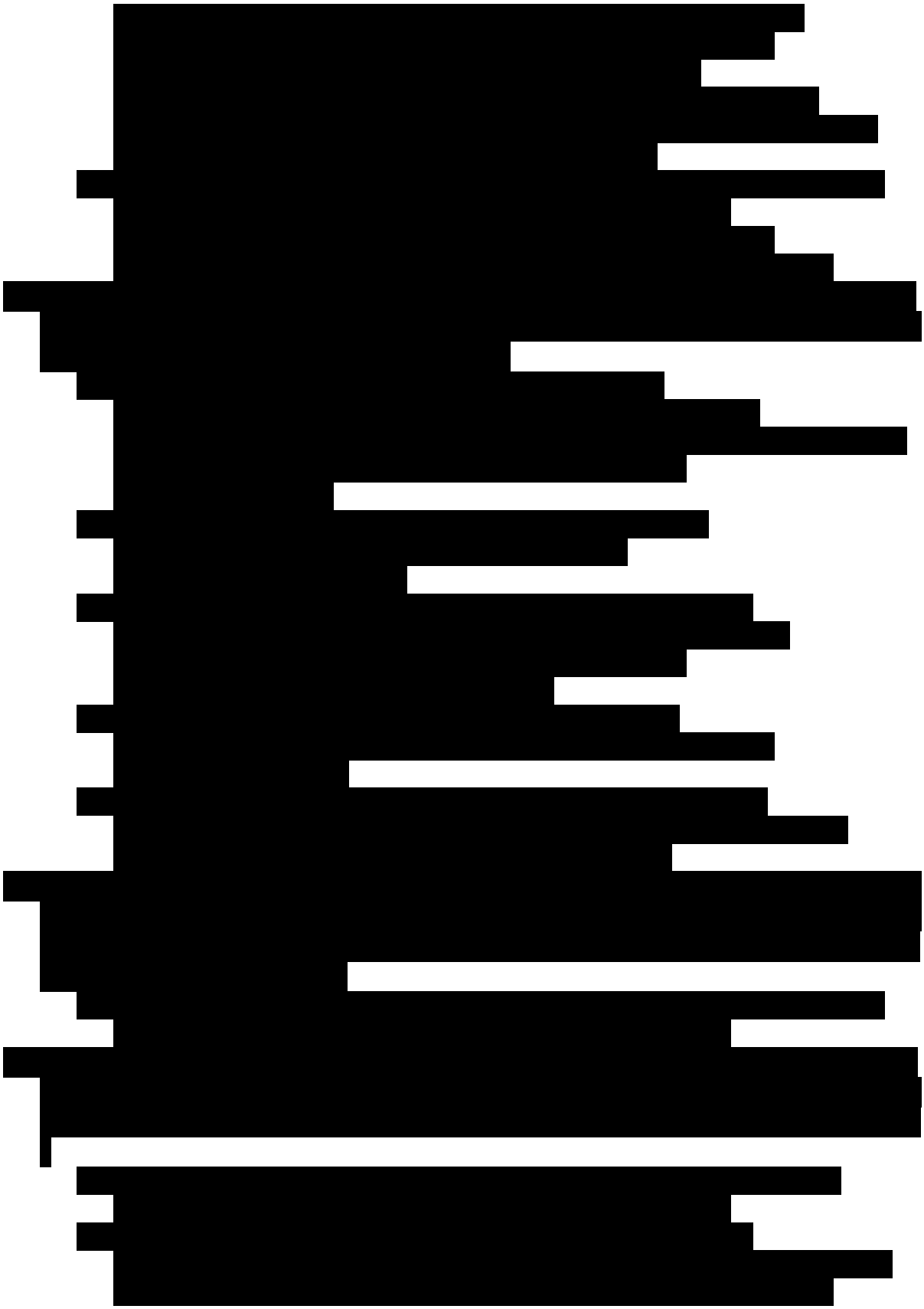

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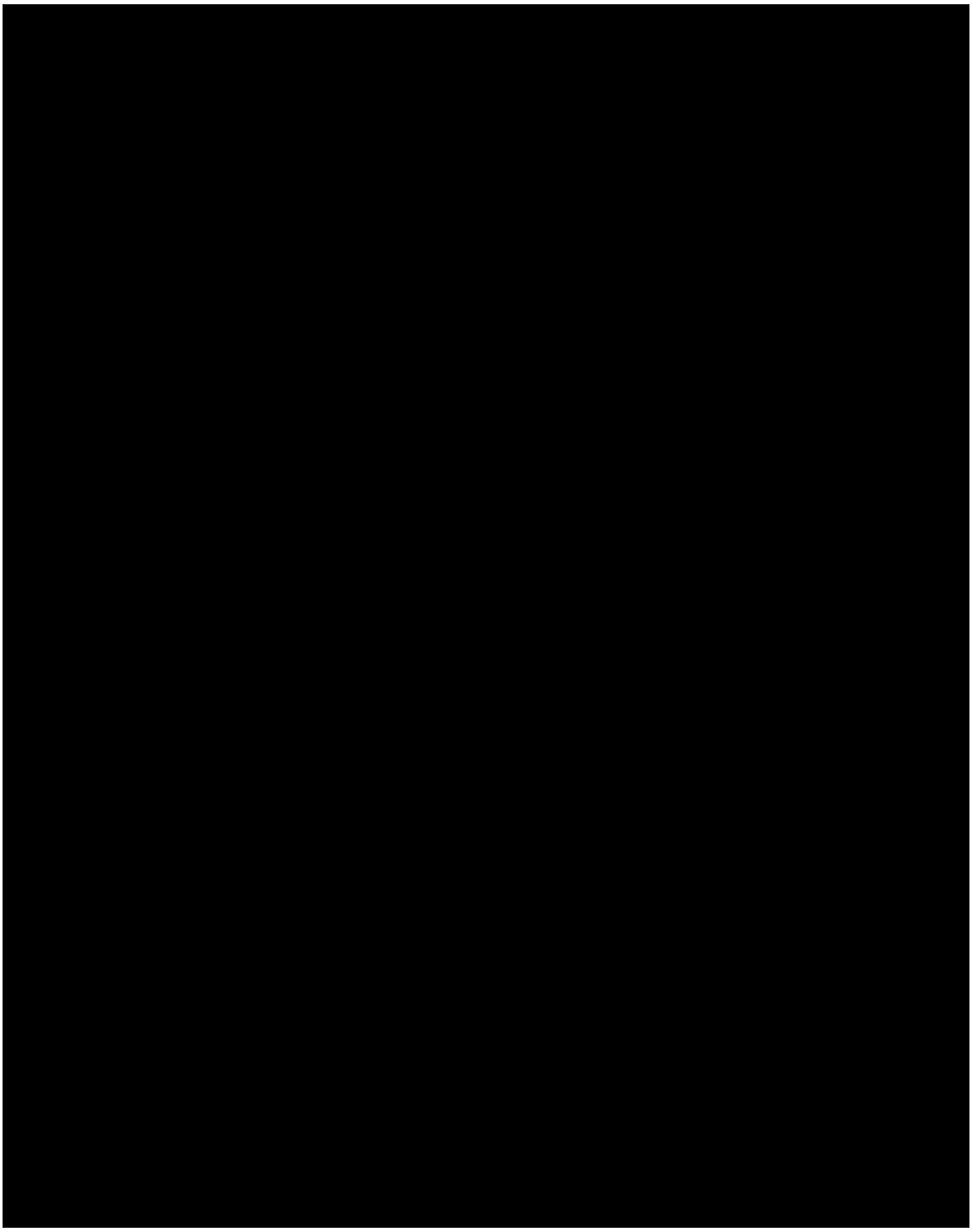

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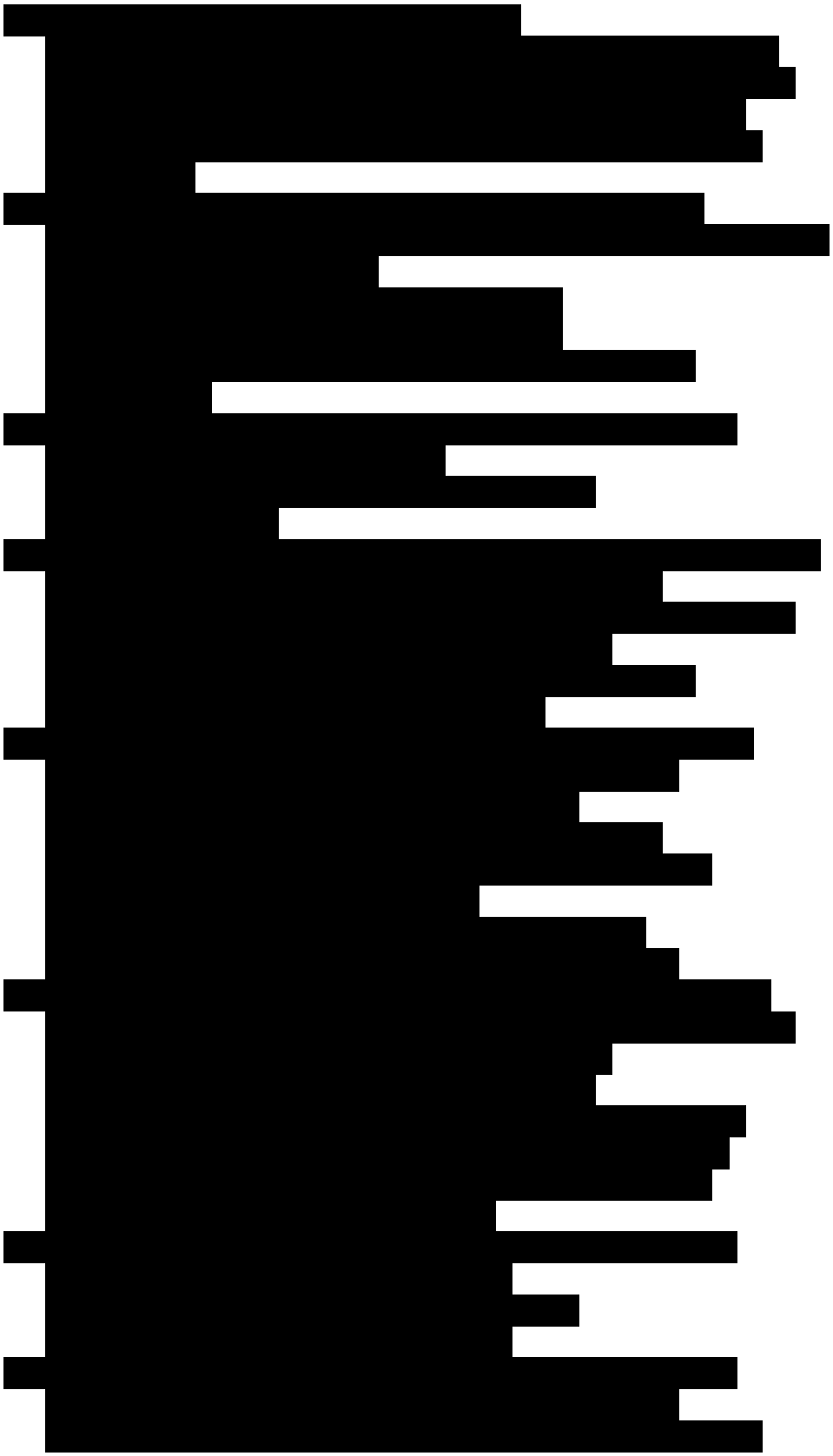

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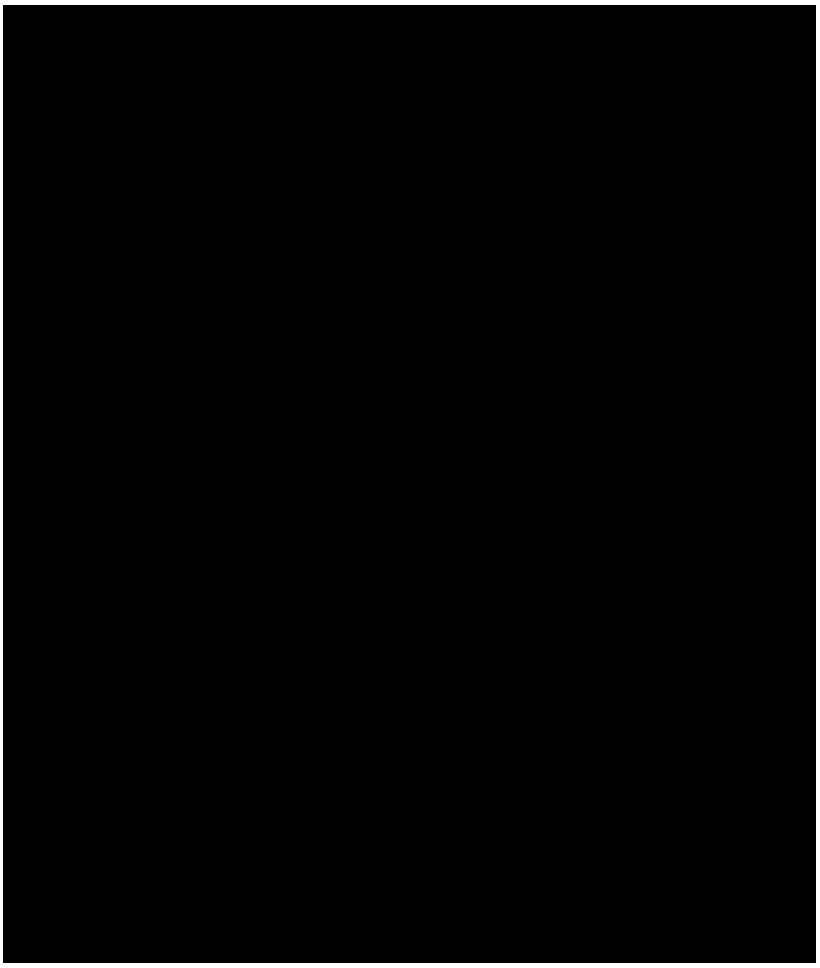

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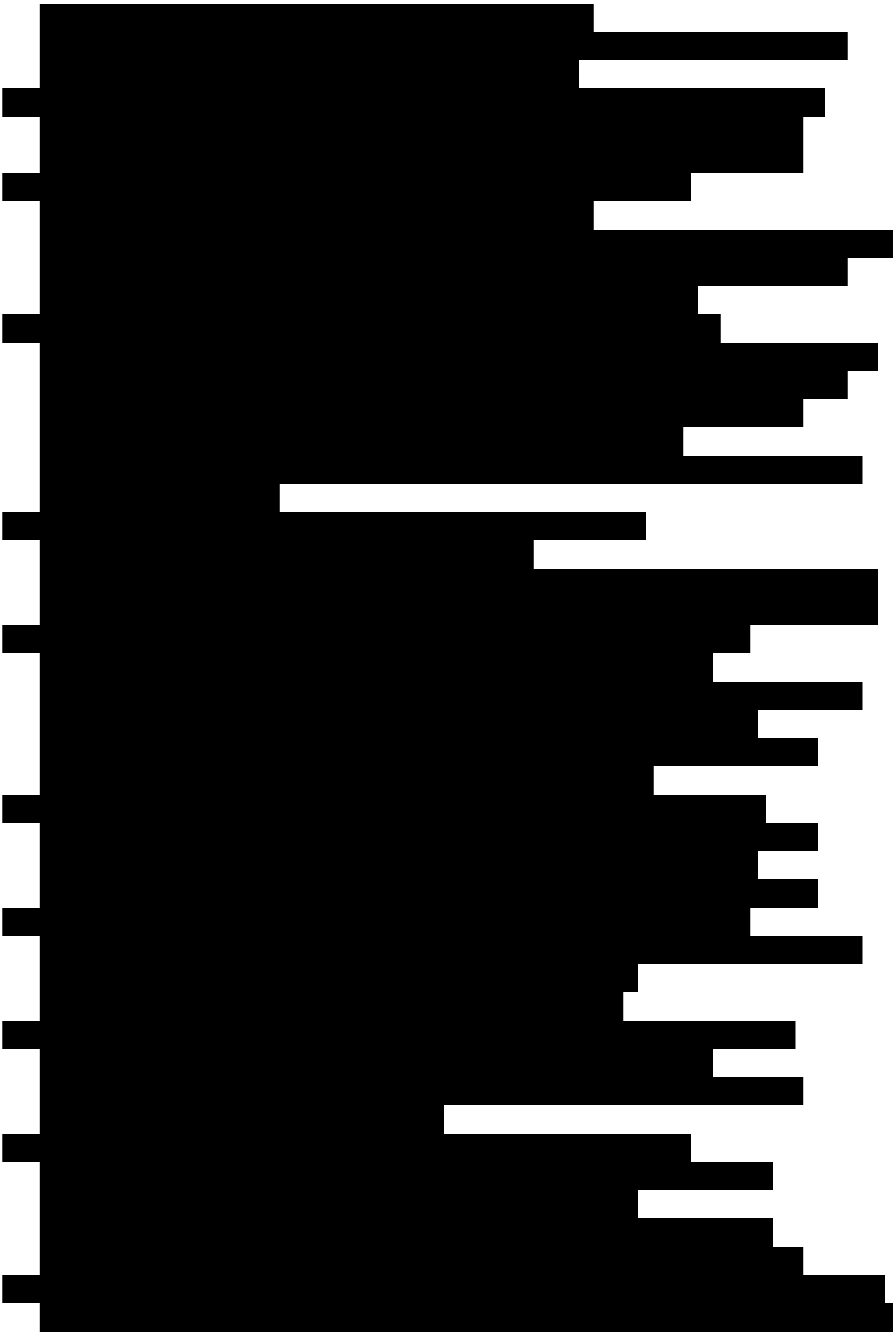

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Exhibit B – Sample Therapeutic Class Review Monograph

Three TCRs have been included as a sample of the thorough and industry-leading work that Goold produces for our clients. The reports include following and being on the next page:

1. Antibiotics, GI;
2. Antineoplastics, Selected Systemic Enzyme Inhibitors; and
3. Colony Stimulating Factors.

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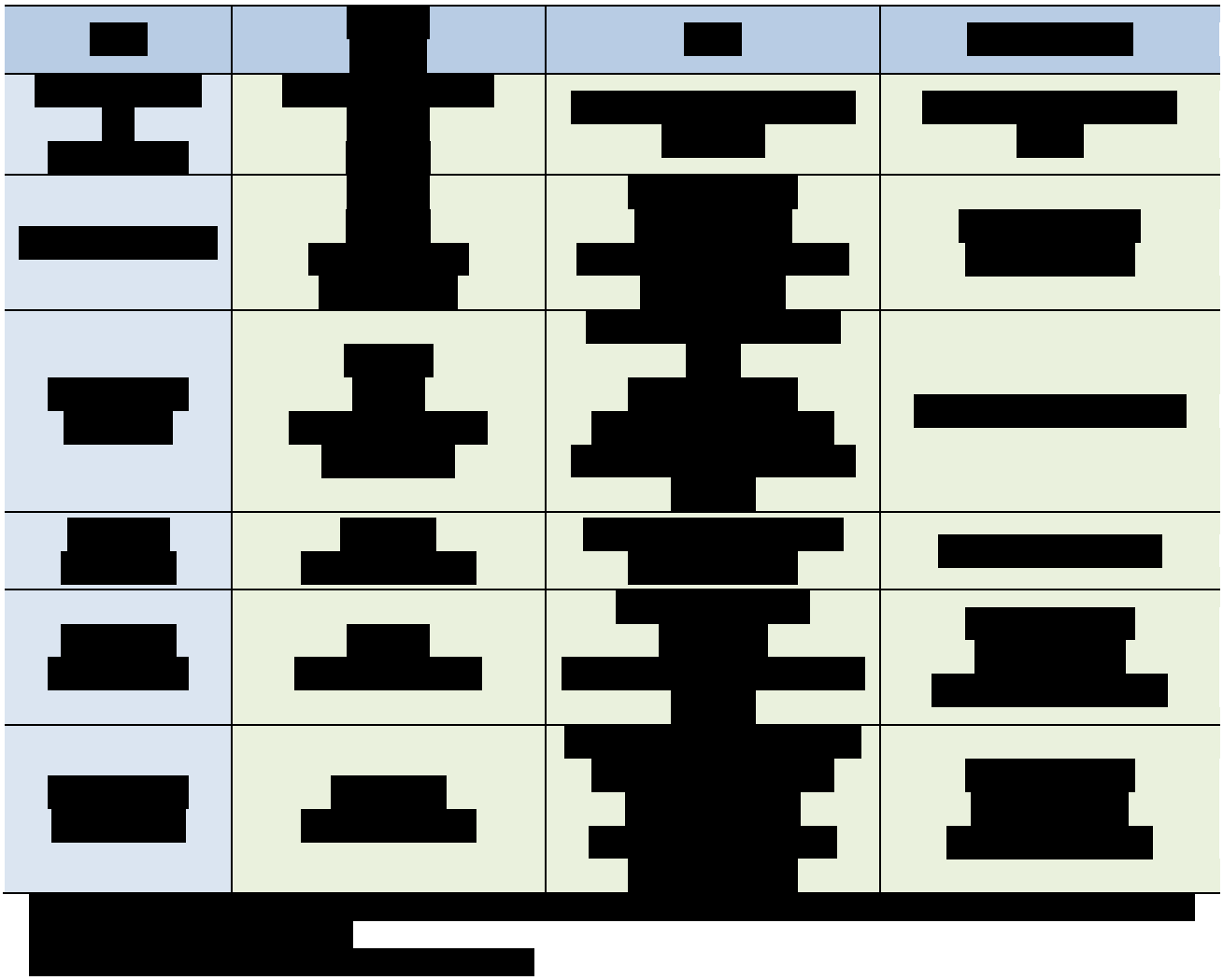

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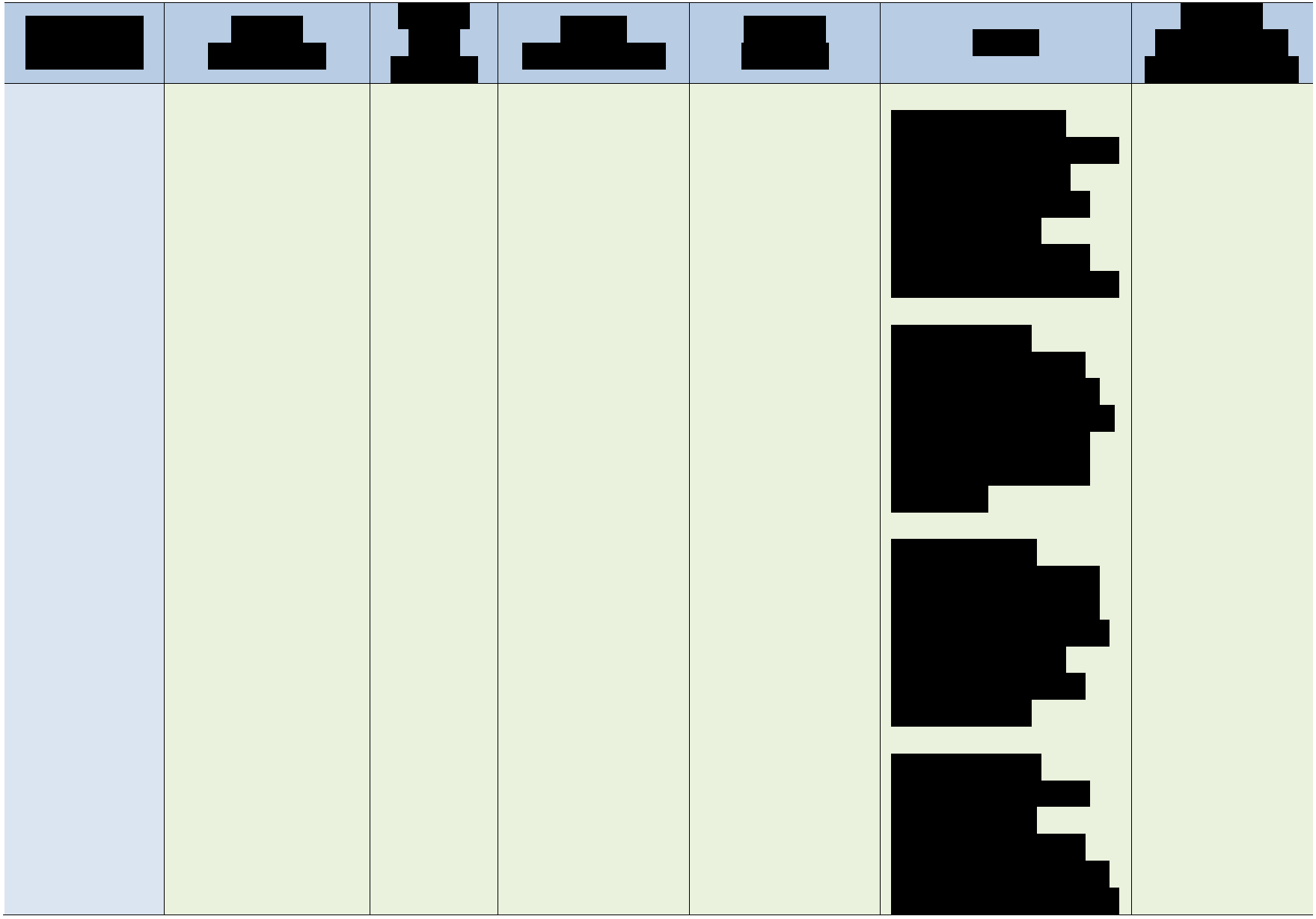

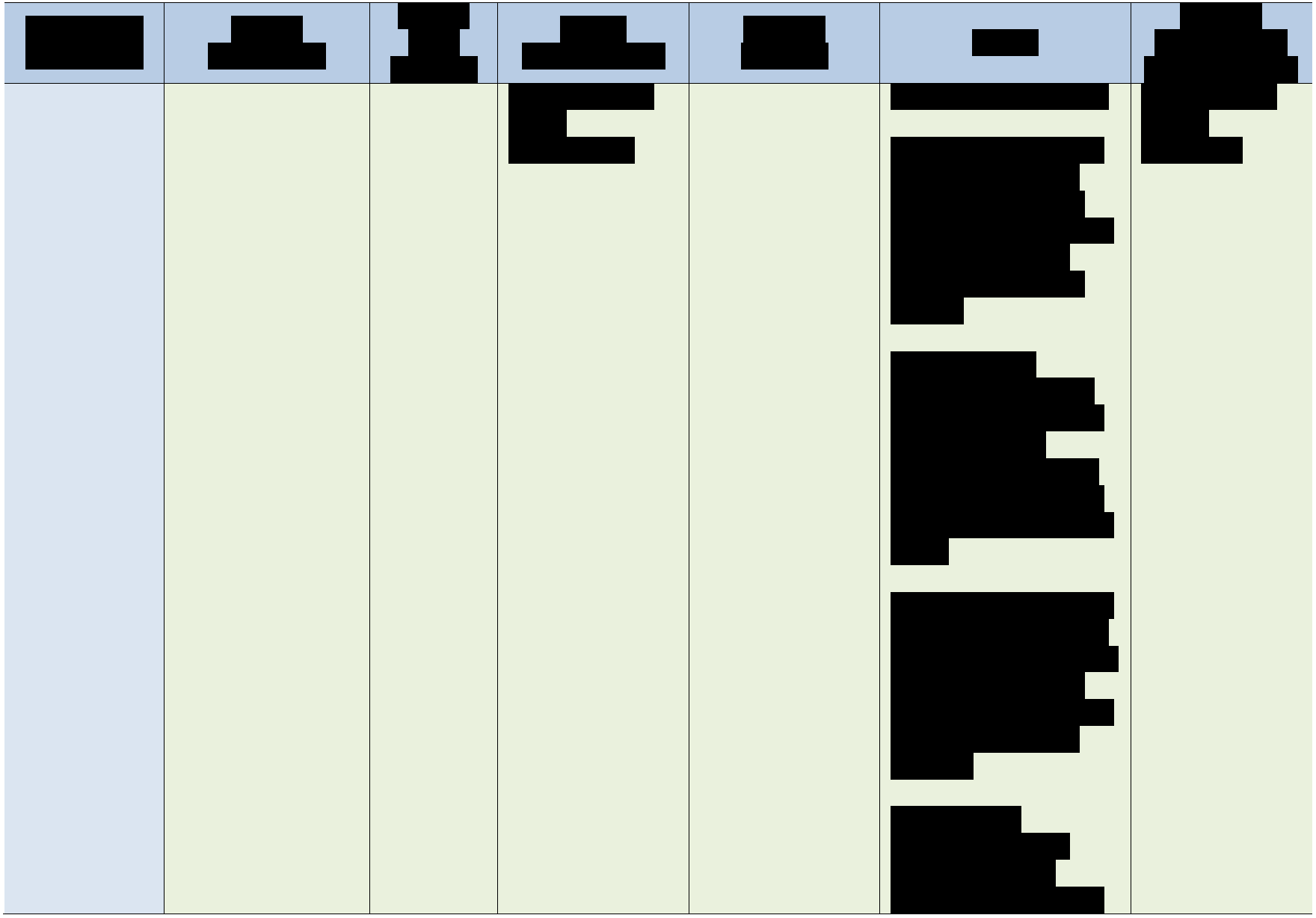

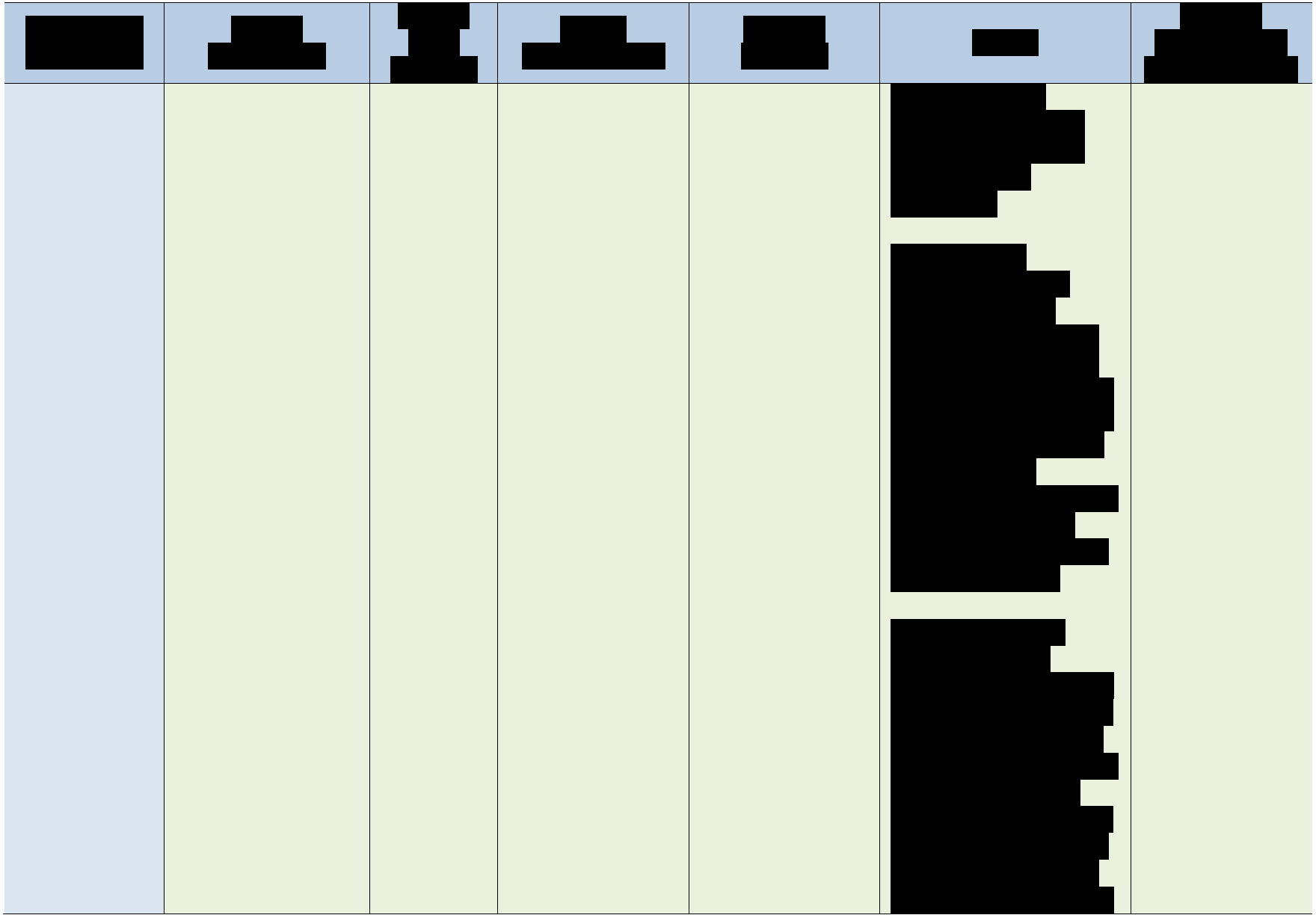

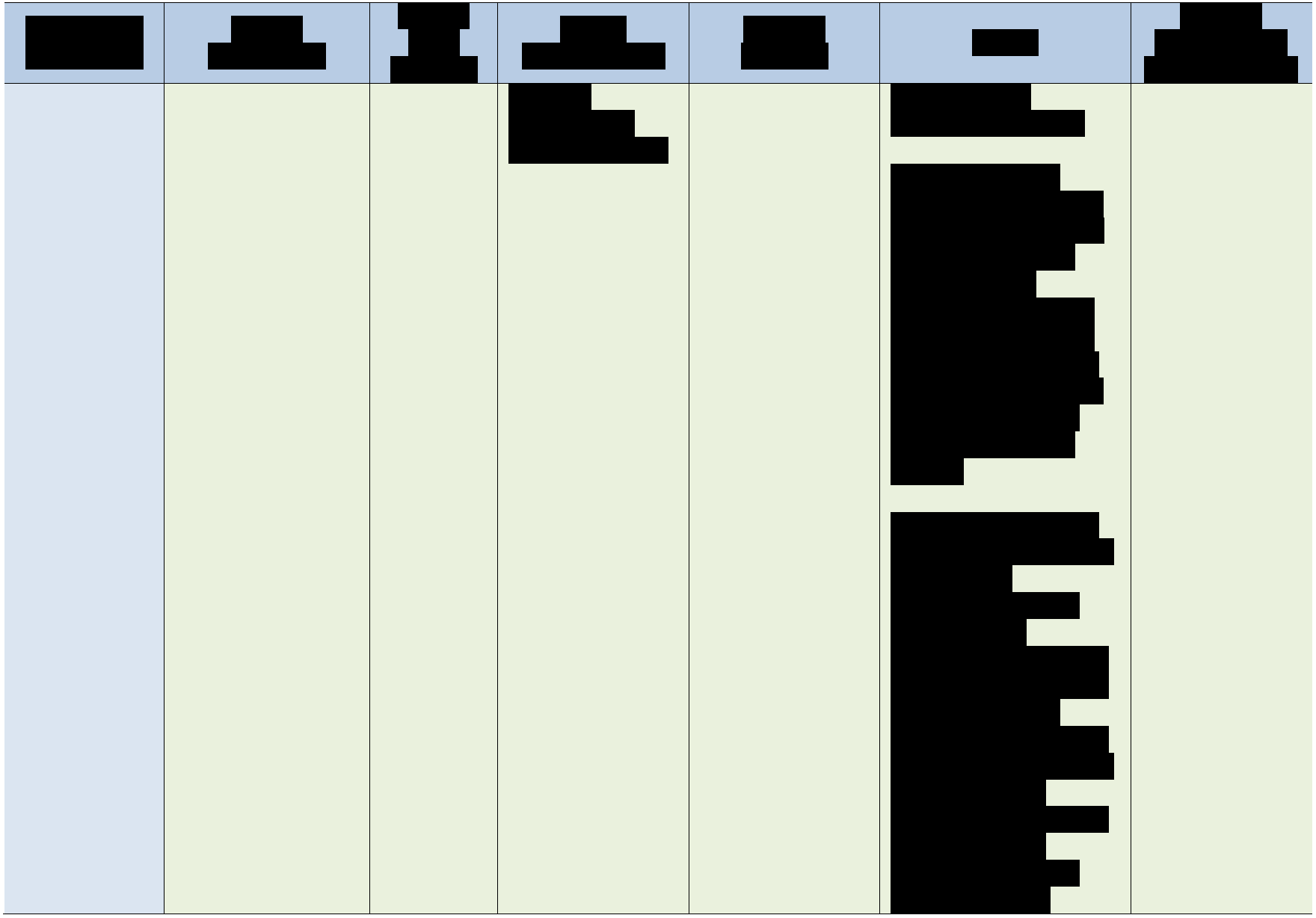

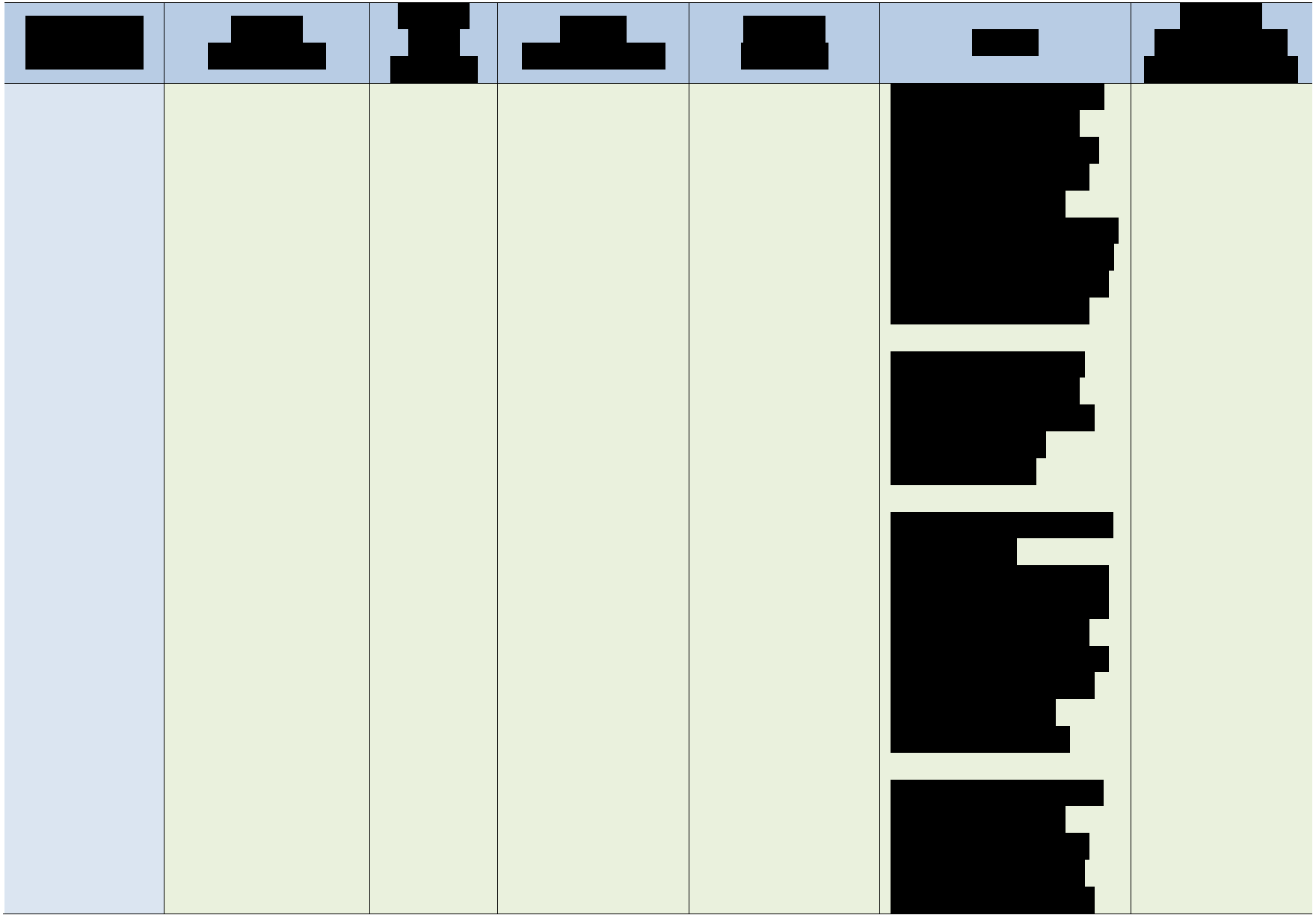

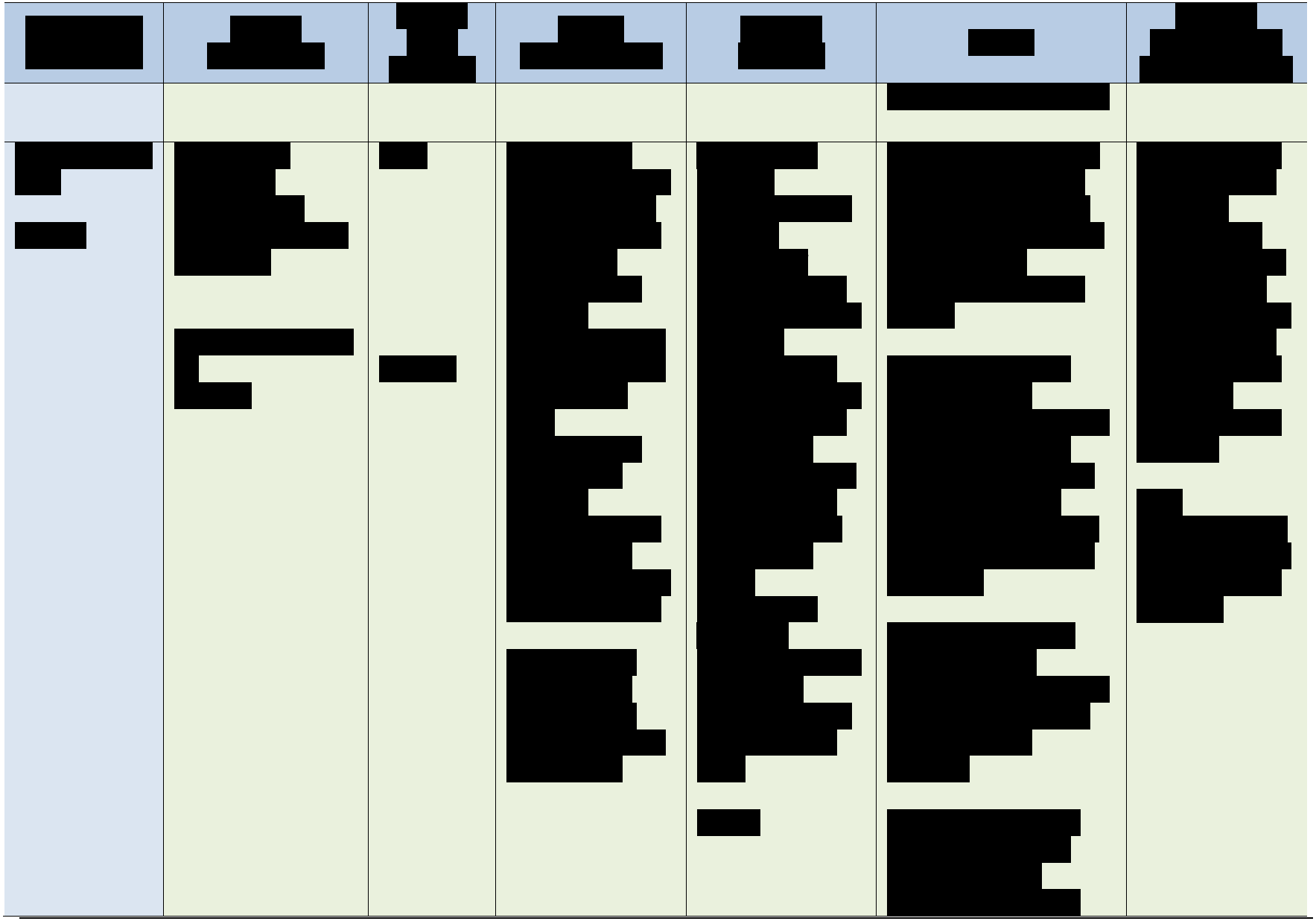

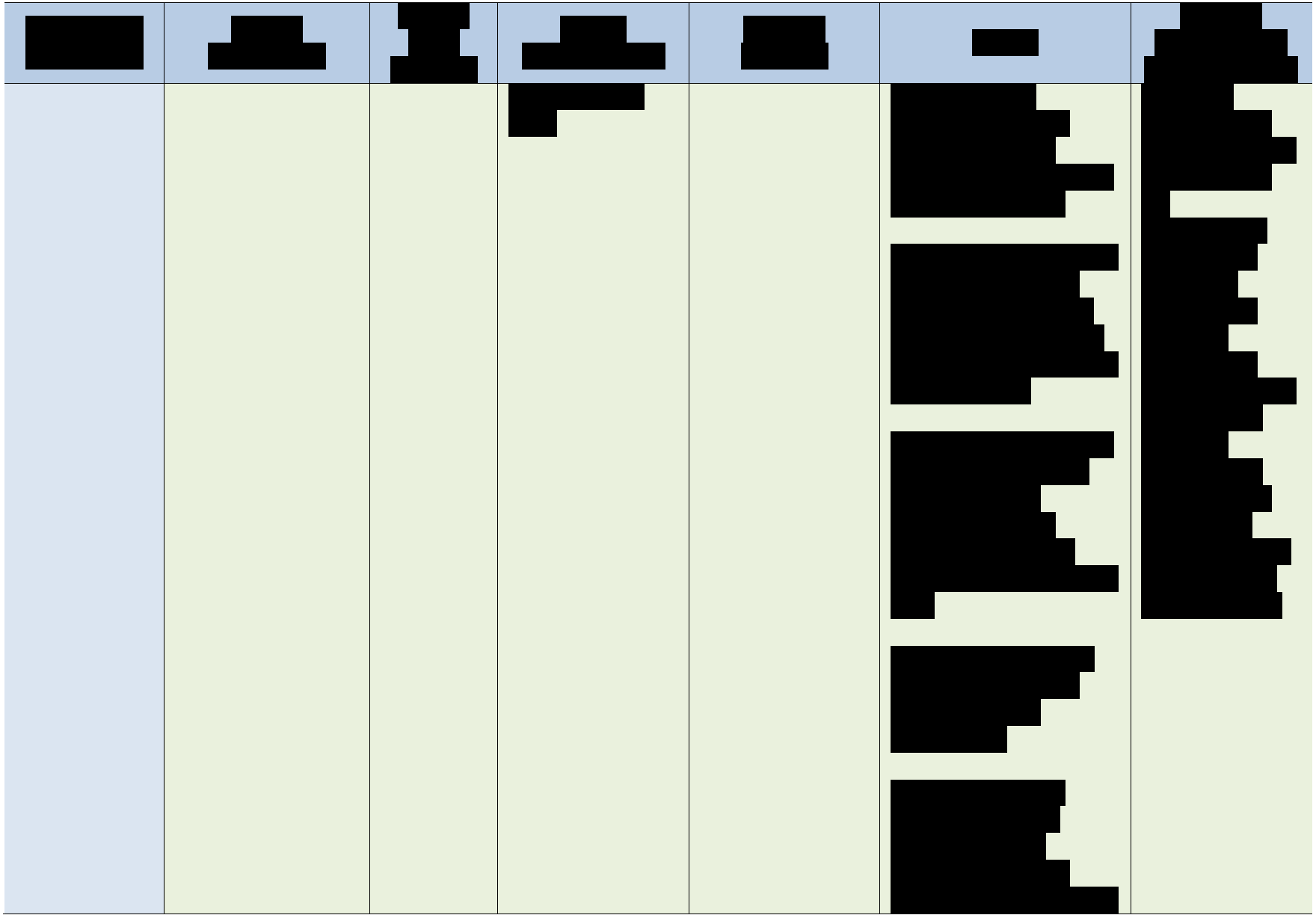

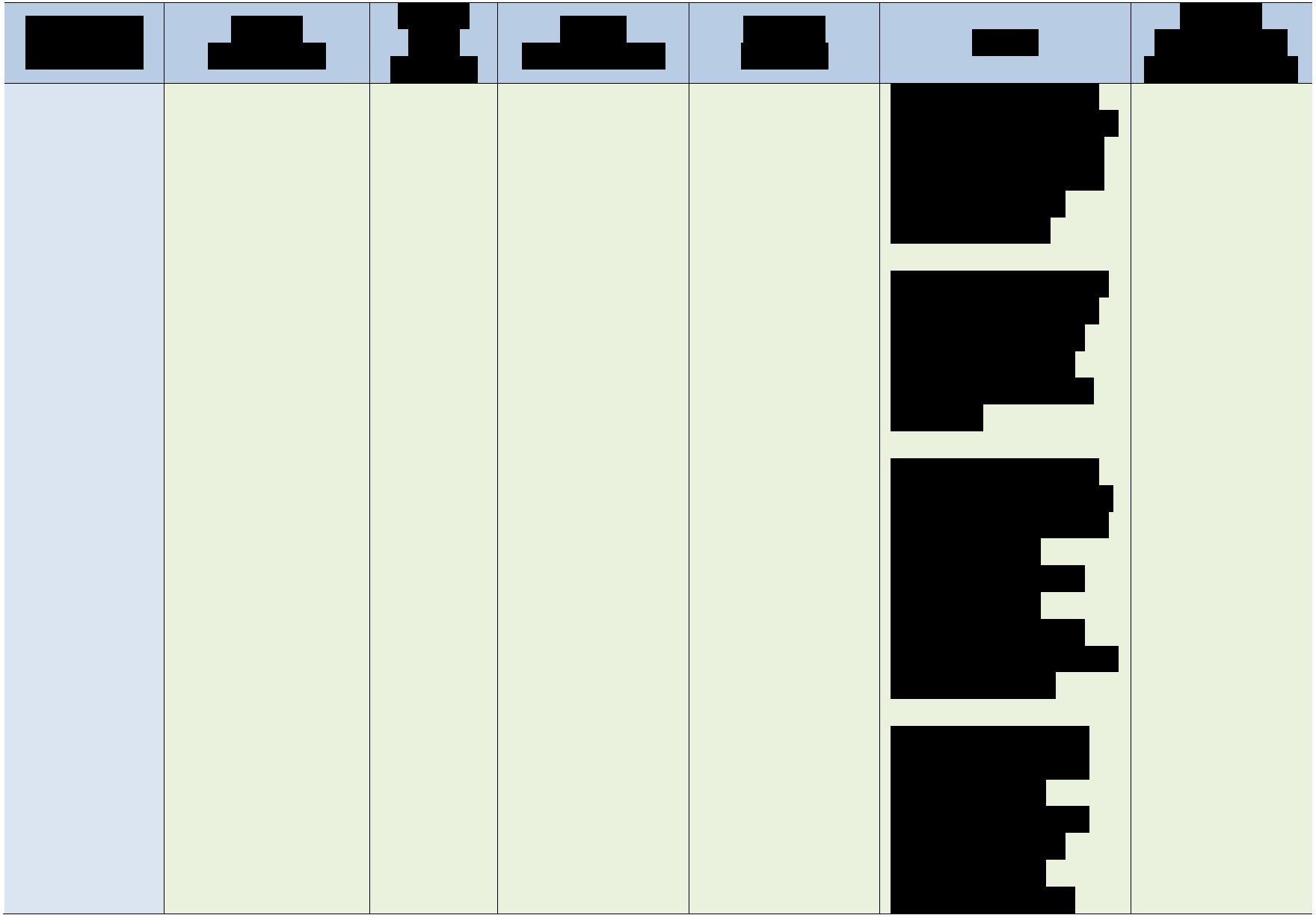

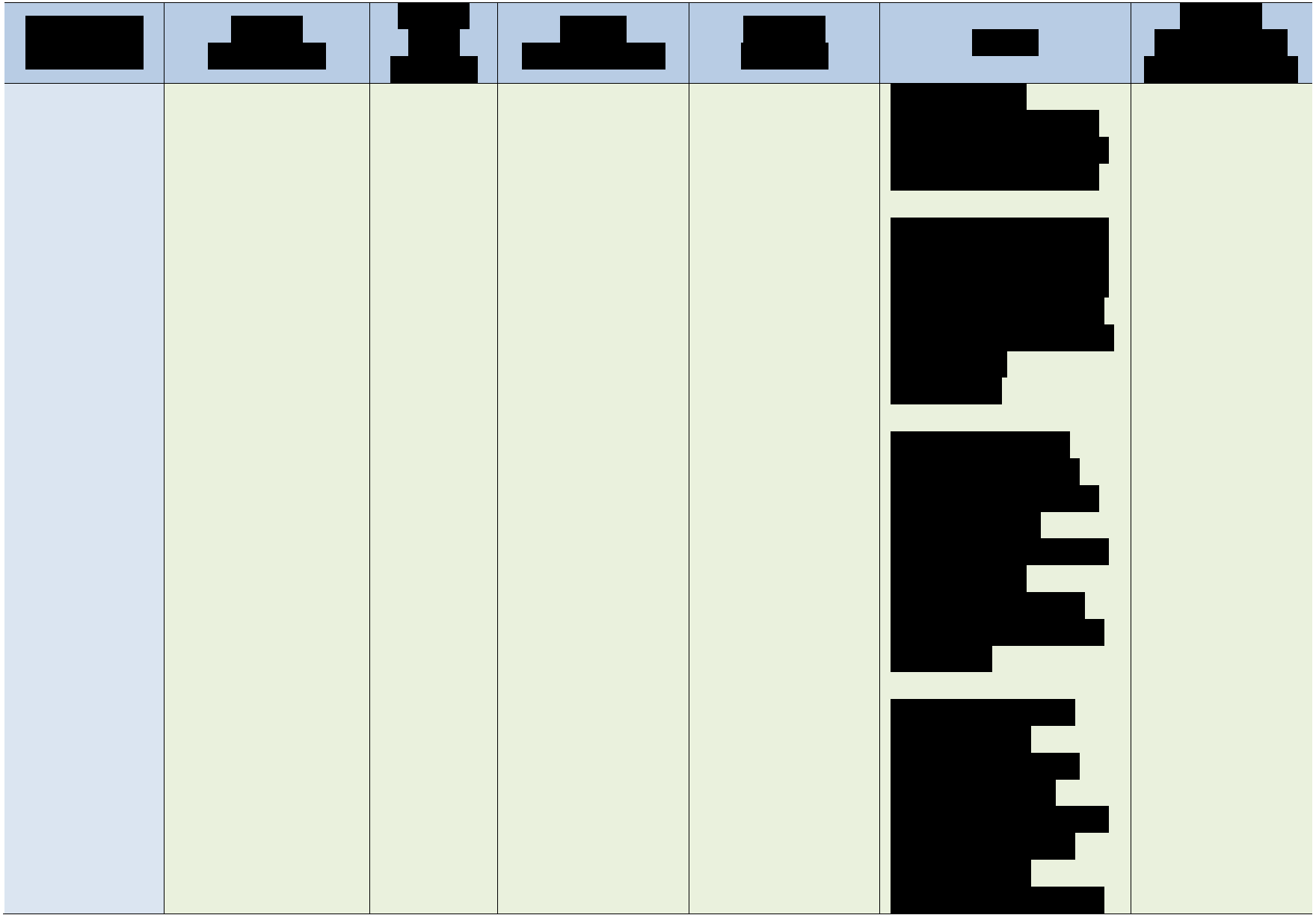

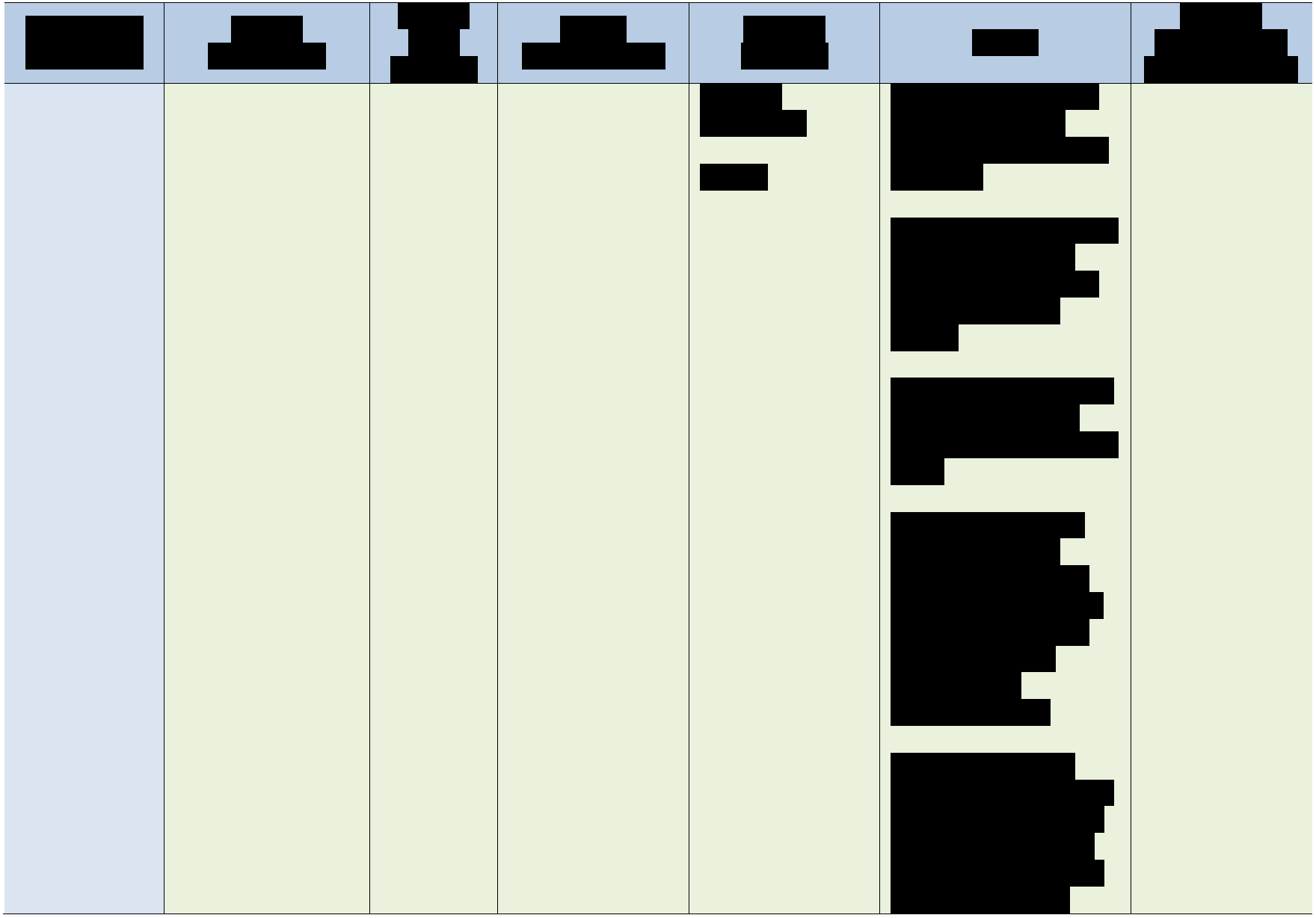

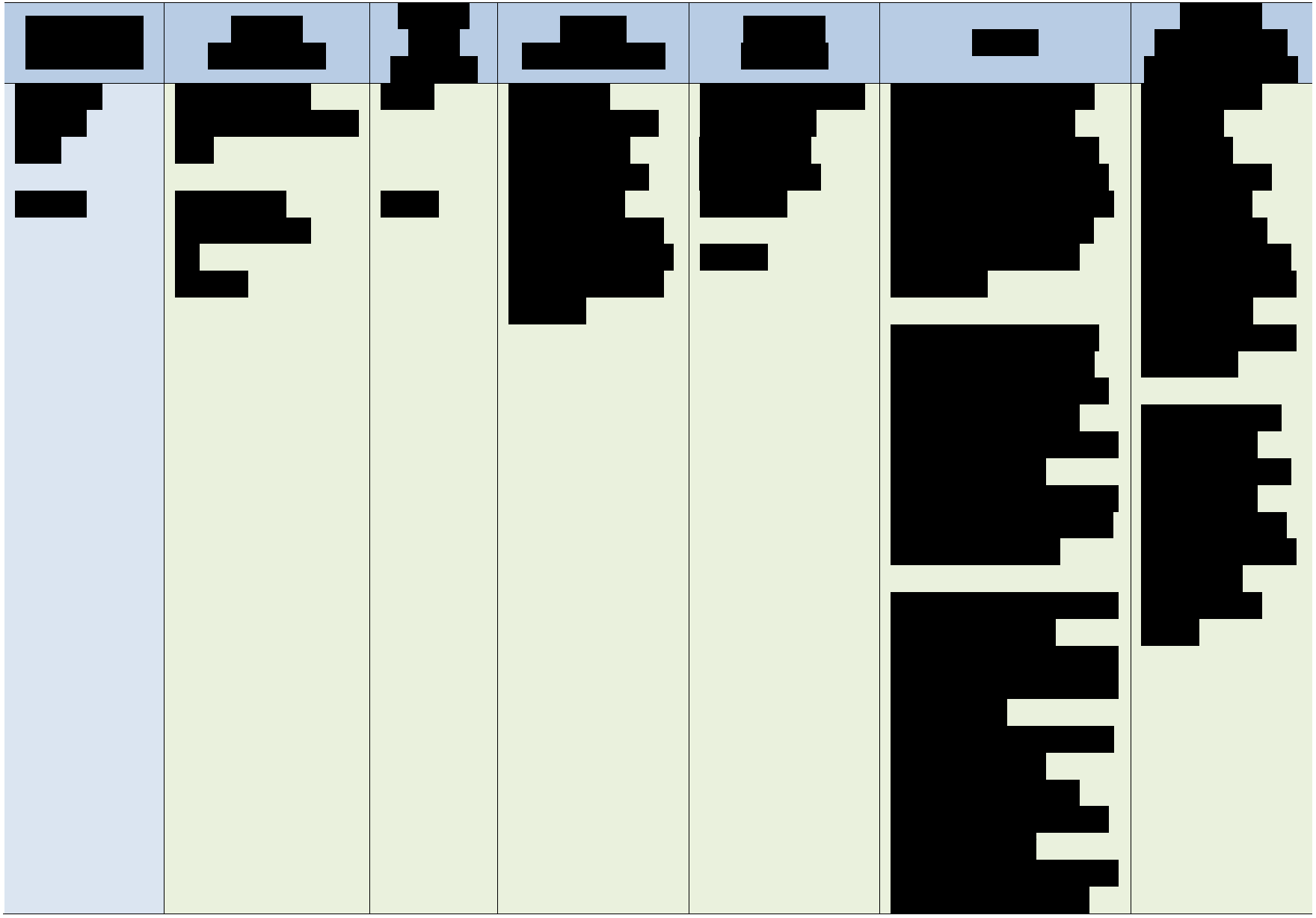

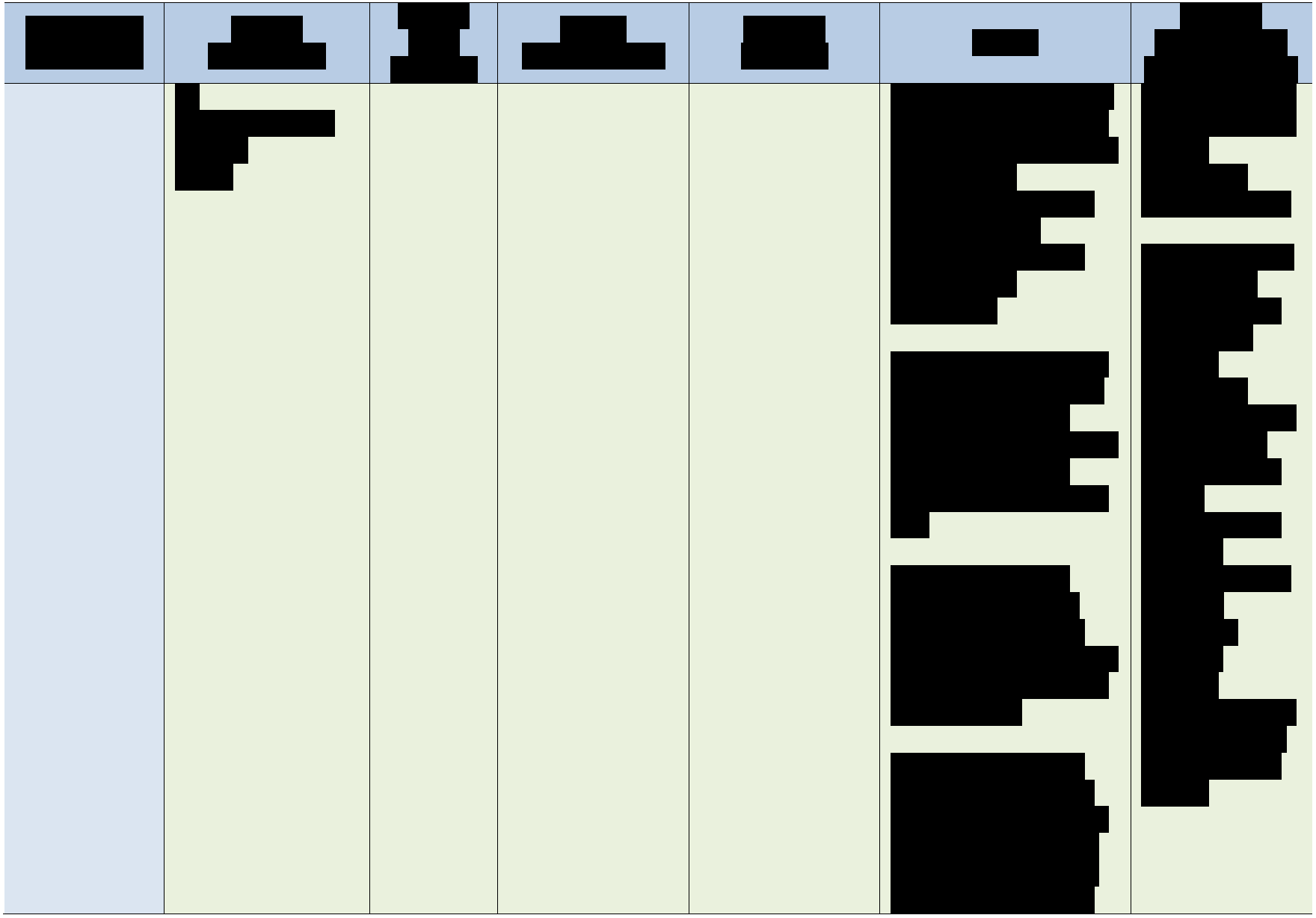

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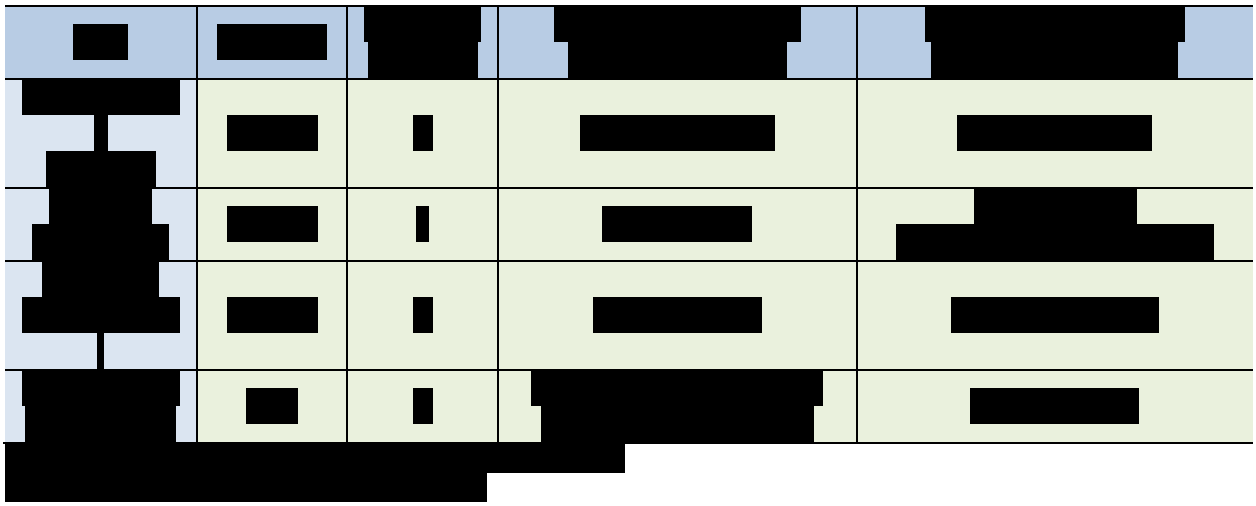

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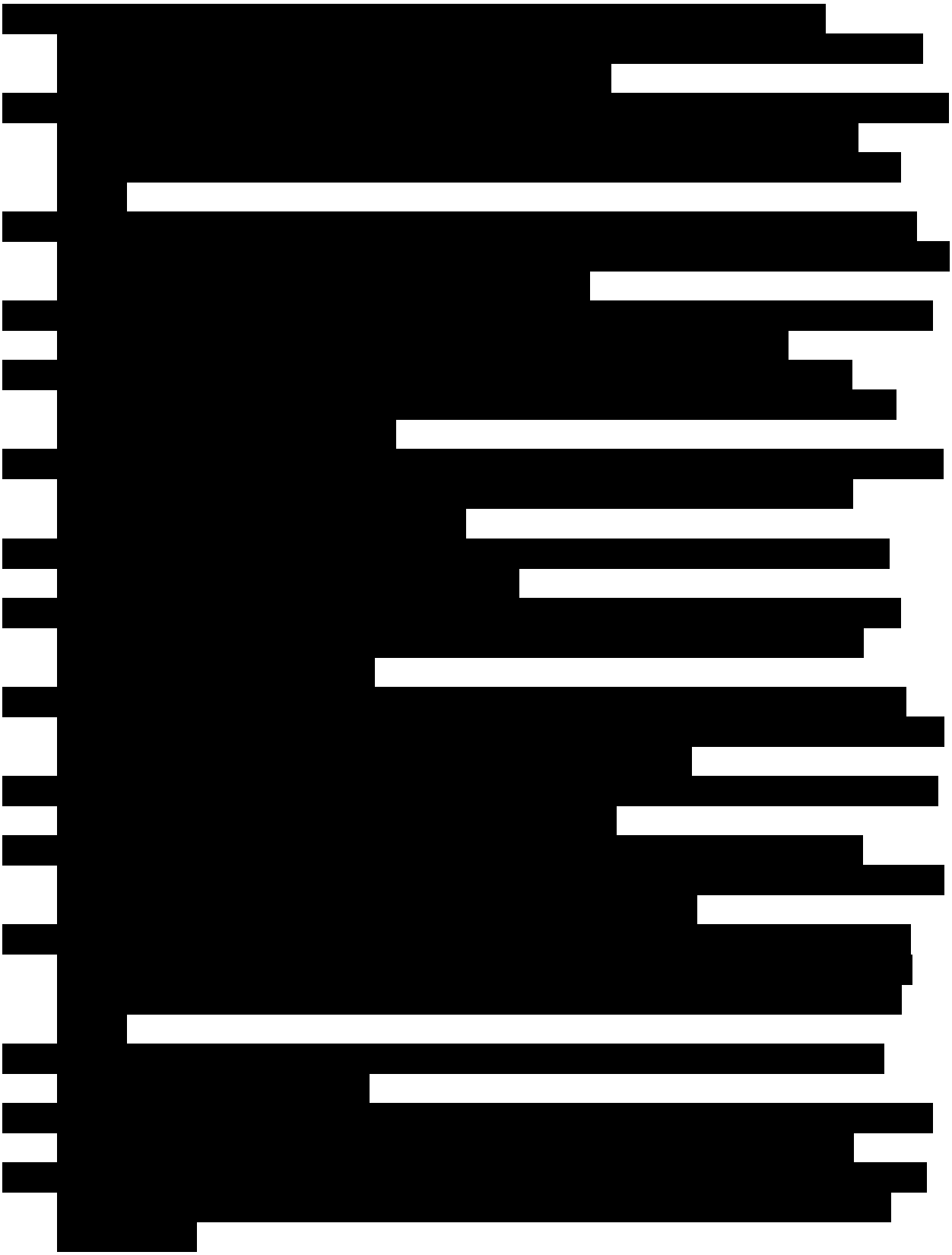

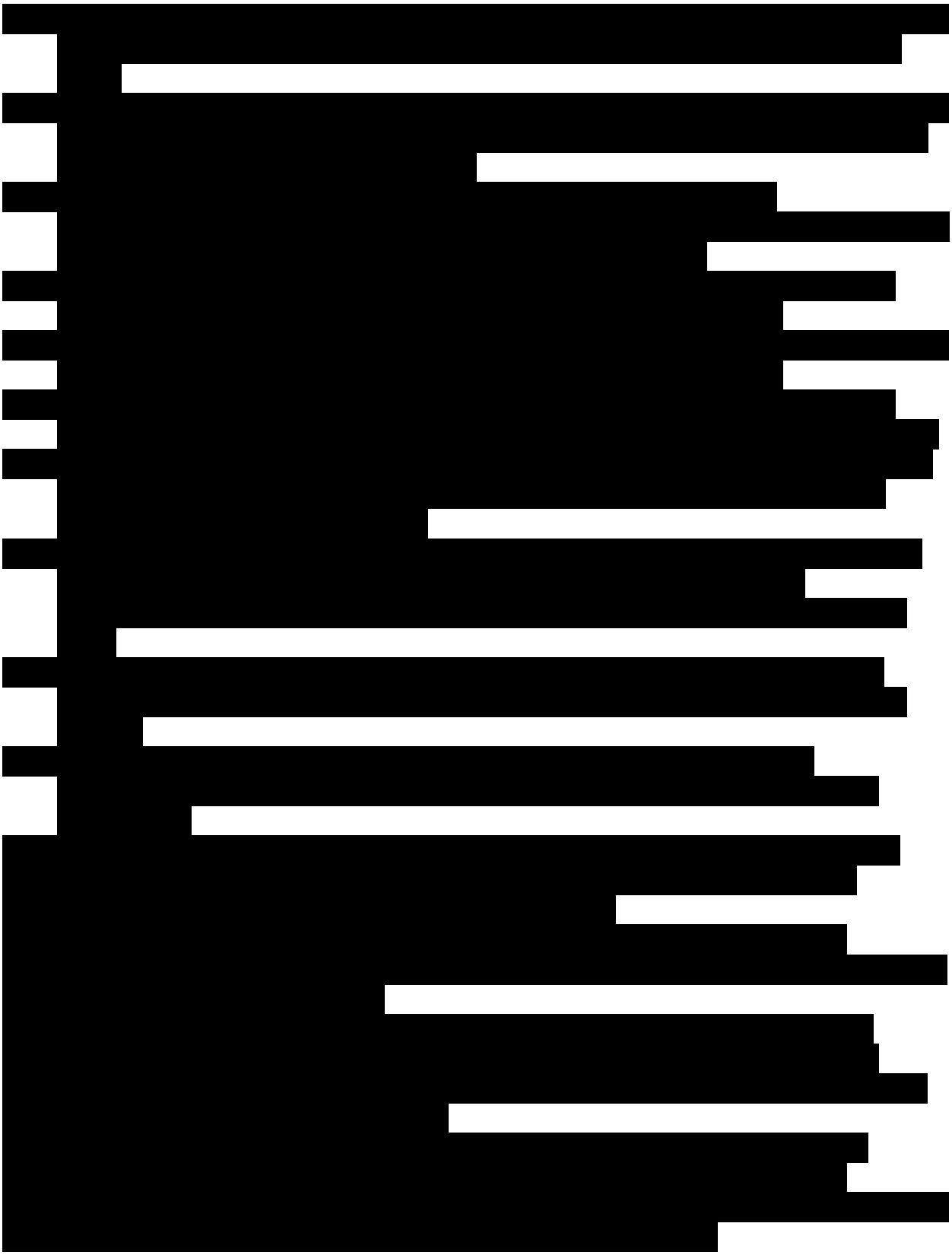

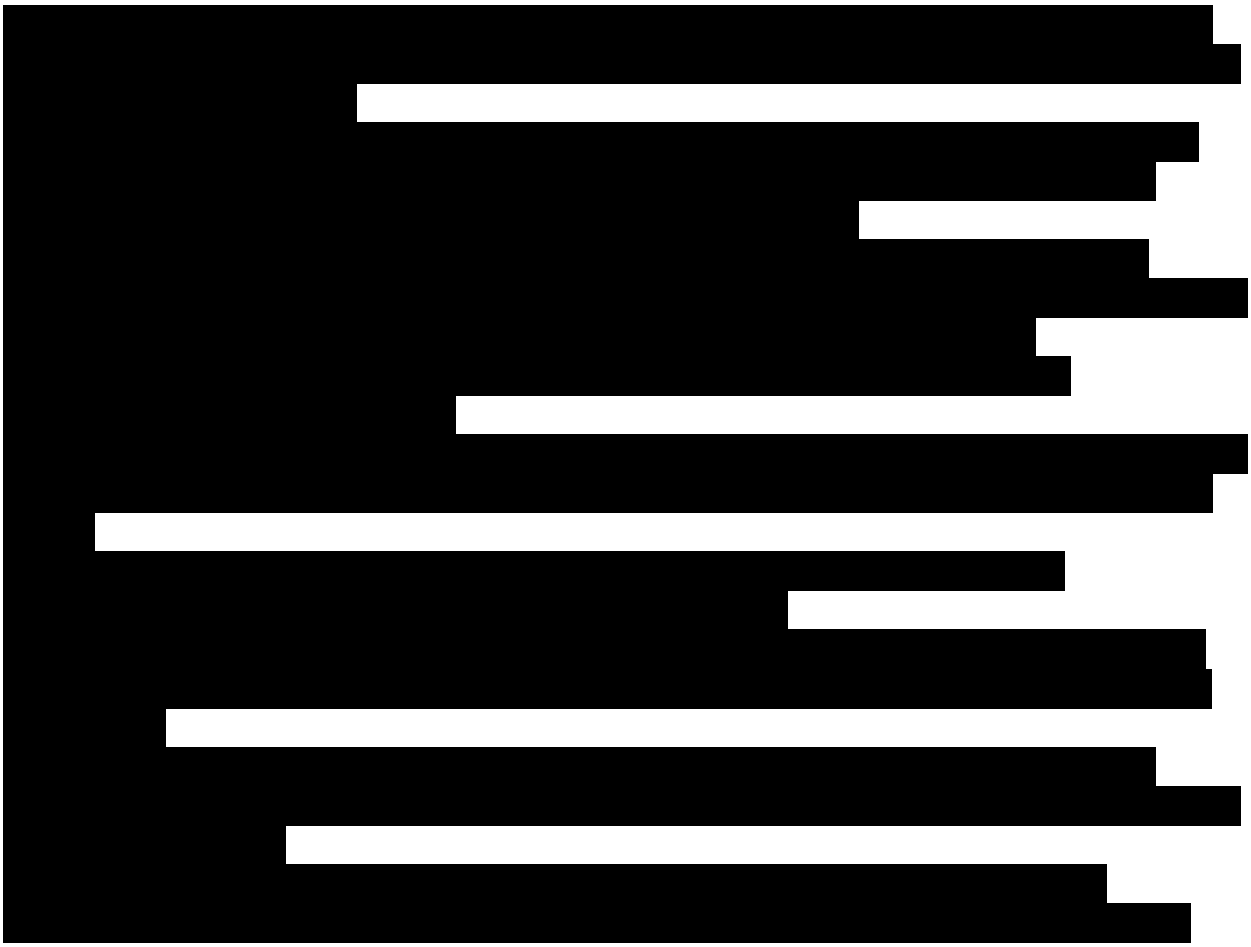

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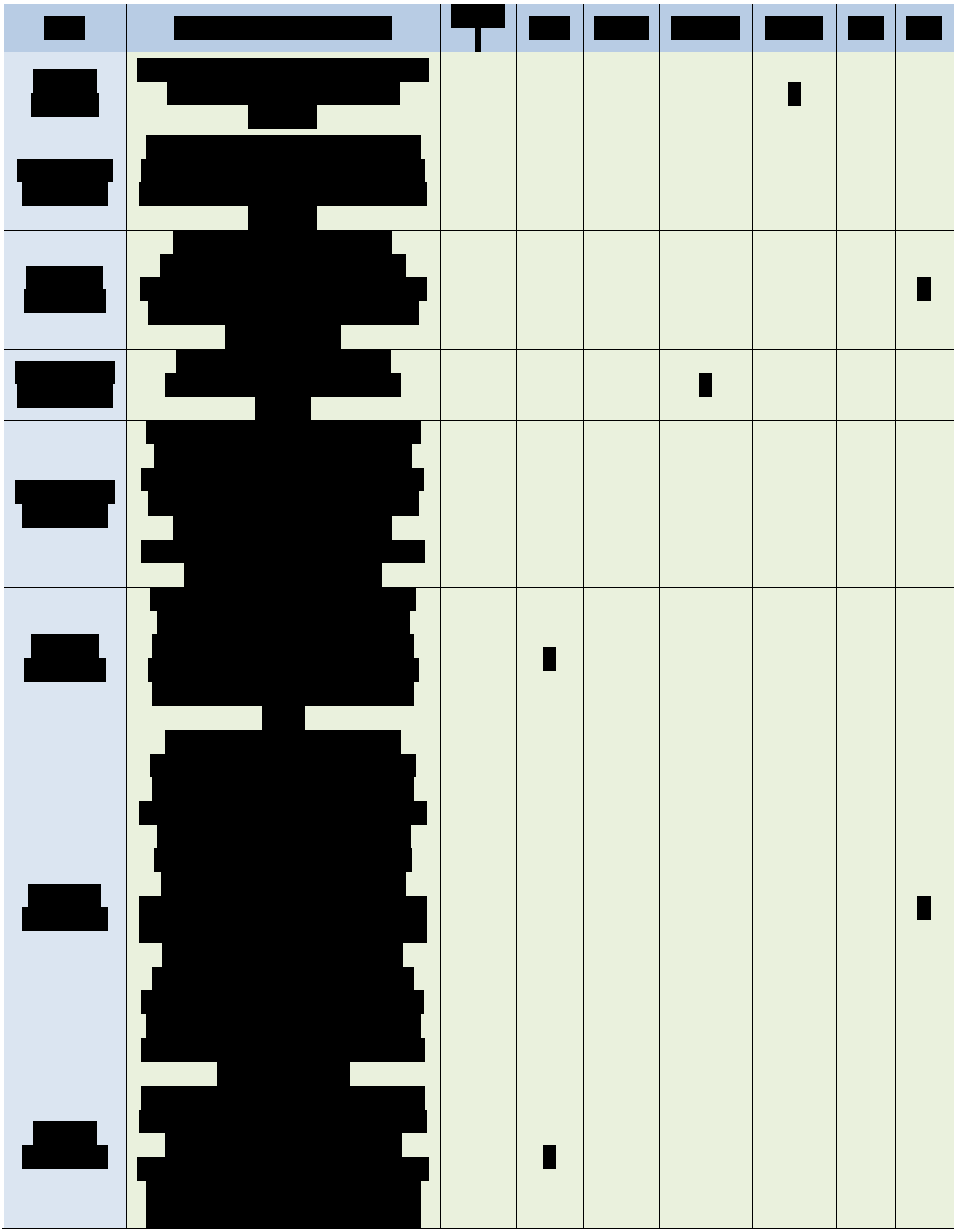

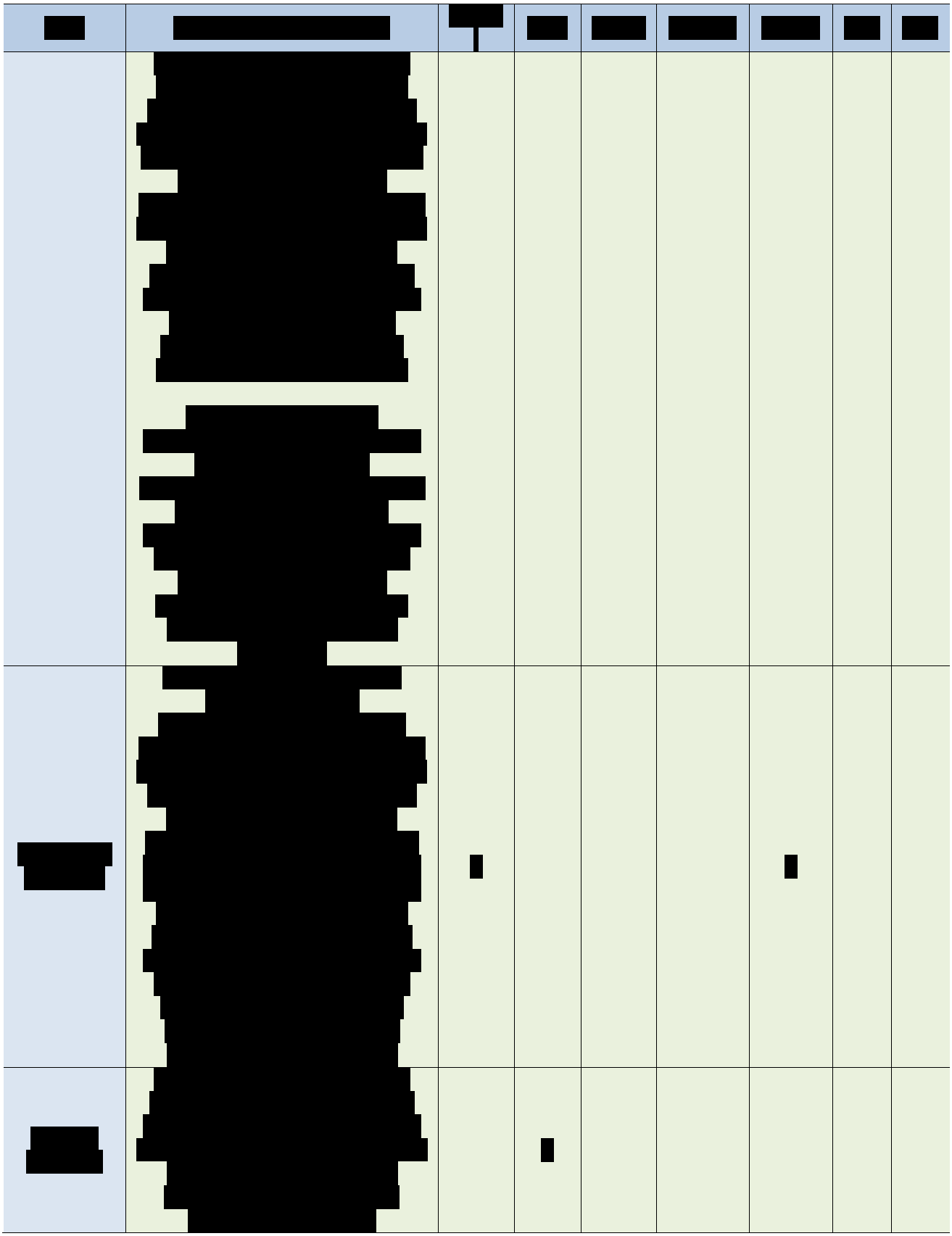

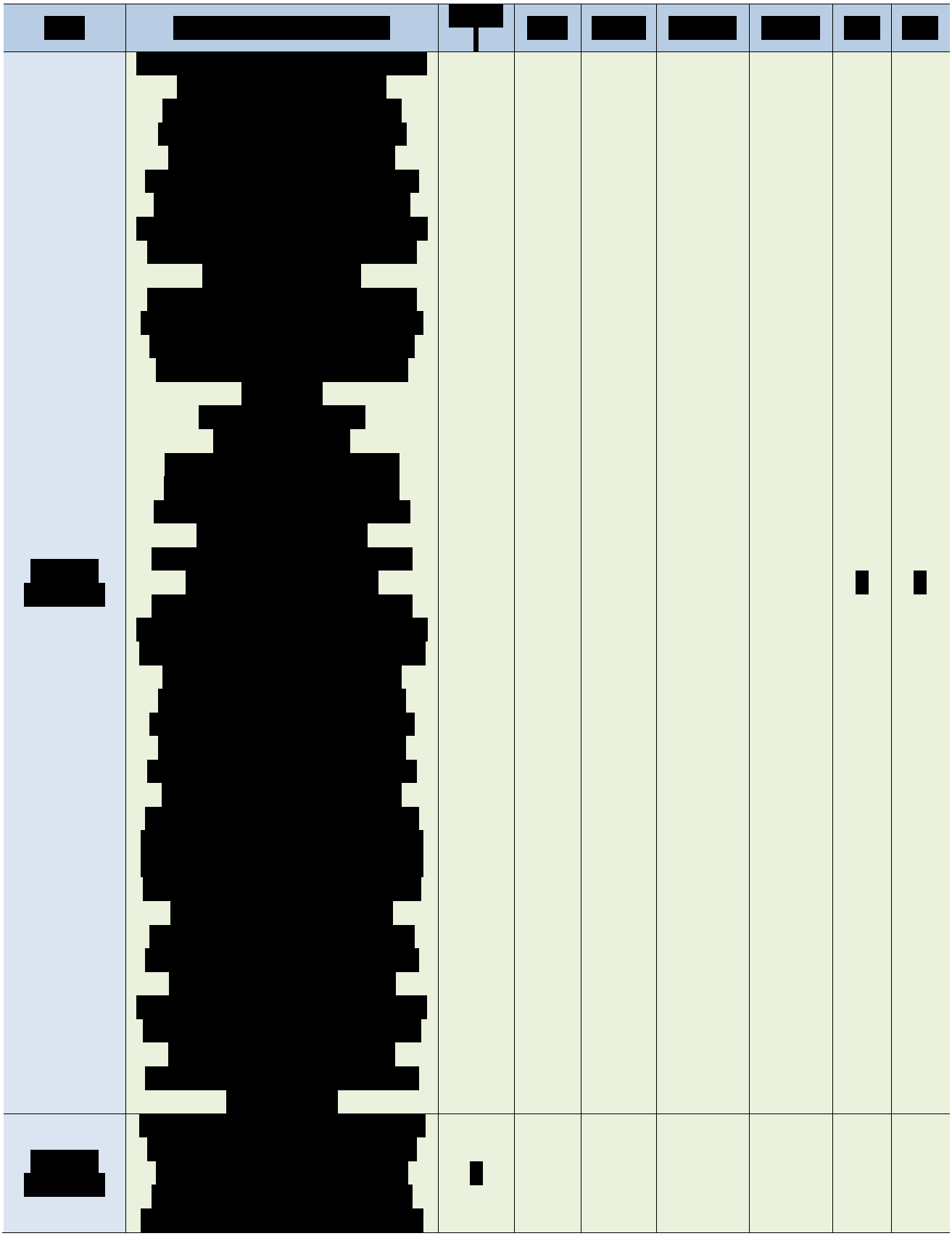

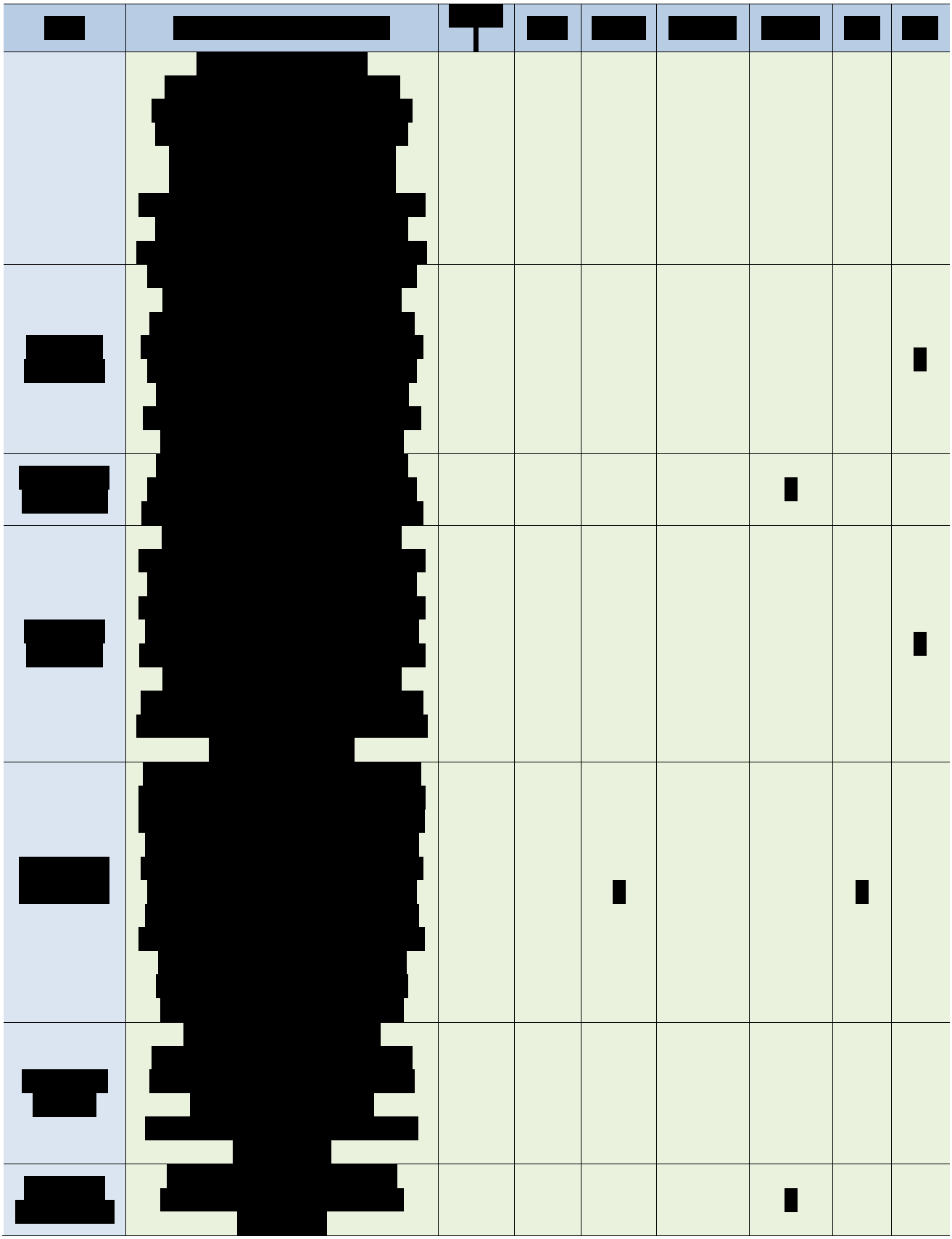

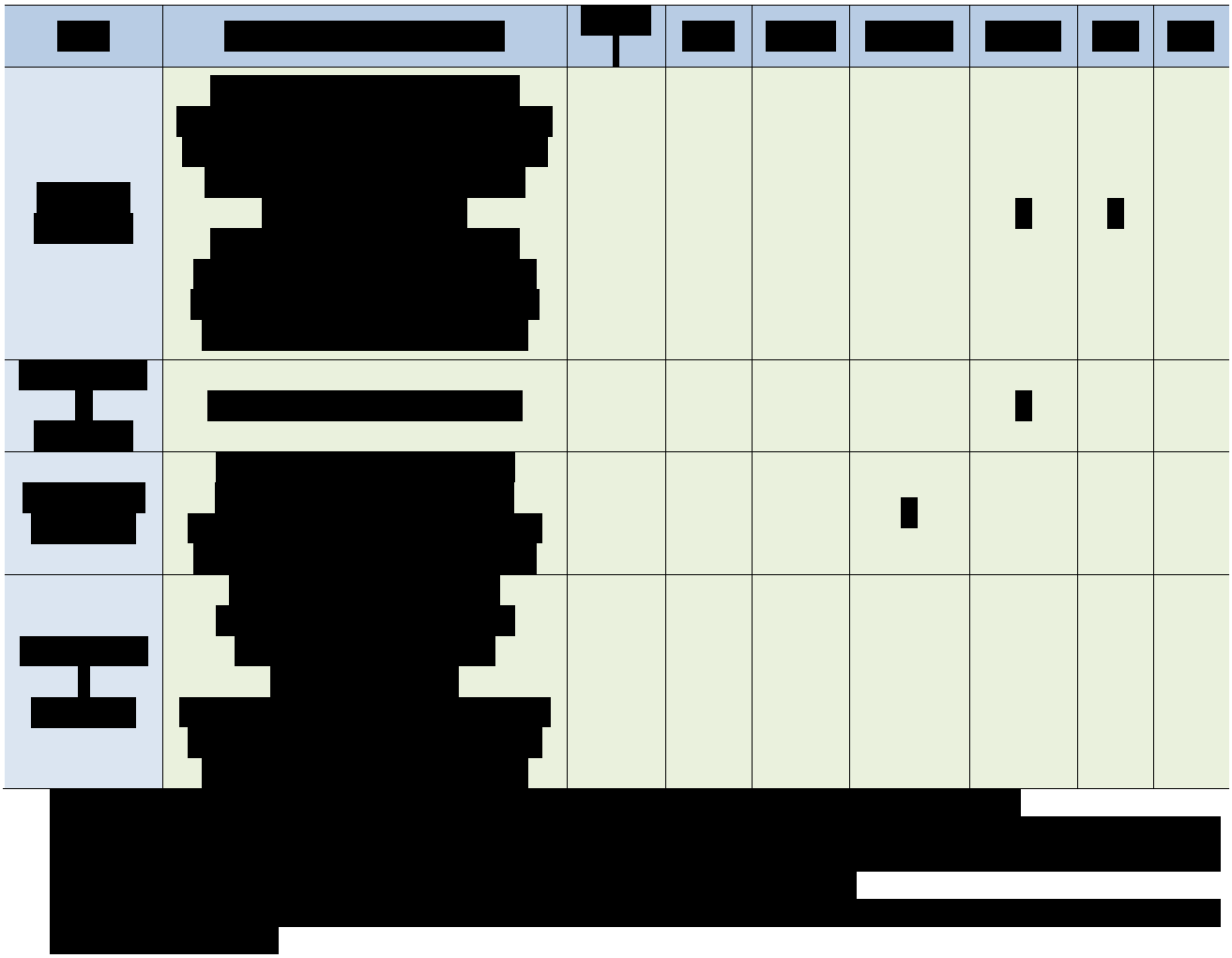

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Exhibit C – Implementation Plan

The following Implementation Plan describes the major task assignments which need to be considered in order to meet PDL, PPL and SMAC program requirements. Goold will comply with all of the requirements outlined above in the RFQ Specification document.

The Implementation Plan begins on the following page.

ID	Task Name	Duration	Start	Finish	Predecessors
0	**WV PDL Prof Serv Project Plan**	**720 days**	**Mon 2/9/15**	**Fri 11/10/17**	
1	Estimated Contract Start Date	0 days	Mon 2/9/15	Mon 2/9/15	
2	Confirm vendor registration status	1 day	Mon 2/9/15	Mon 2/9/15	1
3	Confirm proof of coverage of liability insurance for loss, damage, or injury	1 day	Mon 2/9/15	Mon 2/9/15	1
4	Confirm good standing with the State Agency of Employment Programs	1 day	Mon 2/9/15	Mon 2/9/15	1
5	Provide proof of licensure as requested	1 day	Mon 2/9/15	Mon 2/9/15	1
6	Joint Application Design (JAD) Sessions	2 days	Mon 2/9/15	Tue 2/10/15	1
7	**Implementation**	**32 days**	**Wed 2/11/15**	**Thu 3/26/15**	
8	Review regular meeting schedule	1 day	Wed 2/11/15	Wed 2/11/15	6
9	Review current business rules document	1 day	Wed 2/11/15	Wed 2/11/15	6
10	Submit updated implementation plan for approval	1 day	Wed 2/11/15	Wed 2/11/15	6
11	Submit weekly implementation status reports (recurring throughout Implementation Phase)	5 days	Thu 2/12/15	Wed 2/18/15	10
12	**Pharmaceutical & Therapeutics Committee**	**13 days**	**Wed 2/11/15**	**Fri 2/27/15**	
13	Review theraputic class review/monograph/new drug review templates	2 days	Wed 2/11/15	Thu 2/12/15	6
14	State approves P&T templates	5 days	Fri 2/13/15	Thu 2/19/15	13
15	Plan P&T meeting	2 days	Fri 2/20/15	Mon 2/23/15	14
16	Provide financial information for the P & T Committee for each therapeutic class at least annually	1 day	Tue 2/24/15	Tue 2/24/15	15
17	Provide financial information for the P & T Committee for each new drugs as they are reviewed by the P & T Committee at least quarterly	1 day	Wed 2/25/15	Wed 2/25/15	16
18	Confirm no additional monograph updates are needed	1 day	Thu 2/26/15	Thu 2/26/15	17
19	Review new drugs or drug formulations using a schedule agreed to by the Vendor and BMS, at a minimum quarterly.	1 day	Fri 2/27/15	Fri 2/27/15	18
20	P&T Functions Ready for Operations	0 days	Fri 2/27/15	Fri 2/27/15	19
21	**Preferred Drug List (PDL)**	**32 days**	**Wed 2/11/15**	**Thu 3/26/15**	
22	Meet with fiscal agent to review file requirements for PDL changes and updates	1 day	Wed 2/11/15	Wed 2/11/15	6
23	Review formatting, maintenance needs, file formats, and schedule for all PDL documents, including those publicly posted on website	1 day	Thu 2/12/15	Thu 2/12/15	22
24	Perform PDL data layout and content updates	10 days	Fri 2/13/15	Thu 2/26/15	23
25	State approves PDL	5 days	Fri 2/27/15	Thu 3/5/15	24
26	State/fiscal agent approves updated file feed/layout	5 days	Fri 3/6/15	Thu 3/12/15	25
27	Develop newsletter layouot and initial content	5 days	Fri 3/13/15	Thu 3/19/15	26
28	State approves newsletter	5 days	Fri 3/20/15	Thu 3/26/15	27
29	Ready for PDL Operations	0 days	Thu 3/26/15	Thu 3/26/15	28
30	**State Maximum Allowable Cost (SMAC) Program**	**12 days**	**Thu 2/12/15**	**Fri 2/27/15**	
31	Meet with fiscal agent to review file requirements for SMAC changes and updates	1 day	Thu 2/12/15	Thu 2/12/15	6,22
32	Review formatting, maintenance needs, file formats, and schedule for all SMAC documents, including those publicly posted on website	1 day	Fri 2/13/15	Fri 2/13/15	31

ID	Task Name	Duration	Start	Finish	Predecessors
33	Review current Help Desk operations	1 day	Mon 2/16/15	Mon 2/16/15	32
34	Perform SMAC layout and content updates	3 days	Tue 2/17/15	Thu 2/19/15	33
35	State/vendor approves updated file feed/layout	3 days	Fri 2/20/15	Tue 2/24/15	34
36	Documentation and system review finalized	2 days	Wed 2/25/15	Thu 2/26/15	35
37	State approves final documentation/layouts	1 day	Fri 2/27/15	Fri 2/27/15	36
38	Ready for SMAC Operations	0 days	Fri 2/27/15	Fri 2/27/15	37
39	**Supplemental Rebate Program**	**11 days**	**Wed 2/11/15**	**Wed 2/25/15**	
40	Review SR/OBRA rebate collection with with the State and fiscal agent	1 day	Wed 2/11/15	Wed 2/11/15	6
41	Review formatting, SR agreements, maintenance needs, file formats, and schedule for all SR documents, including those publicly posted on website	1 day	Thu 2/12/15	Thu 2/12/15	40
42	GHS review of layout & signoff	1 day	Fri 2/13/15	Fri 2/13/15	41
43	Documentation and system review finalized	5 days	Mon 2/16/15	Fri 2/20/15	42
44	State and Fiscal Agent approves final documentation and/or file layouts	3 days	Mon 2/23/15	Wed 2/25/15	43
45	Ready for Supplemental Rebate Operations	0 days	Wed 2/25/15	Wed 2/25/15	44
46	**Reporting**	**13 days**	**Wed 2/11/15**	**Fri 2/27/15**	
47	Review and refine current reports, develop and define new standard reports including initial release notes with calculation methodologies, and prototype.	3 days	Wed 2/11/15	Fri 2/13/15	6
48	Update current templates, build new reports	5 days	Mon 2/16/15	Fri 2/20/15	47
49	State approves updates/new reports	5 days	Mon 2/23/15	Fri 2/27/15	48
50	Ready for Reporting Operations	0 days	Fri 2/27/15	Fri 2/27/15	49
51	**Ongoing Operations (The activities and durations below reflect the first cycle of each activity or deliverable. Upon request, GHS can include all recurring operational activities in the final plan)**	**83 days**	**Mon 2/9/15**	**Wed 6/3/15**	
52	Provide access by telephone and/or email to a Board certified psychiatrist physician for clinical advice	1 day	Mon 2/9/15	Mon 2/9/15	1
53	**Pharmaceutical & Therapeutics Committee**	**79 days**	**Fri 2/13/15**	**Wed 6/3/15**	
54	Provide P&T agenda at least thirty-five (35) calendar days prior to meetings	2 days	Mon 3/2/15	Tue 3/3/15	20
55	State approves P&T agenda	5 days	Wed 4/8/15	Tue 4/14/15	54FS+35 edays
56	GHS sends final agenda in PDF format	1 day	Wed 4/15/15	Wed 4/15/15	55
57	State posts final agenda on website	1 day	Thu 4/16/15	Thu 4/16/15	56
58	Develop/update therapeutic class reviews, new drug reviews, and monographs	60 days	Fri 2/13/15	Thu 5/7/15	13
59	Update reporting	2 days	Fri 5/8/15	Mon 5/11/15	58
60	Create clinical packet binder build (tabs, Account Manager letter, CDs, RSVP, etc.)	0.25 days	Tue 5/12/15	Tue 5/12/15	59
61	Prepare clinical packets for Committee members and BMS staff	5 days	Tue 5/12/15	Tue 5/19/15	60
62	Develop, format, and print financial analysis reports for P&T Executive Session	7 days	Tue 5/19/15	Thu 5/28/15	61

ID	Task Name	Duration	Start	Finish	Predecessors
63	State approves financial reports	0.5 days	Thu 5/28/15	Thu 5/28/15	62
64	Deliver the monographs and any other information needed for the P&T Committee meeting via UPS fourteen (14) calendar days prior to meetings.	2 days	Tue 5/19/15	Thu 5/21/15	61
65	**P&T Meeting**	**0.5 days**	**Thu 5/21/15**	**Thu 5/21/15**	**64**
66	Present therapeutic class findings and recommendations to the P&T Committee and BMS	0.25 days	Thu 5/21/15	Thu 5/21/15	64
67	Present SSDC-negotiated supplemental rebates and financial analysis information for each therapeutic class or specific drugs during Executive Session	0.25 days	Thu 5/21/15	Thu 5/21/15	66
68	Submit meeting minutes for approval (delivered within 10 days maximum)	2 days	Thu 5/21/15	Mon 5/25/15	67
69	State approves meeting minutes	5 days	Mon 5/25/15	Mon 6/1/15	68
70	GHS provides minutes in PDF format	0.25 days	Mon 6/1/15	Mon 6/1/15	69
71	State posts meeting minutes	2 days	Tue 6/2/15	Wed 6/3/15	70
72	**Maintain Preferred Drug List**	**19 days**	**Fri 3/13/15**	**Wed 4/8/15**	
73	Update the PDL after each P&T meeting and when major changes are made to the PDL, at a minimum of monthly.	3 days	Fri 3/27/15	Tue 3/31/15	29
74	Assure that the PDL is in compliance with all applicable Federal and State statutes and regulations and the State Plan approved by CMS.	1 day	Wed 4/1/15	Wed 4/1/15	73
75	Apply an effective date and a unique version number for each PDL.	0.25 days	Wed 4/1/15	Wed 4/1/15	73
76	Assist in development of step-care therapy and prior authorization (PA) criteria	2 days	Fri 3/27/15	Mon 3/30/15	29
77	Update the PDL document when PA criteria is changed or updated by the DUR Board and issue an updated version for web posting, at a minimum of monthly.	5 days	Fri 3/27/15	Thu 4/2/15	29
78	Provide written evaluations of Value Added Programs offered in lieu of supplemental rebates, such as disease management programs.	5 days	Fri 3/27/15	Thu 4/2/15	29
79	**PDL Data Files**	**7 days**	**Fri 3/13/15**	**Mon 3/23/15**	
80	Provide the PDL data files for exportation to external sources, including but not limited to the Bureau's Fiscal Agent.	1 day	Fri 3/13/15	Fri 3/13/15	26
81	Provide the PDL data files in accordance with a schedule agreed upon by the Bureau and Vendor, at a minimum of weekly.	7 days	Fri 3/13/15	Mon 3/23/15	26
82	**PDL Communication and Documentation**	**9 days**	**Fri 3/27/15**	**Wed 4/8/15**	
83	Draft letters and/or make telephone calls that respond to inquiries from providers and other interested parties concerning the PDL within five (5) business days of the receipt of the inquiry.	5 days	Wed 4/1/15	Tue 4/7/15	29,73
84	Assist the Bureau with State Plan Amendments related to the PDL.	5 days	Thu 4/2/15	Wed 4/8/15	1,74
85	Fold, stuff, and mail first newsletter	2 days	Fri 3/27/15	Mon 3/30/15	28
86	**Supplemental Rebate Administration**	**60 days**	**Thu 2/26/15**	**Wed 5/20/15**	
87	**Supplemental Rebate Contract Administration**	**33 days**	**Thu 2/26/15**	**Mon 4/13/15**	
88	Work with SSDC partners to accurately determine supplemental rebate contract data	3 days	Thu 2/26/15	Mon 3/2/15	45

ID	Task Name	Duration	Start	Finish	Predecessors
89	Produce and facilitate the signing of supplemental rebate contracts with pharmaceutical manufacturers, the Bureau, and the Secretary of DHHR.	30 days	Tue 3/3/15	Mon 4/13/15	88
90	Track contracts and documents at all points from origin to completion.	30 days	Tue 3/3/15	Mon 4/13/15	88
91	Assure that both BMS and manufacturers receive an original signed agreement/contact.	30 days	Tue 3/3/15	Mon 4/13/15	88
92	**Supplemental Unit Rebate Amounts (SURA) File**	**60 days**	**Thu 2/26/15**	**Wed 5/20/15**	
93	Provide SURA files to the Bureau and its Fiscal Agent within sixty (60) calendar days of the end of a quarter	60 days	Thu 2/26/15	Wed 5/20/15	45
94	Provide data, including but not limited to current and prior quarter adjustment data necessary for BMS to invoice manufacturers on a quarterly basis for supplemental rebates	1 day	Thu 2/26/15	Thu 2/26/15	45
95	Coordinate supplemental rebate submission with submission of traditional Federal rebates.	5 days	Thu 2/26/15	Wed 3/4/15	45
96	Provide necessary documentation to the Bureau and/or its designee to support supplemental rebate invoicing at the NDC level	5 days	Thu 2/26/15	Wed 3/4/15	45
97	**Dispute Resolution Services**	**5 days**	**Thu 2/26/15**	**Wed 3/4/15**	
98	Communicate directly with manufacturers to resolve disputes arising from supplemental rebate calculations or contract issues within five (5) business days of receipt of the dispute.	5 days	Thu 2/26/15	Wed 3/4/15	45
99	Communicate directly with manufacturers regarding unpaid supplemental rebates upon request by BMS.	3 days	Thu 2/26/15	Mon 3/2/15	45
100	Communicate the resolution of disputes in a written document to BMS, within one (1) business day of resolution.	1 day	Thu 2/26/15	Thu 2/26/15	45
101	**State Maximum Allowable Cost Program**	**69 days**	**Tue 2/17/15**	**Fri 5/22/15**	
102	**State Maximum Allowable Cost (SMAC) List**	**60 days**	**Mon 3/2/15**	**Fri 5/22/15**	
103	Update the SMAC list no less than quarterly, and as modifications occur.	60 days	Mon 3/2/15	Fri 5/22/15	38
104	Ensure that each SMAC list submitted has an effective date and a unique version number.	0.25 days	Mon 3/2/15	Mon 3/2/15	38
105	Update the Fiscal Agent with SMAC changes approved by the Bureau.	1 day	Mon 3/2/15	Mon 3/2/15	38
106	Coordinate activities with the Fiscal Agent to support the implementation and updates of the SMAC list.	1 day	Mon 3/2/15	Mon 3/2/15	38
107	Review opportunities for expansion of the SMAC pricing list and regularly report the Vendor's SMAC activities monthly	1 day	Mon 3/2/15	Mon 3/2/15	38
108	Collect acquisition cost data and other required source information to support SMAC pricing.	1 day	Mon 3/2/15	Mon 3/2/15	38
109	Prepare for, attend in person and facilitate the meetings with the provider industry, interested parties, and internal work groups in regard to the SMAC program, at a minimum of quarterly.	1 day	Mon 3/2/15	Mon 3/2/15	38
110	Develop alternative SMAC reimbursement models for the Bureau's consideration when requested by BMS, at a minimum annually.	5 days	Mon 3/2/15	Fri 3/6/15	38

ID	Task Name	Duration	Start	Finish	Predecessors
111	Coordinate the addition of drugs for SMAC pricing with drugs in the same therapeutic category on the PDL to ensure that the PDL and SMAC activities result in the most cost effective results.	1 day	Fri 3/6/15	Fri 3/6/15	
112	**WV Provider Pricing Support and Dispute Resolution**	**20 days**	**Tue 2/17/15**	**Mon 3/16/15**	
113	Acknowledge disputes within one (1) business day of receipt	1 day	Tue 2/17/15	Tue 2/17/15	33
114	Submit pricing disputes within fourteen (14) calendar days of the date of the complaint	14 days	Wed 2/18/15	Mon 3/9/15	113
115	State approves disputes	5 days	Tue 3/10/15	Mon 3/16/15	114
116	**Reports**	**60.75 days**	**Mon 3/2/15**	**Mon 5/25/15**	
117	Update BMS Pharmacy Monthly Utilization (required every 30 days)	2 days	Tue 5/12/15	Wed 5/13/15	50,59
118	Update BMS Pharmacy Annual Utilization	5 days	Tue 5/12/15	Mon 5/18/15	50,59
119	Update BMS Summary Monthly Report (required every 30 days)	2 days	Tue 5/12/15	Wed 5/13/15	50,59
120	Update BMS Summary Annual Report	5 days	Tue 5/12/15	Mon 5/18/15	50,59
121	Update Marketshare Summary Report (required every 90 days)	2 days	Tue 5/12/15	Wed 5/13/15	50,59
122	Update Therapeutic Class Marketshare Report (required every 90 days)	2 days	Tue 5/12/15	Wed 5/13/15	50,59
123	Update Generic Compliance Report (required every 90 days)	2 days	Tue 5/12/15	Wed 5/13/15	50,59
124	Update PDL Compliance Report (required every 90 days)	2 days	Tue 5/12/15	Wed 5/13/15	50,59
125	Update PDL Savings Report (required every 90 days)	2 days	Tue 5/12/15	Wed 5/13/15	50,59
126	Update WV Provider Pricing Support and Dispute Resolution Report (required every 30 days)	2 days	Mon 3/2/15	Tue 3/3/15	50,45
127	Update PDL Changes Report (required 14 days after P & T)	2 days	Thu 5/21/15	Mon 5/25/15	50,65
128	Update Rebate Dispute Status Report (required every 30 days)	2 days	Mon 3/2/15	Tue 3/3/15	50,45
129	Update Supplemental Rebate Contract Tracking Report (required every 30 days)	2 days	Mon 3/2/15	Tue 3/3/15	50,45
130	Update Supplemental Rebate Contract Details Report (required every 30 days)	2 days	Mon 3/2/15	Tue 3/3/15	50,45
131	Update Supplemental Rebate Pricing File Quality Assurance Checklist (required every 30 days)	2 days	Mon 3/2/15	Tue 3/3/15	50,45
132	Update Supplemental Rebate Pricing File Additions and Corrections Report (required every 30 days)	2 days	Mon 3/2/15	Tue 3/3/15	50,45
133	Update Supplemental Rebate Pricing File Spreadsheet (required every 90 days)	2 days	Mon 3/2/15	Tue 3/3/15	50,45
134	Update SMAC Savings Beyond Aggregate FUL Cap (required every 90 days)	2 days	Mon 3/2/15	Tue 3/3/15	50,38
135	Update SMAC Savings Report (required every 30 days)	2 days	Mon 3/2/15	Tue 3/3/15	50,38
136	Update SMAC Dispute Report (required every 7 days)	2 days	Mon 3/2/15	Tue 3/3/15	50,38
137	**Ad Hoc Reports**	**9 days**	**Mon 3/2/15**	**Thu 3/12/15**	
138	Provide to the Bureau ad hoc reports when requested and shall include the report methodology and parameters used in developing the report.	2 days	Mon 3/2/15	Tue 3/3/15	50
139	Deliver the ad hoc reports desired by the Bureau in accordance with the schedule and delivery method approved by the Bureau.	2 days	Wed 3/4/15	Thu 3/5/15	138

ID	Task Name	Duration	Start	Finish	Predecessors
140	State approves ad hoc reports	5 days	Fri 3/6/15	Thu 3/12/15	139
141	**Turnover and Contract Closeout Services**	**30 days**	**Mon 10/2/17**	**Fri 11/10/17**	
142	Receive notification to initiate Close-Out and Turnover	0 days	Mon 10/2/17	Mon 10/2/17	
143	Submit Training Handbook	1 day	Mon 10/2/17	Mon 10/2/17	142
144	Provide the Close-Out and Turnover Plan within thirty (30) calendar days of receiving BMS notification to initiate the Close-out and Turnover Phase.	30 days	Mon 10/2/17	Fri 11/10/17	142
145	Submit data, deliverables, and reports no later than thirty (30) days prior to the end of the contract.	30 days	Mon 10/2/17	Fri 11/10/17	142
146	Submit Turnover Results Report no later than thirty (30) days prior to the end of the contract.	30 days	Mon 10/2/17	Fri 11/10/17	142
147	**Additional Services**	**12.5 days**	**Mon 2/9/15**	**Wed 2/25/15**	
148	The Vendor shall provide a pool of hours annually that can be used by BMS for assistance, advice and consultation for Medicaid pharmacy activities.	12.5 days	Mon 2/9/15	Wed 2/25/15	1
149	**PROJECT MANAGEMENT - ONGOING**	**1 day**	**Wed 10/4/17**	**Wed 10/4/17**	
150	GHS will be available for appearances before the West Virginia Legislature or other interested parties as requested by BMS at a minimum of four (4) and maximum of six (6) times per calendar year.	1 day	Wed 10/4/17	Wed 10/4/17	
151	Provide notice of changes in staff regarding the account manager, clinical pharmacist, physician, rebate manager and SMAC pricing manager	1 day	Wed 10/4/17	Wed 10/4/17	
152	Facilitate status meetings with BMS including providing meeting agendas and minutes	1 day	Wed 10/4/17	Wed 10/4/17	

Exhibit D – Proof of Insurance

Goold holds the appropriate levels of insurance required by West Virginia for performance of the services under this RFQ. Upon contract award, Goold will work with the necessary State officials to finalize the required documentation. The following is proof of insurance held by Goold as of December 2014.