State of West Virginia
Department of Administration
Purchasing Division
2019 Washington Street East
Post Office Box 50130
Charleston, WV 25305-0130

Solicitation

NUMBER	PAGE
EHP14005	1

ADDRESS CORRESPONDENCE TO ATTENTION OF:
ROBERTA WAGNER
304-558-0067

VENDOR
RFQ COPY
TYPE NAME/ADDRESS HERE

SHIP TO
HEALTH AND HUMAN RESOURCES
BPH - EPIDEMIOLOGY AND
HEALTH PROMOTION
VARIOUS LOCALES AS INDICATED

DATE PRINTED
09/24/2013

BID OPENING DATE: 11/05/2013 BID OPENING TIME 01:30PM

LINE	QUANTITY	UOP	CAT. NO.	ITEM NUMBER	UNIT PRICE	AMOUNT
	THE WEST VIRGINIA PURCHASING DIVISION IS SOLICITING BIDS ON BEHALF OF THE WEST VIRGINIA DEPARTMENT OF HEALTH AND HUMAN RESOURCES (DHHR), BUREAU FOR PUBLIC HEALTH, DIVISION OF TOBACCO PREVENTION AND THE BUREAU FOR MEDICAL SERVICES, (MEDICAID) AS A JOINT PARTY TO ESTABLISH A CONTRACT FOR PROFESSIONAL SERVICES TO PROVIDE A NO CHARGE TO THE CALLER, CONVENIENT TELE-PHONE BASED TOBACCO USE CESSATION QUITLINE TO ASSIST WEST VIRGINIANS WITH QUITTING SMOKING AND/OR USING OTHER TOBACCO PRODUCTS PER THE ATTACHED SPECIFICATIONS AND INSTRUCTIONS TO BIDDERS.					
0001	1	YR		948-42		
	TOBACCO CESSATION QUITLINE SERVICES					
	****** THIS IS THE END OF RFQ EHP14005 ******				TOTAL:	

SIGNATURE	TELEPHONE	DATE
TITLE	FEIN	ADDRESS CHANGES TO BE NOTED ABOVE

WHEN RESPONDING TO SOLICITATION, INSERT NAME AND ADDRESS IN SPACE ABOVE LABELED 'VENDOR'

INSTRUCTIONS TO VENDORS SUBMITTING BIDS

1. **REVIEW DOCUMENTS THOROUGHLY:** The attached documents contain a solicitation for bids. Please read these instructions and all documents attached in their entirety. These instructions provide critical information about requirements that if overlooked could lead to disqualification of a Vendor's bid. All bids must be submitted in accordance with the provisions contained in these instructions and the Solicitation. Failure to do so may result in disqualification of Vendor's bid.

2. **MANDATORY TERMS:** The Solicitation may contain mandatory provisions identified by the use of the words "must," "will," and "shall." Failure to comply with a mandatory term in the Solicitation will result in bid disqualification.

3. **PREBID MEETING:** The item identified below shall apply to this Solicitation.

☐ A pre-bid meeting will not be held prior to bid opening.

☐ A **NON-MANDATORY PRE-BID** meeting will be held at the following place and time:

☑ A **MANDATORY PRE-BID** meeting will be held at the following place and time:

350 Capitol Street
2nd Floor Conference Room 220
Charleston, WV 26301

October 8, 2013 - Tuesday @ 1:30 p.m.

All Vendors submitting a bid must attend the mandatory pre-bid meeting. Failure to attend the mandatory pre-bid meeting shall result in disqualification of the Vendor's bid. No one person attending the pre-bid meeting may represent more than one Vendor.

An attendance sheet provided at the pre-bid meeting shall serve as the official document verifying attendance. The State will not accept any other form of proof or documentation to verify attendance. Any person attending the pre-bid meeting on behalf of a Vendor must list on the attendance sheet his or her name and the name of the Vendor he or she is representing. Additionally, the person attending the pre-bid meeting should include the Vendor's E-Mail address, phone number, and Fax number on the attendance sheet. It is the Vendor's responsibility to locate the attendance sheet and provide the required

information. Failure to complete the attendance sheet as required may result in disqualification of Vendor's bid.

All Vendors should arrive prior to the starting time for the pre-bid. Vendors who arrive after the starting time but prior to the end of the pre-bid will be permitted to sign in, but are charged with knowing all matters discussed at the pre-bid.

Questions submitted at least five business days prior to a scheduled pre-bid will be discussed at the pre-bid meeting if possible. Any discussions or answers to questions at the pre-bid meeting are preliminary in nature and are non-binding. Official and binding answers to questions will be published in a written addendum to the Solicitation prior to bid opening.

4. **VENDOR QUESTION DEADLINE:** Vendors may submit questions relating to this Solicitation to the Purchasing Division. Questions must be submitted in writing. All questions must be submitted on or before the date listed below and to the address listed below in order to be considered. A written response will be published in a Solicitation addendum if a response is possible and appropriate. Non-written discussions, conversations, or questions and answers regarding this Solicitation are preliminary in nature and are non-binding.

Question Submission Deadline: October 18, 2013 - end of business

Submit Questions to:

Roberta A. Wagner
2019 Washington Street, East
Charleston, WV 25305
Fax: 304-558-4115
Email: roberta.a.wagner@wv.gov

5. **VERBAL COMMUNICATION:** Any verbal communication between the Vendor and any State personnel is not binding, including that made at the mandatory pre-bid conference. Only information issued in writing and added to the Solicitation by an official written addendum by the Purchasing Division is binding.

6. **BID SUBMISSION:** All bids must be signed and delivered by the Vendor to the Purchasing Division at the address listed below on or before the date and time of the bid opening. Any bid received by the Purchasing Division staff is considered to be in the possession of the Purchasing Division and will not be returned for any reason. The bid delivery address is:

Department of Administration, Purchasing Division
2019 Washington Street East
Charleston, WV 25305-0130

The bid should contain the information listed below on the face of the envelope or the bid may not be considered:

SEALED BID
BUYER: _____
SOLICITATION NO.: _____
BID OPENING DATE: _____
BID OPENING TIME: _____
FAX NUMBER: _____

In the event that Vendor is responding to a request for proposal, the Vendor shall submit one original technical and one original cost proposal plus _____ convenience copies of each to the Purchasing Division at the address shown above. Additionally, the Vendor should identify the bid type as either a technical or cost proposal on the face of each bid envelope submitted in response to a request for proposal as follows:

BID TYPE: ☐ Technical
☐ Cost

7. **BID OPENING:** Bids submitted in response to this Solicitation will be opened at the location identified below on the date and time listed below. Delivery of a bid after the bid opening date and time will result in bid disqualification. For purposes of this Solicitation, a bid is considered delivered when time stamped by the official Purchasing Division time clock.

Bid Opening Date and Time: November 5, 2013 - Tuesday @ 1:30 p.m.

Bid Opening Location: Department of Administration, Purchasing Division
2019 Washington Street East
Charleston, WV 25305-0130

8. **ADDENDUM ACKNOWLEDGEMENT:** Changes or revisions to this Solicitation will be made by an official written addendum issued by the Purchasing Division. Vendor should acknowledge receipt of all addenda issued with this Solicitation by completing an Addendum Acknowledgment Form, a copy of which is included herewith. Failure to acknowledge addenda may result in bid disqualification. The addendum acknowledgement should be submitted with the bid to expedite document processing.

9. **BID FORMATTING:** Vendor should type or electronically enter the information onto its bid to prevent errors in the evaluation. Failure to type or electronically enter the information may result in bid disqualification.

GENERAL TERMS AND CONDITIONS:

1. **CONTRACTUAL AGREEMENT:** Issuance of a Purchase Order signed by the Purchasing Division Director, or his designee, and approved as to form by the Attorney General's office constitutes acceptance of this Contract made by and between the State of West Virginia and the Vendor. Vendor's signature on its bid signifies Vendor's agreement to be bound by and accept the terms and conditions contained in this Contract.

2. **DEFINITIONS:** As used in this Solicitation / Contract, the following terms shall have the meanings attributed to them below. Additional definitions may be found in the specifications included with this Solicitation / Contract.

   2.1 "Agency" or **"Agencies"** means the agency, board, commission, or other entity of the State of West Virginia that is identified on the first page of the Solicitation or any other public entity seeking to procure goods or services under this Contract.

   2.2 "Contract" means the binding agreement that is entered into between the State and the Vendor to provide the goods and services requested in the Solicitation.

   2.3 "Director" means the Director of the West Virginia Department of Administration, Purchasing Division.

   2.4 "Purchasing Division" means the West Virginia Department of Administration, Purchasing Division.

   2.5 "Purchase Order" means the document signed by the Agency and the Purchasing Division, and approved as to form by the Attorney General, that identifies the Vendor as the successful bidder and Contract holder.

   2.6 "Solicitation" means the official solicitation published by the Purchasing Division and identified by number on the first page thereof.

   2.7 "State" means the State of West Virginia and/or any of its agencies, commissions, boards, etc. as context requires.

   2.8 "Vendor" or **"Vendors"** means any entity submitting a bid in response to the Solicitation, the entity that has been selected as the lowest responsible bidder, or the entity that has been awarded the Contract as context requires.

3. **CONTRACT TERM; RENEWAL; EXTENSION:** The term of this Contract shall be determined in accordance with the category that has been identified as applicable to this Contract below:

☑ **Term Contract**

Initial Contract Term: This Contract becomes effective on _____upon award_____

and extends for a period of _____one (1)_____ year(s).

Renewal Term: This Contract may be renewed upon the mutual written consent of the Agency, and the Vendor, with approval of the Purchasing Division and the Attorney General's office (Attorney General approval is as to form only). Any request for renewal must be submitted to the Purchasing Division Director thirty (30) days prior to the expiration date of the initial contract term or appropriate renewal term. A Contract renewal shall be in accordance with the terms and conditions of the original contract. Renewal of this Contract is limited to _____two (2)_____ successive one (1) year periods. Automatic renewal of this Contract is prohibited. Notwithstanding the foregoing, Purchasing Division approval is not required on agency delegated or exempt purchases. Attorney General approval may be required for vendor terms and conditions.

Reasonable Time Extension: At the sole discretion of the Purchasing Division Director, and with approval from the Attorney General's office (Attorney General approval is as to form only), this Contract may be extended for a reasonable time after the initial Contract term or after any renewal term as may be necessary to obtain a new contract or renew this Contract. Any reasonable time extension shall not exceed twelve (12) months. Vendor may avoid a reasonable time extension by providing the Purchasing Division Director with written notice of Vendor's desire to terminate this Contract 30 days prior to the expiration of the then current term. During any reasonable time extension period, the Vendor may terminate this Contract for any reason upon giving the Purchasing Division Director 30 days written notice. Automatic extension of this Contract is prohibited. Notwithstanding the foregoing, Purchasing Division approval is not required on agency delegated or exempt purchases, but Attorney General approval may be required.

Release Order Limitations: In the event that this contract permits release orders, a release order may only be issued during the time this Contract is in effect. Any release order issued within one year of the expiration of this Contract shall be effective for one year from the date the release order is issued. No release order may be extended beyond one year after this Contract has expired.

☐ **Fixed Period Contract:** This Contract becomes effective upon Vendor's receipt of the notice to proceed and must be completed within _____ days.

☐ **One Time Purchase:** The term of this Contract shall run from the issuance of the Purchase Order until all of the goods contracted for have been delivered, but in no event shall this Contract extend for more than one fiscal year.

☐ **Other:** See attached.

4. **NOTICE TO PROCEED:** Vendor shall begin performance of this Contract immediately upon receiving notice to proceed unless otherwise instructed by the Agency. Unless otherwise specified, the fully executed Purchase Order will be considered notice to proceed

5. **QUANTITIES:** The quantities required under this Contract shall be determined in accordance with the category that has been identified as applicable to this Contract below.

☑ **Open End Contract:** Quantities listed in this Solicitation are approximations only, based on estimates supplied by the Agency. It is understood and agreed that the Contract shall cover the quantities actually ordered for delivery during the term of the Contract, whether more or less than the quantities shown.

☐ **Service:** The scope of the service to be provided will be more clearly defined in the specifications included herewith.

☑ **Combined Service and Goods:** The scope of the service and deliverable goods to be provided will be more clearly defined in the specifications included herewith.

☐ **One Time Purchase:** This Contract is for the purchase of a set quantity of goods that are identified in the specifications included herewith. Once those items have been delivered, no additional goods may be procured under this Contract without an appropriate change order approved by the Vendor, Agency, Purchasing Division, and Attorney General's office.

6. **PRICING:** The pricing set forth herein is firm for the life of the Contract, unless specified elsewhere within this Solicitation/Contract by the State. A Vendor's inclusion of price adjustment provisions in its bid, without an express authorization from the State in the Solicitation to do so, may result in bid disqualification.

7. **EMERGENCY PURCHASES:** The Purchasing Division Director may authorize the Agency to purchase goods or services in the open market that Vendor would otherwise provide under this Contract if those goods or services are for immediate or expedited delivery in an emergency. Emergencies shall include, but are not limited to, delays in transportation or an unanticipated increase in the volume of work. An emergency purchase in the open market, approved by the Purchasing Division Director, shall not constitute of breach of this Contract and shall not entitle the Vendor to any form of compensation or damages. This provision does not excuse the State from fulfilling its obligations under a One Time Purchase contract.

8. **REQUIRED DOCUMENTS:** All of the items checked below must be provided to the Purchasing Division by the Vendor as specified below.

☐ **BID BOND:** All Vendors shall furnish a bid bond in the amount of five percent (5%) of the total amount of the bid protecting the State of West Virginia. The bid bond must be submitted with the bid.

☐ **PERFORMANCE BOND:** The apparent successful Vendor shall provide a performance bond in the amount of . The performance bond must be issued and received by the Purchasing Division prior to Contract award. On construction contracts, the performance bond must be 100% of the Contract value.

☐ **LABOR/MATERIAL PAYMENT BOND:** The apparent successful Vendor shall provide a labor/material payment bond in the amount of 100% of the Contract value. The labor/material payment bond must be issued and delivered to the Purchasing Division prior to Contract award.

In lieu of the Bid Bond, Performance Bond, and Labor/Material Payment Bond, the Vendor may provide certified checks, cashier's checks, or irrevocable letters of credit. Any certified check, cashier's check, or irrevocable letter of credit provided in lieu of a bond must be of the same amount and delivered on the same schedule as the bond it replaces. A letter of credit submitted in lieu of a performance and labor/material payment bond will only be allowed for projects under $100,000. Personal or business checks are not acceptable.

☐ **MAINTENANCE BOND:** The apparent successful Vendor shall provide a two (2) year maintenance bond covering the roofing system. The maintenance bond must be issued and delivered to the Purchasing Division prior to Contract award.

☑ **WORKERS' COMPENSATION INSURANCE:** The apparent successful Vendor shall have appropriate workers' compensation insurance and shall provide proof thereof upon request.

☑ **INSURANCE:** The apparent successful Vendor shall furnish proof of the following insurance prior to Contract award and shall list the state as a certificate holder:

☑ **Commercial General Liability Insurance:**
$ 1,000,000.00 or more.

☐ **Builders Risk Insurance:** builders risk – all risk insurance in an amount equal to 100% of the amount of the Contract.

☑ Professional Liability - $ 1,000,000.00 or more

☐

☐

☐

☐

The apparent successful Vendor shall also furnish proof of any additional insurance requirements contained in the specifications prior to Contract award regardless of whether or not that insurance requirement is listed above.

☑ **LICENSE(S) / CERTIFICATIONS / PERMITS:** In addition to anything required under the Section entitled Licensing, of the General Terms and Conditions, the apparent successful Vendor shall furnish proof of the following licenses, certifications, and/or permits prior to Contract award, in a form acceptable to the Purchasing Division.

☑ Counselors - Bachelor's Degree in social , behavioral or health related field

☑ WV Medical/clinical license for clinical and/or medical director

☐

☐

The apparent successful Vendor shall also furnish proof of any additional licenses or certifications contained in the specifications prior to Contract award regardless of whether or not that requirement is listed above.

9. **LITIGATION BOND:** The Director reserves the right to require any Vendor that files a protest of an award to submit a litigation bond in the amount equal to one percent of the lowest bid submitted or $5,000, whichever is greater. The entire amount of the bond shall be forfeited if the hearing officer determines that the protest was filed for frivolous or improper purpose, including but not limited to, the purpose of harassing, causing unnecessary delay, or needless expense for the Agency. All litigation bonds shall be made payable to the Purchasing Division. In lieu of a bond, the protester may submit a cashier's check or certified check payable to the Purchasing Division. Cashier's or certified checks will be deposited with and held by the State Treasurer's office. If it is determined that the protest has not been filed for frivolous or improper purpose, the bond or deposit shall be returned in its entirety.

10. **ALTERNATES:** Any model, brand, or specification listed herein establishes the acceptable level of quality only and is not intended to reflect a preference for, or in any way favor, a particular brand or vendor. Vendors may bid alternates to a listed model or brand provided that the alternate is at least equal to the model or brand and complies with the required specifications. The equality of any alternate being bid shall be determined by the State at its sole discretion. Any Vendor bidding an alternate model or brand should clearly identify the alternate items in its bid and should include manufacturer's specifications, industry literature, and/or any other relevant documentation demonstrating the equality of the alternate items. Failure to provide information for alternate items may be grounds for rejection of a Vendor's bid.

11. **EXCEPTIONS AND CLARIFICATIONS:** The Solicitation contains the specifications that shall form the basis of a contractual agreement. Vendor shall clearly mark any exceptions, clarifications, or

other proposed modifications in its bid. Exceptions to, clarifications of, or modifications of a requirement or term and condition of the Solicitation may result in bid disqualification.

12. LIQUIDATED DAMAGES: Vendor shall pay liquidated damages in the amount for

This clause shall in no way be considered exclusive and shall not limit the State or Agency's right to pursue any other available remedy.

13. ACCEPTANCE/REJECTION: The State may accept or reject any bid in whole, or in part. Vendor's signature on its bid signifies acceptance of the terms and conditions contained in the Solicitation and Vendor agrees to be bound by the terms of the Contract, as reflected in the Purchase Order, upon receipt.

14. REGISTRATION: Prior to Contract award, the apparent successful Vendor must be properly registered with the West Virginia Purchasing Division and must have paid the $125 fee if applicable.

15. COMMUNICATION LIMITATIONS: In accordance with West Virginia Code of State Rules §148-1-6.6, communication with the State of West Virginia or any of its employees regarding this Solicitation during the solicitation, bid, evaluation or award periods, except through the Purchasing Division, is strictly prohibited without prior Purchasing Division approval. Purchasing Division approval for such communication is implied for all agency delegated and exempt purchases.

16. FUNDING: This Contract shall continue for the term stated herein, contingent upon funds being appropriated by the Legislature or otherwise being made available. In the event funds are not appropriated or otherwise made available, this Contract becomes void and of no effect beginning on July 1 of the fiscal year for which funding has not been appropriated or otherwise made available.

17. PAYMENT: Payment in advance is prohibited under this Contract. Payment may only be made after the delivery and acceptance of goods or services. The Vendor shall submit invoices, in arrears, to the Agency at the address on the face of the purchase order labeled "Invoice To."

18. UNIT PRICE: Unit prices shall prevail in cases of a discrepancy in the Vendor's bid.

19. DELIVERY: All quotations are considered freight on board destination ("F.O.B. destination") unless alternate shipping terms are clearly identified in the bid. Vendor's listing of shipping terms that contradict the shipping terms expressly required by this Solicitation may result in bid disqualification.

20. INTEREST: Interest attributable to late payment will only be permitted if authorized by the West Virginia Code. Presently, there is no provision in the law for interest on late payments.

21. PREFERENCE: Vendor Preference may only be granted upon written request and only in accordance with the West Virginia Code § 5A-3-37 and the West Virginia Code of State Rules. A Resident Vendor Certification form has been attached hereto to allow Vendor to apply for the preference. Vendor's

failure to submit the Resident Vendor Certification form with its bid will result in denial of Vendor Preference. Vendor Preference does not apply to construction projects.

22. **SMALL, WOMEN-OWNED, OR MINORITY-OWNED BUSINESSES:** For any solicitations publicly advertised for bid on or after July 1, 2012, in accordance with West Virginia Code §5A-3-37(a)(7) and W. Va. CSR § 148-22-9, any non-resident vendor certified as a small, women-owned, or minority-owned business under W. Va. CSR § 148-22-9 shall be provided the same preference made available to any resident vendor. Any non-resident small, women-owned, or minority-owned business must identify itself as such in writing, must submit that writing to the Purchasing Division with its bid, and must be properly certified under W. Va. CSR § 148-22-9 prior to submission of its bid to receive the preferences made available to resident vendors. Preference for a non-resident small, women-owned, or minority owned business shall be applied in accordance with W. Va. CSR § 148-22-9.

23. **TAXES:** The Vendor shall pay any applicable sales, use, personal property or any other taxes arising out of this Contract and the transactions contemplated thereby. The State of West Virginia is exempt from federal and state taxes and will not pay or reimburse such taxes.

24. **CANCELLATION:** The Purchasing Division Director reserves the right to cancel this Contract immediately upon written notice to the vendor if the materials or workmanship supplied do not conform to the specifications contained in the Contract. The Purchasing Division Director may cancel any purchase or Contract upon 30 days written notice to the Vendor in accordance with West Virginia Code of State Rules § 148-1-7.16.2.

25. **WAIVER OF MINOR IRREGULARITIES:** The Director reserves the right to waive minor irregularities in bids or specifications in accordance with West Virginia Code of State Rules § 148-1-4.6.

26. **TIME:** Time is of the essence with regard to all matters of time and performance in this Contract.

27. **APPLICABLE LAW:** This Contract is governed by and interpreted under West Virginia law without giving effect to its choice of law principles. Any information provided in specification manuals, or any other source, verbal or written, which contradicts or violates the West Virginia Constitution, West Virginia Code or West Virginia Code of State Rules is void and of no effect.

28. **COMPLIANCE:** Vendor shall comply with all applicable federal, state, and local laws, regulations and ordinances. By submitting a bid, Vendors acknowledge that they have reviewed, understand, and will comply with all applicable law.

29. **PREVAILING WAGE:** On any contract for the construction of a public improvement, Vendor and any subcontractors utilized by Vendor shall pay a rate or rates of wages which shall not be less than the fair minimum rate or rates of wages (prevailing wage), as established by the West Virginia Division of Labor under West Virginia Code §§ 21-5A-1 et seq. and available at http://www.sos.wv.gov/administrative-law/wagerates/Pages/default.aspx. Vendor shall be responsible for ensuring compliance with prevailing wage requirements and determining when prevailing wage

requirements are applicable. The required contract provisions contained in West Virginia Code of State Rules § 42-7-3 are specifically incorporated herein by reference.

30. **ARBITRATION:** Any references made to arbitration contained in this Contract, Vendor's bid, or in any American Institute of Architects documents pertaining to this Contract are hereby deleted, void, and of no effect.

31. **MODIFICATIONS:** This writing is the parties' final expression of intent. Notwithstanding anything contained in this Contract to the contrary, no modification of this Contract shall be binding without mutual written consent of the Agency, and the Vendor, with approval of the Purchasing Division and the Attorney General's office (Attorney General approval is as to form only). **No Change shall be implemented by the Vendor until such time as the Vendor receives an approved written change order from the Purchasing Division.**

32. **WAIVER:** The failure of either party to insist upon a strict performance of any of the terms or provision of this Contract, or to exercise any option, right, or remedy herein contained, shall not be construed as a waiver or a relinquishment for the future of such term, provision, option, right, or remedy, but the same shall continue in full force and effect. Any waiver must be expressly stated in writing and signed by the waiving party.

33. **SUBSEQUENT FORMS:** The terms and conditions contained in this Contract shall supersede any and all subsequent terms and conditions which may appear on any form documents submitted by Vendor to the Agency or Purchasing Division such as price lists, order forms, invoices, sales agreements, or maintenance agreements, and includes internet websites or other electronic documents. Acceptance or use of Vendor's forms does not constitute acceptance of the terms and conditions contained thereon.

34. **ASSIGNMENT:** Neither this Contract nor any monies due, or to become due hereunder, may be assigned by the Vendor without the express written consent of the Agency, the Purchasing Division, the Attorney General's office (as to form only), and any other government agency or office that may be required to approve such assignments. Notwithstanding the foregoing, Purchasing Division approval may or may not be required on certain agency delegated or exempt purchases.

35. **WARRANTY:** The Vendor expressly warrants that the goods and/or services covered by this Contract will: (a) conform to the specifications, drawings, samples, or other description furnished or specified by the Agency; (b) be merchantable and fit for the purpose intended; and (c) be free from defect in material and workmanship.

36. **STATE EMPLOYEES:** State employees are not permitted to utilize this Contract for personal use and the Vendor is prohibited from permitting or facilitating the same.

37. **BANKRUPTCY:** In the event the Vendor files for bankruptcy protection, the State of West Virginia may deem this Contract null and void, and terminate this Contract without notice.

38. [RESERVED]

39. CONFIDENTIALITY: The Vendor agrees that it will not disclose to anyone, directly or indirectly, any such personally identifiable information or other confidential information gained from the Agency, unless the individual who is the subject of the information consents to the disclosure in writing or the disclosure is made pursuant to the Agency's policies, procedures, and rules. Vendor further agrees to comply with the Confidentiality Policies and Information Security Accountability Requirements, set forth in http://www.state.wv.us/admin/purchase/privacy/default.html.

40. DISCLOSURE: Vendor's response to the Solicitation and the resulting Contract are considered public documents and will be disclosed to the public in accordance with the laws, rules, and policies governing the West Virginia Purchasing Division. Those laws include, but are not limited to, the Freedom of Information Act found in West Virginia Code § 29B-1-1 et seq.

If a Vendor considers any part of its bid to be exempt from public disclosure, Vendor must so indicate by specifically identifying the exempt information, identifying the exemption that applies, providing a detailed justification for the exemption, segregating the exempt information from the general bid information, and submitting the exempt information as part of its bid but in a segregated and clearly identifiable format. Failure to comply with the foregoing requirements will result in public disclosure of the Vendor's bid without further notice. A Vendor's act of marking all or nearly all of its bid as exempt is not sufficient to avoid disclosure and WILL NOT BE HONORED. Vendor's act of marking a bid or any part thereof as "confidential" or "proprietary" is not sufficient to avoid disclosure and WILL NOT BE HONORED. In addition, a legend or other statement indicating that all or substantially all of the bid is exempt from disclosure is not sufficient to avoid disclosure and WILL NOT BE HONORED. Vendor will be required to defend any claimed exemption for nondiclosure in the event of an administrative or judicial challenge to the State's nondisclosure. Vendor must indemnify the State for any costs incurred related to any exemptions claimed by Vendor. Any questions regarding the applicability of the various public records laws should be addressed to your own legal counsel prior to bid submission.

41. LICENSING: In accordance with West Virginia Code of State Rules §148-1-6.1.7, Vendor must be licensed and in good standing in accordance with any and all state and local laws and requirements by any state or local agency of West Virginia, including, but not limited to, the West Virginia Secretary of State's Office, the West Virginia Tax Department, West Virginia Insurance Commission, or any other state agency or political subdivision. Upon request, the Vendor must provide all necessary releases to obtain information to enable the Purchasing Division Director or the Agency to verify that the Vendor is licensed and in good standing with the above entities.

42. ANTITRUST: In submitting a bid to, signing a contract with, or accepting a Purchase Order from any agency of the State of West Virginia, the Vendor agrees to convey, sell, assign, or transfer to the State of West Virginia all rights, title, and interest in and to all causes of action it may now or hereafter acquire under the antitrust laws of the United States and the State of West Virginia for price fixing and/or unreasonable restraints of trade relating to the particular commodities or services purchased or acquired by the State of West Virginia. Such assignment shall be made and become effective at the time the

purchasing agency tenders the initial payment to Vendor.

43. **VENDOR CERTIFICATIONS:** By signing its bid or entering into this Contract, Vendor certifies (1) that its bid was made without prior understanding, agreement, or connection with any corporation, firm, limited liability company, partnership, person or entity submitting a bid for the same material, supplies, equipment or services; (2) that its bid is in all respects fair and without collusion or fraud; (3) that this Contract is accepted or entered into without any prior understanding, agreement, or connection to any other entity that could be considered a violation of law; and (4) that it has reviewed this RFQ in its entirety; understands the requirements, terms and conditions, and other information contained herein. Vendor's signature on its bid 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 shall be promptly presented in detail to the Agency.

    The individual signing this bid on behalf of Vendor certifies that he or she is authorized by the Vendor to execute this bid or any documents related thereto on Vendor's behalf; that he or she is authorized to bind the Vendor in a contractual relationship; and that, to the best of his or her knowledge, the Vendor has properly registered with any State agency that may require registration.

44. **PURCHASING CARD ACCEPTANCE:** The State of West Virginia currently utilizes a Purchasing Card program, administered under contract by a banking institution, to process payment for goods and services. The Vendor must accept the State of West Virginia's Purchasing Card for payment of all orders under this Contract unless the box below is checked.

    ☐ Vendor is not required to accept the State of West Virginia's Purchasing Card as payment for all goods and services.

45. **VENDOR RELATIONSHIP:** The relationship of the Vendor to the State shall be that of an independent contractor and no principal-agent relationship or employer-employee relationship is contemplated or created by this Contract. The Vendor as an independent contractor is solely liable for the acts and omissions of its employees and agents. Vendor shall be responsible for selecting,

    supervising, and compensating any and all individuals employed pursuant to the terms of this Solicitation and resulting contract. Neither the Vendor, nor any employees or subcontractors of the Vendor, shall be deemed to be employees of the State for any purpose whatsoever. Vendor shall be exclusively responsible for payment of employees and contractors for all wages and salaries, taxes, withholding payments, penalties, fees, fringe benefits, professional liability insurance premiums, contributions to insurance and pension, or other deferred compensation plans, including but not limited to, Workers' Compensation and Social Security obligations, licensing fees, *etc.* and the filing of all necessary documents, forms and returns pertinent to all of the foregoing. Vendor shall hold harmless the State, and shall provide the State and Agency with a defense against any and all claims including, but not limited to, the foregoing payments, withholdings, contributions, taxes, Social Security taxes, and employer income tax returns.

46. **INDEMNIFICATION:** The Vendor agrees to indemnify, defend, and hold harmless the State and the Agency, their officers, and employees from and against: (1) Any claims or losses for services rendered

by any subcontractor, person, or firm performing or supplying services, materials, or supplies in connection with the performance of the Contract; (2) Any claims or losses resulting to any person or entity injured or damaged by the Vendor, its officers, employees, or subcontractors by the publication, translation, reproduction, delivery, performance, use, or disposition of any data used under the Contract in a manner not authorized by the Contract, or by Federal or State statutes or regulations; and (3) Any failure of the Vendor, its officers, employees, or subcontractors to observe State and Federal laws including, but not limited to, labor and wage and hour laws.

47. **PURCHASING AFFIDAVIT:** In accordance with West Virginia Code § 5A-3-10a, all Vendors are required to sign, notarize, and submit the Purchasing Affidavit stating that neither the Vendor nor a related party owe a debt to the State in excess of $1,000. The affidavit must be submitted prior to award, but should be submitted with the Vendor's bid. A copy of the Purchasing Affidavit is included herewith.

48. **ADDITIONAL AGENCY AND LOCAL GOVERNMENT USE:** This Contract may be utilized by and extends to other agencies, spending units, and political subdivisions of the State of West Virginia; county, municipal, and other local government bodies; and school districts ("Other Government Entities"). This Contract shall be extended to the aforementioned Other Government Entities on the same prices, terms, and conditions as those offered and agreed to in this Contract. If the Vendor does not wish to extend the prices, terms, and conditions of its bid and subsequent contract to the Other Government Entities, the Vendor must clearly indicate such refusal in its bid. A refusal to extend this Contract to the Other Government Entities shall not impact or influence the award of this Contract in any manner.

49. **CONFLICT OF INTEREST:** Vendor, its officers or members or employees, shall not presently have or acquire any interest, direct or indirect, which would conflict with or compromise the performance of its obligations hereunder. Vendor shall periodically inquire of its officers, members and employees to ensure that a conflict of interest does not arise. Any conflict of interest discovered shall be promptly presented in detail to the Agency.

50. **REPORTS:** Vendor shall provide the Agency and/or the Purchasing Division with the following reports identified by a checked box below:

☑ Such reports as the Agency and/or the Purchasing Division may request. Requested reports may include, but are not limited to, quantities purchased, agencies utilizing the contract, total contract expenditures by agency, etc.

☑ Quarterly reports detailing the total quantity of purchases in units and dollars, along with a listing of purchases by agency. Quarterly reports should be delivered to the Purchasing Division via email at purchasing.requisitions@wv.gov.

51. **BACKGROUND CHECK:** In accordance with W. Va. Code § 15-2D-3, the Director of the Division of Protective Services shall require any service provider whose employees are regularly employed on the grounds or in the buildings of the Capitol complex or who have access to sensitive or critical information to submit to a fingerprint-based state and federal background inquiry through the state

repository. The service provider is responsible for any costs associated with the fingerprint-based state and federal background inquiry.

After the contract for such services has been approved, but before any such employees are permitted to be on the grounds or in the buildings of the Capitol complex or have access to sensitive or critical information, the service provider shall submit a list of all persons who will be physically present and working at the Capitol complex to the Director of the Division of Protective Services for purposes of verifying compliance with this provision.

The State reserves the right to prohibit a service provider's employees from accessing sensitive or critical information or to be present at the Capitol complex based upon results addressed from a criminal background check.

Service providers should contact the West Virginia Division of Protective Services by phone at (304) 558-9911 for more information.

52. PREFERENCE FOR USE OF DOMESTIC STEEL PRODUCTS: Except when authorized by the Director of the Purchasing Division pursuant to W. Va. Code § 5A-3-56, no contractor may use or supply steel products for a State Contract Project other than those steel products made in the United States. A contractor who uses steel products in violation of this section may be subject to civil penalties pursuant to W. Va. Code § 5A-3-56. As used in this section:

a. "State Contract Project" means any erection or construction of, or any addition to, alteration of or other improvement to any building or structure, including, but not limited to, roads or highways, or the installation of any heating or cooling or ventilating plants or other equipment, or the supply of and materials for such projects, pursuant to a contract with the State of West Virginia for which bids were solicited on or after June 6, 2001.

b. "Steel Products" means products rolled, formed, shaped, drawn, extruded, forged, cast, fabricated or otherwise similarly processed, or processed by a combination of two or more or such operations, from steel made by the open heath, basic oxygen, electric furnace, Bessemer or other steel making process.

The Purchasing Division Director may, in writing, authorize the use of foreign steel products if:

a. The cost for each contract item used does not exceed one tenth of one percent (.1%) of the total contract cost or two thousand five hundred dollars ($2,500.00), whichever is greater. For the purposes of this section, the cost is the value of the steel product as delivered to the project; or

b. The Director of the Purchasing Division determines that specified steel materials are not produced in the United States in sufficient quantity or otherwise are not reasonably available to meet contract requirements.

53. PREFERENCE FOR USE OF DOMESTIC ALUMINUM, GLASS, AND STEEL: In Accordance

with W. Va. Code § 5-19-1 et seq., and W. Va. CSR § 148-10-1 et seq., for every contract or subcontract, subject to the limitations contained herein, for the construction, reconstruction, alteration, repair, improvement or maintenance of public works or for the purchase of any item of machinery or equipment to be used at sites of public works, only domestic aluminum, glass or steel products shall be supplied unless the spending officer determines, in writing, after the receipt of offers or bids, (1) that the cost of domestic aluminum, glass or steel products is unreasonable or inconsistent with the public interest of the State of West Virginia, (2) that domestic aluminum, glass or steel products are not produced in sufficient quantities to meet the contract requirements, or (3) the available domestic aluminum, glass, or steel do not meet the contract specifications. This provision only applies to public works contracts awarded in an amount more than fifty thousand dollars ($50,000) or public works contracts that require more than ten thousand pounds of steel products.

The cost of domestic aluminum, glass, or steel products may be unreasonable if the cost is more than twenty percent (20%) of the bid or offered price for foreign made aluminum, glass, or steel products. If the domestic aluminum, glass or steel products to be supplied or produced in a "substantial labor surplus area", as defined by the United States Department of Labor, the cost of domestic aluminum, glass, or steel products may be unreasonable if the cost is more than thirty percent (30%) of the bid or offered price for foreign made aluminum, glass, or steel products.

This preference shall be applied to an item of machinery or equipment, as indicated above, when the item is a single unit of equipment or machinery manufactured primarily of aluminum, glass or steel, is part of a public works contract and has the sole purpose or of being a permanent part of a single public works project. This provision does not apply to equipment or machinery purchased by a spending unit for use by that spending unit and not as part of a single public works project.

All bids and offers including domestic aluminum, glass or steel products that exceed bid or offer prices including foreign aluminum, glass or steel products after application of the preferences provided in this provision may be reduced to a price equal to or lower than the lowest bid or offer price for foreign aluminum, glass or steel products plus the applicable preference. If the reduced bid or offer prices are made in writing and supersede the prior bid or offer prices, all bids or offers, including the reduced bid or offer prices, will be reevaluated in accordance with this rule.

SPECIFICATIONS

1. **PURPOSE AND SCOPE:** The West Virginia Purchasing Division is soliciting bids on behalf of the West Virginia Department of Health and Human Resources, Bureau for Public Health, Division of Tobacco Prevention and the Bureau for Medical Services, (Medicaid) as a joint party to establish a contract for professional services to provide a no charge to the caller, convenient telephone based tobacco use cessation Quitline to assist West Virginians with quitting smoking and/or using other tobacco products.

1.1 PURPOSE:

The mission or purpose of the project is to provide tobacco cessation services to those residents of West Virginia who are uninsured, underinsured and Medicaid eligible. Medicaid members that are enrolled in a Managed Care Organization (MCO) will receive tobacco cessation services through the MCO.

1.2 SCOPE OF WORK:

The vendor shall implement a no-charge to the caller convenient telephone based tobacco use cessation Quitline to assist West Virginians with quitting smoking and using other tobacco products [i.e. smokeless, snus]. As appropriate to each individual's readiness to quit, the Quitline shall provide screening, assessment, proactive coaching, support materials, (provided by DTP), and referrals to community based cessation programs when and if community programs are available.

1.3 PROJECT BACKGROUND:

Tobacco use remains West Virginia's leading cause of preventable death, killing an estimated 3,800 people each year. This number does not include those who become sick or die as a result of smoking cigars, using other tobacco products [i.e. snuff, chew, snus], or from exposure to second hand smoke.

- In 2010 approximately 26.8% (383,293) of West Virginia adults were current smokers, the highest rate among the 50 states and D.C., and significantly higher than the U.S. average of 19.3% (Behavioral Risk Factor Surveillance System [BRFSS], 2011).

- In the years 2007-2010, adult cigarette smoking ranged from a high of approximately 36% in McDowell County to a low of 20% in Putnam County.

- About 19% of all deaths (nearly 1 in 5) of adults age 35 and older were caused by cigarette smoking.
- In each year every West Virginian smoker who died lost an average of 14.6 years of life due to premature death.
- Since March 2002, the Bureau for Public Health has sponsored the WV Tobacco Cessation Quitline by providing services to all West Virginians.
- During the calendar year 2012, there was a significant increase in informational calls and enrollment for services. Enrollment for Quitline services increased by 50% during the January –May 2012 period due to the Centers for Disease Control and Prevention's TIPS media campaign. Total Quitline enrollment for 2012 was 7,229 which also represent an almost 70% increase over prior year's totals.

2. **DEFINITIONS:** The terms listed below shall have the meanings assigned to them below. Additional definitions can be found in section 2 of the General Terms and Conditions.

2.1 "Contract Services" means required services

2.2 "Pricing Page" means the pages upon which Vendor should list its proposed price for the Contract Services. The Pricing Page is either included on the last page of this RFQ or attached hereto as Exhibit A.

2.3 "RFQ" means the official request for quotation published by the Purchasing Division and identified as EHP140005

2.4 "DHHR" means the Department of Health and Human Resources.

2.5 "DTP" means the Division of Tobacco Prevention.

2.6 "BPH" means the Bureau for Public Health

2.7 "NAQC" means the National Association of Quitline Consortiums

2.8 "BRFSS" means Behavioral Risk Factor Surveillance System

2.9 "TDD" means Telecommunication Device for the deaf.

2.10 "NRT" means Nicotine Replacement Therapy.

2.11 **"FDA"** means Food and Drug Administration.

2.12 **"BMS"** means Bureau for Medical Services

2.13 **"MCO"** means Managed Care Organization

2.14 **"PROACTIVE CALL"** means a call from a Quitline coach

2.15 **"REACTIVE CALL"** means a call to a Quitline coach

2.16 **"HIPAA"** means Health Insurance Portability and Accountability Act of 1996.

2.17 **"MDS"** means Minimal Data Set developed by the National Association of Quitline Consortium. Minimal Data Set offers a standard approach to evaluating tobacco cessation Quitlines. The MDS is valuable for the following activities:
*Establishing commonly defined performance indicators to assist in assessing Quitline performance, improving the quality of Quitlines, identifying knowledge gaps and designing new strategies to fill the gaps.
*Providing a common language allowing for consistent communications with others within and external to the Consortium
*Identifying Quitline performance benchmarks that can be used to determine effective, cost-efficient tobacco cessation interventions.
*Testing and assessing new treatment techniques across large diverse populations not possible by a single Quitline.
*Collecting consistent data and allowing aggregation of data across Quitlines for improved analyses of a variety of variables relevant to the success of Quitlines in North America.

2.18 **"AHRQ"** means Agency for Healthcare Research and Quality.

3. **QUALIFICATIONS:** Vendor shall have the following minimum qualifications:

3.1. The successful vendor shall have at least fifteen years' experience in providing Quitline services.

3.2. Quitline coaches must have Bachelor's Degree in social, behavioral or related health field with a minimum of two years counseling experience.

3.3. The successful vendor shall have a full time clinical and/or medical director available to provide technical assistance and oversight of the WV Tobacco Cessation Quitline services. This/these positions must have medical and/or clinical license for West Virginia, as the State of West Virginia agencies requiring WV Tobacco Cessation Quitline services will draw upon the knowledge and expertise of the successful vendor's physician/clinician to provide clinically proven approach to tobacco cessation.

4. MANDATORY REQUIREMENTS:

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

4.1 FOR THE DIVISION OF TOBACCO PREVENTION

4.1.1 The vendor shall implement at no-charge to the caller a convenient telephone-based tobacco use cessation Quitline to assist West Virginians with quitting smoking and/or using other tobacco products [i.e. snuff, chew, snus]. As appropriate to each individual's readiness to quit, the Quitline shall provide screening assessment, proactive coaching, support materials and referral to community based cessation programs when and if community programs are available.

4.1.2 The Vendor shall provide for registration eligibility authentication addressing DTP verification and benefit limits.

4.1.3 The Vendor shall provide a simple no-cost point of access to services to assist tobacco users in quitting by providing screening and assessment of readiness to quit, counseling and advice, support materials, information on the U.S. Public Health Service recommendations on the use of pharmacological cessation aids and referral to community-based services as appropriate.

4.1.4 The Vendor shall provide screening of applicant's readiness to quit. The Quitline shall assist the caller to develop a personalized quit plan, provide comprehensive proactive phone based behavioral counseling to interested enrollees, linkage with available health plan coverage for tobacco dependence treatment, and/or referral to community based services, if desired and available. For those not ready to quit, vendor shall assure provision of appropriate motivational materials, which include brochures specific to smoking, smokeless tobacco and pregnancy.

4.1.5 The Vendor through established protocols for Division of Tobacco Prevention enrollees shall obtain stock, (nicotine replacement therapies-patches, gum and lozenges), and deliver non-prescription nicotine replacement therapy (NRT) through mail or other

delivery services. Non-prescription nicotine replacement therapy (NRT) shall be in the form of gum, lozenges and patches.

4.2 FOR THE DIVISION OF TOBACCO PREVENTION AND FOR MEDICAID

4.2.1 The Vendor shall have a computerized tracking system to document Quitline activity. The computerized tracking system will be able to accurately tabulate discrete individuals, services provided, caller demographics and other characteristics including all referrals into and out of the system.

4.2.2 The vendor shall collect data that measures the performance of the vendor in terms of waiting time for callers, volume of calls received during times when a live answer is not available, and abandonment.

4.2.3 The vendor shall assure a ratio of at least one supervisor to every ten to fifteen coaches, and provide adequate orientation and ongoing training for all staff.

4.2.4 The Vendor shall assure that all Quitline staff and phone coaches are to receive on-going training in order to maintain maximum understanding and comprehension of accepted industry standards. Training activities shall include both internal and external training and educational resources. All phone center staff shall be trained quarterly on contract specifications and changes, customer service, tobacco cessation, and core coaching competencies, including Motivational Interviewing techniques.

4.2.5 The Vendor shall be required to become a member of the North American Quitline Consortium (NAQC), pay yearly membership dues and include DTP and Medicaid under Associate Member Status, and must attend its meetings and technical assistance updates.

4.2.6 The successful vendor must establish a liaison office in West Virginia within a two hour response time, referring to any problems/issues that may occur during a regular business day, including, but not limited to questions about enrollment, NRT shipments or other situations, for the duration of the contract term.

4.2.7 The Vendor must have a medical director with established roles in working with Quitline staff and identified enrollees to resolve any complex issues involving NRT therapy.

4.2.8 A staffing plan shall be in place that provides a live call response for a minimum of 78 Hours per week, (minimum 8:00a.m.-8:00p.m. Monday through Friday, 8:00a.m.-5p.m.Saturday and Sunday), and provide trained behavioral health specialists for assistance/coaching.

4.2.9 The Vendor must agree to the provisions set forth by the HIPAA Act of 1996. See Exhibit C.

4.3 ENROLLMENT AND ELIGIBILITY PROTOCOL FOR DTP

4.3.1 Tobacco user calls the Quitline and the Quitline vendor must obtain enrollment demographics including name, address, date of birth, and other MDS data points.

4.3.2 Enrollee must be evaluated by trained coaches using a tool such as the Fagerstrom Scale, (see Exhibit D), to determine motivation and willingness to quit.

4.3.3 Quitline coach shall contact the enrollee every two weeks for a total of 4 calls.

4.3.4 Quitline must provide at least four *reactive* coaching (enrollee calls into the Quitline) calls.

4.3.5 Tobacco history and current use must be recorded.

4.3.6 Member's previous attempts to quit must be recorded

4.3.7 Upon completion of four coaching calls to the enrollee, or if an enrollee becomes hard to reach, the case must be resolved. Resolved means the case will be closed and it will be notated on the client's case that they were hard to reach, (did not answer the phone when the coach attempted to call at least four attempts).

4.4 ENROLLMENT AND ELIGIBILITY PROTOCOL FOR MEDICAID

4.4.1 The Quitline vendor must obtain enrollment demographics including name, address, date of birth, and other MDS data points.

4.4.2 Quitline vendor must call Molina Automated Voice Response System to obtain member eligibility verification information. If member is not eligible, they will not be covered for Quitline services.

4.4.3 Quitline must record insurance specifics and verifies pregnancy status.

4.4.4 Medicaid MCO members must contact MCO for tobacco cessation coverage

4.4.5 Member must be evaluated by trained coaches using a tool such as the Fagerstrom Scale, (see Exhibit D) for motivation and willingness to quit.

4.4.6 Member's tobacco history and current use must be recorded.

4.4.7 Member must be directed to visit primary care provider to obtain prescription for NRT

4.4.8 Quitline vendor must contact Rational Drug Therapy (Medicaid Pharmacy) to authorize prescription for NRT.

4.4.9 Quitline coach must contact the member every two weeks for a total of 4 calls.

4.4.10 Quitline must provide four *reactive* coaching (Medicaid member calls into the Quitline) calls.

4.4.11 Upon completion of four coaching calls to the member, or if a member becomes hard to reach, the case must be resolved. Resolved means the case will be closed and it will be notated on the client's case that they were hard to reach, (did not answer the phone when the coach attempted to call at least four attempts).

4.4.12 Medicaid member shall be limited to one 12 week treatment period per calendar year.

4.4.13 Pregnant females shall be eligible for additional courses(s) of treatment for every pregnancy.

4.5 HOURS OF OPERATION

4.5.1 The vendor shall assure a system infrastructure to provide live response for a minimum of 78 hours per week. Recorded information and callback capacity shall be required for the remaining 90 hours of the week.

4.5.2 The Vendor shall at a minimum, offer live hours of operation from Monday through Friday from 8:00 A.M. to 8:00 P.M. and Saturday and Sunday 8:00 A.M. to 5:00 P.M., Eastern Standard Time.

4.5.3 The Vendor shall continuously monitor peak times for calls, and hours of live staff shall be available to answer calls.

4.5.4 Operation of the Quitline will not be required for Easter, Independence Day, Thanksgiving Day, and Christmas Day. The Quitline must have coverage on New Year's Day. The Quitline must have coverage until at least 12PM on Christmas Eve and until at least 5PM on New Year's Eve.

4.6 RESEARCH FOR DTP ONLY

4.6.1 The Vendor shall participate in the production of a minimum three and a maximum of four special research projects by providing specialized data. The projects may encompass several years of data and the vendor shall provide quantative/qualitative data analysis. (Example: FDA Smokeless study, Smokeless tobacco study, pregnant smokers, dual tobacco users).

4.7 DATA AND REPORTING SERVICES FOR DTP AND MEDICAID

4.7.1 The system shall produce reports on the types and amounts of services provided per caller, call patterns by time of day, day of week and month.

4.7.2 The Vendor shall send a monthly report attached to the monthly invoice(s). The report shall be delivered no later than fifteen (15) days after the end of the previous month. Quarterly reports and an Annual Summary of standardized reports that provide aggregate data by county shall also be submitted in the same manner.

4.7.3 The vendor shall be required to use the NAQC minimal data set (MDS) recommended elements included in current month and year-to-date reporting.

4.7.4 Vendor shall provide transparent access to ALL Quitline data- meaning the vendor shall provide an easily accessible, easily searchable, user friendly, portal to the vendor database for inquiry.

4.7.5 The Vendor shall work closely with the Independent Quitline Evaluator to supply data for reporting purposes.

4.8 SUPPORT AND EDUCATIONAL MATERIALS

4.8.1 DTP will provide the vendor support and educational materials to distribute as part of the intake/eligibility verification, tobacco cessation and educational materials including self-help books, brochures, and specialized materials for special populations such as snus users, smokeless tobacco users and pregnant smokers.

4.9 QUITLINE MEDIA CAMPAIGNS

4.9.1 Upon the event of a mass media campaign DHHR will advise the successful vendor with a minimum of two weeks' written notice so that the successful vendor is adequately staffed for such an event.

4.10 NICOTINE REPLACEMENT THERAPY (NRT)

4.10.1 PROTOCOL FOR DTP

4.10.1.1 Vendor shall describe documented, minimum smoking and s mokeless tobacco product protocols for the Nicotine Replacement Therapy (NRT)

4.10.1.2 Vendor shall provide NRT via the quitline services to all enrollees identified by established protocol.

4.10.1.3 Vendor shall provide protocols for how callers shall receive information on pharmacological cessation therapies, how NRT shall be identified, approved and initiated for each client, and how it shall be provided via the quitline.

4.10.1.4 Vendor must establish a protocol for determining the participants' receipt of information on pharmacological cessation therapies, including delivery to each participant's home in two separate shipments, (each shipment shall contain a four week supply of NRT).

4.10.1.5 NRT to be provided by vendor to treat tobacco dependence to include the following:

- Nicotine Gum – 2mg or 4 mg – 24 pieces per day
- Nicotine Patch – 7mg or 14 or, 21 or, 28mg – 1 patch per day
- Nicotine Lozenges – 2mg or 4mg – 20 lozenges per day

Note: Dosage based on the 2008 AHRQ clinical recommendations.

4.10.1.6 NRT Smokeless/Heavily Addicted Dual Therapy: Will receive dual therapy, provided by the vendor, (patches and gum; patches and lozenges) on a case by case basis as determined by Quitline Medical Director.

4.10.1.7 NRT will not be made available to Quitline enrollees less than eighteen (18) years of age.

4.10.2 PROTOCOL FOR MEDICAID

4.10.2.1 The vendor shall contact Rational Drug Therapy (Medicaid's Fee for Service Pharmacy Contractor) to determine eligibility and provide authorization of Medicaid member to receive approved drugs to treat tobacco cessation.

Drugs to treat tobacco dependence are limited to members who register with Medicaid's Quitline Program. Drug products require prior authorization and are limited to a maximum of:

- Nicotine Gum – 24 pieces per day
- Nicotine Patches – 1 patch per day
- Nicotine Lozenges – 20 lozenges per day
- Nicotine Inhalers – 168 inhalers per 30 days
- Nicotine Nasal Spray – 4 spray bottles per 30 days (this therapy is reserved for those who have failed other forms of nicotine replacement therapy)
- Bupropion – 300mg daily

See the BMS website at www.dhhr@wv.gov/bms for additional information and details. Please see Chapter 518-Covered Services, Limitation, and Exclusions for Pharmacy Service, Exhibit B of this Request for Quotation.

4.11 ADMINISTRATIVE REQUIREMENT

4.11.1 The vendor shall designate a project administrator. The vendor's project administrator shall report to DTP/Medicaid regarding all matters related to quitline services.

5. CONTRACT AWARD:

5.1 Contract Award: The Contract is intended to provide Agency with a purchase price for the Contract Services. The Contract shall be awarded to the Vendor that provides the Contract Services meeting the required specifications for the lowest grand total cost as shown on the Pricing Pages.

5.2: Pricing Page: Vendor should complete the Pricing Page (Exhibit A) by completing Section A (DTP) and Section B (Medicaid) by inserting projected costs for each line item. Estimated volume quantities are for bid evaluation purposes only. Vendor should complete the Pricing Page in full as failure to complete the Pricing Page in its entirety may result in Vendor's bid being disqualified.

Notwithstanding the foregoing, the Purchasing Division may correct errors as it deems appropriate. Vendor should type or electronically enter the information into the Pricing Page to prevent errors in the evaluation.

6. **PERFORMANCE:** Vendor and Agency shall agree upon a schedule for performance of Contract Services and Contract Services Deliverables, unless such a schedule is already included herein by Agency. In the event that this Contract is designated as an open-end contract, Vendor shall perform in accordance with the release orders that may be issued against this Contract.

7. **PAYMENT:** Agency shall pay monthly in arrears as shown on the Pricing Pages, for all Contract Services performed and accepted under this Contract. Vendor shall accept payment in accordance with the payment procedures of the State of West Virginia.

8. **TRAVEL:** Vendor shall be responsible for all mileage and travel costs, including travel time, associated with performance of this Contract. Any anticipated mileage or travel costs may be included in the flat fee or hourly rate listed on Vendor's bid, but such costs will not be paid by the Agency separately.

9. **FACILITIES ACCESS:** Performance of Contract Services may require access cards and/or keys to gain entrance to Agency's facilities. In the event that access cards and/or keys are required:

9.1 Vendor must identify principal service personnel which will be issued access cards and/or keys to perform service.

9.2. Vendor will be responsible for controlling cards and keys and will pay replacement fee, if the cards or keys become lost or stolen.

9.3 Vendor shall notify Agency immediately of any lost, stolen, or missing card or key.

9.4 Anyone performing under this Contract will be subject to Agency's security protocol and procedures.

9.5 Vendor shall inform all staff of Agency's security protocol and procedures.

10. VENDOR DEFAULT:

10.1. The following shall be considered a vendor default under this Contract.

10.1.1 Failure to perform Contract Services in accordance with the requirements contained herein.

10.1.2 Failure to comply with other specifications and requirements contained herein.

10.1.3 Failure to comply with any laws, rules, and ordinances applicable to the Contract Services provided under this Contract.

10.1.4 Failure to remedy deficient performance upon request.

10.2 The following remedies shall be available to Agency upon default.

10.2.1. Cancellation of the Contract.
10.2.2 Cancellation of one or more release orders issued under this Contract.
10.2.3 Any other remedies available in law or equity.

11. MISCELLANEOUS:

11.1. Contract Manager: During its performance of this Contract, Vendor must designate and maintain a primary contract manager responsible for overseeing Vendor's responsibilities under this Contract. The Contract manager must be available during normal business hours to address any customer service or other issues related to this Contract. Vendor should list its Contract manager and his or her contact information below.

Contract Manager: _____
Telephone Number: _____
Fax Number: _____
Email Address: _____

EXHIBIT A: EHP14005 PRICING PAGE

Section A-Division of Tobacco Prevention Description of Service		Pricing of Service	Unit of Measure	Estimated Volume	Total
1. Intake/Eligibility Verification	Section 4.3.1-4.3.2		Per enrolled person	7,000**	
2. Coaching Call #1	Section 4.3.3		Per Call	7,000**	
Coaching Call #2	Section 4.3.3		Per Call	6,650**	
Coaching Call #3	Section 4.3.3		Per Call	6,300**	
Coaching Call #4	Section 4.3.3		Per Call	5,250**	
3. Reactive Calls #1-4	Section 4.3.4		Per Call	3,000**	
4. Nicotine Replacement Therapy (4 weeks supply)					
Nicotine Patch 21mg	Section 4.10.1.5		Per Shipment*	3,500**	
Nicotine Patch 7mg and 14 mg	Section 4.10.1.5		Per Shipment*	3,500**	
Nicotine Gum 2mg	Section 4.10.1.5		Per Shipment*	2,600**	
Nicotine Gum 4mg	Section 4.10.1.5		Per Shipment*	2,600**	
Nicotine Lozenge 2mg and 4 mg	Section 4.10.1.5		Per Shipment*	1,300**	
5. Smokeless/Heavily Addicted – Dual Therapy***	Section 4.10.1.6		Per Shipment*	100**	
6. Research	Section 4.6		Per Project	3	

Sub-total DTP _____

Section B-Medicaid Description of Service		Pricing of Service	Unit of Measure	Estimated Volume	Total
Intake/Eligibility Verification	Section 4.4.1 to 4.4.9		Per enrolled person	4000*	
Coaching Call #1	Section 4.4.10		Per Call	2500*	
Coaching Call #2	Section 4.4.10		Per Call	2500*	
Coaching Call #3	Section 4.4.10		Per Call	2000*	
Coaching Call #4	Section 4.4.10		Per Call	2000*	
Reactive Calls #1-4	Section 4.4.11		Per Call	1500*	

*Estimated Volumes are for Bid Purposes only

Subtotal Medicaid _____

*Per shipment defined as one four week supply of NRT delivered to enrollee after eligibility verified and 1st coaching call completed. A second four week supply delivered only when requested by the enrollee. Cost shall include shipment fees.

**Quantities are for bid evaluation purposes only.

***Smokeless/Heavily Addicted Dual Therapy: Will receive dual therapy (patches & gum; patches & lozenges) on a case by case basis as determined by Quitline Medical Director.

Sub-total DTP (Section A) _____

Sub-total Medicaid (Section B) _____

GRAND TOTAL (Section A+B) _____

Vendor Name _____

Vendor Representative _____

Vendor Signature _____

Vendor Address _____

Vendor Phone _____

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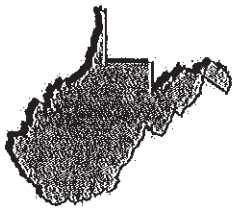
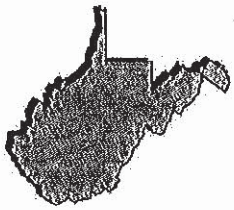
EXHIBIT B

CHAPTER 518 – COVERED SERVICES, LIMITATIONS, AND EXCLUSIONS FOR PHARMACY CHANGE LOG

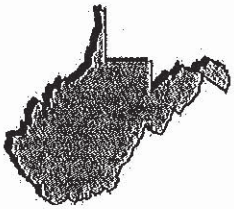


CHAPTER 518 – COVERED SERVICES, LIMITATIONS, AND EXCLUSIONS FOR PHARMACY SERVICES
CHANGE LOG

Replace	Title	Change Date	Effective Date
Section 518.1	Definitions Medicaid AWP Definitions State MAC (SMAC)	May 1, 2013	January 1, 2013
Throughout	Website Address update: BMS's website updated from www.wvdhhr.org/bms to www.dhhr.wv.gov/bms	May 1, 2013	January 1, 2013
Section 518.3.1.1	Mountain Health Choices (MHC)	May 1, 2013	April 1, 2013
Section 518.3.1.3	Medicaid Members Enrolled in Medicaid Managed Care Organizational Plans	May 1, 2013	April 1, 2013
Section 518.3.2.1	AIDS Drug Assistance Program (ADAP) or Ryan White Program	May 1, 2013	April 1, 2013
Section 518.4	Description of Covered Services	May 1, 2013	July 1, 2013
Section 518.4.2	Over-the-Counter Drugs	May 1, 2013	April 1, 2013
Section 518.4.3	Diabetic Testing Supplies and Syringes/Needles	May 1, 2013	April 1, 2013
Section 518.4.5	Home Infusion Therapy Pharmacy Services	May 1, 2013	January 1, 2013
Section 518.4.6	Tobacco Cessation Program	May 1, 2013	April 1, 2013
Section 518.4.7	Buprenorphine-Naloxone (Suboxone®) / Buprenorphine (Subutex®) Coverage	May 1, 2013	January 1, 2013
Section 518.5	Service Limitation	May 1, 2013	January 1, 2013
Section 518.6	Coverage of Brand Name Versus Generic Drugs	May 1, 2013	May 1, 2013
Section 518.7	Non-Covered Services	May 1, 2013	January 1, 2013
Section 518.8	Prior Authorization (PA)	May 1, 2013	May 1, 2013
Section 518.8.1	Process of Requesting Prior Authorization	May 1, 2013	May 1, 2013
Section 518.9.1	Prospective Drug Utilization	May 1, 2013	January 1, 2013



	Review (DUR)		
Section 518.9.2.1	Pharmacy Lock-in Program	May 1, 2013	July 1, 2013
Section 518.10.4	Shipping/Receiving	May 1, 2013	May 1, 2013
Section 518.11.1	Point-of-Sale System	May 1, 2013	January 1, 2013
Section 518.11.2	National Council on Prescription Drug Programs (NCPDP) Payer Sheet	May 1, 2013	January 1, 2013
Section 518.11.3	Paper Claim Submission for Pharmacy Services	May 1, 2013	January 1, 2013
Section 518.11.10	Compounded Prescriptions	May 1, 2013	January 1, 2013
Section 518.11.11	Abuse and Inappropriate Utilization	May 1, 2013	January 1, 2013
Section 518.12	Reimbursement	May 1, 2013	January 1, 2013
Section 518.12.1	Ingredient Cost	May 1, 2013	January 1, 2013
Section 518.12.2	Application of Dispensing Fee	May 1, 2013	January 1, 2013
Section 518.12.3	Co-Payments	May 1, 2013	January 1, 2013
Section 518.12.4	Third-Party Liability (TPL) or Coordination of Benefits (COB)	May 1, 2013	January 1, 2013
Section 518.12.4.2	Medicare Covered Drugs, Part D	May 1, 2013	January 1, 2013
Section 518.13.4	Additional Information	May 1, 2013	January 1, 2013
Section 518.4	Description of Covered Services	November 19, 2012	October 1, 2010
Section 518.3.1.4	Medicaid Members with End Stage Renal Disease (ESRD)	April 1, 2012	April 1, 2012
Section 518.3.2.6	Juvenile Services	April 1, 2012	April 1, 2012
Section 518.4.5	Home Infusion Therapy Pharmacy Services, formerly In-Home Parenteral Therapy (IHPT) Pharmacy Services	April 1, 2012	April 1, 2012
Section 518.4.7	Buprenorphine-Naloxone(Suboxone®)/Buprenorphine(Subutex®) Coverage	April 1, 2012	April 1, 2012
Section 518.5.1	Bulk Chemicals	April 1, 2012	April 1, 2012



Section 518.7	NON COVERED SERVICES	April 1, 2012	April 1, 2012
Section 518.10.4	Shipping/Receiving	April 1, 2012	April 1, 2012
Section 518.11.13	Wasted Medication	April 1, 2012	April 1, 2012
Section 518.2.5	Pharmacy Change of Ownership	September 15, 2010	November 1, 2010
Section 518.3.1.1	Mountain Health Choices	September 15, 2010	November 1, 2010
Section 518.3.1.7	Incarcerated Members	September 15, 2010	November 1, 2010
Section 518.5	Service Limitations	September 15, 2010	November 1, 2010
Section 518.10.2	Prescriptions Returned to Stock	September 15, 2010	November 1, 2010
Section 518.11	Billing Procedure	September 15, 2010	November 1, 2010
Section 518.11.14	False Claims	September 15, 2010	November 1, 2010
Appendix 1	In-Home Parenteral Therapy	September 15, 2010	November 1, 2010
Section 518.4	Description of Covered Services	September 15, 2010	October 1, 2010
Section 518.7	Non-Covered Services	September 15, 2010	October 1, 2010
Section 518.12.3	Co-Payments	September 15, 2010	October 1, 2010
Section 518.5.1	Coverage of Brand Name versus Generic Drugs	March 31, 2010	June 1, 2010
Section 518.6	Non-covered services	March 31, 2010	June 1, 2010
Section 518.7	Prior Authorization (PA)	March 31, 2010	June 1, 2010
Section 518.7.2	Prior Authorization Appeal Process	March 31, 2010	June 1, 2010
Section 518.8.3	Reporting of Cash Payments	March 31, 2010	June 1, 2010
Section 518.9.1	Tamper-Resistant Prescription Pad Requirement	March 31, 2010	June 1, 2010

Section 518.9.4	Shipping/Receiving	March 31, 2010	June 1, 2010
Section 518.10.10	Compounded Prescription	March 31, 2010	June 1, 2010
Section 518.10.11	Abuse and Inappropriate Utilization	March 31, 2010	June 1, 2010
Section 518.11.3	Co-payments	March 31, 2010	June 1, 2010
Section 518.11.4	Third-Party Liability (TPL) or Coordination of Benefits (COB)	March 31, 2010	June 1, 2010
Entire Manual	Entire Manual	November 10, 2009	January 1, 2010
Entire Manual	Entire Manual	November 10, 2009	January 1, 2010

2013

Section 518.1 Definitions

Old Policy: Medicaid AWP: Average wholesale prices established by the Federal Office of the Inspector General.

New Policy: Remove Section

Old Policy: State MAC (SMAC): Maximum allowable cost for drug products established by the state Medicaid agency.

New Policy: State MAC (SMAC): Maximum allowable cost for drug products or supplies established by the state Medicaid agency.

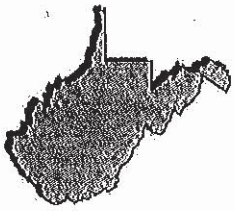
Email address listed throughout the Manual

Old Policy: BMS website, www.wvdhhr.org/bms.

New Policy: BMS website, www.dhhr.wv.gov/bms.

Section 518.3.1.1 Mountain Health Choices (MHC)

Old Policy: Pharmacy services are covered for all benefit plans. All existing rules regarding prior authorization, the Preferred Drug List and quantity limits for medications covered by the Outpatient Pharmacy Program apply to the pharmacy benefit for the Mountain Health Choices Program.



New Policy: Pharmacy services are covered for all benefit plans, either through Medicaid fee-for-service or Medicaid Managed Care Organizations (MCO). Members enrolled in the Medicaid MCOs must follow the rules and policies of their respective MCO. The managed care plans are required to provide pharmacy benefits consistent with the Medicaid Preferred Drug List (PDL), both in the selection of preferred/non-preferred drugs and criteria for coverage. The plans are responsible for policies for drugs not included in the Medicaid PDL. There is no copayment requirement for pharmacy services covered through the managed care organization plans.

Section 518.3.1.3 Medicaid Members Enrolled in Medicaid Managed Care Organization Plans

Old Policy: With the exception of drugs used for in-home parenteral therapy and physician/outpatient facility- administered drugs, West Virginia Medicaid members enrolled in a Managed Care Organization (MCO) receive fee-for-service pharmacy benefits. These members will have two identification cards – the managed care identification card for medical services, i.e. physician, hospital, etc., and the Medicaid identification card for pharmacy and other carved-out services. In-home parenteral therapy and physician/outpatient facility- administered drug services are covered by the MCO and are subject to the plans' requirements.

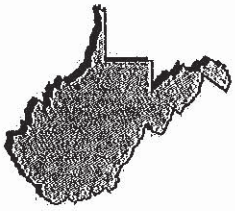
New Policy: Effective April 1, 2013, Medicaid members enrolled in the Medicaid managed care organization plans receive pharmacy services from the managed care plan. These members will have two identification cards – the managed care identification card for managed care covered services, and the Medicaid identification card for carved-out services. The managed care plans are required to provide pharmacy benefits consistent with the Medicaid Preferred Drug List (PDL), both in the selection of preferred/non-preferred drugs and criteria for coverage. The plans are responsible for policies for drugs not included in the Medicaid PDL. There is no copayment requirement for pharmacy services covered through the managed care organization plans.

Section 518.3.2.1 AIDS Drug Assistance Program (ADAP) or Ryan White Program

Old Policy: The AIDS Drug Assistance Program (ADAP) is funded by the Ryan White Title II CARE Act in West Virginia, and claims are processed through the BMS claims processing system. The program assists eligible persons with HIV infection in obtaining drugs covered by the ADAP formulary. To be eligible for the ADAP, a person must meet the following:

- be an HIV infected resident of West Virginia;
- with a family income less than 325% of the federal poverty level (FPL), and;
- not be eligible for other forms of reimbursement such as Medicaid or full insurance coverage, and;
- have completed the ADAP and Medicaid application at their Department of Health and Human Resources county office.

ADAP participants do not receive a medical identification card, but do receive a letter that verifies eligibility and includes their identification number with a prefix of "69". All claims except those for vaccines may be submitted online through the pharmacy Point-of-Sale system or by



using the approved paper claim form. Covered drugs are limited to a 30-day supply. Claims must be submitted within 60 days from the date of service. Formulary drugs must be dispensed in generic form if available. Brand-name drugs that have generic equivalents require prior authorization. There are no co-payment requirements for this program. ADAP may cover co-pays for eligible residents who are covered by insurance or Medicare Part D. Claims for vaccines must be submitted on the approved pharmacy paper claim form and mailed to HIVCC, P. O. Box 6360, Wheeling, West Virginia 26003. Certain drugs may require prior authorization and emergency supplies of these drug may not be dispensed. Please refer to the BMS website, www.wvdhhr.org/bms, for the ADAP formulary. More information regarding ADAP can be found at the Bureau for Public Health's website at www.wvdhhr.org/bph.

New Policy: The AIDS Drug Assistance Program (ADAP) is funded under Part B of the Ryan White HIV/AIDS Treatment Extension Act in West Virginia, and claims are processed through the BMS claims processing system. The program assists eligible persons with HIV infection in obtaining drugs covered by the ADAP formulary. To be eligible for the ADAP, a person must meet the following:

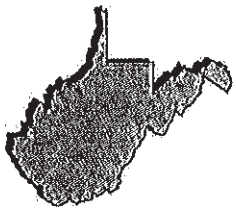
- be an HIV infected resident of West Virginia;
- with a family income less than 400% of the federal poverty level (FPL), and;
- not be eligible for other forms of reimbursement such as Medicaid or full insurance coverage, and;
- have completed the ADAP and Medicaid application at their Department of Health and Human Resources county office.

ADAP participants do not receive a medical identification card, but do receive a letter that verifies eligibility and includes their identification number with a prefix of "69". All claims except those for vaccines may be submitted online through the pharmacy Point-of-Sale system or by using the approved paper claim form. Covered drugs are limited to a 30-day supply. Claims must be submitted within 60 days from the date of service. Formulary drugs must be dispensed in generic form if available. Brand-name drugs that have generic equivalents require prior authorization. There are no co-payment requirements for this program. ADAP may cover co-pays for eligible residents who are covered by insurance or Medicare Part D. Claims for vaccines must be submitted on the approved pharmacy paper claim form and mailed to ATF, P.O. Box 6360, Wheeling, West Virginia 26003. Certain drugs may require prior authorization and emergency supplies of these drug may not be dispensed. Please refer to the BMS website, www.dhhr.wv.gov/bms, for the ADAP formulary. More information regarding ADAP can be found at the Bureau for Public Health's website at www.dhhr.wv.gov/bph or by calling the AIDS Task Force at 304-232-6822.

518.4 DESCRIPTION OF COVERED SERVICES

Old Policy: Except for certain limitations and exclusions, BMS will reimburse for the following:

- Outpatient legend drugs
- Specific over-the-counter drugs
- Compounded prescriptions



- Drugs that require prior authorization, when approved by BMS
- Family planning supplies, including certain over-the-counter supplies
- Certain diabetic supplies
- Influenza and pneumonia vaccines for adults over 19 years of age administered by a pharmacist.

New Policy: Except for certain limitations and exclusions, BMS will reimburse for the following:

- Outpatient legend drugs
- Specific over-the-counter drugs
- Compounded prescriptions
- Drugs that require prior authorization, when approved by BMS
- Family planning supplies, including certain over-the-counter supplies
- Certain diabetic supplies
- Influenza, pneumonia, Hepatitis A, Hepatitis B, tetanus, tetanus-diphtheria (Td), and tetanus-diphtheria-and-pertussis (Tdap) vaccines for adults nineteen (19) years of age and older administered by a pharmacist. (Members up to nineteen (19) years of age have access to vaccines via the Vaccines for Children Program.)
- Herpes zoster vaccine for adults fifty (60) years of age and older administered by a pharmacist

Section 518.4.2 Over-the-Counter Drugs

Old Policy: N/A

New Policy: Coverage of over-the-counter drugs for members enrolled in Medicaid managed care plans will follow each plan's coverage policies, unless the OTC drug is included in the Medicaid Preferred Drug List.

Section 518.4.3 Diabetic Testing Supplies and Syringes/Needles

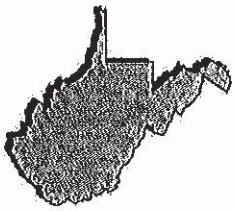
Old Policy: N/A

New Policy: Medicaid members enrolled in Medicaid managed care plans will have coverage of diabetic supplies through their managed care plan.

Section 518.4.5 Home Infusion Therapy Pharmacy Services

Old Policy: N/A

New Policy: Total Parenteral Nutrition (TPN) services are not pharmacy point of sale (POS) covered services. Please see *Chapter 506, DME/Medical Supplies* for information regarding these services.



Section 518.4.6 Tobacco Cessation Program

Old Policy: West Virginia Medicaid makes tobacco cessation services available to members enrolled in the Traditional Benefits Package and those enrolled with a participating West Virginia Medicaid MCO. For a member not enrolled with a participating West Virginia Medicaid MCO to participate in the program, members are required to enroll through the WV YNOTQUIT Line at 1-877-966-8784. Participants are screened for their readiness to quit the use of tobacco. Written materials and phone coaching are available through the quit line program. Additional information regarding the YNOTQUIT Line can be accessed through the beBetter Network at www.ynotquit.com.

For members enrolled in Medicaid managed care plans, West Virginia Medicaid covers tobacco cessation for members in the Enhanced Benefit Package and all children's' benefit packages. Medicaid does not cover tobacco cessation programs for those enrolled in the Basic Adult Benefit Package. The West Virginia Division of Tobacco Prevention, administered through the West Virginia Department for Health and Human Resources' Bureau for Public Health, may also assist in providing services for those who are uninsured or under-insured.

West Virginia Medicaid operates a tobacco cessation program to assist members to discontinue use of tobacco products. In order for members to have access to drugs and other tobacco cessation services, the member is required to see their primary care provider and enroll in the program their managed care plan uses. Participants are screened for their readiness to quit the use of tobacco. Written materials and phone coaching are also available through the program. All tobacco cessation products must be prescribed by a licensed practitioner within the scope of his/her license under West Virginia law. Prior authorization is required for coverage of tobacco cessation medications and is coordinated through the tobacco quit line.

Members are limited to one 12-week treatment period per year. Pregnant females are eligible for additional course(s) of treatment, if appropriate.

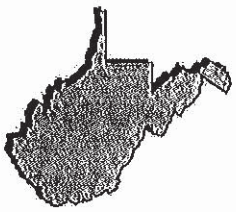
Additional information regarding the tobacco cessation program can be accessed through www.wvdtp.com or www.wvquitline.com.

If a Medicaid member is enrolled in a MCO, please contact the member's MCO for service limitations and all other requirements related to this benefit.

Drugs to treat tobacco cessation are limited to members who register with Medicaid's quit line program. Dual eligible members have coverage of legend drugs through their Medicare Part D plans and coverage of the over-the-counter drugs and quit line services through Medicaid.

New Policy: West Virginia Medicaid makes tobacco cessation services available to members enrolled in the fee-for-service Medicaid Program (except for those enrolled in the Basic Adult Package) and those enrolled with a participating West Virginia Medicaid MCO.

Members enrolled in the fee-for-service Medicaid Program are required to enroll through the WV Tobacco Cessation Quitline Line at 1-877-966-8784. Participants are screened for their readiness to quit the use of tobacco. Written materials and phone coaching are available



through the Quitline program. Additional information regarding the WV Tobacco Cessation Quitline can be accessed through at www.ynotquit.com.

Members enrolled in Medicaid managed care plans have tobacco cessation services provided by their plans, including drug treatments.

In order for members to have access to drugs and other tobacco cessation services, the member is required to see their primary care provider. All tobacco cessation products must be prescribed by a licensed practitioner within the scope of his/her license under West Virginia law. Prior authorization is required for coverage of tobacco cessation medications and is coordinated through the tobacco Quitline.

Members are limited to one 12-week treatment period per year. Pregnant females are eligible for additional course(s) of treatment, if appropriate.

Additional information regarding the tobacco cessation program can be accessed through www.wvdtp.com or www.wvquitline.com or by calling the Quitline at 1-877-966-8784 for assistance.

If a Medicaid member is enrolled in a MCO, please contact the member's MCO for service limitations and all other requirements related to this benefit.

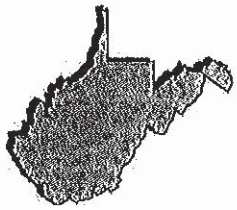
Drugs to treat tobacco cessation are limited to members who register with the tobacco Quitline program. Dual eligible members have coverage of legend drugs through their Medicare Part D plans and coverage of the over-the-counter drugs and Quitline services through Medicaid. Medicaid does not cover tobacco cessation programs for those enrolled in the Basic Adult Benefit Package.

Section 518.4.7 Buprenorphine-Naloxone (Suboxone®) / Buprenorphine (Subutex®) Coverage

Old Policy: Buprenorphine-Naloxone and Buprenorphine are covered through the Pharmacy program, and must be written by a prescriber enrolled with WV Medicaid or employed by a facility enrolled with WV Medicaid, or enrolled with one of the Medicaid MCOs. Buprenorphine-Naloxone and Buprenorphine is obtained only through a prior authorization. Other limitations may apply.

New Policy: Buprenorphine-Naloxone and Buprenorphine are covered through the Pharmacy program, and must be written by a prescriber enrolled with WV Medicaid or employed by a facility enrolled with WV Medicaid, or enrolled with one of the Medicaid MCOs. Buprenorphine-Naloxone and Buprenorphine is obtained only through a prior authorization. All members treated with Buprenorphine-Naloxone or Buprenorphine are required to participate in the pharmacy lock-in program. Other limitations may apply.

Section 518.5 SERVICE LIMITATIONS



Old Policy: Dual eligible members are limited to coverage of Medicare Part D excluded drugs. Coverage is limited to drugs that are covered for other Medicaid eligible members in the following classes:

- Benzodiazepines
- Barbiturates
- Over-the-counter medications
- Agents for the symptomatic relief of cough and cold symptoms
- Prescription vitamins and minerals

New Policy: Dual eligible members are limited to coverage of Medicare Part D excluded drugs. Coverage is limited to drugs that are covered for other Medicaid eligible members in the following classes:

- Barbiturates (if not for treatment of epilepsy, cancer, or mental health disorder, as Medicare Part D covers these conditions)
- Over-the-counter medications
- Agents for the symptomatic relief of cough and cold symptoms
- Prescription vitamins and minerals

Section 518.6 COVERAGE OF BRAND NAME VERSUS GENERIC DRUGS

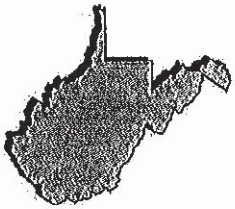
Old Policy: **DAW 4** - A generic equivalent is not available or not stocked at the time of dispensing. This code shall only be used when a generic drug is sold out or a generic drug is unavailable on a wide-spread basis. *It shall not be used routinely to circumvent the mandatory generic program for reasons other than these.*

New Policy: **DAW 4** - A generic equivalent is not available or not stocked at the time of dispensing. This code shall only be used when a generic drug is sold out or a generic drug is unavailable on a wide-spread basis. *It shall not be used routinely to circumvent the mandatory generic program for reasons other than these.* A call to the Rational Drug Therapy Program help desk is required for the use of DAW 4 and appropriate justification must be provided. The brand name rate will be reimbursed when approved.

Section 518.7 NON-COVERED SERVICES

Old Policy: The following list of drugs, drug products, and related services are not reimbursable. Non-covered services are not eligible for a West Virginia Department of Health and Human Resources (WVDHHR) fair hearing. Non-covered services include, but are not limited to:

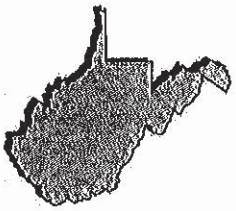
- Drugs supplied by drug manufacturers who have not entered into a drug rebate agreement with CMS
- Agents used for weight loss or weight gain
- Agents used for cosmetic purposes or hair growth
- Drugs identified by CMS as being less-than-effective (DESI).



- Agents used for fertility
- Drugs used to treat erectile dysfunction
- Drugs that are investigational or approved drugs used for investigational purpose
- Drugs used for off-label indications which are not found in official compendia or generally accepted in peer reviewed literature
- Drugs dispensed after their expiration date
- The cost of shipping or delivering a drug
- Herbal or homeopathic products
- Drugs which result in therapeutic duplication, ingredient duplication, early refills or other Drug Utilization Review events that are not medically necessary
- Drugs which are not medically necessary
- Covered outpatient drugs for which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee
- Nutritional supplements
- Free pharmaceutical samples
- Diagnostic agents
- Vacation supplies
- Allergenic extracts
- Excipients except when used in compounded prescriptions containing a covered legend drug. Excipients must be eligible for federal rebates in order to be eligible for reimbursement.
- Vaccines via the pharmacy POS, except for influenza and pneumonia vaccines for adults over the age of 19 years administered by a pharmacist
- Factors to treat hemophilia via the pharmacy POS (Refer to *Chapter 519, Practitioner Services Manual,* for additional information regarding hemophilia services
- Methadone for the treatment of drug dependence/addiction

New Policy: The following list of drugs, drug products, and related services are not reimbursable. Non-covered services are not eligible for a West Virginia Department of Health and Human Resources (WVDHHR) fair hearing. Non-covered services include, but are not limited to:

- Drugs supplied by drug manufacturers who have not entered into a drug rebate agreement with CMS
- Agents used for weight loss or weight gain
- Agents used for cosmetic purposes or hair growth
- Drugs identified by CMS as being less-than-effective (DESI).
- ~~Agents used for fertility~~
- Drugs used to treat erectile dysfunction
- Drugs that are investigational or approved drugs used for investigational purpose
- Drugs used for off-label indications which are not found in official compendia or generally accepted in peer reviewed literature
- Drugs dispensed after their expiration date

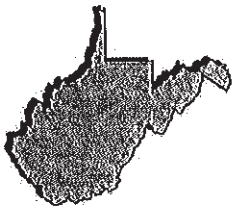


- The cost of shipping or delivering a drug
- Herbal or homeopathic products
- Drugs which result in therapeutic duplication, ingredient duplication, early refills or other Drug Utilization Review events that are not medically necessary
- Drugs which are not medically necessary
- Covered outpatient drugs for which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee
- Nutritional supplements
- Free pharmaceutical samples
- Diagnostic agents
- Vacation supplies
- Allergenic extracts
- Excipients except when used in compounded prescriptions containing a covered legend drug. Excipients must be eligible for federal rebates in order to be eligible for reimbursement.
- Vaccines via the pharmacy POS, except for influenza, pneumonia, Hepatitis A, Hepatitis B, tetanus, tetanus-diphtheria (Td), and tetanus-diphtheria-and-pertussis (Tdap) vaccines for adults nineteen (19) years of age and older administered by a pharmacist; and herpes zoster vaccine for adults fifty (60) years of age and older administered by a pharmacist.
- Factors to treat hemophilia via the pharmacy POS (Refer to *Chapter 519, Practitioner Services,* for additional information regarding hemophilia services.)
- Methadone for the treatment of drug dependence/addiction

Section 518.8 PRIOR AUTHORIZATION (PA)

Old Policy: Prior authorization (PA) for Medicaid-covered drugs is required for reimbursement of certain drugs to assure the appropriateness of drug therapy. Specific PA criteria are based on review of the most current clinical information, FDA approved indications, and manufacturers' recommendations. These criteria are reviewed by the Medicaid Drug Utilization Review (DUR) Board and recommended to the Bureau for Medical Services. These criteria then form the basis of acceptable drug therapy for members of Medicaid pharmacy services. Current criteria for coverage of non-preferred drugs and other drugs requiring prior authorization are found on the BMS website at www.wvdhhr.org/bms. Drugs which require prior authorization and for which prior authorization criteria have not been met are considered non-reimbursable until appealed by the prescribing practitioner on behalf of the member.

New Policy: Prior authorization (PA) for Medicaid-covered drugs is required for reimbursement of certain drugs to assure the appropriateness of drug therapy. Specific PA criteria are based on review of the most current clinical information, FDA approved indications, and manufacturers' recommendations. These criteria are reviewed by the Medicaid Drug Utilization Review (DUR) Board and recommended to the Bureau for Medical Services. These criteria then form the basis of acceptable drug therapy for members of Medicaid pharmacy services. Current criteria for coverage of non-preferred drugs and other drugs requiring prior authorization are found on the BMS website at www.dhhr.wv.gov/bms. Drugs which require



prior authorization and for which prior authorization criteria have not been met are considered non-reimbursable unless, upon appeal by the prescribing provider, the Medicaid Medical Director determines that the drug meets the appropriateness and medical necessity criteria.

Section 518.8.1 Process of Requesting Prior Authorization

Old Policy: The Rational Drug Therapy Program (RDTP) is the agency contracted to provide prior authorization services to the West Virginia Medicaid Pharmacy Program. RDTP is a non-profit organization affiliated with the West Virginia University School of Pharmacy.

Prior authorization may be initiated either by the dispensing pharmacist, the prescriber, or the prescriber's designee. Requests may be made by telephone, fax, or mail. If all the necessary information is provided, requests will be addressed within 24 hours. It is the responsibility of the provider of the service, either the physician or pharmacist, to obtain the authorization before rendering the service. Requests for prior authorization after the service is rendered will be denied, except in cases of back-dated eligibility. If the service is provided before prior authorization is obtained, the Medicaid member must be informed that he/she will be responsible for the bill. There is a maximum approval limit of one year.

Prior authorization requests shall include the following:

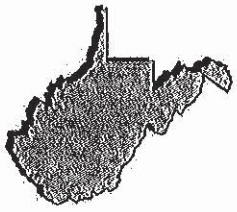
- Member name and address
- Member Medicaid identification number
- Name of drug, strength, dosage, and duration of treatment
- Diagnosis
- Pertinent laboratory information
- Justification for the use of the drug
- Return fax number
- Signature of prescriber or pharmacist

Rational Drug Therapy Program's operating hours are:
Monday through Saturday – 8:30 AM until 9:00 PM
Sunday – 12 noon until 6:00 PM

Prior authorization forms can be downloaded from the Rational Drug Therapy Program's website at www.hsc.wvu.edu/sop/rdtp/. These forms may be duplicated.

New Policy: The Rational Drug Therapy Program (RDTP) is the agency contracted to provide prior authorization services to the West Virginia Medicaid Pharmacy Program. RDTP is a non-profit organization affiliated with the West Virginia University School of Pharmacy.

Prior authorization may be initiated either by the dispensing pharmacist, the prescriber, or the prescriber's designee. Prior authorization requests from third party vendors or contractors will be denied. Requests may be made by telephone, fax, or mail. If all the necessary information is provided, requests will be addressed within 24 hours. It is the responsibility of the provider of the service, either the physician or pharmacist, to obtain the authorization before rendering the service. Requests for prior authorization after the service is rendered will be denied. In cases



of back-dated eligibility, prior authorizations may be considered on a case by case basis using coverage policies in place on the dates the services were rendered. If the service is provided before prior authorization is obtained, the Medicaid member must be informed that he/she will be responsible for the bill.

There is a maximum approval limit of one year.

Prior authorization requests shall include the following:

- Member name and address
- Member Medicaid identification number
- Name of drug, strength, dosage, and duration of treatment
- Diagnosis
- Pertinent laboratory information
- Justification for the use of the drug
- Return fax number
- Signature of prescriber or pharmacist

Rational Drug Therapy Program's operating hours are:
Monday through Saturday – 8:30 AM until 9:00 PM
Sunday – 12 noon until 6:00 PM

Prior authorization forms can be downloaded from the Bureau for Medical Services' website at http://www.dhhr.wv.gov/bms/Pharmacy/Pages/pac.aspx. These forms may be duplicated. Providers enrolled to access the BMS MediWeb portal may complete PA forms electronically and submit them via the portal.

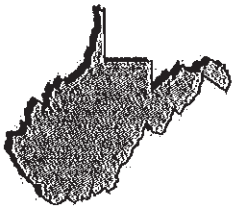
Section 518.9.1 Prospective Drug Utilization Review (DUR)

Old Policy: Pharmacists may continue to process claims that contain prospective DUR messages by using DUR outcome and intervention codes. A call to the RDTP help desk may be required in certain instances as determined by BMS. More detailed information regarding DUR procedures is found in the Health PAS-RX Pharmacy Point-of-Sale (POS) User Guide, found on BMS' link to the fiscal agent website, www.wvdhhr.org/bms.

New Policy: Pharmacists may continue to process claims that contain prospective DUR messages by using DUR outcome and intervention codes. A call to the RDTP help desk may be required in certain instances as determined by BMS to obtain an edit override. Requests for edit overrides after the service is rendered will be denied, except in cases of back-dated eligibility. More detailed information regarding DUR procedures is found in the Health PAS-RX Pharmacy Point-of-Sale (POS) User Guide, found on BMS' link to the fiscal agent website, www.dhhr.wv.gov/bms.

Section 518.9.2.1 Pharmacy Lock-in Program

Old Policy: N/A



New Policy: Criteria for Lock-in determination can be found on the Bureau's website, www.dhhr.wv.gov/bms.

Members, upon discharge from a substance abuse program, or while receiving outpatient substance abuse treatment, will be locked into a single pharmacy provider. Upon admission to a facility for treatment of substance abuse or during the initial visit for outpatient substance abuse services, the member will be required to choose a pharmacy from which to receive all controlled substances. The lock-in form may be found on the Bureau website at www.dhhr.wv.gov/bms.

Section 518.10.4 Shipping/Receiving

Old Policy: Claims for medications not received by the member in a timely manner may be reversed for billing by a local pharmacy provider to meet the member's needs.

New Policy: Claims for medications not received by the member in a timely manner may be reversed by the fiscal agent, if necessary, in order to allow for billing by a local pharmacy provider to meet the member's needs.

Section 518.11.1 Point-of-Sale System

Old Policy: Currently, online processing for Medicaid pharmacy claims is available for all pharmacies using NCPDP Version 5.1.

See the Pharmacy Point-of-Sale (POS) NCPDP Version 5.1 Vendor Specification Document, for specifications and information for switch vendors.

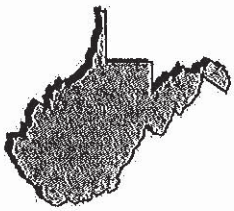
New Policy: Currently, online processing for Medicaid pharmacy claims is available for all pharmacies using NCPDP Version D.0.

See the Pharmacy Point-of-Sale (POS) NCPDP Version D.0 Vendor Specification Document, for specifications and information for switch vendors.

Section 518.11.2 National Council on Prescription Drug Programs (NCPDP) Payer Sheet

Old Policy: West Virginia Medicaid accepts pharmacy Point-of-Sale claims submitted using NCPDP Version 5.1 or Batch Version 1.1. ... (See the Pharmacy Point-of-Sale (POS) NCPDP Version 5.1 Vendor Specification Document, located on BMS' link to the fiscal agent website, for the West Virginia Medicaid payer sheet.)

New Policy: West Virginia Medicaid accepts pharmacy Point-of-Sale claims submitted using NCPDP Version D.0 or Batch Version 1.1. ... (See the Pharmacy Point-of-Sale (POS) NCPDP Version D.0 Vendor Specification Document, located on BMS' link to the fiscal agent website, for the West Virginia Medicaid payer sheet.)



Section 518.11.3 Paper Claim Submission for Pharmacy Services

Old Policy: Pharmacies have the alternative of submitting a manual claim using a paper claim form, when necessary. The Universal Claim Form (UCF) provides a standard format for paper submission of drug claims to Medicaid. The UCF adheres to the data elements found in the Telecommunication Standard and Data Dictionary. The new UCF that supports the Telecommunication Standard Version 5.1 is "DAH 2 PT". **Medicaid will not supply these forms to providers.** NCPDP has an agreement with R.R. Donnelley to distribute the UCF. Their telephone number is 1-800-635-9500. The order number for the UCF is Laser UCF form, number UCFL 1. Forms are also available from pharmaceutical wholesalers. An example of the UCF and completion instructions can be found in the Health PAS-RX Pharmacy Point-of-Sale (POS) User Guide, located on BMS' link to the fiscal agent website, www.wvdhhr.org/bms.

New Policy: Pharmacies have the alternative of submitting a manual claim using a paper claim form, when necessary. The Universal Claim Form (UCF) provides a standard format for paper submission of drug claims to Medicaid. The UCF adheres to the data elements found in the Telecommunication Standard and Data Dictionary. **Medicaid will not supply these forms to providers.**

Section 518.11.10 Compounded Prescriptions

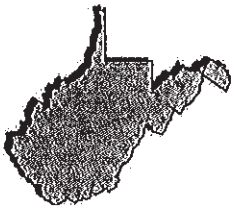
Old Policy: Billing compounded prescriptions follows NCPDP Version 5.1 guidelines.

New Policy: Billing compounded prescriptions follows NCPDP Version D.0 guidelines.

Section 518.11.11 Abuse and Inappropriate Utilization

Old Policy: The following practices constitute abuse and inappropriate utilization, and are subject to audit:

- Excessive fees (commonly known as prescription splitting or incorrect or excessive dispensing fees): Billing inappropriately in order to obtain dispensing fees in excess of those allowed by:
  - Supplying medication in amounts less than necessary to cover the period of the prescription; and/or
  - Supplying multiple medications in strengths less than those prescribed to gain more than one dispensing fee.
- Excessive filling: Billing for an amount of a drug or supply greater than the prescribed quantity.
- Prescription shorting: Billing for drug or supply greater than the quantity actually dispensed.
- Substitution to achieve a higher price: Billing for a higher priced drug than prescribed even though the prescribed lower priced drug was available.
- Automatic filling of prescriptions or automatic shipping of medications to the member is prohibited unless members request the filling or shipping of these medications each time.



New Policy: The following practices constitute abuse and inappropriate utilization, and are subject to audit:

- Excessive fees (commonly known as prescription splitting or incorrect or excessive dispensing fees): Billing inappropriately in order to obtain dispensing fees in excess of those allowed by:
  - Supplying medication in amounts less than necessary to cover the period of the prescription; and/or
  - Supplying multiple medications in strengths less than those prescribed to gain more than one dispensing fee.
- Excessive filling: Billing for an amount of a drug or supply greater than the prescribed quantity.
- Prescription shorting: Billing for drug or supply greater than the quantity actually dispensed.
- Substitution to achieve a higher price: Billing for a higher priced drug than prescribed even though the prescribed lower priced drug was available.

Automated refills and automatic shipments are prohibited. Medicaid does not pay for any prescription without an explicit request from a member or the member's responsible party, such as a caregiver, for each refilling event. The pharmacy provider shall not contact the member in an effort to initiate a refill unless it is part of a good faith clinical effort to assess the member's medication regimen. The possession, by a provider, of a prescription with remaining refills authorized does not in itself constitute a request to refill the prescription. Members or providers cannot waive the explicit refill request and enroll in an electronic automatic refill program. Any prescriptions filled without a request from a member or their responsible party will be subject to recovery. Any pharmacy provider with a policy that includes filling prescriptions on a regular date or any type of cyclical procedure will be subject to audit, claim recovery or possible suspension or termination of the provider agreement.

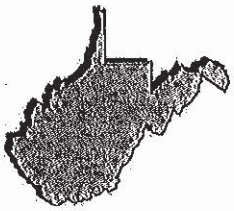
Section 518.12 REIMBURSEMENT

Old Policy: N/A.

New Policy: If a provider accepts the member as a Medicaid patient, the provider must bill WV Medicaid for covered services and must accept the Medicaid reimbursement amount as full payment. No charge may be billed to a Medicaid member for a covered service unless a co-payment is applicable by regulation. However, the provider may bill the member for services not covered by the WV Medicaid Program if the parties agree in writing to this payment arrangement before such services are rendered. Refer to *Chapter 300, Section 320.2* for more information about billing Medicaid members.

Section 518.12.1 Ingredient Cost

Old Policy: The Maximum Allowable Cost (MAC) plus a reasonable dispensing fee. The MAC for each multiple-source drug as defined in 42 CFR 447.332 and published in the Federal



Register, plus a dispensing fee. A listing of Federal Multiple Source Drug Limits is available on the CMS' website, www.CMS.hhs.gov/Reimbursement.

New Policy: The Maximum Allowable Cost (MAC) plus a reasonable dispensing fee. The MAC for each multiple-source drug as defined in 42 CFR 447.332 and published in the Federal Register, plus a dispensing fee. Information relating to Federal Multiple Source Drug Limits is available on the CMS website at http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Federal-Upper-Limits.html.

Old Policy: (4) The Medicaid AWP (MAWP) established by the Federal Office of the Inspector General, plus a dispensing fee;

New Policy: (Remove bullet 4, MAWP)

Section 518.12.2 Application of Dispensing Fee

Old Policy: For covered legend and over-the-counter drugs, a professional dispensing fee of $2.50 per prescription for brand name drugs or a professional dispensing fee of $5.30 per prescription for generic drugs will be added to the federally established MAC, state established MAC, Medicaid AWP, or state established EAC of each prescribed drug.

For a compounded prescription, an additional $1.00 will be added to the dispensing fee. A compounded prescription is defined as any prescription requiring the combination of two or more substances, one of which must be a legend drug

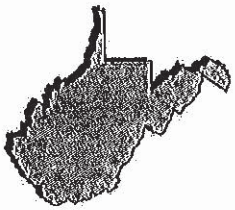
New Policy: For covered legend and over-the-counter drugs, a professional dispensing fee of $2.50 per prescription for brand name drugs or a professional dispensing fee of $5.30 per prescription for generic drugs will be added to the federally established MAC, state established MAC, or state established EAC of each prescribed drug.

For a compounded prescription, an additional $1.00 will be added to the dispensing fee. A compounded prescription is defined as any prescription requiring the combination of two or more substances, one of which must be a legend drug. Compounding is considered an integral part of the prescription services and must not be billed separately.

Section 518.12.3 Co-Payments

Old Policy: Providers are prohibited from advertising or soliciting business by waiving members' co-payment responsibility.

New Policy: Providers are prohibited from advertising or soliciting business by waiving members' co-payment responsibility. Members are responsible for applicable copays, and providers are prohibited from waiving the copay requirement to attract business from other providers.



Section 518.12.4 Third-Party Liability (TPL) or Coordination of Benefits (COB)

Old Policy: See the User Guide for billing instructions for NCPDP Version 5.1 in regard to Coordination of Benefits.

New Policy: See the User Guide for billing instructions for NCPDP Version D.0 in regard to Coordination of Benefits.

Section 518.12.4.2 Medicare Covered Drugs, Part D

Old Policy: Dual eligible members have prescription drug coverage through Medicare Part D. Medicaid is not responsible for covering pharmacy benefits for these individuals, except for drugs in the Medicare excluded categories. Dual eligible members are limited to coverage of Medicare Part D excluded drugs. Coverage is limited to drugs that are covered for other Medicaid eligible members in the following classes:

- Benzodiazepines
- Barbiturates
- Over-the-counter medications
- Agents for the symptomatic relief of cough and cold symptoms
- Prescription vitamins and minerals

Medicaid does not reimburse for Medicare Part D co-payments. Medicaid does not pay as the secondary payer on Medicare Part D covered drugs.

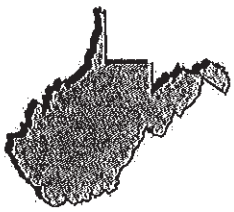
New Policy: Dual eligible members have prescription drug coverage through Medicare Part D. Medicaid is not responsible for covering pharmacy benefits for these individuals, except for drugs in the Medicare excluded categories. Dual eligible members are limited to coverage of Medicare Part D excluded drugs. Coverage is limited to drugs that are covered for other Medicaid eligible members in the following classes:

- Barbiturates (if not for treatment of epilepsy, cancer, or mental health disorder, as Medicare Part D covers these conditions)
- Over-the-counter medications
- Agents for the symptomatic relief of cough and cold symptoms
- Prescription vitamins and minerals

Medicaid does not reimburse for Medicare Part D co-payments. Medicaid does not pay as the secondary payer on Medicare Part D covered drugs.

Section 518.13.4 Additional Information

Old Policy:
Person or Company: Goold Health Services
Phone Number: 800-340-5970



New Policy:
Person or Company: Magellan Medicaid Administration, Inc.
Phone Number: 800-763-7382

November 19, 2012

Introduction: Section 518.4 Description of Covered Services, Bullet item 7

Old Policy: Influenza and pneumonia vaccines for adults over 21 years of age administered by a pharmacist.

New Policy: Influenza and pneumonia vaccines for adults over 19 years of age administered by a pharmacist. (Note: Correction to age in policy wording.)

April 1, 2012

Introduction: Section 518.3.1.4, Medicaid Members with End Stage Renal Disease (ESRD)

Old Policy: Members diagnosed with End Stage Renal Disease (ESRD) may require additional over-the-counter drug treatments not usually covered by the pharmacy program. In order to accommodate these members, a letter signed and dated by the treating physician is required to verify the diagnosis of ESRD and must include the date dialysis began. This letter shall be directed to:

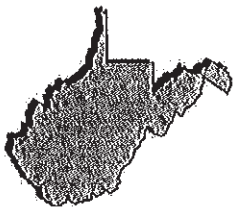
Bureau for Medical Services
Member Eligibility
350 Capitol Street, Room 251
Charleston, West Virginia 25301-2675

Refer to the BMS website, www.wvdhhr.org/bms, for a list of additional over-the-counter drugs covered for ESRD patients.

New Policy: Members diagnosed with End Stage Renal Disease (ESRD) may require additional vitamin/mineral supplements not usually covered by the pharmacy program. In order to accommodate these members, a letter signed and dated by the treating physician is required to verify the diagnosis of ESRD and must include the date dialysis began. This letter shall be directed to:

Bureau for Medical Services
Member Eligibility
350 Capitol Street, Room 251
Charleston, West Virginia 25301-2675

Refer to the BMS website, www.dhhr.wv.gov/bms, for a list of additional vitamin/mineral supplements covered for ESRD patients.



Once a member receives a kidney transplant, the member is no longer considered as having ESRD, and no longer qualifies for these additional supplements.

Introduction: Section 518.3.2.6, Juvenile Services

Old Policy: Certain individuals have pharmacy services coverage through Juvenile Services. A letter of eligibility will be presented to the pharmacy which includes the individual's identification number beginning with prefix "17". Claims for these services may be submitted through the online Point-of-Sale system or by using the approved paper claim form. Medicaid coverage rules apply.

New Policy: Incarcerated minors have pharmacy services coverage through Juvenile Services. A letter of eligibility will be presented to the pharmacy which includes the individual's identification number beginning with prefix "17". Claims for these services may be submitted through the online Point-of-Sale system or by using the approved paper claim form. Medicaid coverage rules apply.

Introduction: Section 518.4.5, Home Infusion Therapy Pharmacy Services, formerly In-Home Parenteral Therapy (IHPT) Pharmacy Services

Old Policy: Drugs used for in-home parenteral therapy services are covered under the Medicaid Pharmacy Program. These drugs require prior authorization and must be justified by the ordering practitioner, including why oral therapy is unsuitable for the patient. **Members enrolled in Medicaid managed care plans have coverage of IHPT pharmacy services through their managed care plan. Dual eligible members have coverage of IHPT pharmacy services through their Medicare Part D plans.**

See *Appendix 1* for detailed information regarding IHPT pharmacy services.

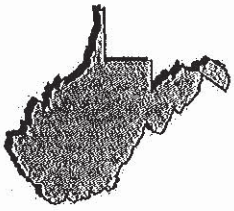
New Policy: Drugs used for home infusion therapy services are covered under the Medicaid Pharmacy Program. These drugs require prior authorization and must be justified by the ordering practitioner, including why oral therapy is unsuitable for the patient. **Members enrolled in Medicaid managed care plans have coverage of home infusion pharmacy services through their managed care plan. Dual eligible members have coverage of home infusion pharmacy services through their Medicare Part D plans.**

See *Appendix 1* for detailed information regarding Home Infusion Therapy pharmacy services.

Introduction: Section 518.4.7, Buprenorphine-Naloxone(Suboxone®)/Buprenorphine(Subuxtex®) Coverage

Old Policy: N/A

New Policy: Buprenorphine-Naloxone and Buprenorphine are covered through the Pharmacy program, and must be written by a prescriber enrolled with WV Medicaid or employed by a facility enrolled with WV Medicaid, or enrolled with one of the Medicaid MCOs. Buprenorphine-



Naloxone and Buprenorphine are obtained only through a prior authorization. Other limitations may apply.

See the BMS website at www.dhhr.wv.gov/bms for additional information and detailed coverage criteria.

Introduction: Section 518.5.1, Bulk Chemicals

Old Policy: N/A

New Policy: Per CMS Medicaid Drug Rebate Program Release No. 155, bulk chemicals are substances which when used in the manufacturing of a drug become the active ingredient of the drug product. As such they do not meet the definition of covered outpatient drugs as defined in section 1927(k)(2) of the Social Security Act. However, bulk chemicals may be considered in rare circumstances if prescribed for an FDA-approved indication and/or medically accepted indication supported in official compendia. Prior authorization is required.

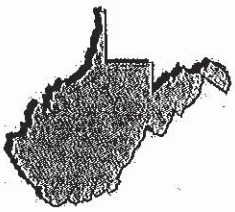
All rules, regulations, limitations, and exclusions set forth in the Pharmacy Services manual apply also to bulk chemicals.

Refer to the BMS website, www.dhhr.wv.gov/bms, for a list of covered bulk chemicals and criteria for coverage.

Introduction: Section 518.7, NON COVERED SERVICES

Old Policy: The following list of drugs, drug products, and related services are not reimbursable. Non-covered services are not eligible for a West Virginia Department of Health and Human Resources (WVDHHR) fair hearing. Non-covered services include, but are not limited to:

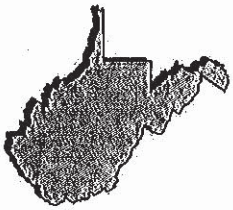
- Drugs supplied by drug manufacturers who have not entered into a drug rebate agreement with CMS
- Agents used for weight loss or weight gain
- Agents used for cosmetic purposes or hair growth
- Drugs identified by CMS as being less-than-effective (DESI). The DESI list and more information about DESI drugs may be found on the Centers for Medicare and Medicaid Services' (CMS) website at www.cms.hhs.gov/MedicaidDrugRebateProgram.
- Agents used for fertility
- Drugs used to treat erectile dysfunction
- Drugs that are investigational or approved drugs used for investigational purpose
- Drugs used for off-label indications which are not found in official compendia or generally accepted in peer reviewed literature
- Drugs dispensed after their expiration date
- The cost of shipping or delivering a drug
- Herbal or homeopathic products
- Drugs which result in therapeutic duplication, ingredient duplication, early refills or other Drug Utilization Review events that are not medically necessary



- Drugs which are not medically necessary
- Covered outpatient drugs for which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee
- Nutritional supplements
- Free pharmaceutical samples
- Diagnostic agents
- Vacation supplies
- Allergenic extracts
- Excipients except when used in compounded prescriptions containing a covered legend drug
- Vaccines via the pharmacy POS, except for influenza and pneumonia vaccines for adults over the age of 21 years administered by a pharmacist
- Factors to treat hemophilia via the pharmacy POS (Refer to *Chapter 519, Practitioner Services Manual,* for additional information regarding hemophilia services.

New Policy: The following list of drugs, drug products, and related services are not reimbursable. Non-covered services are not eligible for a West Virginia Department of Health and Human Resources (WVDHHR) fair hearing. Non-covered services include, but are not limited to:

- Drugs supplied by drug manufacturers who have not entered into a drug rebate agreement with CMS
- Agents used for weight loss or weight gain
- Agents used for cosmetic purposes or hair growth
- Drugs identified by CMS as being less-than-effective (DESI). The DESI list and more information about DESI drugs may be found on the Centers for Medicare and Medicaid Services' (CMS) website at www.cms.hhs.gov/MedicaidDrugRebateProgram.
- Agents used for fertility
- Drugs used to treat erectile dysfunction
- Drugs that are investigational or approved drugs used for investigational purpose
- Drugs used for off-label indications which are not found in official compendia or generally accepted in peer reviewed literature
- Drugs dispensed after their expiration date
- The cost of shipping or delivering a drug
- Herbal or homeopathic products
- Drugs which result in therapeutic duplication, ingredient duplication, early refills or other Drug Utilization Review events that are not medically necessary
- Drugs which are not medically necessary
- Covered outpatient drugs for which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee
- Nutritional supplements
- Free pharmaceutical samples
- Diagnostic agents



- Vacation supplies
- Allergenic extracts
- Excipients except when used in compounded prescriptions containing a covered legend drug
- Vaccines via the pharmacy POS, except for influenza and pneumonia vaccines for adults over the age of 21 years administered by a pharmacist
- Factors to treat hemophilia via the pharmacy POS (Refer to *Chapter 519, Practitioner Services Manual,* for additional information regarding hemophilia services.
- Methadone for the treatment of drug dependence/addiction

Introduction: Section 518.10.4, Shipping/Receiving

Old Policy: Drugs reimbursed by West Virginia Medicaid that are mailed or shipped to members require a signature of the individual receiving delivery of the medication. A log of these signatures must be maintained by the pharmacy for a period of 5 years for auditing purposes. Providers shall take the necessary steps to prevent loss of medications in the shipping process, as Medicaid will not reimburse for medications not received by the member.

New Policy: Drugs reimbursed by West Virginia Medicaid that are mailed or shipped to members require a signature of the individual receiving delivery of the medication. A log of these signatures must be maintained by the pharmacy for a period of 5 years for auditing purposes. Providers shall take the necessary steps to prevent loss of medications in the shipping process and to assure that the member receives the shipment when needed, as Medicaid will not reimburse for medications not received by the member.

Claims for medications not received by the member in a timely manner may be reversed for billing by a local pharmacy provider.

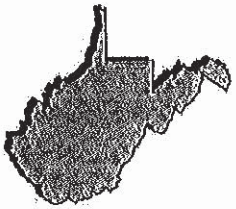
Introduction: Section 518. 11.13, Wasted Medication

Old Policy: Members who have wasted medication due to improper use or storage may have their medication replaced. This will be determined on a case-by-case basis. Members shall be properly instructed on the storage and use of their medications and any special delivery device used to administer their medications. Requests for replacement of wasted medications due to improper storage or delivery by the pharmacy will be denied.

New Policy: Members who have wasted medication due to improper use or storage may have their medication replaced. This will be determined on a case-by-case basis. Members shall be properly instructed on the storage and use of their medications and any special delivery device used to administer their medications. Requests for replacement of wasted medications due to improper storage or delivery by the pharmacy, or improper handling by the administrating provider will be denied.

November 1, 2010

Introduction: Section 518.2.5, Pharmacy Change of Ownership



Old Policy: N/A

New Policy: Change of ownership policy is addressed in *Common Chapter 300, Provider Participation Requirements,* and additional information may be found on the fiscal agent's website, see *Common Chapter 100, General Information,* for information on the fiscal agent. Although a pharmacy provider's NPI may be legally transferred from one owner to the next, BMS recommends that a new owner obtain a new NPI to facilitate a seamless transition.

Introduction: Section 518.3.1.1, Mountain Health Choices

Old Policy: Pharmacy services are covered for all benefit plans. All existing rules regarding prior authorization, the Preferred Drug List and quantity limits for medications covered by the Outpatient Pharmacy Program apply to the pharmacy benefit for the Mountain Health Choices Program.

Mountain Health Choices members who choose the Enhanced Benefit Package will not have a limit on the number of prescriptions obtained for a 34-day period. All rules and edits pertaining to prior authorization and the Preferred Drug List apply to the pharmacy benefit for this program.

Members in the MHC Basic Benefit Package or Plan will be limited to 4 prescriptions per 34 day period.

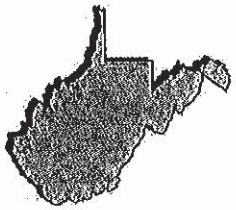
Certain categories of drugs will not be included in the 4 prescription limit for members who choose the Basic Benefit Package. Drugs in the following therapeutic classes will not count toward the prescription limit for **children** with the Basic Benefit Package, which will be indicated by "BC" on their Medicaid Identification Card:

a. Diabetes supplies and all insulins
b. Medications used for the treatment of seizures
c. Certain antibiotics-cephalosporins, macrolides, penicillins, and sulfonamides
d. Drugs used for the treatment of HIV/AIDS
e. Birth Control

The following therapeutic classes will not count toward the 4-prescription limit for **adults** with the Basic Benefit Package, which will be indicated by "BA" on their Medicaid Identification Card:

a. Diabetes supplies and all insulins
b. Atypical antipsychotics
c. Antidepressants (all therapeutic classes)
d. Drugs used for the treatment of HIV/AIDS
e. Birth Control

When the 4-prescription limit is exceeded, a call may be made to the Rational Drug Therapy Program Help Desk (1-800-847-3859) for a medication review. These requests will be considered on a case-by-case basis after review of the member's medication profile.



New Policy: Pharmacy services are covered for all benefit plans. All existing rules regarding prior authorization, the Preferred Drug List and quantity limits for medications covered by the Outpatient Pharmacy Program apply to the pharmacy benefit for the Mountain Health Choices Program.

Mountain Health Choices members who choose the Enhanced Benefit Package will not have a limit on the number of prescriptions obtained per calendar month. All rules and edits pertaining to prior authorization and the Preferred Drug List apply to the pharmacy benefit for this program.

Members in the MHC Adult Basic Benefit Package or Plan will be limited to 4 prescriptions per calendar month period. Children under the age of 21 years are not limited in the number of prescriptions they may receive.

The following therapeutic classes will not count toward the 4-prescription limit for adults with the Basic Benefit Package, which will be indicated by "BA" on their Medicaid Identification Card:

a. Diabetes supplies and all insulins
b. Atypical antipsychotics
c. Antidepressants (all therapeutic classes)
d. Drugs used for the treatment of HIV/AIDS
e. Birth Control

When the 4-prescription limit is exceeded, a call may be made to the Rational Drug Therapy Program Help Desk (1-800-847-3859) for a medication review. These requests will be considered on a case-by-case basis after review of the member's medication profile.

Introduction: Section 518.3.1.7, Incarcerated Members

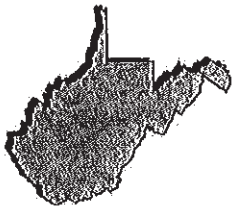
Old Policy: N/A

New Policy: Medicaid members who are incarcerated are restricted from coverage of pharmacy benefits until they are released from the correctional system. Claims submitted with dates of service during a period of incarceration will deny. If the member has been released before the restriction is updated, positive identification is required. A call to the Rational Drug Therapy Program help desk must be made to request an override.

Introduction: Section 518.5, SERVICE LIMITATIONS

Old Policy:

- Members enrolled in the Mountain Health Choice's (MHC) basic plans are limited to coverage of four prescriptions per calendar month, with the exception of the following therapeutic classes for children:
    - Diabetic supplies and all insulins,
    - Medications used in the treatment of seizures,
    - Certain antibiotics—cephalosporins, macrolides, penicillins, and sulfonamides



- Drugs used for the treatment of HIV/AIDS
- All contraceptives.

And for adults enrolled in the MHC basic plan, the following exceptions of therapeutic classes to the four prescription limit are:

- Diabetic supplies and all insulins,
- Atypical antipsychotics,
- Antidepressants (all therapeutic classes),
- Drugs used for the treatment of HIV/AIDS,
- All contraceptives.

New Policy:

- Members enrolled in the Mountain Health Choice's (MHC) Adult basic plan are limited to coverage of four prescriptions per calendar month.

  The following therapeutic classes will not count toward the 4-prescription limit:

  - Diabetic supplies and all insulins,
  - Atypical antipsychotics,
  - Antidepressants(all therapeutic classes),
  - Drugs used for the treatment of HIV/AIDS,
  - All contraceptives.

Introduction: Section 518.10.2, Prescriptions Returned to Stock

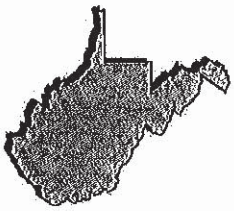
Old Policy: Claims for prescriptions which have been filled by the participating pharmacy, but not dispensed to the patient, shall be reversed. This shall be done on a timely basis. A log of these returns must be maintained by the pharmacy for a period of 5 years for auditing purposes.

New Policy: Claims for prescriptions which have been filled by the participating pharmacy, but not dispensed to the patient, shall be reversed. This shall be done on a timely basis, within 15 days. A log of these returns must be maintained by the pharmacy for a period of 5 years for auditing purposes.

Introduction: Section 518.11, BILLING PROCEDURE

Old Policy: N/A

New Policy: Claims must accurately report the NDC dispensed, the number of units dispensed, days' supply, and other required data for claims processing. Use of an incorrect NDC or inaccurate reporting of a drug quantity will cause BMS to report false data to drug manufacturers when billed for drug rebates. BMS will recover payments made on erroneous claims discovered during dispute resolution with drug manufacturers or during claim reviews. Pharmacies are required to submit documentation for purchases of drugs reimbursed by BMS upon request.



Introduction: Section 518.11.14, False Claims

Old Policy: N/A

New Policy: Pharmacies are prohibited from submitting false claims to test for drug coverage, member eligibility, or for other purposes. Claims of this type result in false member drug history records and may result in the member or prescriber being included in lawsuits or reviews in error. All claims submitted for reimbursement must be the result of actual prescription requests.

Introduction: Appendix 1, In-Home Parenteral Therapy

Old Policy: Prior authorization form included

New Policy: See the BMS web site at www.wvdhhr.org/bms for the approved prior authorization form.

October 1, 2010

Introduction: Section 518.4, Description Of Covered Services

Old Policy: Except for certain limitations and exclusions, BMS will reimburse for the following:

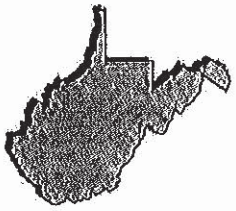
- Outpatient legend drugs
- Specific over-the-counter drugs
- Compounded prescriptions
- Drugs that require prior authorization, when approved by BMS
- Family planning supplies, including over-the-counter supplies
- Certain diabetic supplies.

New Policy: Except for certain limitations and exclusions, BMS will reimburse for the following:

- Outpatient legend drugs
- Specific over-the-counter drugs
- Compounded prescriptions
- Drugs that require prior authorization, when approved by BMS
- Family planning supplies, including over-the-counter supplies
- Certain diabetic supplies
- Influenza and pneumonia vaccines for adults over 21 years of age administered by a pharmacist.

Introduction: Section, 518.7, Non-Covered Services

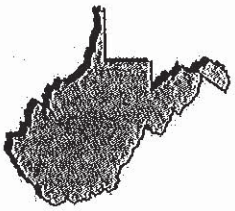
Old Policy: The following list of drugs, drug products, and related services are not reimbursable. Noncovered services are not eligible for a West Virginia Department of Health and Human Resources (WVDHHR) fair hearing. Non-covered services include, but are not limited to:



- Drugs supplied by drug manufacturers who have not entered into a drug rebate agreement with CMS
- Agents used for weight loss or weight gain
- Agents used for cosmetic purposes or hair growth
- Drugs identified by CMS as being less-than-effective (DESI). The DESI list and more information about DESI drugs may be found on the Centers for Medicare and Medicaid Services' (CMS) website at www.cms.hhs.gov/MedicaidDrugRebateProgram.
- Agents used for fertility
- Drugs used to treat erectile dysfunction
- Drugs that are investigational or approved drugs used for investigational purposes
- Drugs used for off-label indications which are not found in official compendia or generally accepted in peer reviewed literature
- Drugs dispensed after their expiration date
- The cost of shipping or delivering a drug
- Herbal or homeopathic products
- Drugs which result in therapeutic duplication, ingredient duplication, early refills or other Drug Utilization Review events that are not medically necessary
- Drugs which are not medically necessary
- Covered outpatient drugs for which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee
- Nutritional supplements
- Free pharmaceutical samples
- Diagnostic agents
- Vacation supplies
- Allergenic extracts
- Excipients except when used in compounded prescriptions containing a covered legend drug
- Vaccines via the pharmacy POS
- Factors to treat hemophilia via the pharmacy POS (Refer to *Chapter 519, Practitioner Services,* for additional information regarding hemophilia services.

New Policy: The following list of drugs, drug products, and related services are not reimbursable. Non-covered services are not eligible for a West Virginia Department of Health and Human Resources (WVDHHR) fair hearing. Non-covered services include, but are not limited to:

- Drugs supplied by drug manufacturers who have not entered into a drug rebate agreement with CMS
- Agents used for weight loss or weight gain
- Agents used for cosmetic purposes or hair growth
- Drugs identified by CMS as being less-than-effective (DESI). The DESI list and more information about DESI drugs may be found on the Centers for Medicare and Medicaid Services' (CMS) website at www.cms.hhs.gov/MedicaidDrugRebateProgram.
- Agents used for fertility
- Drugs used to treat erectile dysfunction
- Drugs that are investigational or approved drugs used for investigational purposes



- Drugs used for off-label indications which are not found in official compendia or generally accepted in peer reviewed literature
- Drugs dispensed after their expiration date
- The cost of shipping or delivering a drug
- Herbal or homeopathic products
- Drugs which result in therapeutic duplication, ingredient duplication, early refills or other Drug Utilization Review events that are not medically necessary
- Drugs which are not medically necessary
- Covered outpatient drugs for which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee
- Nutritional supplements
- Free pharmaceutical samples
- Diagnostic agents
- Vacation supplies
- Allergenic extracts
- Excipients except when used in compounded prescriptions containing a covered legend drug
- Vaccines via the pharmacy POS, except for influenza and pneumonia vaccines for adults over the age of 21 years administered by a pharmacist
- Factors to treat hemophilia via the pharmacy POS (Refer to *Chapter 519, Practitioner Services Manual,* for additional information regarding hemophilia services.

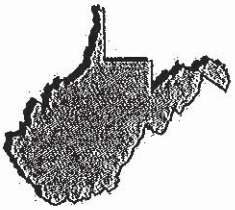
Introduction: Section 518.12.3, Co-Payments

Old Policy: A co-payment is required for each prescription with the exception of prescriptions for members excluded by regulation and/or those items specifically excluded from the co-payment requirement. The member co-payment per prescription will be deducted from the allowed total charge to determine the amount payable for each prescription billed to the Program. The deduction will apply as follows:

- If the allowed total charge is $10.00 or less, the co-payment is $.50 per prescription
- If the allowed total charge is $10.01 through $25.00, the co-payment is $1.00 per prescription
- If the allowed total charge is $25.01 through $50.00, the co-payment is $2.00 per prescription
- If the allowed total charge is $50.01 or more, the co-payment is $3.00 per prescription

Certain individuals or covered services are exempt from the co-payment requirement, as follows:

- Prescriptions for family planning services and supplies
- Prescriptions for members in long-term care facilities (i.e., nursing facilities or intermediate care facilities for mentally retarded)
- Prescriptions for pregnant women
- Prescriptions for members under 18 years of age
- 3-day emergency supplies
- Diabetic testing supplies and syringes/needles



• BMS approved home infusion supply

New Policy: A co-payment is required for each prescription with the exception of prescriptions for members excluded by regulation and/or those items specifically excluded from the co-payment requirement. The member co-payment per prescription will be deducted from the allowed total charge to determine the amount payable for each prescription billed to the Program. The deduction will apply as follows:

- If the allowed total charge is $10.00 or less, the co-payment is $.50 per prescription
- If the allowed total charge is $10.01 through $25.00, the co-payment is $1.00 per prescription
- If the allowed total charge is $25.01 through $50.00, the co-payment is $2.00 per prescription
- If the allowed total charge is $50.01 or more, the co-payment is $3.00 per prescription

Certain individuals or covered services are exempt from the co-payment requirement, as follows:

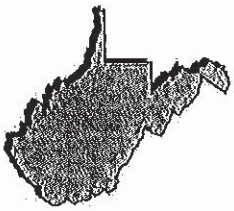
- Prescriptions for family planning services and supplies
- Prescriptions for members in long-term care facilities (i.e., nursing facilities or intermediate care facilities for mentally retarded)
- Prescriptions for pregnant women
- Prescriptions for members under 18 years of age
- 3-day emergency supplies
- Diabetic testing supplies and syringes/needles
- BMS approved home infusion supply
- POS-approved vaccines

May 15, 2010
Section 518.5.1

Introduction: Section 518.5.1, Coverage of Brand Name versus Generic Drugs

Old Policy: DAW 1 - Prescriber states that the brand name drug is "medically necessary". This information must be supplied in writing by the **physician** via written prescriptions and by the **physician** on verbal prescriptions. Approval from the help desk is required for the use of DAW 1 and appropriate justification must be provided.

New Policy: Prescriber states that the brand name drug is "medically necessary". This information must be supplied in writing by the **prescriber** via written prescriptions in their own handwriting, and must write on the prescription "Brand Medically Necessary". A check-box or other methods to indicate that the brand should be dispensed shall not be accepted. Approval from the help desk is required for the use of DAW 1 and appropriate justification must be provided.



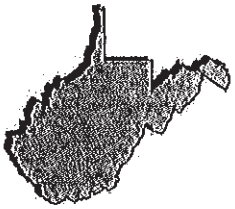
Introduction: Section 518.6, Non-covered services

Old Policy:

- Drugs supplied by drug manufacturers who have not entered into a drug rebate agreement with CMS
- Agents used for weight loss or weight gain
- Agents used for cosmetic purposes or hair growth
- Drugs identified by CMS as being less-than-effective (DESI). The DESI list and more information about DESI drugs may be found on the Centers for Medicare and Medicaid Services' (CMS) website at www.cms.hhs.gov/MedicaidDrugRebateProgram.
- Agents used for fertility
- Drugs used to treat erectile dysfunction
- Drugs that are investigational or approved drugs used for investigational purposes
- Drugs used for off-label indications which are not found in official compendia or generally accepted in peer reviewed literature
- Drugs dispensed after their expiration date
- The cost of shipping or delivering a drug
- Herbal or homeopathic products
- Drugs which require prior authorization and for which prior authorization criteria have not been met
- Drugs which are not medically necessary
- Covered outpatient drugs for which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee
- Nutritional supplements
- Free pharmaceutical samples
- Diagnostic agents
- Vacation supplies
- Allergenic extracts
- Excipients except when used in compounded prescriptions containing a covered legend drug
- Inappropriate therapeutic/ingredient duplications, early refills, and other Drug Utilization Review events.
- Vaccines via the pharmacy POS
- Factors to treat hemophilia via the pharmacy POS
  (Refer to *Chapter 519, Practitioner Services Manual,* for additional information regarding hemophilia services.)

New Policy:

- Drugs supplied by drug manufacturers who have not entered into a drug rebate agreement with CMS
- Agents used for weight loss or weight gain
- Agents used for cosmetic purposes or hair growth



- Drugs identified by CMS as being less-than-effective (DESI). The DESI list and more information about DESI drugs may be found on the Centers for Medicare and Medicaid Services' (CMS) website at www.cms.hhs.gov/MedicaidDrugRebateProgram.
- Agents used for fertility
- Drugs used to treat erectile dysfunction
- Drugs that are investigational or approved drugs used for investigational purposes
- Drugs used for off-label indications which are not found in official compendia or generally accepted in peer reviewed literature
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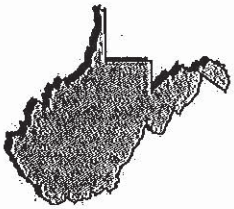
- Drugs which are not medically necessary
- Covered outpatient drugs for which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee
- Nutritional supplements
- Free pharmaceutical samples
- Diagnostic agents
- Vacation supplies
- Allergenic extracts
- Excipients except when used in compounded prescriptions containing a covered legend drug
- Vaccines via the pharmacy POS
- Factors to treat hemophilia via the pharmacy POS
  (Refer to *Chapter 519, Practitioner Services Manual,* for additional information regarding hemophilia services.)

Introduction: Section 518.7, Prior Authorization (PA)

Old Policy: Prior authorization (PA) for Medicaid-covered drugs is required for reimbursement of certain drugs to assure the appropriateness of drug therapy. Specific PA criteria are based on review of the most current clinical information, FDA approved indications, and manufacturers' recommendations. These criteria are reviewed by the Medicaid Drug Utilization Review (DUR) Board and recommended to the Bureau for Medical Services. These criteria then form the basis of acceptable drug therapy for members of Medicaid pharmacy services. Current criteria for coverage of non-preferred drugs and other drugs requiring prior authorization are found on the BMS website at www.wvdhhr.org/bms.

New Policy: Prior authorization (PA) for Medicaid-covered drugs is required for reimbursement of certain drugs to assure the appropriateness of drug therapy. Specific PA criteria are based on review of the most current clinical information, FDA approved indications, and manufacturers' recommendations. These criteria are reviewed by the Medicaid Drug Utilization Review (DUR) Board and recommended to the Bureau for Medical Services. These



criteria then form the basis of acceptable drug therapy for members of Medicaid pharmacy services. Current criteria for coverage of non-preferred drugs and other drugs requiring prior authorization are found on the BMS website at www.wvdhhr.org/bms. Drugs which require prior authorization and for which prior authorization criteria have not been met are considered non-reimbursable until appealed by the prescribing practitioner on behalf of the member.

Old Policy: N/A

New Policy: The use of pharmaceutical samples will not be considered when evaluating the members' medical condition or prior prescription history for drugs that require prior authorization.

Introduction: Section 518.7.2, Prior Authorization Appeal Process

Old Policy: Appeals will be processed within 3 business days of their receipt. Appeals shall be faxed to the Rational Drug Therapy Program (RDTP), Appeals Department at 1-800-531-7787. All appeals denied by RDTP will be sent to BMS for physician review.
If the outcome of the physician review upholds the denial, the Medicaid member is notified of this denial and of their right to request a fair hearing.

New Policy: Appeals will be processed within 3 business days of their receipt. Appeals shall be faxed to the Rational Drug Therapy Program (RDTP), Appeals Department at 1-800-531-7787. All appeals denied by RDTP will be sent to BMS for physician review. Any denial resulting from physician review is final. The Medicaid member is notified of this denial and of their right to request a fair hearing.

Introduction: Section 518.8.3, Reporting of Cash Payments

Old Policy: N/A

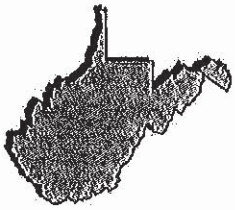
New Policy: Pharmacies are encouraged to report to BMS when a member pays cash for prescriptions that would otherwise be covered by Medicaid or considered for reimbursement upon a call to the RDTP, or when the pharmacy provider suspects overutilization by the member. A form used for this reporting can be found on the BMS website, www.wvdhhr.org/bms. The form should be faxed to BMS at 304-558-1542. Information collected through this process may be used for member lock-in consideration and continued eligibility.

Introduction: Section 518.8.4, Member Counseling

Old Policy: N/A

New Policy: Renumber entire section due to addition of section 518.8.3, Reporting of Cash Payments

Introduction: Section 518.9.1, Tamper-Resistant Prescription Pad Requirement



Old Policy: As of October 1, 2008, all prescriptions written for West Virginia Medicaid members must be on tamper-resistant pads/paper which meets all 3 characteristics set forth in the guidelines from the Centers for Medicare and Medicaid Services (CMS).

New Policy: All prescriptions written for West Virginia Medicaid members must be on tamper-resistant pads/paper which meet all 3 characteristics set forth in the guidelines from the Centers for Medicare and Medicaid Services (CMS). The three characteristics to meet the tamper-resistant prescription requirement:

1. Prevent unauthorized copying of a completed or blank prescription form;
2. Prevent the erasure or modification of information written on the prescription, and;
3. Prevent the use of counterfeit prescription forms.

Old Policy: N/A

New Policy: Computer-generated prescriptions, EMR, or ePrescribing generated prescriptions may be printed on plain paper and be fully compliant with all three categories of tamper resistance, provided they contain the features listed in the table below. Prescribers are urged to contact their software companies to ensure that computer generated prescriptions have all requirements necessary for tamper resistance.

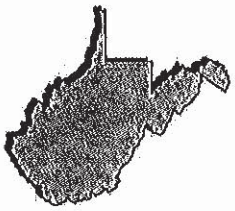
Computer-generated prescriptions must contain the following:

1. One or more industry-recognized features designed to prevent unauthorized copying of a completed or blank prescription form.

Feature	Description
"Void" pantograph	The word "Void" appears when document is photocopied. Pharmacy will need to record on document if received via fax. *This requires the purchase of special paper.*
OR	
Micro print signature line	Very small font which is legible (readable) when viewed at 5x magnification or greater, and illegible when copied.

2. One or more industry-recognized features designed to prevent the erasure or modification of information written on the prescription by the prescriber.

Feature	Description



UNIFORM NON-WHITE BACKGROUND COLOR – *PREFERABLY GREEN* OR "Toner-lock" paper for laser printed prescriptions, or plain bond paper for inkjet printed prescriptions	Background is one color (*preferably green*), inhibits a forger from physically erasing written or printed information on a prescription form. If someone tries to erase copy – the consistent background color will look altered. Toner-lock paper is special printer paper that establishes a strong bond between laser-printed text and paper, making erasure obvious. Note – this is NOT necessary for inkjet printers – as the ink from the inkjet printers is absorbed into normal "bond" paper.
QUANTITY WRITTEN AND QUANTITY WITH BORDER CHARACTERISTICS FOR COMPUTER GENERATED PRINTED PRESCRIPTIONS	Quantity written and Quantity surrounded by special characters such as asterisks to prevent modification, e.g. *QTY Fifty ***50****.*
Refill written and refill with border characteristic for computer generated printed prescriptions	Refills written and Refill surrounded by special characters such as asterisks to prevent modification, e.g. *Five refills ****5 refills*****.*

3. One or more industry-recognized features designed to prevent the use of counterfeit prescription forms.

Feature	Description
SECURITY FEATURES AND DESCRIPTIONS LISTED ON THE PRESCRIPTION	A complete list of the security features of the prescription for compliance purposes. This will assist the pharmacist and auditors on what security features are included on the paper.

Prescriptions for West Virginia Medicaid members written by prescribers that reside outside of West Virginia may meet the federal tamper-resistant prescription requirement if the prescription addresses the three distinct characteristics outlined above, and may contain the same or other features than those adopted by BMS.

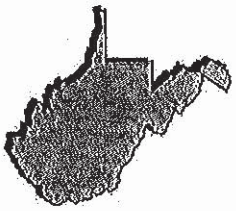
Introduction: Section 518.9.4, Shipping/Receiving

Old Policy: N/A

New Policy: Drugs reimbursed by West Virginia Medicaid that are mailed or shipped to members require a signature of the individual receiving delivery of the medication. A log of these signatures must be maintained by the pharmacy for a period of 5 years for auditing purposes. Providers shall take the necessary steps to prevent loss of medications in the shipping process, as Medicaid will not reimburse for medications not received by the member.

Introduction: Section 518.10.10, Compounded Prescription

Old Policy: N/A



New Policy: Products such as suppository molds and other items identified as supplies included in a compounded prescription will not be reimbursed by West Virginia Medicaid.

Introduction: Section 518.10.11, Abuse and Inappropriate Utilization

Old Policy: N/A

New Policy: Automatic filling of prescriptions or automatic shipping of medications to the member is prohibited unless members request the filling or shipping of these medications each time.

Introduction: Section 518.11.3, Co-payments

Old Policy: N/A

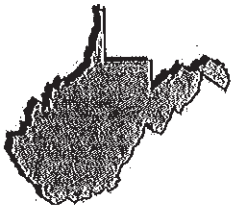
New Policy: Providers are prohibited from advertising or soliciting business by waiving members' co-payment responsibility.

Introduction: Section 518.11.4, Third-Party Liability (TPL) or Coordination of Benefits (COB)

Old Policy: N/A

New Policy: Medicaid covered drugs which currently require a prior authorization (PA) from BMS will continue to require a PA if a primary insurer approves that service, and Medicaid reimburses any part of the cost.

Medicaid co-payment is still required, if applicable, for claims considered by third party payers and reimbursed by BMS.



CHAPTER 518—COVERED SERVICES, LIMITATIONS AND EXCLUSIONS FOR PHARMACY SERVICES

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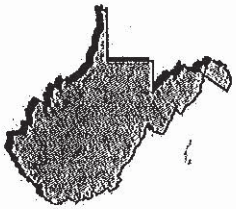
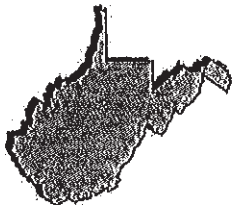
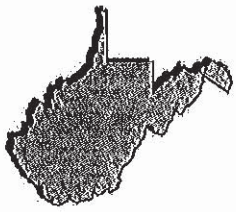






CHAPTER 518–COVERED SERVICES, LIMITATIONS, AND EXCLUSIONS FOR PHARMACY SERVICES

INTRODUCTION

The West Virginia Medicaid Program is administered pursuant to Title XIX of the Social Security Act and Chapter 9 of West Virginia code. The Bureau for Medical Services (BMS) in the West Virginia Department of Health and Human Resources (DHHR) is the single State agency responsible for administering the Program. This program, therefore, must also function within federally defined parameters. Any service, procedure, item, or situation not discussed in the manual must be presumed non-covered.

Medicaid offers a comprehensive scope of medically necessary medical and mental health services. All covered and authorized services must be provided by enrolled providers practicing within the scope of their license, utilizing professionally accepted standards of care, and in accordance with all State and Federal requirements. Enrolled providers are subject to review of services provided to Medicaid members by BMS whether or not the services require prior authorization. All providers of services must maintain current, accurate, legible, and complete documentation to justify medical necessity of services provided to each Medicaid member and made available to BMS or its designee upon request.

The Omnibus Budget Reconciliation Act of 1990 (OBRA '90) mandated major changes in coverage and reimbursement for Medicaid-covered outpatient drugs. West Virginia Medicaid reimbursement is limited to drugs whose manufacturers have entered into and have in effect a rebate agreement with the Secretary, Department of Health and Human Services.

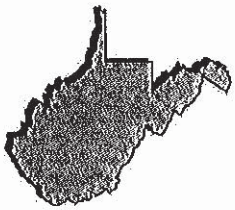
West Virginia Medicaid offers a comprehensive scope of Pharmacy services to Medicaid members as an optional program, subject to medical necessity, appropriateness criteria, and prior authorization requirements. The West Virginia Medicaid Pharmacy Program is funded by both West Virginia State and Federal funds. All covered drugs, whether legend or non-legend, prescribed by a physician or other authorized practitioner, are addressed within the program. Applicable state and federal laws governing dispensing of drugs and biologicals must be followed.

This manual identifies and explains covered services, their limits, eligibility requirements, and polices that are required to be followed by providers of outpatient prescription drugs in order to obtain reimbursement from federal and state funds.

518.1 DEFINITIONS

Definitions governing the provision of all West Virginia Medicaid services will apply pursuant to the Provider Manual, *Chapter 200, Definitions*. In addition, the following definitions apply and/or relate to Pharmacy Services.

340b Program: a federal program administered by Health Resources and Services Administration (HRSA) whereby certain designated facilities purchase prescription medications at



deep discounts, allowing these facilities to offer some medications to their patients at greatly reduced prices.

Dispensed As Written (DAW): a numerical value used by providers to explain the dispensing of a brand-name product instead of a generic one.

Drug Efficacy Study and Implementation Program (DESI): Drugs determined by the Food and Drug Administration as lacking substantial evidence of effectiveness.

End Stage Renal Disease (ESRD): the stage of renal impairment that appears irreversible and permanent, and requires a regular course of dialysis or kidney transplantation to maintain life.

First Data Bank (FDB): a database company for drug pricing and drug utilization review (DUR) edits.

Federal Drug Rebates: a payment made by pharmaceutical manufacturers to the states for drugs dispensed to Medicaid members.

Federal Upper Limit (FUL): maximum allowable cost (MAC) established by the Centers for Medicare and Medicaid Services for certain prescribed drugs.

Home IV: Intravenous medications administered in the home, provided by specialized pharmacies, which require the services of a nurse or trained caregiver.

Lock-In: Program administered through the retrospective drug utilization review process to limit members to the use of one pharmacy provider.

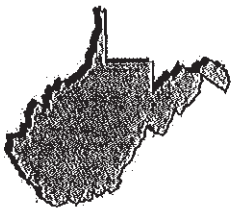
Mountain Health Choices: The name of West Virginia Medicaid's program where members have a choice of benefit packages. This program promotes member choice, member responsibility and health improvement. This program was developed as a result of the Deficit Reduction Act 2005 and allows for the tailoring of benefit packages to meet the needs of certain populations. This program is a part of the redesign of Medicaid to promote wellness and to prevent and/or manage the progression of chronic diseases by encouraging healthier lifestyles for Medicaid members.

Multi-Source Drugs: Drugs that are marketed or sold by two or more manufacturers or labelers.

National Provider Identifier (NPI): A standard unique healthcare provider identification number mandated by the Health Insurance Portability and Accountability Act (HIPAA) of 1996.

Orange Book: Publication by the Food and Drug Administration which establishes therapeutic equivalency ratings for drugs.

Pharmaceutical and Therapeutics Committee (P & T Committee): an advisory body that recommends drugs to Medicaid for inclusion or exclusion relating to the Preferred Drug List.



Rational Drug Therapy Program (RDTP): agency designated by the Bureau for Medical Services for prior authorizing prescription drugs.

Retrospective Drug Utilization Review (RETRO DUR): review of member drug history records against predetermined standards to improve quality of healthcare and to educate physicians and pharmacists on common drug therapy issues.

Single-Source Drug: A drug that is available from only one manufacturer.

State MAC (SMAC): Maximum allowable cost for drug products or supplies established by the state Medicaid agency.

Supplemental Drug Rebate: A payment from a pharmaceutical manufacturer, negotiated by the state, in addition to the federal rebate.

518.2 PROVIDER PARTICIPATION REQUIREMENTS

In order to participate in the West Virginia Medicaid Program and receive payment from BMS, pharmacy providers must:

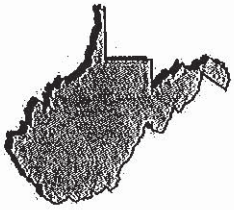
- Meet and maintain all applicable licensing, accreditation, and certification requirements;
- Meet and maintain all BMS enrollment requirements;
- Have a valid trading partner agreement on file that is signed by the provider and BMS upon application for enrollment into the West Virginia Medicaid Program; and
- Meet and maintain the standards established by the Secretary of the U. S. Department of Health and Human Services and all applicable State and Federal Laws governing the provision of their services

Provider enrollment requirements in general are detailed in *Common Chapter 300, Provider Participation Requirements*.

518.2.1 Certification

A pharmacy eligible to participate in Medicaid must hold a current permit from the West Virginia State Board of Pharmacy and adhere to all state and federal regulations. Pharmacies located out-of-state and filling prescriptions for West Virginia Medicaid members must be licensed by the state in which they are located. Pharmacies located out-of-state and shipping or mailing prescriptions into West Virginia must be licensed by the state in which they are located **and** hold a permit from the West Virginia Board of Pharmacy. Pharmacies are required to file a copy of their current permits with BMS annually. Failure to do so may result in the withholding of payments and/or enrollment termination.

When the current license and/or permit is not on file, the provider shall not be reimbursed by Medicaid until such time the BMS' Provider Enrollment Unit receives a copy of the current license and/or permit.



Pharmacies completing West Virginia Medicaid enrollment applications must indicate on the form the pharmacy designation, i.e. retail; institutional; hospital outpatient - open to the public; hospital outpatient - closed to the public; mail order; in-home parenteral therapy (home infusion pharmacy).

518.2.2 Dispensing Physicians

Reimbursement for self-administered prescription drugs is limited to licensed and participating pharmacies. BMS does not enroll dispensing physicians for reimbursement as a pharmacy provider type.

518.2.3 In-Home Parenteral Therapy Pharmacy Requirements

Pharmacies requesting reimbursement for in-home parenteral therapy compounding services must meet all state and federal licensure and certification requirements. See Appendix 1 for information pertaining to this program.

518.2.4 Pharmacies Participating in the 340B Program

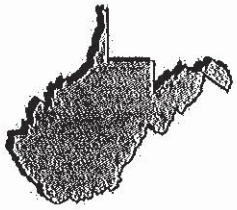
Pharmacies participating in the program established by Section 340B of the Public Health Services Act of 1992 must notify BMS of their participation in the 340B program by completing the required certification form and supplying 3 recent comprehensive invoices annually. This form is available on the BMS website, www.dhhr.wv.gov/bms. Drugs with discounts generated from participation in this program are not eligible for federal drug rebates and drug claims from these pharmacies must be exempted from drug rebate invoices that Medicaid sends to the drug manufacturers. Pharmacies participating in this program must submit their actual acquisition costs when billing the Medicaid program. Submission of additional invoices may be required for audit purposes.

518.2.5 Pharmacy Change of Ownership

Change of ownership policy is addressed in *Common Chapter 300, Provider Participation Requirements,* and additional information may be found on the fiscal agent's website, see *Common Chapter 100, General Information* for information on the fiscal agent. Although a pharmacy provider's NPI may be legally transferred from one owner to the next, BMS recommends that a new owner obtain a new NPI to facilitate a seamless transition.

518.3 MEMBER ELIGIBILITY

Medicaid covers pharmacy services for all individuals who meet Medicaid eligibility guidelines. Drug coverage may also be available to other eligibility groups as described below. Refer to Common *Chapter 400, Member Eligibility*, for more information regarding eligibility requirements.



518.3.1 Medicaid Members Eligible for Pharmacy Services

Medicaid members eligible for pharmacy services have access to legend and over-the-counter drugs as defined in the State Plan filed with CMS. An eligibility card is issued to these individuals. This card must be presented to assure eligibility of the member. Any person requesting services without a Medicaid identification card shall be advised that he/she is responsible for furnishing his or her identification card to the provider prior to services being rendered. If the card is unavailable, eligibility may be verified through the Medicaid Voice Response System at 1-888-483-0793 or by sending an electronic NCPDP E-1 transaction through the pharmacy Point-of-Sale (POS) billing system.

518.3.1.1 Mountain Health Choices (MHC)

Pharmacy services are covered for all benefit plans, either through Medicaid fee-for-service or Medicaid Managed Care Organizations (MCO). Members enrolled in the Medicaid MCOs must follow the rules and policies of their respective MCO. The managed care plans are required to provide pharmacy benefits consistent with the Medicaid Preferred Drug List (PDL), both in the selection of preferred/non-preferred drugs and criteria for coverage. The plans are responsible for policies for drugs not included in the Medicaid PDL. There is no copayment requirement for pharmacy services covered through the managed care organization plans.

Mountain Health Choices members who choose the Enhanced Benefit Package will not have a limit on the number of prescriptions obtained per calendar month. All rules and edits pertaining to prior authorization and the Preferred Drug List apply to the pharmacy benefit for this program.

Members in the MHC Adult Basic Benefit Package or Plan will be limited to 4 prescriptions per calendar month period. Children under the age of 21 years are not limited in the number of prescriptions they may receive.

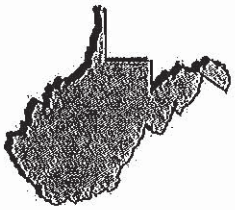
The following therapeutic classes will not count toward the 4-prescription limit for adults with the Basic Benefit Package, which will be indicated by "BA" on their Medicaid Identification Card:

- Diabetes supplies and all insulins
- Atypical antipsychotics
- Antidepressants (all therapeutic classes)
- Drugs used for the treatment of HIV/AIDS
- Birth Control

When the 4-prescription limit is exceeded, a call may be made to the Rational Drug Therapy Program Help Desk (1-800-847-3859) for a medication review. These requests will be considered on a case-by-case basis after review of the member's medication profile.

518.3.1.2 Dual Eligible Members

Members eligible for both Medicare and Medicaid are called dual eligible members. Medicare is the primary payer for dual eligible members. Medicare, a federal health insurance program for the



aged and disabled, covers certain hospital (Part A), outpatient medical benefits and physicians' services (Part B) and prescription benefits (Part D) for participating individuals. Some dual eligible members may participate in Medicare Managed Care plans (Advantage or Part C plans) which include pharmacy services.

Dual eligible members have prescription drug coverage through Medicare Part D, or Part C if enrolled in a Medicare Managed Care plan. Medicaid is not responsible for covering pharmacy benefits for these individuals, except for drugs in the Medicare excluded categories. Medicaid does not reimburse for Medicare Part D or Part C co-payments. Medicaid does not pay as the secondary payer on Medicare Part D or Part C covered drugs.

518.3.1.3 Medicaid Members Enrolled in Medicaid Managed Care Organization Plans

Effective April 1, 2013, Medicaid members enrolled in the Medicaid managed care organization plans receive pharmacy services from the managed care plan. These members will have two identification cards – the managed care identification card for managed care covered services, and the Medicaid identification card for carved-out services. The managed care plans are required to provide pharmacy benefits consistent with the Medicaid Preferred Drug List (PDL), both in the selection of preferred/non-preferred drugs and criteria for coverage. The plans are responsible for policies for drugs not included in the Medicaid PDL. There is no copayment requirement for pharmacy services covered through the managed care organization plans.

518.3.1.4 Medicaid Members with End Stage Renal Disease (ESRD)

Members diagnosed with End Stage Renal Disease (ESRD) may require additional vitamin/mineral supplements not usually covered by the pharmacy program. In order to accommodate these members, a letter signed and dated by the treating physician is required to verify the diagnosis of ESRD and must include the date dialysis began. This letter shall be directed to:

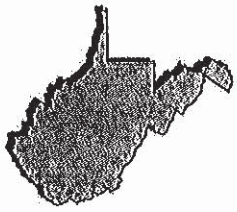
Bureau for Medical Services
Member Eligibility
350 Capitol Street, Room 251
Charleston, West Virginia 25301-2675

Refer to the BMS website, www.dhhr.wv.gov/bms, for a list of additional vitamin/mineral supplements covered for ESRD patients.

Once a member receives a kidney transplant, the member is no longer considered as having ESRD, and no longer qualifies for these additional supplements.

518.3.1.5 Qualified Medicare Beneficiary (QMB)

QMB members do not receive pharmacy coverage benefits through the Medicaid program. Medicaid does provide coverage of deductibles and co-insurance amounts for Medicare Part B covered drugs and other Medicare covered services with the exception of those covered under



Part D. These members receive a medical identification card, but coverage, as noted on the card, is limited to Medicare co-insurance and deductibles only.

518.3.1.6 Children in Foster and Adoptive Placement

Children in state custody and entered into foster, residential or adoptive placements may be Medicaid eligible. They receive a medical identification card. The eligibility number begins with "039". Drug claims may be submitted online through the pharmacy Point-of-Sale system or on the approved paper claim form. Medicaid coverage rules apply.

518.3.1.7 Incarcerated Members

Medicaid members who are incarcerated are restricted from coverage of pharmacy benefits until they are released from the correctional system. Claims submitted with dates of service during a period of incarceration will deny. If the member has been released before the restriction is updated, positive identification is required. A call to the Rational Drug Therapy Program help desk must be made to request an override.

518.3.2 Non-Medicaid Individuals Eligible for Pharmacy Services

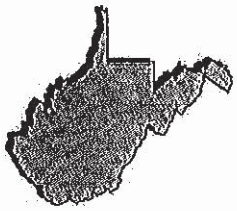
Individuals who do not qualify for the Medicaid Program may have pharmacy coverage under other federal or state-funded programs. These individuals do not receive medical identification cards, but may receive a letter or other form of eligibility authorization.

518.3.2.1 AIDS Drug Assistance Program (ADAP) or Ryan White Program

The AIDS Drug Assistance Program (ADAP) is funded under Part B of the Ryan White HIV/AIDS Treatment Extension Act in West Virginia, and claims are processed through the BMS claims processing system. The program assists eligible persons with HIV infection in obtaining drugs covered by the ADAP formulary. To be eligible for the ADAP, a person must meet the following:

- be an HIV infected resident of West Virginia;
- with a family income less than 400% of the federal poverty level (FPL), and;
- not be eligible for other forms of reimbursement such as Medicaid or full insurance coverage, and;
- have completed the ADAP and Medicaid application at their Department of Health and Human Resources county office.

ADAP participants do not receive a medical identification card, but do receive a letter that verifies eligibility and includes their identification number with a prefix of "69". All claims except those for vaccines may be submitted online through the pharmacy Point-of-Sale system or by using the approved paper claim form. Covered drugs are limited to a 30-day supply. Claims must be submitted within 60 days from the date of service. Formulary drugs must be dispensed in generic form if available. Brand-name drugs that have generic equivalents require prior authorization. There are no co-payment requirements for this program. ADAP may cover co-pays for eligible



residents who are covered by insurance or Medicare Part D. Claims for vaccines must be submitted on the approved pharmacy paper claim form and mailed to ATF, P.O. Box 6360, Wheeling, West Virginia 26003. Certain drugs may require prior authorization and emergency supplies of these drug may not be dispensed. Please refer to the BMS website, www.dhhr.wv.gov/bms, for the ADAP formulary. More information regarding ADAP can be found at the Bureau for Public Health's website at www.dhhr.wv.gov/bph or by calling the AIDS Task Force at 304-232-6822.

518.3.2.2 Children with Special Health Care Needs (CSHCN)

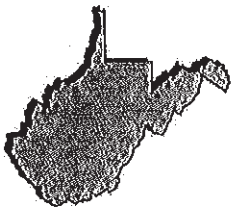
Pharmacy services are available for certain children under 21 years of age receiving medical care under the Children with Special Health Care Needs Program. Services are not limited to children of families receiving public assistance grants. Coverage is limited to the formulary established under the program's policy administration. These members do not receive a medical identification card. An identification number with a prefix of "99" is assigned. Claims may be submitted online using the pharmacy Point-of-Sale system or by using the approved paper claim form. Policy questions regarding this program shall be directed to the CSHCN unit at 1-800-642-9704.

518.3.2.3 Individuals Eligible for Immunosuppressant or Antipsychotic Medications

Certain individuals who are not eligible for Medicaid services may be eligible for coverage of immunosuppressant or antipsychotic medications using all state funds. Eligibility for these services is determined at the individual's local county Department of Health and Human Resources office. A six-month eligibility period is established and it is the member's responsibility to reapply for these services. No identification card will be issued. Medicaid receives a written communication from the Division of Family Assistance defining the drug(s) that will be covered for a particular individual. A letter including the services to be covered and the individual's identification number, prefix "39", will be forwarded to the pharmacy provider and the individual. Claims for these services may be submitted online through the pharmacy Point-of-Sale system or on the approved paper claim form. Medicaid coverage rules apply to these claims. (Please note: Some individuals may also be eligible for coverage of immunosuppressant drugs by Medicare Part B. Medicare must be billed first. This state program will pay co-insurance and deductible amounts on Medicare Part B crossover claims only. All other Medicare eligible individuals must pursue coverage of immunosuppressant drugs and antipsychotic medications through their Part D plans.)

518.3.2.4 Tiger Morton Fund

Certain individuals who are not eligible for Medicaid services may be eligible for coverage of selected medications using state funds through the Tiger Morton Fund. These individuals will not have an identification card and coverage will be communicated to the pharmacy provider on a case-by-case basis. Claims for these services must be submitted using the approved paper claim form.



518.3.2.5 Emergency Medical Assistance or Other State Programs

Certain individuals who are not eligible for Medicaid services may be eligible for emergency medical assistance or other pharmacy services using state funds. These individuals will present a letter to the pharmacy provider listing particular drug(s) to be covered. A prefix of "15" or "38" along with the respective county code will be noted on the authorization letter to identify the eligible individual. Claims for these services must be submitted using the approved paper claim form with a copy of the eligibility letter attached.

518.3.2.6 Juvenile Services

Incarcerated minors have pharmacy services coverage through Juvenile Services. A letter of eligibility will be presented to the pharmacy which includes the individual's identification number beginning with prefix "17". Claims for these services may be submitted through the online Point-of-Sale system or by using the approved paper claim form. Medicaid coverage rules apply.

518.3.2.7 Adult Family Care and Protective Services

Children and adults receiving Protective Services as a result of abuse and/or neglect or other individuals in need of assistance may be provided limited eligibility for state-funded services. A Special Medical Authorization Letter is issued as needed by the field staff. This letter specifies the individual, the medical provider authorized to provide services, the services authorized and the coverage period. An identification number for use in billing the services is also provided. Pharmacy claims for these individuals may be submitted online or on the approved paper claim form. Medicaid coverage rules apply.

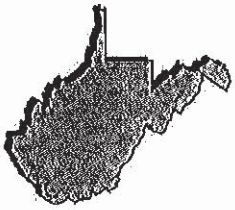
518.3.3 Denials Due to Eligibility

If an online denial occurs due to eligibility problems, and the member presents a valid Medicaid card or other proof of eligibility, take the following steps:

- Dispense the prescription for valid and covered services.
- Obtain a copy of a valid Medicaid card or other proof of eligibility.
- Choose one of two options:
  (1) Resubmit the claim online at a later date, using the original date of service; or
  (2) Submit the claim on the approved paper claim form and attach a copy of the valid Medicaid card or other proof of eligibility. Mail these claims to:

Molina Corporation
Pharmacy Claims
Post Office Box 3765
Charleston, West Virginia 25327-3709

518.4 DESCRIPTION OF COVERED SERVICES



Except for certain limitations and exclusions, BMS will reimburse for the following:

- Outpatient legend drugs
- Specific over-the-counter drugs
- Compounded prescriptions
- Drugs that require prior authorization, when approved by BMS
- Family planning supplies, including certain over-the-counter supplies
- Certain diabetic supplies
- Influenza, pneumonia, Hepatitis A, Hepatitis B, tetanus, tetanus-diphtheria (Td), and tetanus-diphtheria-and-pertussis (Tdap) vaccines for adults nineteen (19) years of age and older administered by a pharmacist. (Members up to nineteen (19) years of age have access to vaccines via the Vaccines for Children Program.)
- Herpes zoster vaccine for adults fifty (60) years of age and older administered by a pharmacist

Drugs covered under the Medicaid outpatient pharmacy program are those that have been approved for safety and effectiveness under the Federal Food, Drug, and Cosmetic Act, when used for medically accepted indications.

Medically accepted indication means any use that is supported by one or more of the following official compendia:

- The American Hospital Formulary Service Drug Information;
- The United States Pharmacopoeia Drug Information or it's approved replacement;
- The DRUGDEX Information System

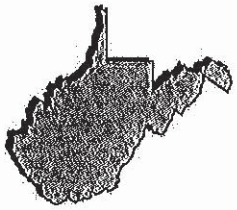
All covered drugs, whether legend or over-the-counter, must be prescribed by a practitioner qualified under state law within the scope of his/her license and in accordance with all state and federal requirements.

The West Virginia Medicaid program follows the Office of Inspector General's (OIG) guidelines in excluding prescribers from participating with West Virginia Medicaid who are barred from participating in federal health programs. Reimbursement of prescriptions issued by these excluded prescribers is denied.

West Virginia Medicaid also excludes from reimbursement any prescription ordered by:

- prescribers not enrolled as providers with West Virginia Medicaid, nor enrolled with a participating West Virginia Medicaid MCO; or,
- prescribers not employed by or contracted with a facility or group practice that is enrolled as a Medicaid provider.

518.4.1 Preferred Drug List (PDL)



The West Virginia Preferred Drug List (PDL) is a list of medications recommended to BMS by the West Virginia Medicaid Pharmaceutical and Therapeutics (P & T) Committee and approved by the Secretary of the Department of Health and Human Resources. The P & T Committee is composed of actively practicing physicians, pharmacists, a nurse practitioner, and a physician's assistant. Meetings of the P & T Committee are held a minimum of 3 times per year and are open to the public.

The drugs that are designated as "preferred" have been selected for their clinical significance and overall cost efficiencies. All Medicaid-covered drugs noted as "non-preferred" continue to be available through the prior authorization process.

The PDL only addresses certain drug classes. Some classes of drugs will not be reviewed for preferential agents because there are no or limited cost savings associated with these classes. Drugs that meet the criteria for coverage and have no preferred status are considered covered drugs.

The PDL is updated at minimum annually and as needed. Newly released drugs in classes which are included in the PDL will be considered non-preferred until the drug itself has been reviewed.

The complete PDL, criteria for coverage of non-preferred drugs, minutes of P & T Committee meetings, and other pertinent information may be accessed on the Bureau for Medical Services' website at www.dhhr.wv.gov/bms.

518.4.2 Over-the-Counter Drugs

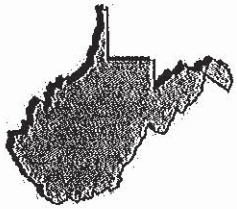
Certain over-the-counter (OTC) drugs are reimbursed for eligible Medicaid members when prescribed by a qualified practitioner. OTC drugs must be manufactured by companies participating in the federal drug rebate program and are limited to generic products when available. Any OTC drug available in packaging designed for OTC sale to the public must be dispensed in the original packaging. These products must be billed at the shelf price of the pharmacy. If a pharmacy is not accessible to, or frequented by the general public, or if the OTC drug is not on display for sale to the general public, then the product will be reimbursed at the same rate as legend drugs.

Over-the-counter drugs are not covered for residents of skilled nursing homes or ICF/MR facilities except for insulin. These drugs are included in the rates paid to these facilities.

Coverage of over-the-counter drugs for members enrolled in Medicaid managed care plans will follow each plan's coverage policies, unless the OTC drug is included in the Medicaid Preferred Drug List.

For a current list of covered OTC drugs, see the BMS website, www.dhhr.wv.gov/bms.

518.4.3 Diabetic Testing Supplies and Syringes/Needles



Certain supplies used by eligible diabetic Medicaid members are covered through the outpatient pharmacy program. A prescription issued by a licensed prescriber within the scope of his/her practice is required for coverage of these items. Verbal prescriptions that meet federal and state regulations are permitted. Prescriptions must define the number of tests to be performed per day. Co-payments are not required on prescriptions for these items. Covered supplies include:

- Blood glucose testing strips
- Urine testing tablets and strips
- Lancets
- Insulin syringe and needle combinations for the administration of insulin
- Needles for insulin pen systems

Needle and syringe combinations and disposable pen needles for insulin pens are reimbursed through the pharmacy POS program only for the administration of insulin.

Diabetic testing supplies and syringes/needles are not covered pharmacy services for members residing in skilled nursing or ICF/MR facilities.

The following limits apply for those members who have insulin dependent diabetes:

Urine and blood glucose testing tablets and strips	150 per 30 days
Lancets	200 per 30 days
Insulin syringe and needle combinations	100 per 30 days
Pen needles	100 per 30 days

The following limits apply for those members who have non-insulin dependent diabetes:

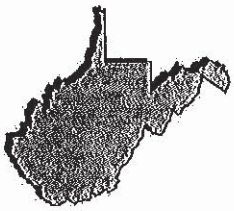
Urine and blood glucose testing tablets and strips	100 per 30 days
Lancets	100 per 30 days

Prescriptions for quantities greater than the above referenced amounts require prior authorization through the Rational Drug Therapy Program (RDTP). The prior authorization criteria shall follow the Medicare regional carrier guidelines in effect at the time. Pharmacies should access the CMS website for the carrier servicing West Virginia on the date of service.

Coverage of blood glucose testing monitors, other types of diabetic testing supplies, insulin pumps and supplies, and/or syringes and needles for other purposes may be available to members through the Durable Medical Equipment (DME) benefit. See *Chapter 506, DME/Medical Supplies Manual* for more detailed information.

Medicaid members enrolled in Medicaid managed care plans will have coverage of diabetic supplies through their managed care plan.

Dual eligible members have coverage of diabetic supplies through Medicare. Medicaid will not cover these supplies for dual eligible individuals, except for amounts that may be reimbursed on Medicare Part B crossover.



518.4.4 Medical Supplies

Pharmacies may also be enrolled with West Virginia Medicaid to provide other DME supplies. See *Chapter 506, DME/Medical Supplies Manual* for more information regarding these services.

518.4.5 Home Infusion Therapy Pharmacy Services

Drugs used for home infusion therapy services are covered under the Medicaid Pharmacy Program. These drugs require prior authorization and must be justified by the ordering practitioner, including why oral therapy is unsuitable for the patient. **Members enrolled in Medicaid managed care plans have coverage of home infusion pharmacy services through their managed care plan. Dual eligible members have coverage of home infusion pharmacy services through their Medicare Part D plans.**

Total Parenteral Nutrition (TPN) services are not pharmacy point-of-sale (POS) covered services. Please see *Chapter 506, DME/Medical Supplies* for information regarding these services.

See *Appendix 1* for detailed information regarding home infusion pharmacy services.

518.4.6 Tobacco Cessation Program

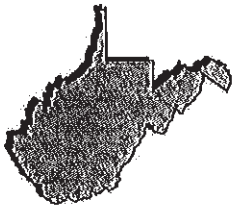
West Virginia Medicaid makes tobacco cessation services available to members enrolled in the fee-for-service Medicaid Program (except for those enrolled in the Basic Adult Package) and those enrolled with a participating West Virginia Medicaid MCO.
Members enrolled in the fee-for-service Medicaid Program are required to enroll through the WV Tobacco Cessation Quitline Line at 1-877-966-8784. Participants are screened for their readiness to quit the use of tobacco. Written materials and phone coaching are available through the Quitline program. Additional information regarding the WV Tobacco Cessation Quitline can be accessed through at www.ynotquit.com.

Members enrolled in Medicaid managed care plans have tobacco cessation services provided by their plans, including drug treatments.

In order for members to have access to drugs and other tobacco cessation services, the member is required to see their primary care provider. All tobacco cessation products must be prescribed by a licensed practitioner within the scope of his/her license under West Virginia law. Prior authorization is required for coverage of tobacco cessation medications and is coordinated through the tobacco Quitline.

Members are limited to one 12-week treatment period per year. Pregnant females are eligible for additional course(s) of treatment, if appropriate.

Additional information regarding the tobacco cessation program can be accessed through http://www.wvdtp.com/ or www.wvquitline.com or by calling the Quitline at 1-877-966-8784 for assistance.



If a Medicaid member is enrolled in a MCO, please contact the member's MCO for service limitations and all other requirements related to this benefit.

Drugs to treat tobacco cessation are limited to members who register with the tobacco Quitline program. Dual eligible members have coverage of legend drugs through their Medicare Part D plans and coverage of the over-the-counter drugs and Quitline services through Medicaid. Medicaid does not cover tobacco cessation programs for those enrolled in the Basic Adult Benefit Package.

Drug products are limited to a maximum of:

- Nicotine gum – 24 pieces per day
- Nicotine patches – 1 patch per day
- Nicotine lozenges – 20 lozenges per day
- Nicotine inhalers – 168 inhalers per 30 days
- Nicotine nasal spray – 4 spray bottles per 30 days (This therapy is reserved for those who have failed other forms of nicotine replacement therapy.)
- Bupropion – 300 mg. daily

518.4.7 Buprenorphine-Naloxone(Suboxone®)/Buprenorphine(Subutex®) Coverage

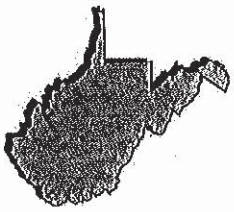
Buprenorphine-Naloxone and Buprenorphine are covered through the Pharmacy program, and must be written by a prescriber enrolled with WV Medicaid. Buprenorphine-Naloxone and Buprenorphine is obtained only through a prior authorization. All members treated with Buprenorphine-Naloxone or Buprenorphine are required to participate in the pharmacy lock-in program. Other limitations may apply.

See the BMS website at http://www.dhhr.wv.gov/bms for additional information and detailed coverage criteria.

518.5 SERVICE LIMITATIONS

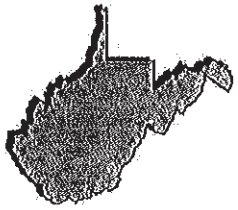
Service limitations governing the provision of all West Virginia Medicaid pharmacy services will apply for eligible members as follows:

- Covered drugs are limited to their Food and Drug Administration (FDA) approved or medically accepted indications and dosing limits.
- When appropriate, PDL-preferred drugs must be tried before non-preferred drugs are approved.
- All covered outpatient drugs must be prescribed by a practitioner qualified under state law within the scope of his/her license and in accordance with all state and federal requirements.
- Prescriptions may be written or verbal, and must meet all the federal and state guidelines for legal prescriptions.
- Covered outpatient drugs are reimbursed up to a 34-day supply and may be refilled according to state and federal laws. Certain exceptions apply, for example, most oral systemic



antibiotics are covered for a 14-day supply with one refill. Exceptions to this policy may apply if the only available package size of the product is one that exceeds the 34-day supply limit.

- Only those legend drugs for the symptomatic relief of cough and colds that appear on the approved BMS list are covered for this therapeutic indication. Certain over-the-counter cough and cold medications are also covered. The list is available on the BMS website, www.dhhr.wv.gov/bms. Dual eligible members have coverage of cough and cold medications through Medicaid if these products are not covered by their Medicare Part D or Part C plans.
- Barbiturates are not covered except for phenobarbital and mephobarbital, unless the barbiturate is in combination with another active ingredient. Dual eligible members have coverage of phenobarbital; mephobarbital; and butalbital, acetaminophen, and caffeine combination products through Medicaid if these products are not covered by their Medicare Part D plans. (Note: Combination products of butalbital, acetaminophen, caffeine and *codeine* will be covered by Medicare Part D or Part C plans for dual eligible members.)
- Vitamins and minerals are limited to:
    - Legend vitamins A, D, K, folic acid, B-12 for injection, and niacin
    - Minerals including calcium, iron, magnesium, fluoride and additional mineral requirements for the treatment of End Stage Renal Disease
    - Multivitamins for children through age 20
    - Prenatal vitamins for women through age 45
    - Legend fluoride preparations
- Drugs to treat tobacco cessation are limited to members who register with the YNOTQUIT Program. Dual eligible members have coverage of over-the-counter tobacco cessation products through Medicaid if these products are not covered by their Medicare Part D plans; legend tobacco cessation agents are not covered for dual eligible members, as these are covered by the Medicare Part D plans.
- Other drugs may be limited in quantity, duration, or based on gender. See the BMS website, www.dhhr.wv.gov/bms, for information regarding these drug products and their limitations. Exceptions are considered on a case-by-case basis through the Rational Drug Therapy Program.
- Additional drugs may have quantity limits to assure accurate billing of units.
- Limitations apply to diabetic testing supplies and insulin syringes/needles depending on the member's diagnosis, i.e. insulin dependent or non-insulin dependent diabetes. Medicaid does not cover diabetic supplies for dual eligible members, except for coverage of Part B deductibles and coinsurance amounts. These individuals have coverage for diabetic supplies either through Medicare Part B or Part D.
- Dual eligible members are limited to coverage of Medicare Part D excluded drugs. Coverage is limited to drugs that are covered for other Medicaid eligible members in the following classes:
    - Barbiturates (if not for treatment of epilepsy, cancer, or mental health disorder, as Medicare Part D covers these conditions)
    - Over-the-counter medications
    - Agents for the symptomatic relief of cough and cold symptoms
    - Prescription vitamins and minerals
- Members enrolled in the Mountain Health Choice's (MHC) Adult basic plan are limited to coverage of four prescriptions per calendar month.



The following therapeutic classes will not count toward the 4-prescription limit:

- Diabetic supplies and all insulins,
- Atypical antipsychotics,
- Antidepressants(all therapeutic classes),
- Drugs used for the treatment of HIV/AIDS,
- All contraceptives.

518.5.1 Bulk Chemicals

Per CMS Medicaid Drug Rebate Program Release No. 155, bulk chemicals are substances which when used in the manufacturing of a drug become the active ingredient of the drug product. As such they do not meet the definition of covered outpatient drugs as defined in section 1927(k)(2) of the Social Security Act. However, bulk chemicals may be considered in rare circumstances if prescribed for an FDA-approved indication and/or medically accepted indication supported in official compendia. Prior authorization is required.

All rules, regulations, limitations, and exclusions set forth in the Pharmacy Services manual apply also to bulk chemicals.

Refer to the BMS website, http://www.dhhr.wv.gov/bms, for a list of covered bulk chemicals and criteria for coverage.

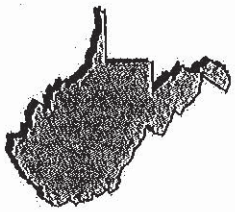
518.6 COVERAGE OF BRAND NAME VERSUS GENERIC DRUGS

Brand name multi-source legend drugs that have therapeutic equivalents available will be denied for payment. Generic drugs must be substituted, if available. In certain instances, pharmacies may indicate brand name drug usage on submitted electronic and paper pharmacy claims by using Dispensed as Written (DAW) codes. The DAW codes that are recognized by West Virginia Medicaid and can be used by providers to explain the dispensing of a brand name product instead of a generic one are as follows:

DAW 1 - Prescriber states that the brand name drug is "medically necessary". This information must be supplied in writing by the **prescriber** via written prescriptions in their own handwriting, and must write on the prescription "Brand Medically Necessary". A check-box or other methods to indicate that the brand should be dispensed shall not be accepted. Approval from the help desk is required for the use of DAW 1 and appropriate justification must be provided.

DAW 4 - A generic equivalent is not available or not stocked at the time of dispensing. This code shall only be used when a generic drug is sold out or a generic drug is unavailable on a wide-spread basis. *It shall not be used routinely to circumvent the mandatory generic program for reasons other than these.* A call to the Rational Drug Therapy Program help desk is required for the use of DAW 4 and appropriate justification must be provided. The brand name rate will be reimbursed when approved.

DAW 5 - Pharmacy uses this brand as a generic and realizes it will be paid at the generic rate.



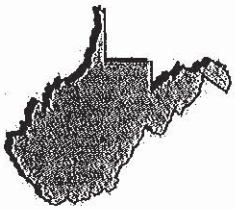
DAW 6 - Pharmacy is dispensing a generic drug that has been identified by the drug database as a brand name drug due to pricing issues. These generic drugs have high Average Wholesale Prices (AWP) in relation to other generic drugs that are available. An effort shall be made to obtain lower-priced alternatives.

- For auditing purposes, documentation shall be made on the prescription to justify use of the DAW codes.
- All other DAW codes that are recognized by NCPDP are not active in the West Virginia Medicaid Program and will not affect the processing of claims if submitted.
- The use of DAW codes is not permitted for non-preferred drugs included in the Preferred Drug List program. Completion of an FDA MedWatch form is required for the failure of a generic product to produce the same outcome as the equivalent brand name drug. The MedWatch form shall be sent by mail or fax to the Rational Drug Therapy Program. The MedWatch form may be accessed from the FDA website at www.fda.gov/downloads/Safety/MedWatch/HowToReport/DownloadForms/ucm082725.pdf. Please note that some generic drugs may be classified as non-preferred by West Virginia Medicaid and require prior authorization. This occurs when brand name drugs are less expensive to Medicaid due to supplemental rebate negotiations. In this case, the pharmacy will be required to dispense the brand name drug instead of the generic equivalent.

518.7 NON-COVERED SERVICES

The following list of drugs, drug products, and related services are not reimbursable. Non-covered services are not eligible for a West Virginia Department of Health and Human Resources (WVDHHR) fair hearing. Non-covered services include, but are not limited to:

- Drugs supplied by drug manufacturers who have not entered into a drug rebate agreement with CMS
- Agents used for weight loss or weight gain
- Agents used for cosmetic purposes or hair growth
- Drugs identified by CMS as being less-than-effective (DESI).
- Agents used for fertility
- Drugs used to treat erectile dysfunction
- Drugs that are investigational or approved drugs used for investigational purpose
- Drugs used for off-label indications which are not found in official compendia or generally accepted in peer reviewed literature
- Drugs dispensed after their expiration date
- The cost of shipping or delivering a drug
- Herbal or homeopathic products
- Drugs which result in therapeutic duplication, ingredient duplication, early refills or other Drug Utilization Review events that are not medically necessary
- Drugs which are not medically necessary
- Covered outpatient drugs for which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee



- Nutritional supplements
- Free pharmaceutical samples
- Diagnostic agents
- Vacation supplies
- Allergenic extracts
- Excipients except when used in compounded prescriptions containing a covered legend drug. Excipients must be eligible for federal rebates in order to be eligible for reimbursement.
- Vaccines via the pharmacy POS, except for Influenza, pneumonia, Hepatitis A, Hepatitis B, tetanus, tetanus-diphtheria (Td), and tetanus-diphtheria-and-pertussis (Tdap) vaccines for adults nineteen (19) years of age and older administered by a pharmacist; and herpes zoster vaccine for adults fifty (60) years of age and older administered by a pharmacist.
- Factors to treat hemophilia via the pharmacy POS (Refer to *Chapter 519, Practitioner Services,* for additional information regarding hemophilia services.)
- Methadone for the treatment of drug dependence/addiction

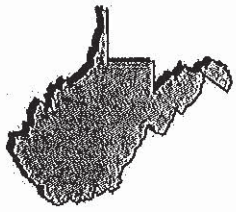
518.8 PRIOR AUTHORIZATION (PA)

Prior authorization (PA) for Medicaid-covered drugs is required for reimbursement of certain drugs to assure the appropriateness of drug therapy. Specific PA criteria are based on review of the most current clinical information, FDA approved indications, and manufacturers' recommendations. These criteria are reviewed by the Medicaid Drug Utilization Review (DUR) Board and recommended to the Bureau for Medical Services. These criteria then form the basis of acceptable drug therapy for members of Medicaid pharmacy services. Current criteria for coverage of non-preferred drugs and other drugs requiring prior authorization are found on the BMS website at www.dhhr.wv.gov/bms. Drugs which require prior authorization and for which prior authorization criteria have not been met are considered non-reimbursable unless, upon appeal by the prescribing provider, the Medicaid Medical Director determines that the drug meets the appropriateness and medical necessity criteria.

The use of pharmaceutical samples will not be considered when evaluating the members' medical condition or prior prescription history for drugs that require prior authorization.

Federal regulations state that Medicaid-covered drugs that require PA must have a 24-hour turnaround for responses. In emergent situations, a 72-hour supply of medication must be made available to members until the PA process can be completed. No more than a 72-hour supply shall be dispensed. Submitting a quantity greater than a 72-hour supply constitutes an improper claim unless it is for a package that cannot be broken. If a product package cannot be broken, then the whole package may be dispensed, if necessary, to meet the member's needs. Documentation of this action shall be made on the prescription for auditing purposes. Repeated submissions of 72-hour supplies for the same patient and same drug to circumvent the prior authorization process constitute an improper billing method. This practice is subject to audit.

518.8.1 Process of Requesting Prior Authorization



The Rational Drug Therapy Program (RDTP) is the agency contracted to provide prior authorization services to the West Virginia Medicaid Pharmacy Program. RDTP is a non-profit organization affiliated with the West Virginia University School of Pharmacy.

Prior authorization may be initiated either by the dispensing pharmacist, the prescriber, or the prescriber's designee. Prior authorization requests from third party vendors or contractors will be denied. Requests may be made by telephone, fax, or mail. If all the necessary information is provided, requests will be addressed within 24 hours. It is the responsibility of the provider of the service, either the physician or pharmacist, to obtain the authorization before rendering the service. Requests for prior authorization after the service is rendered will be denied. In cases of back-dated eligibility, prior authorizations may be considered on a case by case basis using coverage policies in place on the dates the services were rendered. If the service is provided before prior authorization is obtained, the Medicaid member must be informed that he/she will be responsible for the bill.

There is a maximum approval limit of one year.

Prior authorization requests shall include the following:

- Member name and address
- Member Medicaid identification number
- Name of drug, strength, dosage, and duration of treatment
- Diagnosis
- Pertinent laboratory information
- Justification for the use of the drug
- Return fax number
- Signature of prescriber or pharmacist

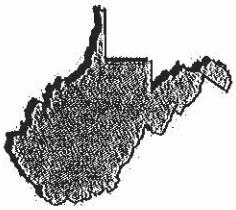
Rational Drug Therapy Program's operating hours are:
Monday through Saturday – 8:30 AM until 9:00 PM
Sunday – 12 noon until 6:00 PM

Prior authorization forms can be downloaded from the Bureau for Medical Services' website at http://www.dhhr.wv.gov/bms/Pharmacy/Pages/pac.aspx. These forms may be duplicated. Providers enrolled to access the BMS MediWeb portal may complete PA forms electronically and submit them via the portal.

518.8.2 Prior Authorization Denial Appeals Process

If a prior authorization request is not approved, the prescriber may appeal the decision to the Rational Drug Therapy Program Appeals Department in writing (first level appeal). Requests must include the following information:

- Member name and address
- Member Medicaid identification number
- Name of drug, strength, dosage, and duration of treatment



- Diagnosis
- Pertinent laboratory information
- Justification for the use of the drug, including any other treatments that have been tried
- Supporting literature
- Return fax number
- Signature of prescriber

Office and/or hospital notes, including signed ones, are not acceptable and do not constitute an appeal.

Appeals will be processed within 3 business days of their receipt. Appeals shall be faxed to the Rational Drug Therapy Program (RDTP), Appeals Department at 1-800-531-7787.

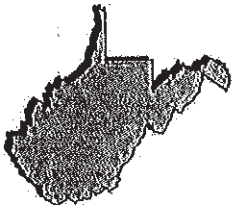
All appeals denied by RDTP will be sent to BMS for physician review. Any denial resulting from physician review is final. The Medicaid member is notified of this denial and of their right to request a fair hearing.

518.9 DRUG UTILIZATION REVIEW (DUR)

The Omnibus Budget Reconciliation Act (OBRA '90) required that states establish a Drug Utilization Review (DUR) program. The DUR program must consist of prospective and retrospective components as well as components to educate physicians and pharmacists on common drug therapy problems and assessments of whether usage complies with predetermined standards. In order to meet the requirements of the statute, the DUR program must assure that prescriptions are appropriate, are medically necessary, and are not likely to result in adverse medical results. The two primary objectives of DUR systems are (1) to improve quality of care; and (2) to assist in containing health care costs.

The establishment of a DUR Board was required by OBRA '90. This Board, consisting of local pharmacists, physicians, and other healthcare providers from around the state, is charged with making recommendations for educational interventions to prescribers and pharmacists to identify and reduce, for both providers and patients, the frequency of patterns of fraud, abuse, gross overuse, and inappropriate or medically unnecessary care. Specific drugs or classes of drugs may be targeted in regard to:

- Therapeutic appropriateness
- Over utilization
- Under utilization
- Appropriate use of generic products
- Therapeutic duplication (same or different prescriber)
- Drug-disease contraindications
- Drug-drug interactions
- Incorrect drug dosage
- Incorrect duration of drug treatment
- Drug-allergy interactions
- Clinical abuse/misuse



The West Virginia Medicaid DUR Board meets quarterly to discuss methods of achieving the goals of assuring the appropriate use of drugs in the Medicaid program. These meetings are open to the public. The DUR Board also assists BMS in defining criteria for coverage of drugs that require prior authorization. Meeting agendas, minutes, and other DUR information are available on the Bureau for Medical Services' website, www.dhhr.wv.gov/bms.

Detailed DUR Event parameters can also be found on the BMS website at www.dhhr.wv.gov/bms.

518.9.1 Prospective Drug Utilization Review (DUR)

Prospective DUR is conducted at the pharmacy Point-of-Sale (POS) before delivery of a medication by the pharmacist to the Medicaid member or caregiver. Prescription claims are screened to identify potential drug therapy problems of the following types:

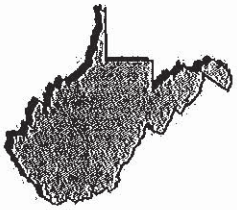
- Therapeutic duplication
- Ingredient duplication
- Adverse drug-drug interactions
- Early refill
- Late refill
- High dosage
- Low dosage
- Incorrect duration of drug treatment
- Age/gender precaution
- Pregnancy precaution
- Breast feeding precaution

Dispensing pharmacists use the information provided by the pharmacy POS and their professional judgment to determine if the prescription shall be filled. The pharmacist determines the appropriateness of the prescribed therapy and intervenes with the prescribing physician and/or member in the event of a suspected problem.

Pharmacists may continue to process claims that contain prospective DUR messages by using DUR outcome and intervention codes. A call to the RDTP help desk may be required in certain instances as determined by BMS to obtain an edit override. Requests for edit overrides after the service is rendered will be denied, except in cases of back-dated eligibility. More detailed information regarding DUR procedures is found in the Health PAS-RX Pharmacy Point-of-Sale (POS) User Guide, found on BMS' link to the fiscal agent website, www.dhhr.wv.gov/bms.

518.9.2 Retrospective Drug Utilization Review

Retrospective Drug Utilization Review is required in order to identify patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care among physicians, pharmacists, and Medicaid members, or associated with specific drugs or groups of drugs. West Virginia Medicaid conducts retrospective DUR with the assistance of a vendor. They provide patient profiles addressing drug use that may be inappropriate based on predetermined standards. A



Retrospective DUR Committee, consisting of healthcare professionals, meets monthly to review these patient profiles that are used to generate letters to physicians and pharmacists relating to these issues.

518.9.2.1 Pharmacy Lock-in Program

Members who use pharmacy services excessively or inappropriately may be assigned to a single pharmacy provider where they receive their Medicaid-covered medications. The purpose of this program is to assist beneficiaries in using pharmacy services appropriately.

As part of this program, the Retrospective DUR Committee reviews Medicaid member utilization profiles to determine if controlled substances are being used at a frequency or amount that results in a level that may be harmful or not medically necessary. Inappropriate utilization can include frequent use of multiple controlled substances, use of multiple prescribing physicians and/or pharmacies, overlapping prescription drugs within the same drug class and drug seeking behavior, i.e., doctor shopping.

A series of letters is sent to prescribers and/or the member to seek information regarding his/her drug utilization or to warn that continued over utilization may result in restricting the member to a single pharmacy provider. If the pharmacy lock-in criteria are met, the member is given the opportunity to select a pharmacy, but pharmacy participation is voluntary. Pharmacists serving these members are requested to use their professional judgment in regard to filling prescriptions for controlled substances.

Criteria for Lock-in determination can be found on the Bureau's website, www.dhhr.wv.gov/bms.

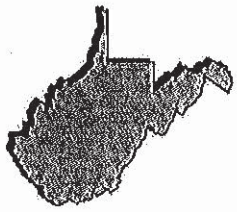
Members, upon discharge from a substance abuse program, or while receiving outpatient substance abuse treatment, will be locked into a single pharmacy provider. Upon admission to a facility for treatment of substance abuse or during the initial visit for outpatient substance abuse services, the member will be required to choose a pharmacy from which to receive all controlled substances. The lock-in form may be found on the Bureau's website at www.dhhr.wv.gov/bms.

518.9.3 Reporting of Cash Payments

Pharmacies are encouraged to report to BMS when a member pays cash for prescriptions that would otherwise be covered by Medicaid or considered for reimbursement upon a call to the RDTP, or when the pharmacy provider suspects overutilization by the member. A form used for this reporting can be found on the BMS website, www.dhhr.wv.gov/bms. The form should be faxed to BMS at 304-558-1542. Information collected through this process may be used for member lock-in consideration and continued eligibility.

518.9.4 Member Counseling

OBRA '90 requires that pharmacists offer counseling to Medicaid patients and must include the following:



- Name and description of the medication;
- The route of administration, dosage form, dosage, and duration of therapy;
- Special directions and precautions for preparation, administration and use by the patient;
- Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;
- Techniques for self-monitoring prescription therapy;
- Proper storage;
- Prescription refill information; and
- Action to be taken in the event of a missed dose.

The West Virginia Medicaid program relies on the West Virginia Board of Pharmacy to monitor these activities, but BMS may audit these requirements through routine or special reviews.

518.10 DOCUMENTATION AND RECORD RETENTION REQUIREMENTS

Documentation and record retention requirements governing the provision of all West Virginia Medicaid services apply pursuant to *Chapter 300, General Provider Participation Requirements*, and *Chapter 800, General Administration*, of the Provider Manual.

Prescriptions must comply with the regulations of the West Virginia State Board of Pharmacy as to content requirements and must be kept for a period of five years. Prescription records must be made available to BMS upon request.

518.10.1 Tamper-Resistant Prescription Pad Requirement

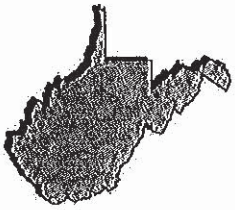
All prescriptions written for West Virginia Medicaid members must be on tamper-resistant pads/paper which meet all 3 characteristics set forth in the guidelines from the Centers for Medicare and Medicaid Services (CMS). The three characteristics to meet the tamper-resistant prescription requirement are:

1. Prevent unauthorized copying of a completed or blank prescription form;
2. Prevent the erasure or modification of information written on the prescription, and;
3. Prevent the use of counterfeit prescription forms.

Written prescriptions must contain **ALL** of the following:

Feature	Description
"Void" pantograph	The word "Void" appears when document is photocopied. Pharmacy will need to record on document if received via fax.

Feature	Description
Uniform non-white background color – *preferably green*	Background is one color (*preferably green*), inhibits a forger from physically erasing written or printed information on a prescription form. If an attempt is made to erase copy – the consistent background color will look altered.



Quantity check off boxes	In addition to the written quantity on the prescription, quantities are indicated in ranges of 25's (or some other, similar range). Box MUST be checked for this feature to be valid.
Refill indicator	Refill indicator (circle or check number of refills or "NR"). Refill indicator must be used to be a valid feature.

Feature	Description
Security features and descriptions listed on the front of the prescription	Listing of the security features of the prescription for compliance purposes. This will assist the pharmacist and auditors on what security features are included on the pads/paper.

Computer-generated prescriptions, EMR, or ePrescribing generated prescriptions may be printed on plain paper and be fully compliant with all three categories of tamper resistance, provided they contain the features listed in the table below. Prescribers are urged to contact their software companies to ensure that computer generated prescriptions have all requirements necessary for tamper resistance.

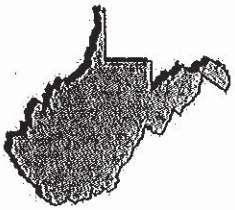
Computer-generated prescriptions must contain the following:

1. One or more industry-recognized features designed to prevent unauthorized copying of a completed or blank prescription form.

Feature	Description
"Void" pantograph	The word "Void" appears when document is photocopied. Pharmacy will need to record on document if received via fax. *This requires the purchase of special paper.*
OR	
Micro print signature line	Very small font which is legible (readable) when viewed at 5x magnification or greater, and illegible when copied.

2. One or more industry-recognized features designed to prevent the erasure or modification of information written on the prescription by the prescriber.

Feature	Description
Uniform non-white background color – preferably green	Background is one color (*preferably green*), inhibits a forger from physically erasing written or printed information on a prescription form. If someone tries to erase copy – the consistent background color will look altered.
OR	
"Toner-lock" paper for laser printed prescriptions, or plain bond paper for inkjet printed prescriptions	Toner-lock paper is special printer paper that establishes a strong bond between laser-printed text and paper, making erasure obvious. Note – this is NOT necessary for inkjet printers – as the ink from the inkjet printers is absorbed into normal "bond" paper.



Quantity written and quantity with border characteristics for computer generated printed prescriptions	Quantity written and Quantity surrounded by special characters such as asterisks to prevent modification, e.g. *QTY Fifty ***50****.*
Refill written and refill with border characteristic for computer generated printed prescriptions	Refills written and Refill surrounded by special characters such as asterisks to prevent modification, e.g. *Five refills ****5 refills*****.*

3. One or more industry-recognized features designed to prevent the use of counterfeit prescription forms.

Feature	Description
Security features and descriptions listed on the prescription	A complete list of the security features of the prescription for compliance purposes. This will assist the pharmacist and auditors on what security features are included on the paper.

Prescriptions for West Virginia Medicaid members written by prescribers that reside outside of West Virginia may meet the federal tamper-resistant prescription requirement if the prescription addresses the three distinct characteristics outlined above, and may contain the same or other features than those adopted by BMS.

518.10.2 Prescriptions Returned to Stock

Claims for prescriptions which have been filled by the participating pharmacy, but not dispensed to the patient, shall be reversed. This shall be done on a timely basis, within 15 days. A log of these returns must be maintained by the pharmacy for a period of 5 years for auditing purposes.

518.10.3 Nursing Home Returns

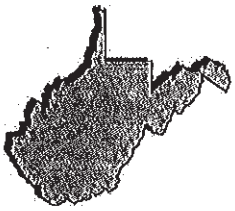
Drugs dispensed to nursing home residents that are not used by the member must be either returned to the dispensing pharmacy or destroyed according to applicable rules and regulations.

Drugs that are returned unused by the Medicaid member and are available for re-dispensing, per West Virginia State Board of Pharmacy rules and regulations, must be credited to Medicaid.

Claims for these returned medications must be reversed and resubmitted for the quantity used by the member.

518.10.4 Shipping/Receiving

Drugs reimbursed by West Virginia Medicaid that are mailed or shipped to members require a signature of the individual receiving delivery of the medication. A log of these signatures must be maintained by the pharmacy for a period of 5 years for auditing purposes. Providers shall take the necessary steps to prevent loss of medications in the shipping process and to assure that the



member receives the shipment when needed, as Medicaid will not reimburse for medications not received by the member.

Claims for medications not received by the member in a timely manner, and which the member was compelled to obtain from a local pharmacy, may be reversed by the fiscal agent, if necessary, in order to allow for billing by a local pharmacy provider to meet the member's needs.

518.11 BILLING PROCEDURES

Claims for prescribed drugs dispensed to Medicaid members may be submitted electronically using the Point-of-Sale system or on paper claim forms. Claims must be filed within 12 months from the date of service.

Submitting claims via electronic media offers the advantage of speed and accuracy in processing. All claims, regardless of method of submission, are subject to drug utilization review edits, prior authorization, and other Medicaid requirements.

Medications for West Virginia Medicaid members must be dispensed at the facility from which the drug products are prepared and the services rendered.

Claims must accurately report the NDC dispensed, the number of units dispensed, days' supply, and other required data for claims processing. Use of an incorrect NDC or inaccurate reporting of a drug quantity will cause BMS to report false data to drug manufacturers when billed for drug rebates. BMS will recover payments made on erroneous claims discovered during dispute resolution with drug manufacturers or during claim reviews. Pharmacies are required to submit documentation for purchases of drugs reimbursed by BMS upon request.

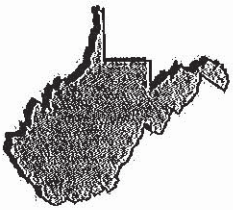
518.11.1 Point-of-Sale System

Currently, online processing for Medicaid pharmacy claims is available for all pharmacies using NCPDP Version D.0. The provider must complete and submit the provider trading partner agreement prior to use of Point-of-Sale submission for claims.

See the Molina Health PAS-Rx Pharmacy Point-of-Sale (POS) User Guide for complete billing instructions for the Point-of-Sale system. See the Pharmacy Point-of-Sale (POS) NCPDP Version D.0 Vendor Specification Document, for specifications and information for switch vendors. These documents and other information are located on the BMS' link to the fiscal agent website.

518.11.2 National Council on Prescription Drug Programs (NCPDP) Payer Sheet

West Virginia Medicaid accepts pharmacy Point-of-Sale claims submitted using NCPDP Version D.0 or Batch Version 1.1. According to the NCPDP accepted standards, some fields are required, optional, or conditional. See the Pharmacy Point-of-Sale (POS) NCPDP Version D.0 Vendor Specification Document, located on BMS' link to the fiscal agent website, for the West Virginia Medicaid payer sheet.



518.11.3 Paper Claim Submission for Pharmacy Services

Pharmacies have the alternative of submitting a manual claim using a paper claim form, when necessary. The Universal Claim Form (UCF) provides a standard format for paper submission of drug claims to Medicaid. The UCF adheres to the data elements found in the Telecommunication Standard and Data Dictionary. **Medicaid will not supply these forms to providers.**

518.11.4 Claim Reversals

Pharmacy claims submitted by Point-of-Sale cannot be adjusted. To correct information submitted on a Point-of-Sale claim, the claim shall be reversed online and then resubmitted using the corrected information. There is currently no paper reversal claim form. If a paper claim submission requires corrections, the pharmacy Help Desk shall be contacted.

518.11.5 Pharmacy Identification Number

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) mandated the use of the National Provider Identifier (NPI) as the standard for identifying covered healthcare providers, including pharmacies. Pharmacies must use their NPI number on electronic submissions for reimbursement of pharmacy claims. NCPDP numbers will no longer be accepted on electronic claims. The NPI or NCPDP number will continue to be used on the approved paper claim form. For additional NPI information or to complete an NPI application, visit the CMS website, https://nppes.cms.hhs.gov.

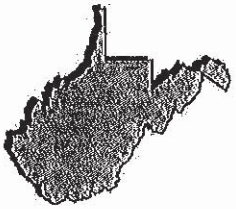
518.11.6 Prescriber Identification Number

The National Provider Identifier (NPI) is required for the prescriber identification information on electronic POS claims. Either the DEA number or the NPI is allowed on the manual claim form (UCF).

Only prescribing NPI entities are permissible. Claims submitted with non-prescribing NPI entities will be denied, including but not limited to pharmacies, laboratories, hospitals, and dialysis centers.

518.11.7 National Drug Codes (NDC)

All pharmacy claims submitted to West Virginia Medicaid must identify the 11-digit NDC printed on the stock container in which the drug was purchased. **Using the correct NDC is extremely important in order to avoid disputes with manufacturers for rebate payments.** For example, if a drug is purchased in a 5000-count bottle and repackaged in 100-count bottles prior to dispensing, submitting the NDC for a 100-count bottle is not permitted. Most drugs distributed by repackagers are not covered by Medicaid because the repackager has not signed a rebate agreement with CMS. A pharmacy may not dispense a repackager's drug and then bill Medicaid using the original manufacturer's NDC.



518.11.8 Decimal Units

The Medicaid pharmacy system is capable of accepting quantity amounts which contain decimal units. Pharmacy claims must be submitted using the standard units, including any decimal increments. Units must not be rounded up or down. Rounding results in over or under payments and creates inaccurate invoicing to manufacturers for the drug rebates owed to the state.

518.11.9 Days' Supply

Each Medicaid-covered prescription is limited to a maximum supply of 34-days, with some exceptions. These exceptions are to accommodate packaging that cannot be broken. The following are examples of drugs that may be submitted as specified below:

Seasonal	91-day supply
Depo-Provera 150mg/ml	90-day supply

The pharmacist is responsible for submitting prescription claims up to this limit. Should a prescription be written for a quantity that is greater than the allowed limit, the pharmacist is responsible for notifying the prescriber of this limit and asking permission to reduce the number of units to be dispensed.

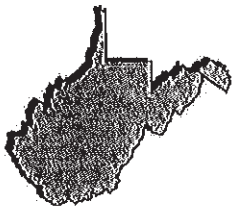
If the prescriber does not allow the prescription quantity to be reduced, the member shall be told that the cost of the prescription is his/her responsibility. Filling a prescription for a 34-days' supply when the prescription is intended to last longer constitutes a false claim and is subject to recovery of the paid amounts.

518.11.10 Compounded Prescriptions

A compounded prescription is defined as any prescription requiring the combination of two or more substances, one of which must be a covered legend drug. The covered legend drug must be the first NDC submitted on a compounded prescription claim. DESI drugs or non-covered drugs **not appearing as the first NDC** in a compounded product will not cause the claim to deny, but those ingredients will not be included in the reimbursement. Over-the-counter (OTC) ancillary products will be reimbursed provided the drug is manufactured by a company which participates in the federal drug rebate program. A compound may contain up to 25 ingredients.

Products such as suppository molds and other items identified as supplies included in a compounded prescription will not be reimbursed by West Virginia Medicaid.

Billing compounded prescriptions follows NCPDP Version D.0 guidelines. For a compounded prescription, an additional $1.00 will be added to the dispensing fee. Compounding is considered an integral part of the prescription services and must not be billed separately. More information can be found in the User Guide, located on BMS' link to the Fiscal agent website, www.dhhr.wv.gov/bms.



518.11.11 Abuse and Inappropriate Utilization

The following practices constitute abuse and inappropriate utilization, and are subject to audit:

- Excessive fees (commonly known as prescription splitting or incorrect or excessive dispensing fees): Billing inappropriately in order to obtain dispensing fees in excess of those allowed by:
  - Supplying medication in amounts less than necessary to cover the period of the prescription; and/or
  - Supplying multiple medications in strengths less than those prescribed to gain more than one dispensing fee.
- Excessive filling: Billing for an amount of a drug or supply greater than the prescribed quantity.
- Prescription shorting: Billing for drug or supply greater than the quantity actually dispensed.
- Substitution to achieve a higher price: Billing for a higher priced drug than prescribed even though the prescribed lower priced drug was available.
- Automated refills and automatic shipments are prohibited. Medicaid does not pay for any prescription without an explicit request from a member or the member's responsible party, such as a caregiver, for each refilling event. The pharmacy provider shall not contact the member in an effort to initiate a refill unless it is part of a good faith clinical effort to assess the member's medication regimen. The possession, by a provider, of a prescription with remaining refills authorized does not in itself constitute a request to refill the prescription. Members or providers cannot waive the explicit refill request and enroll in an electronic automatic refill program. Any prescriptions filled without a request from a member or their responsible party will be subject to recovery. Any pharmacy provider with a policy that includes filling prescriptions on a regular date or any type of cyclical procedure will be subject to audit, claim recovery or possible suspension or termination of the provider agreement.

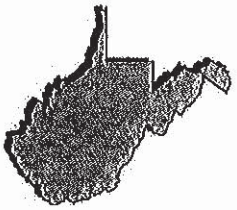
518.11.12 Lost/Stolen Medications

For members who report to the pharmacy that their medications have either been lost or stolen, the following procedure applies:

- The member must supply the pharmacy with a police report for stolen controlled substances; the pharmacy must retain a copy for audit purposes.
- The prescribing practitioner must agree that the lost or stolen medication shall be replaced.
- Lost/stolen medication approvals are limited to one occurrence per drug per year.

518.11.13 Wasted Medication

Members who have wasted medication due to improper use or storage may have their medication replaced. This will be determined on a case-by-case basis. Members shall be properly instructed on the storage and use of their medications and any special delivery device used to administer their medications. Requests for replacement of wasted medications due to improper storage or delivery by the pharmacy or improper handling by the administrating provider will be denied.



518.11.14 False Claims

Pharmacies are prohibited from submitting false claims to test for drug coverage, member eligibility, or for other purposes. Claims of this type result in false member drug history records and may result in the member or prescriber being included in lawsuits or reviews in error. All claims submitted for reimbursement must be the result of actual prescription requests.

518.12 REIMBURSEMENT

Federal Medicaid regulations governing pharmacy services establish upper limits for payment; i.e., the payment shall be based on the lower of the allowable cost of the drug, plus a dispensing fee or the provider's usual and customary charge to the general public.

Reimbursement for outpatient drugs is limited to products manufactured by companies participating in the Federal Drug Rebate Program.

If a provider accepts the member as a Medicaid patient, the provider must bill WV Medicaid for covered services and must accept the Medicaid reimbursement amount as full payment. No charge may be billed to a Medicaid member for a covered service unless a co-payment is applicable by regulation. However, the provider may bill the member for services not covered by the WV Medicaid Program if the parties agree in writing to this payment arrangement before such services are rendered. Refer to *Chapter 300, Section 320.2* for more information about billing Medicaid members.

518.12.1 Ingredient Cost

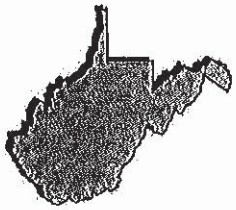
Maximum reimbursement for each drug claim processed will be based on the lowest of:

(1) The usual and customary charge to the general public;

(2) The Maximum Allowable Cost (MAC) plus a reasonable dispensing fee. The MAC for each multiple-source drug as defined in 42 CFR 447.332 and published in the Federal Register, plus a dispensing fee. Information relating to Federal Multiple Source Drug Limits is available on the CMS' website, http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Federal-Upper-Limits.html.

> **EXCEPTION**: The MAC shall not apply in any case where a physician certifies in his/her own handwriting that, in his/her medical judgment, a specific brand is medically necessary for a particular patient. A notation like "brand medically necessary" written by the physician on the prescription above his/her signature is an acceptable certification. A procedure for checking a box on a form will not constitute an acceptable certification. All such certified prescriptions must be maintained in the pharmacy files and are subject to audit by BMS.

(3) The State Maximum Allowable Cost (SMAC), plus a dispensing fee;



State Maximum Allowable Cost (SMAC) rates are established with the assistance of a vendor. Rates are determined by using 130% of the lowest Wholesale Acquisition Cost (WAC) as provided by national drug information suppliers for 3 manufacturers of the same drug product or, based upon a mean average of pharmacy provider costs obtained through a survey of a percentage of pharmacy providers that are representative of the overall geographical distribution, service volume, and business structures of all pharmacies serving the West Virginia Medicaid Program. This mean average methodology is used to adjust the pricing in accordance with drug market competition and to establish SMAC pricing in those instances where less than 3 manufacturers are supplying products in a specific drug market.

The SMAC rate is applied to all brand and generic drug products in each drug group. Non-AB rated drugs recognized by national drug information suppliers as comparable to a particular brand drug is subjected to the same SMAC rate applicable to the brand and "AB" rated generic drugs of the same chemical composition, package size, dose, and drug group.

The determination of which drugs will be part of the SMAC list will be designated by BMS. Drugs no longer available at the SMAC price are removed. New drugs will be added to the SMAC as they are identified. The vendor on behalf of BMS will continually monitor pharmacies and industry information and make changes to the SMAC to reflect current pharmaceutical market conditions.

The SMAC list is available on the BMS website at www.dhhr.wv.gov/bms. Comments and questions regarding the SMAC list can be made to the vendor.

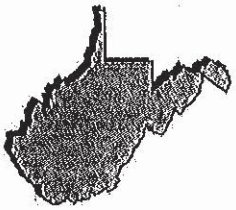
(4) Estimated Acquisition Cost (EAC), plus a dispensing fee. The EAC is defined as Average Wholesale Price (AWP) minus 15% for brand name drugs and AWP minus 30% for generic drugs.

518.12.2 Application of Dispensing Fee

- For covered legend and over-the-counter drugs, a professional dispensing fee of $2.50 per prescription for brand name drugs or a professional dispensing fee of $5.30 per prescription for generic drugs will be added to the federally established MAC, state established MAC, or state established EAC of each prescribed drug.

- Pharmacies participating in the 340b program, upon completion of the Certification form and submission of the required documentation, are paid a dispensing fee of $8.25 for each paid prescription for drug items dispensed to Medicaid members. These pharmacies are required to submit their actual acquisition costs to Medicaid. This policy is limited to those pharmacies located within Federally Qualified Health Centers (FQHC).

- For a compounded prescription, an additional $1.00 will be added to the dispensing fee. A compounded prescription is defined as any prescription requiring the combination of two or



more substances, one of which must be a legend drug. Compounding is considered an integral part of the prescription services and must not be billed separately.

- The dispensing fee may only be paid once every 30 days per drug entity for members residing in ICF/MR or nursing facilities.

- Claims paid on the basis of the usual and customary charge to the general public do not include an additional dispensing fee.

518.12.3 Co-Payments

A co-payment is required for each prescription with the exception of prescriptions for members excluded by regulation and/or those items specifically excluded from the co-payment requirement. The member co-payment per prescription will be deducted from the allowed total charge to determine the amount payable for each prescription billed to the Program. The deduction will apply as follows:

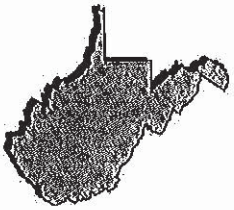
- If the allowed total charge is $10.00 or less, the co-payment is $.50 per prescription
- If the allowed total charge is $10.01 through $25.00, the co-payment is $1.00 per prescription
- If the allowed total charge is $25.01 through $50.00, the co-payment is $2.00 per prescription
- If the allowed total charge is $50.01 or more, the co-payment is $3.00 per prescription

Certain individuals or covered services are exempt from the co-payment requirement, as follows:

- Prescriptions for family planning services and supplies
- Prescriptions for members in long-term care facilities (i.e., nursing facilities or intermediate care facilities for mentally retarded)
- Prescriptions for pregnant women
- Prescriptions for members under 18 years of age
- 3-day emergency supplies
- Diabetic testing supplies and syringes/needles
- BMS approved home infusion supplies
- POS-approved vaccines

Members have been informed of co-payment requirements and the exclusions from co-payment. Federal regulations stipulate that no provider may deny services to an eligible individual in situations when the member is unable to pay co-payment charges. However, this does not extinguish the liability of the member receiving the services for payment of the co-payment charge to the provider.

Providers may bill the member or refer the member to a collection agency, etc., in the same manner that the provider initiates collections from private pay customers. If it is the routine business practice of the provider to refuse service to any individual, regardless of payer source, for uncollected debt, the provider may refuse future services to Medicaid members if adequate prior notice is provided.



Providers are prohibited from advertising or soliciting business by waiving members' co-payment responsibility. Members are responsible for applicable copays, and providers are prohibited from waiving the copay requirement to attract business from other providers.

518.12.4 Third-Party Liability (TPL) or Coordination of Benefits (COB)

Medicaid is payer of last resort. TPL ensures that Medicaid is the last payer to reimburse for covered Medicaid services. In particular, Medicaid participating providers must always seek reimbursement from other liable resources, including private or public insurance entities. Before submitting claims to Medicaid, providers must pursue all requirements of the primary insurer including, but not limited to prior authorization, brand name justifications, and Drug Utilization Review events.

Federal regulations require that state Medicaid administration identify any third-party resource available to meet the medical expenses of a member. The "third party" may be an individual, institution, corporation, or a public/private agency liable for all or part of the member's medical costs; e.g., private health insurance, UMWA benefits, Veterans Administration benefits, CHAMPUS, Medicare, Hospice, etc. Additionally, no Medicaid reimbursement may be made if the service is the responsibility of a public or private Workers Compensation Plan.

Medicaid covered drugs which currently require a prior authorization (PA) from BMS will continue to require a PA if a primary insurer approves that service, and Medicaid reimburses any part of the cost.

Medicaid co-payment is still required, if applicable, for claims considered by third party payers and reimbursed by BMS.

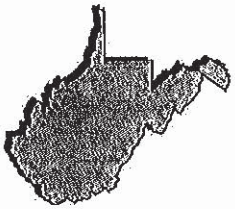
Chapter 600, Reimbursement Methodologies, of the Common Chapters of the Medicaid Manual provides more detailed information regarding Third Party Liability.

See the User Guide for billing instructions for NCPDP Version D.0 in regard to Coordination of Benefits.

518.12.4.1 Medicare-Covered Drugs & Supplies, Part B

Pharmacies are required to verify and pursue members' Medicare coverage and to submit pharmacy claims to Medicare for those pharmacy services covered by Medicare. Pharmacies can submit claims to Medicare Part B either on the acceptable paper claim form (CMS 1500) or electronically. Once the Medicare claim has been approved and processed, Medicare will automatically submit the balance of the claim as a "crossover" to Medicaid electronically, if the provider's Medicare number is on file with Medicaid. These claims should not be submitted to Medicaid separately if the claim crossed over from Medicare.

For Dually Eligible Beneficiaries and Qualified Medicare Beneficiaries (QMB), if the service is covered by Medicare and Medicaid, Medicaid will pay the lesser of:



- The full coinsurance and deductible amounts due, based upon the Medicare allowed amount, or
- Medicaid's maximum allowable fee for that service minus the amount paid by Medicare.

For Qualified Medicare Beneficiaries (QMB), if the service is not covered or is denied by Medicare, Medicaid will not reimburse.

Drugs that are not covered by Medicare Part B may be covered by Medicare Part D. Medicaid does not reimburse for Part D co-payments.

518.12.4.2 Medicare Covered Drugs, Part D

Dual eligible members have prescription drug coverage through Medicare Part D. Medicaid is not responsible for covering pharmacy benefits for these individuals, except for drugs in the Medicare excluded categories. Dual eligible members are limited to coverage of Medicare Part D excluded drugs. Coverage is limited to drugs that are covered for other Medicaid eligible members in the following classes:

- Barbiturates (if not for treatment of epilepsy, cancer, or mental health disorder, as Medicare Part D covers these conditions)
- Over-the-counter medications
- Agents for the symptomatic relief of cough and cold symptoms
- Prescription vitamins and minerals

Medicaid does not reimburse for Medicare Part D co-payments. Medicaid does not pay as the secondary payer on Medicare Part D covered drugs.

518.13 HOW TO OBTAIN INFORMATION

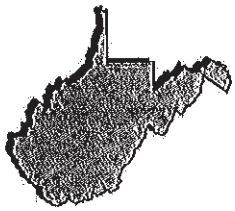
An effective medical assistance program is dependent upon the support and cooperation of the providers of medical care and services. The fiscal agent is responsible for establishing and maintaining communication with providers participating in the program. Appropriate staff is available to respond to inquiries regarding program issues.

518.13.1 Policy/Reimbursement

For assistance with issues of program policy or reimbursement, contact Provider Relations, P. O. Box 2002, Charleston, West Virginia 25327-2002; telephone 1-888-483-0793 or 1-888-483-0801, (West Virginia and border providers); all other providers, (304) 348-3360.

518.13.2 Point-of-Sale (POS)

For assistance with POS claims submission, contact the pharmacy POS help desk, Rational Drug Therapy Program. The telephone number is 1-800-847-3859.



518.13.3 Prior Authorization

For obtaining a prior authorization for a prescribed drug, contact the Rational Drug Therapy Program, Robert C. Byrd Health Sciences Center, Post Office Box 9511; Morgantown, West Virginia 26506-9511, telephone 1-800-847-3859, fax 1-800-531-7787.

518.13.4 Additional Information

For obtaining additional information, refer to the following:

SERVICE	PERSON OR COMPANY	PHONE NUMBER	FAX NUMBER
Pharmacy Program Director	Bureau for Medical Services	304-558-1700	304-558-1542
Drug Utilization Review	Bureau for Medical Services	304-558-1700	304-558-1542
Drug Rebate	Bureau for Medical Services	304-558-1700	304-558-1542
Point-of-Sale Help Desk	Rational Drug Therapy Program	800-847-3859	800-531-7787
Prior Authorization	Rational Drug Therapy Program	800-847-3859	800-531-7787
Eligibility	Voice Response System	888-483-0793	
Eligibility Assistance	Bureau for Medical Services	304-558-1700	304-558-1776
Technical support	Molina Help Desk	888-483-0801	
AIDS Drug Assistance Program (ADAP)	Program Director	304-232-6822	740-695-3252
Children with Special Health Care Needs	Office of Maternal, Child, and Family Health	800-642-9704	304-558-2866
Member Denials	Molina Client Services	888-483-0797 800-642-8589	
State Maximum Allowable Costs	Magellan Medicaid Administration, Inc.	800-763-7382	

CHAPTER 518
PHARMACY SERVICES

APPENDIX 1
WEST VIRGINIA MEDICAID PHARMACY PROGRAM
IN-HOME PARENTERAL THERAPY
PAGE 1 OF 6

WEST VIRGINIA MEDICAID PHARMACY PROGRAM
IN-HOME PARENTERAL THERAPY (IHPT)

DEFINITIONS

Antineoplastic - an agent that prevents the development, growth or proliferation of malignant cells.

Chemotherapy - the administration of chemical agents designed to have a specific effect upon disease causing cells or organisms.

In-Home Parenteral Therapy or IHPT - the parenteral administration of fluids, drugs, chemical agents, or nutritional substances to members in the home setting.

Parenteral - all routes of administration of substances other than via the gastrointestinal canal. This includes intravenous, subcutaneous, intramuscularly, intrathecal, or epidural and less commonly, mucosal (as in intravaginal).

Total Parenteral Nutrition (TPN) - the administration of nutritional substances by intravenous infusion to nourish members who are not candidates for enteral support.

INTRODUCTION

In-home parenteral therapy (IHPT) is a Medicaid covered service. Medicaid coverage for this service will include drugs and services that are:

- Medically necessary
- Prescribed by a licensed physician
- Administered via central line, peripheral line, infusion port, epidural, intrathecal or subcutaneous site
- Provided by a licensed pharmacy enrolled with the State of West Virginia Department of Health and Human Services, Bureau for Medical Services (BMS)
- Billed via electronic transmission according to standard guidelines or on the approved pharmacy paper claim form
- Prior authorized as directed by BMS

PROVIDER REQUIREMENTS AND RESPONSIBILITIES

In order to participate in the West Virginia Medicaid Program and receive payment from BMS, IHPT providers must:

- Submit an IHPT Medicaid Provider Enrollment Form to the Bureau for Medical Services.
- Submit a copy of the provider's West Virginia Board of Pharmacy (WV BOP) Sterile Compounding Permit or respective state Board of Pharmacy Sterile Compounding Permit.

Participating pharmacies that bill services for West Virginia Medicaid members shall be subject to the laws and regulations set forth by the WV BOP that govern the requirements to hold a Sterile Compounding Permit.

MEMBER REQUIREMENTS

Members receiving In-Home Parenteral Therapy must meet the following requirements:

- The member must reside in either a private home or domiciliary care facility, such as an adult care residence. Members who are residents or patients of a hospital, nursing home (including ICF/MR group homes), rehabilitation centers, and other institutional settings are not eligible for this service.
- The member must be under the care of a physician who prescribes the in-home infusion therapy and monitors the progress of the therapy.
- The member must have sites available for intravenous catheters or needle placement or have central venous access.
- The member must be capable of self-administering or have a nurse or a caregiver who can be adequately trained, capable and is willing to administer/monitor home infusion therapy safely and efficiently following appropriate teaching and adequate monitoring.

PRIOR AUTHORIZATION

All IHPT services require prior authorization. Requests must be made through the Rational Drug Therapy Program (RDTP).

See the BMS web site at www.dhhr.wv.gov/bms for the approved prior authorization form.

- **Pre-mixed Solutions or products requiring no compounding**

  Pre-mixed solutions or products include those injectable items that do not require compounding by the pharmacist because a) the items are marketed as pre-mixed, thus requiring no dilution and/or compounding, or b) compounding is performed by the patient, the nurse or the caregiver. Commercially prepared products are mandated to be dispensed if available. Compounded products and related professional services shall not be reimbursed when the commercially prepared product is available.

  The request for prior authorization must include the diagnosis, duration of therapy, prescribing physician information, and appropriate documentation. The prior approval will be effective from the date of physician's original order and continue for the specified length of therapy unless there is a change in prescription or level of care. Changes in therapy require new prior authorizations. Written requests for prior authorization must be submitted via fax or mail to the RDTP on form IV-1. This form can be found at the BMS website at www.dhhr.wv.gov/bms.

- **Products requiring compounding**

  Certain injectable products require compounding in order to meet the needs of the member, and are not available commercially.

  The request for prior authorization must include the diagnosis, duration of therapy, prescribing physician information, and appropriate documentation. The prior approval will be effective from the date of physician's original order and continue for the specified length of therapy unless there is a change in prescription or level of care. Changes in therapy require new prior authorizations. Written requests for prior authorization must be submitted via fax or mail to the RDTP on form IV-1. This form can be found at the BMS website at www.dhhr.wv.gov/bms. Signed physicians orders for compounded IHPT

medications must be provided to RDTP if reimbursement for compounding activities is requested.

Refer to *Chapter 506, DME/Medical Supplies Manual*, for the policy governing parenteral nutrition.

BILLING AND REIMBURSEMENT VIA POINT-OF-SALE

Billing for IHPT claims is accomplished through NCPDP Version D.0 electronic or 1.1 batch (paper claim) system. Instructions for the processing of claims are found in the general pharmacy manual information.

The active ingredient(s) for each prescription is/are to be billed using the National Drug Code (NDC) and its respective unit of use. The drug portion of IHPT will be reimbursed online according to the current reimbursement policy. The codes used for the reimbursement of compounding services are inclusive of but not limited to diluents for reconstitution, IV fluids, and other supplies used in the compounding process.

Billing shall correspond to those items and fees reflecting therapy for a duration of a maximum of 34 days as prior authorized by RDTP. If the order is discontinued, any therapy that has been billed but not delivered to the member, must be reversed.

- **Pre-mixed Solutions or products requiring no compounding**
  After receiving prior authorization, prescriptions for items which are dispensed with no compounding requirements shall be submitted for payment via Point-of-Sale or approved paper claim form using the NDC number of the product and the quantity dispensed. Reimbursement will be made using the established retail reimbursement policy. (Do not use the NCPDP compound indicator).

- **IV Drugs Requiring Compounding**
  Products for IHPT requiring compounding involve billing in multiple parts. Drug components shall be submitted online or on the approved paper claim form using the actual NDC's that were used and quantity of each drug component, as approved by the Rational Drug Therapy Program. Use the NCPDP compound indicator when the product includes multiple agents. Please note: reimbursement for the diluting agent is included in the compounding fee and shall not be billed as a component of the compounded IHPT product if reimbursement for a compounding fee is requested.

- **Compounding Fee**
  The compounding fee which includes all components of the prescription compounding, such as sterile water, alcohol swabs, IV fluids, needles/syringes, etc., and professional services shall be submitted online or on the approved paper claim form. The authorization for reimbursement of the compounding fee will be issued from RDTP upon receipt of a copy of the signed order from the prescribing physician. (Do not use the NCPDP compound indicator).

- **Units Dispensed**
  Units are defined by First Data Bank product classification. In general, if a drug requires reconstitution, the units submitted will be the number of vials. For example, a 2 gm vial of cephazolin is submitted as a quantity of "1" for each vial. If the drug or component is

available in solution, the units are submitted in milliliters. For example, a 2ml vial of gentamicin injection (80mg/vial) is submitted as "2" for each vial. The actual amount used in compounding shall be submitted. Wastage shall be kept to a minimum. The units dispensed must match the amount prior authorized by RDTP.

The RDTP Help Desk is available to assist providers with questions regarding proper unit billing. In all cases, the amount and duration of therapy for which BMS is billed must match those ordered by the physician and delivered to the member.

- **Brand Name Justification**

  If a drug being dispensed is a product for which a generic equivalent exists, the generic must be dispensed. The use of brand name products must be justified, as referenced in the general pharmacy instructions.

- **Supplies**

  Refer to *Chapter 506, DME/Medical Supplies Manual* for coverage policy and billing instructions for supplies associated with IHPT.

ASSIGNED NDC CODES FOR IHPT COMPOUNDING

CODES AND DESCRIPTIONS:

TABLE OF PROGRAM-ASSIGNED NDC NUMBERS FOR THE SUPPLY/COMPOUNDING PORTION OF THE ANTIBIOTIC/CHEMO/HYDRATION/PAIN MANAGEMENT HOME IV THERAPY CLAIM

ANTIBIOTIC THERAPY

	Every 24 hrs	Every 18 hrs	Every 12 hrs	Every 8 hrs	Every 6 hrs	Every 4 hrs	Every 3 hrs
Bag	$15.92 99999-2124-00	$14.04 99999-2118-00	$12.23 99999-2112-00	$11.02 99999-2108-00	$10.42 99999-2106-00	$9.81 99999-2104-00	$9.50 99999-2103-00
Syringe	$11.54 99999-2224-00	$9.73 99999-2218-00	$7.92 99999-2212-00	$6.71 99999-2208-00	$6.11 99999-2206-00	$5.50 99999-2204-00	$5.19 99999-2203-00
Cassettes	$33.60 99999-2424-00		$29.98 99999-2412-00				

CHEMOTHERAPY

	Every 24 hrs	Every 18 hrs	Every 12 hrs	Every 8 hrs	Every 6 hrs	Every 4 hrs	Every 3 hrs
Bag/Syr.	$17.02 99999-3424-00	$15.21 99999-3118-00	$32.71 99999-3412-00	$12.19 99999-3108-00	$11.59 99999-3106-00	$10.98 99999-3104-00	$10.67 99999-3103-00
Cassettes	$36.33 99999-3424-00		$32.71 99999-3412-00				

PAIN MANAGEMENT/CHEMOTHERAPY/ANTIBIOTICS

Cassette – reimbursement per cassette: $36.11
99999-4400-00

Intrathecal Pain Pump Refills – reimbursement per refill: $130.00
99999-5500-00

NOTE: THE ABOVE – REFERENCED COMPOUNDING FEES ARE CALCULATED PER UNIT. EACH BAG, CASSETTE, OR SYRINGE IS CONSIDERED ONE UNIT, REGARDLESS OF VOLUME.

Dispensing fees and co-payment requirements do not apply to the above referenced compounding fees.

EXHIBIT C

WV STATE GOVERNMENT

HIPAA BUSINESS ASSOCIATE ADDENDUM

WV STATE GOVERNMENT

HIPAA BUSINESS ASSOCIATE ADDENDUM

This Health Insurance Portability and Accountability Act of 1996 (hereafter, HIPAA) Business Associate Addendum ("Addendum") is made a part of the Agreement ("Agreement") by and between the State of West Virginia ("Agency"), and Business Associate ("Associate"), and is effective as of the date of execution of the Addendum.

The Associate performs certain services on behalf of or for the Agency pursuant to the underlying Agreement that requires the exchange of information including protected health information protected by the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), as amended by the American Recovery and Reinvestment Act of 2009 (Pub. L. No. 111-5) (the "HITECH Act"), any associated regulations and the federal regulations published at 45 CFR parts 160 and 164 (sometimes collectively referred to as "HIPAA"). The Agency is a "Covered Entity" as that term is defined in HIPAA, and the parties to the underlying Agreement are entering into this Addendum to establish the responsibilities of both parties regarding HIPAA-covered information and to bring the underlying Agreement into compliance with HIPAA.

Whereas it is desirable, in order to further the continued efficient operations of Agency to disclose to its Associate certain information which may contain confidential individually identifiable health information (hereafter, Protected Health Information or PHI); and

Whereas, it is the desire of both parties that the confidentiality of the PHI disclosed hereunder be maintained and treated in accordance with all applicable laws relating to confidentiality, including the Privacy and Security Rules, the HITECH Act and its associated regulations, and the parties do agree to at all times treat the PHI and interpret this Addendum consistent with that desire.

NOW THEREFORE: the parties agree that in consideration of the mutual promises herein, in the Agreement, and of the exchange of PHI hereunder that:

1. **Definitions.** Terms used, but not otherwise defined, in this Addendum shall have the same meaning as those terms in the Privacy, Security, Breach Notification, and Enforcement Rules at 45 CFR Part 160 and Part 164.

    a. **Agency Procurement Officer** shall mean the appropriate Agency individual listed at: http://www.state.wv.us/admin/purchase/vrc/agencyli.html.

    b. **Agent** shall mean those person(s) who are agent(s) of the Business Associate, in accordance with the Federal common law of agency, as referenced in 45 CFR § 160.402(c).

    c. **Breach** shall mean the acquisition, access, use or disclosure of protected health information which compromises the security or privacy of such information, except as excluded in the definition of Breach in 45 CFR § 164.402.

    d. **Business Associate** shall have the meaning given to such term in 45 CFR § 160.103.

    e. **HITECH Act** shall mean the Health Information Technology for Economic and Clinical Health Act. Public Law No. 111-05. 111th Congress (2009).

f. **Privacy Rule** means the Standards for Privacy of Individually Identifiable Health Information found at 45 CFR Parts 160 and 164.

g. **Protected Health Information or PHI** shall have the meaning given to such term in 45 CFR § 160.103, limited to the information created or received by Associate from or on behalf of Agency.

h. **Security Incident** means any known successful or unsuccessful attempt by an authorized or unauthorized individual to inappropriately use, disclose, modify, access, or destroy any information or interference with system operations in an information system.

I. **Security Rule** means the Security Standards for the Protection of Electronic Protected Health Information found at 45 CFR Parts 160 and 164.

j. **Subcontractor** means a person to whom a business associate delegates a function, activity, or service, other than in the capacity of a member of the workforce of such business associate.

2. **Permitted Uses and Disclosures.**

a. **PHI Described.** This means PHI created, received, maintained or transmitted on behalf of the Agency by the Associate. This PHI is governed by this Addendum and is limited to the minimum necessary, to complete the tasks or to provide the services associated with the terms of the original Agreement, and is described in Appendix A.

b. **Purposes.** Except as otherwise limited in this Addendum, Associate may use or disclose the PHI on behalf of, or to provide services to, Agency for the purposes necessary to complete the tasks, or provide the services, associated with, and required by the terms of the original Agreement, or as required by law, if such use or disclosure of the PHI would not violate the Privacy or Security Rules or applicable state law if done by Agency or Associate, or violate the minimum necessary and related Privacy and Security policies and procedures of the Agency. The Associate is directly liable under HIPAA for impermissible uses and disclosures of the PHI it handles on behalf of Agency.

c. **Further Uses and Disclosures.** Except as otherwise limited in this Addendum, the Associate may disclose PHI to third parties for the purpose of its own proper management and administration, or as required by law, provided that (i) the disclosure is required by law, or (ii) the Associate has obtained from the third party reasonable assurances that the PHI will be held confidentially and used or further disclosed only as required by law or for the purpose for which it was disclosed to the third party by the Associate; and, (iii) an agreement to notify the Associate and Agency of any instances of which it (the third party) is aware in which the confidentiality of the information has been breached. To the extent practical, the information should be in a limited data set or the minimum necessary information pursuant to 45 CFR § 164.502, or take other measures as necessary to satisfy the Agency's obligations under 45 CFR § 164.502.

3. **Obligations of Associate.**

a. **Stated Purposes Only.** The PHI may not be used by the Associate for any purpose other than as stated in this Addendum or as required or permitted by law.

b. **Limited Disclosure.** The PHI is confidential and will not be disclosed by the Associate other than as stated in this Addendum or as required or permitted by law. Associate is prohibited from directly or indirectly receiving any remuneration in exchange for an individual's PHI unless Agency gives written approval and the individual provides a valid authorization. Associate will refrain from marketing activities that would violate HIPAA, including specifically Section 13406 of the HITECH Act. Associate will report to Agency any use or disclosure of the PHI, including any Security Incident not provided for by this Agreement of which it becomes aware.

c. **Safeguards.** The Associate will use appropriate safeguards, and comply with Subpart C of 45 CFR Part 164 with respect to electronic protected health information, to prevent use or disclosure of the PHI, except as provided for in this Addendum. This shall include, but not be limited to:

i. Limitation of the groups of its workforce and agents, to whom the PHI is disclosed to those reasonably required to accomplish the purposes stated in this Addendum, and the use and disclosure of the minimum PHI necessary or a Limited Data Set;

ii. Appropriate notification and training of its workforce and agents in order to protect the PHI from unauthorized use and disclosure;

iii. Maintenance of a comprehensive, reasonable and appropriate written PHI privacy and security program that includes administrative, technical and physical safeguards appropriate to the size, nature, scope and complexity of the Associate's operations, in compliance with the Security Rule;

iv. In accordance with 45 CFR §§ 164.502(e)(1)(ii) and 164.308(b)(2), if applicable, ensure that any subcontractors that create, receive, maintain, or transmit protected health information on behalf of the business associate agree to the same restrictions, conditions, and requirements that apply to the business associate with respect to such information.

d. **Compliance With Law.** The Associate will not use or disclose the PHI in a manner in violation of existing law and specifically not in violation of laws relating to confidentiality of PHI, including but not limited to, the Privacy and Security Rules.

e. **Mitigation.** Associate agrees to mitigate, to the extent practicable, any harmful effect that is known to Associate of a use or disclosure of the PHI by Associate in violation of the requirements of this Addendum, and report its mitigation activity back to the Agency.

f. **Support of Individual Rights.**

i. **Access to PHI.** Associate shall make the PHI maintained by Associate or its agents or subcontractors in Designated Record Sets available to Agency for inspection and copying, and in electronic format, if requested, within ten (10) days of a request by Agency to enable Agency to fulfill its obligations under the Privacy Rule, including, but not limited to, 45 CFR § 164.524 and consistent with Section 13405 of the HITECH Act.

ii. **Amendment of PHI.** Within ten (10) days of receipt of a request from Agency for an amendment of the PHI or a record about an individual contained in a Designated Record Set, Associate or its agents or subcontractors shall make such PHI available to Agency for amendment and incorporate any such amendment to enable Agency to fulfill its obligations under the Privacy Rule, including, but not limited to, 45 CFR § 164.526.

iii. **Accounting Rights.** Within ten (10) days of notice of a request for an accounting of disclosures of the PHI, Associate and its agents or subcontractors shall make available to Agency the documentation required to provide an accounting of disclosures to enable Agency to fulfill its obligations under the Privacy Rule, including, but not limited to, 45 CFR §164.528 and consistent with Section 13405 of the HITECH Act. Associate agrees to document disclosures of the PHI and information related to such disclosures as would be required for Agency to respond to a request by an individual for an accounting of disclosures of PHI in accordance with 45 CFR § 164.528. This should include a process that allows for an accounting to be collected and maintained by Associate and its agents or subcontractors for at least six (6) years from the date of disclosure, or longer if required by state law. At a minimum, such documentation shall include:

- the date of disclosure;
- the name of the entity or person who received the PHI, and if known, the address of the entity or person;
- a brief description of the PHI disclosed; and
- a brief statement of purposes of the disclosure that reasonably informs the individual of the basis for the disclosure, or a copy of the individual's authorization, or a copy of the written request for disclosure.

iv. **Request for Restriction.** Under the direction of the Agency, abide by any individual's request to restrict the disclosure of PHI, consistent with the requirements of Section 13405 of the HITECH Act and 45 CFR § 164.522, when the Agency determines to do so (except as required by law) and if the disclosure is to a health plan for payment or health care operations and it pertains to a health care item or service for which the health care provider was paid in full "out-of-pocket."

v. **Immediate Discontinuance of Use or Disclosure.** The Associate will immediately discontinue use or disclosure of Agency PHI pertaining to any individual when so requested by Agency. This includes, but is not limited to, cases in which an individual has withdrawn or modified an authorization to use or disclose PHI.

g. **Retention of PHI.** Notwithstanding section 4.a. of this Addendum, Associate and its subcontractors or agents shall retain all PHI pursuant to state and federal law and shall continue to maintain the PHI required under Section 3.f. of this Addendum for a period of six (6) years after termination of the Agreement, or longer if required under state law.

h. **Agent's, Subcontractor's Compliance.** The Associate shall notify the Agency of all subcontracts and agreements relating to the Agreement, where the subcontractor or agent receives PHI as described in section 2.a. of this Addendum. Such notification shall occur within 30 (thirty) calendar days of the execution of the subcontract and shall be delivered to the Agency Procurement Officer. The Associate will ensure that any of its subcontractors, to whom it provides any of the PHI it receives hereunder, or to whom it provides any PHI which the Associate creates or receives on behalf of the Agency, agree to the restrictions and conditions which apply to the Associate hereunder. The Agency may request copies of downstream subcontracts and agreements to determine whether all restrictions, terms and conditions have been flowed down. Failure to ensure that downstream contracts, subcontracts and agreements contain the required restrictions, terms and conditions may result in termination of the Agreement.

j. **Federal and Agency Access.** The Associate shall make its internal practices, books, and records relating to the use and disclosure of PHI, as well as the PHI, received from, or created or received by the Associate on behalf of the Agency available to the U.S. Secretary of Health and Human Services consistent with 45 CFR § 164.504. The Associate shall also make these records available to Agency, or Agency's contractor, for periodic audit of Associate's compliance with the Privacy and Security Rules. Upon Agency's request, the Associate shall provide proof of compliance with HIPAA and HITECH data privacy/protection guidelines, certification of a secure network and other assurance relative to compliance with the Privacy and Security Rules. This section shall also apply to Associate's subcontractors, if any.

k. **Security.** The Associate shall take all steps necessary to ensure the continuous security of all PHI and data systems containing PHI. In addition, compliance with 74 FR 19006 Guidance Specifying the Technologies and Methodologies That Render PHI Unusable, Unreadable, or Indecipherable to Unauthorized Individuals for Purposes of the Breach Notification Requirements under Section 13402 of Title XIII is required, to the extent practicable. If Associate chooses not to adopt such methodologies as defined in 74 FR 19006 to secure the PHI governed by this Addendum, it must submit such written rationale, including its Security Risk Analysis, to the Agency Procurement Officer for review prior to the execution of the Addendum. This review may take up to ten (10) days.

l. **Notification of Breach.** During the term of this Addendum, the Associate shall notify the Agency and, unless otherwise directed by the Agency in writing, the WV Office of Technology immediately by e-mail or web form upon the discovery of any Breach of unsecured PHI; or within 24 hours by e-mail or web form of any suspected Security Incident, intrusion or unauthorized use or disclosure of PHI in violation of this Agreement and this Addendum, or potential loss of confidential data affecting this Agreement. Notification shall be provided to the Agency Procurement Officer at www.state.wv.us/admin/purchase/vrc/agencyli.htm and,

unless otherwise directed by the Agency in writing, the Office of Technology at incident@wv.gov or https://apps.wv.gov/ot/ir/Default.aspx.

The Associate shall immediately investigate such Security Incident, Breach, or unauthorized use or disclosure of PHI or confidential data. Within 72 hours of the discovery, the Associate shall notify the Agency Procurement Officer, and, unless otherwise directed by the Agency in writing, the Office of Technology of: (a) Date of discovery; (b) What data elements were involved and the extent of the data involved in the Breach; (c) A description of the unauthorized persons known or reasonably believed to have improperly used or disclosed PHI or confidential data; (d) A description of where the PHI or confidential data is believed to have been improperly transmitted, sent, or utilized; (e) A description of the probable causes of the improper use or disclosure; and (f) Whether any federal or state laws requiring individual notifications of Breaches are triggered.

Agency will coordinate with Associate to determine additional specific actions that will be required of the Associate for mitigation of the Breach, which may include notification to the individual or other authorities.

All associated costs shall be borne by the Associate. This may include, but not be limited to costs associated with notifying affected individuals.

If the Associate enters into a subcontract relating to the Agreement where the subcontractor or agent receives PHI as described in section 2.a. of this Addendum, all such subcontracts or downstream agreements shall contain the same incident notification requirements as contained herein, with reporting directly to the Agency Procurement Officer. Failure to include such requirement in any subcontract or agreement may result in the Agency's termination of the Agreement.

m. **Assistance in Litigation or Administrative Proceedings.** The Associate shall make itself and any subcontractors, workforce or agents assisting Associate in the performance of its obligations under this Agreement, available to the Agency at no cost to the Agency to testify as witnesses, or otherwise, in the event of litigation or administrative proceedings being commenced against the Agency, its officers or employees based upon claimed violations of HIPAA, the HIPAA regulations or other laws relating to security and privacy, which involves inaction or actions by the Associate, except where Associate or its subcontractor, workforce or agent is a named as an adverse party.

4. **Addendum Administration.**

a. **Term.** This Addendum shall terminate on termination of the underlying Agreement or on the date the Agency terminates for cause as authorized in paragraph (c) of this Section, whichever is sooner.

b. **Duties at Termination.** Upon any termination of the underlying Agreement, the Associate shall return or destroy, at the Agency's option, all PHI received from, or created or received by the Associate on behalf of the Agency that the Associate still maintains in any form and retain no copies of such PHI or, if such return or destruction is not feasible, the Associate shall extend the protections of this Addendum to the PHI and limit further uses and disclosures to the purposes that make the return or destruction of the PHI infeasible. This shall also apply to all agents and subcontractors of Associate. The duty of the Associate and its agents

and subcontractors to assist the Agency with any HIPAA required accounting of disclosures survives the termination of the underlying Agreement.

c. **Termination for Cause.** Associate authorizes termination of this Agreement by Agency, if Agency determines Associate has violated a material term of the Agreement. Agency may, at its sole discretion, allow Associate a reasonable period of time to cure the material breach before termination.

d. **Judicial or Administrative Proceedings.** The Agency may terminate this Agreement if the Associate is found guilty of a criminal violation of HIPAA. The Agency may terminate this Agreement if a finding or stipulation that the Associate has violated any standard or requirement of HIPAA/HITECH, or other security or privacy laws is made in any administrative or civil proceeding in which the Associate is a party or has been joined. Associate shall be subject to prosecution by the Department of Justice for violations of HIPAA/HITECH and shall be responsible for any and all costs associated with prosecution.

e. **Survival.** The respective rights and obligations of Associate under this Addendum shall survive the termination of the underlying Agreement.

5. **General Provisions/Ownership of PHI.**

a. **Retention of Ownership.** Ownership of the PHI resides with the Agency and is to be returned on demand or destroyed at the Agency's option, at any time, and subject to the restrictions found within section 4.b. above.

b. **Secondary PHI.** Any data or PHI generated from the PHI disclosed hereunder which would permit identification of an individual must be held confidential and is also the property of Agency.

c. **Electronic Transmission.** Except as permitted by law or this Addendum, the PHI or any data generated from the PHI which would permit identification of an individual must not be transmitted to another party by electronic or other means for additional uses or disclosures not authorized by this Addendum or to another contractor, or allied agency, or affiliate without prior written approval of Agency.

d. **No Sales.** Reports or data containing the PHI may not be sold without Agency's or the affected individual's written consent.

e. **No Third-Party Beneficiaries.** Nothing express or implied in this Addendum is intended to confer, nor shall anything herein confer, upon any person other than Agency, Associate and their respective successors or assigns, any rights, remedies, obligations or liabilities whatsoever.

f. **Interpretation.** The provisions of this Addendum shall prevail over any provisions in the Agreement that may conflict or appear inconsistent with any provisions in this Addendum. The interpretation of this Addendum shall be made under the laws of the state of West Virginia.

g. **Amendment.** The parties agree that to the extent necessary to comply with applicable law they will agree to further amend this Addendum.

h. **Additional Terms and Conditions.** Additional discretionary terms may be included in the release order or change order process.

AGREED:

Name of Agency:_____ Name of Associate:_____

Signature:_____ Signature:_____

Title:_____ Title:_____

Date:_____ Date:_____

Form - WVBAA-012004
Amended 06.26.2013

APPROVED AS TO FORM THIS 26th
DAY OF January 20 17
Patrick Morrisey
Attorney General
BY _____

Appendix A

(To be completed by the Agency's Procurement Officer prior to the execution of the Addendum, and shall be made a part of the Addendum. PHI not identified prior to execution of the Addendum may only be added by amending Appendix A and the Addendum, via Change Order.)

Name of Associate: WVDHHR Office of Community Health and Health Promotions/WV Bureau for Medical Services

Name of Agency: Division of Tobacco Prevention/Medicaid

Describe the PHI (do not include any actual PHI). If not applicable, please indicate the same.

Patient Information

Health History

Patient History

EXHIBIT D

FAGERSTROM TEST FOR NICOTINE DEPENDENCE

Fagerstrom Test for Nicotine Dependence

	PLEASE TICK (✓) ONE BOX FOR EACH QUESTION	
How soon after waking do you smoke your first cigarette?	Within 5 minutes 5-30 minutes 31-60 minutes	☐ 3 ☐ 2 ☐ 1
Do you find it difficult to refrain from smoking in places where it is forbidden? e.g. Church, Library, etc.	Yes No	☐ 1 ☐ 0
Which cigarette would you hate to give up?	The first in the morning Any other	☐ 1 ☐ 0
How many cigarettes a day do you smoke?	10 or less 11 – 20 21 – 30 31 or more	☐ 0 ☐ 1 ☐ 2 ☐ 3
Do you smoke more frequently in the morning?	Yes No	☐ 1 ☐ 0
Do you smoke even if you are sick in bed most of the day?	Yes No	☐ 1 ☐ 0
	Total Score	
SCORE	1-2 = low dependence 3-4 = low to mod dependence	5 - 7= moderate dependence 8 + = high dependence

Add up the scores from the questionnaire.

Information about scoring the Test is on the next page.

Scoring the Fagerstrom Test for Nicotine Dependence

To remind you of information (covered in Module 1) about scoring the Test:

Score of 1 - 2

A patient who scores between 1 and 2 on the Fagerstrom Test for Nicotine Dependence is classified as having a low dependence on nicotine. This suggests that they may not need Nicotine Replacement Therapy (NRT), although it is recommended that they still be monitored for withdrawal symptoms.

Score of 3-4

A patient who scores 3 or 4 would be considered to have a low to moderate dependence on nicotine and could be offered patches, inhaler, lozenges or gum. Please check NRT recommendations chart (insert link).

Score of 5-7

A patient who scores 4 would be considered to be moderately dependent on nicotine and can be offered patches, inhaler, lozenge or gum. They can also be offered the combined therapy of patches with lozenge and gum. Please check NRT recommendations chart (insert link).

Score of 8 and over

A patient who scores 5 and over would be considered highly dependent on nicotine and can be offered patches, inhaler, lozenges and/or gum. They can also be offered the combined therapy of patches and lozenges or gum. Please check the NRT recommendations chart (see the chart on the next page).

NRT recommendations chart

Dependence level	Nicotine Replacement Therapy Dosage	Combination Therapy
High	**Patches:** 21mg/24hr or 15mg/16hr **Inhaler:** 6 –12 cartridges per day **Lozenge:** 4mg **Gum:** 4mg	**Patches: 21mg/24hr or 15mg/16hr** AND **Lozenge or Gum: 2mg**
Moderate	**Patches:** 21mg/24hr or 15mg/16hr **Inhaler:** 6 –12 cartridges per day **Lozenge:** 4mg **Gum:** 4mg	**Patches: 21mg/24hr or 15mg/16 hr** AND **Lozenge or Gum: 2mg**
Low to moderate	**Patches:** 14mg/24hr patch or 10mg/16hr **Inhaler:** 6 –12 cartridges per day **Lozenge:** 2mg **Gum:** 2mg	**Patches: 14mg/24hr or 15mg/16hr** AND **Lozenge or Gum: 2mg**
Low	May not need NRT Monitor for withdrawal symptoms **Patches:** 7mg/24hr patch or 5mg/16hr **Lozenge:** 2mg **Gum:** 2mg	

Nicotine Replacement Therapy recommendations (from Clinical Guidelines – Part 7).

State of West Virginia

VENDOR PREFERENCE CERTIFICATE

Certification and application* is hereby made for Preference in accordance with ***West Virginia Code***, §5A-3-37. (Does not apply to construction contracts). ***West Virginia Code***, §5A-3-37, provides an opportunity for qualifying vendors to request (at the time of bid) preference for their residency status. Such preference is an evaluation method only and will be applied only to the cost bid in accordance with the ***West Virginia Code***. This certificate for application is to be used to request such preference. The Purchasing Division will make the determination of the Resident Vendor Preference, if applicable.

1. **Application is made for 2.5% resident vendor preference for the reason checked:**

____ Bidder is an individual resident vendor and has resided continuously in West Virginia for four (4) years immediately preceding the date of this certification; **or,**

____ Bidder is a partnership, association or corporation resident vendor and has maintained its headquarters or principal place of business continuously in West Virginia for four (4) years immediately preceding the date of this certification; or 80% of the ownership interest of Bidder is held by another individual, partnership, association or corporation resident vendor who has maintained its headquarters or principal place of business continuously in West Virginia for four (4) years immediately preceding the date of this certification; **or,**

____ Bidder is a nonresident vendor which has an affiliate or subsidiary which employs a minimum of one hundred state residents and which has maintained its headquarters or principal place of business within West Virginia continuously for the four (4) years immediately preceding the date of this certification; **or,**

2. **Application is made for 2.5% resident vendor preference for the reason checked:**

____ Bidder is a resident vendor who certifies that, during the life of the contract, on average at least 75% of the employees working on the project being bid are residents of West Virginia who have resided in the state continuously for the two years immediately preceding submission of this bid; **or,**

3. **Application is made for 2.5% resident vendor preference for the reason checked:**

____ Bidder is a nonresident vendor employing a minimum of one hundred state residents or is a nonresident vendor with an affiliate or subsidiary which maintains its headquarters or principal place of business within West Virginia employing a minimum of one hundred state residents who certifies that, during the life of the contract, on average at least 75% of the employees or Bidder's affiliate's or subsidiary's employees are residents of West Virginia who have resided in the state continuously for the two years immediately preceding submission of this bid; **or,**

4. **Application is made for 5% resident vendor preference for the reason checked:**

____ Bidder meets either the requirement of both subdivisions (1) and (2) or subdivision (1) and (3) as stated above; **or,**

5. **Application is made for 3.5% resident vendor preference who is a veteran for the reason checked:**

____ Bidder is an individual resident vendor who is a veteran of the United States armed forces, the reserves or the National Guard and has resided in West Virginia continuously for the four years immediately preceding the date on which the bid is submitted; **or,**

6. **Application is made for 3.5% resident vendor preference who is a veteran for the reason checked:**

____ Bidder is a resident vendor who is a veteran of the United States armed forces, the reserves or the National Guard, if, for purposes of producing or distributing the commodities or completing the project which is the subject of the vendor's bid and continuously over the entire term of the project, on average at least seventy-five percent of the vendor's employees are residents of West Virginia who have resided in the state continuously for the two immediately preceding years.

7. **Application is made for preference as a non-resident small, women- and minority-owned business, in accordance with *West Virginia Code* §5A-3-59 and *West Virginia Code of State Rules*.**

____ Bidder has been or expects to be approved prior to contract award by the Purchasing Division as a certified small, women- and minority-owned business.

Bidder understands if the Secretary of Revenue determines that a Bidder receiving preference has failed to continue to meet the requirements for such preference, the Secretary may order the Director of Purchasing to: (a) reject the bid; or (b) assess a penalty against such Bidder in an amount not to exceed 5% of the bid amount and that such penalty will be paid to the contracting agency or deducted from any unpaid balance on the contract or purchase order.

By submission of this certificate, Bidder agrees to disclose any reasonably requested information to the Purchasing Division and authorizes the Department of Revenue to disclose to the Director of Purchasing appropriate information verifying that Bidder has paid the required business taxes, provided that such information does not contain the amounts of taxes paid nor any other information deemed by the Tax Commissioner to be confidential.

Under penalty of law for false swearing (West Virginia Code, §61-5-3), Bidder hereby certifies that this certificate is true and accurate in all respects; and that if a contract is issued to Bidder and if anything contained within this certificate changes during the term of the contract, Bidder will notify the Purchasing Division in writing immediately.

Bidder: _____ **Signed:** _____

Date: _____ **Title:** _____

RFQ No. EHP14005

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: _____

Authorized Signature: _____ Date: _____

State of _____

County of _____, to-wit:

Taken, subscribed, and sworn to before me this ___ day of _____, 20___.

My Commission expires _____, 20___.

AFFIX SEAL HERE **NOTARY PUBLIC** _____

CERTIFICATION AND SIGNATURE PAGE

By signing below, 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 or proposal for review and consideration; that I am authorized by the bidder to execute this bid or any documents related thereto on bidder's behalf; that I am authorized to bind the bidder in a contractual relationship; and that to the best of my knowledge, the bidder has properly registered with any State agency that may require registration.

_____

(Company)

_____

(Authorized Signature)

_____

(Representative Name, Title)

_____

(Phone Number) (Fax Number)

_____

(Date)

ADDENDUM ACKNOWLEDGEMENT FORM
SOLICITATION NO.: EHP14005

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
☐ 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.

_____
Company

_____
Authorized Signature

_____
Date

NOTE: This addendum acknowledgement should be submitted with the bid to expedite document processing.