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

Solicitation

NUMBER	PAGE
BMS14096	1

ADDRESS CORRESPONDENCE TO ATTENTION OF:
BOB KILPATRICK
304-558-0067

RFQ COPY

VENDOR
TYPE NAME/ADDRESS HERE

SHIP TO
HEALTH AND HUMAN RESOURCES
BUREAU FOR MEDICAL SERVICES
ROOM 251
350 CAPITOL STREET
CHARLESTON, WV
25301-3709 304-558-1737

DATE PRINTED
03/19/2014

BID OPENING DATE: 04/16/2014 BID OPENING TIME 1:30PM

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 & HUMAN RESOURCES, BUREAU FOR MEDICAL SERVICES, TO ESTABLISH A CONTRACT TO PROVIDE FOR RETROSPECTIVE DRUG UTILIZATION REVIEW (RETRODUR) SERVICES, PER THE ATTACHED SPECIFICATIONS.

ATTACHMENTS INCLUDE:

1. INSTRUCTIONS TO VENDORS SUBMITTING BIDS
2. GENERAL TERMS AND CONDITIONS
3. BMS14096 SPECIFICATIONS, INCLUDING PRICING PAGE
4. HIPAA BUSINESS ASSOCIATE ADDENDUM
5. CERTIFICATION AND SIGNATURE PAGE
6. PURCHASING AFFIDAVIT
7. VENDOR PREFERENCE CERTIFICATE

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RETROSPECTIVE DRUG UTILIZATION REVIEW SERVICES

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:

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: Wednesday, April 2, 2014, by 12:00pm EST

Submit Questions to: Robert P Kilpatrick, Senior Buyer
2019 Washington Street, East
Charleston, WV 25305
Fax: 304-558-4115
Email: robert.p.kilpatrick@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 Purchasing Division will not accept bids, modification of bids, or addendum acknowledgment forms via e-mail. Acceptable delivery methods include hand delivery, delivery by courier, or facsimile. 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 maynot be considered:

SEALED BID
BUYER: Bob Kilpatrick, Buyer#22
SOLICITATION NO.: BMS14096
BID OPENING DATE: Wednesday, April 16, 2014
BID OPENING TIME: 1:30pm EST
FAX NUMBER: 304-558-3970

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 NA convenience copies of each to the Purchasing Division at the address shown above. Additionally, the Vendor should identifythe 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 bythe official Purchasing Division time clock.

Bid Opening Date and Time: Wednesday, April 16, 2014, at 1:30pm EST

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.

☑ Property Damage Insurance, $1,000,000.00 or more.

☑ Professional Liability Insurance, $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.

☐

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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 NA for NA

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 nondisclosure 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.

REQUEST FOR QUOTATION
BMS14096
Retrospective Drug Utilization Review Services

SPECIFICATIONS

1. **PURPOSE AND SCOPE:** The West Virginia Purchasing Division is soliciting bids on behalf of the Department of Health and Human Resources (DHHR), Bureau for Medical Services (BMS) to establish a contract for Retrospective Drug Utilization Review Services (RetroDUR).

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 implementation of a Retrospective Drug Utilization Program which includes the establishment of a Retrospective Drug Utilization Review (RetroDUR) database of Medicaid members' medical and drug history claims, which can be used to construct a medical and pharmacy profile of each Medicaid member, whether fee-for-service or enrolled in a Medicaid Managed Care Organization.

   2.2 "RFQ" means the official request for quotation published by the Purchasing Division and identified as BMS14096.

   2.3 "Lock In Program" means a program that coordinates the care of members whose medication utilization demonstrates the potential for overutilization of controlled substances. Member utilization of controlled substances, number of prescribers of controlled substances, and numbers of pharmacy providers used for obtaining controlled substances is monitored though a member profile review. If certain criteria are met, the member is locked into one pharmacy for obtaining prescriptions for controlled substances. All members taking Suboxone/Subutex are also locked into one pharmacy.

   2.4 "LTC Members" means members living in facilities that typically provide living accommodation for people who require on-site delivery of around-the-clock supervised care, including professional health services, personal care and services such as meals, laundry and housekeeping

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

3.1. A minimum of five years of experience in providing RetroDUR services similar to those specified herein to state Medicaid Programs. A letter of attestation documenting the required experience of the Vendor is preferred with the bid, but will be required prior to award of any Contract.

3.2. Current provision of Medicaid RetroDUR Services in at least three other states, excluding West Virginia. Provide the names and contact information for the state personnel who can attest to this provisioning; this information is preferred with the bid, and can be included in the letter required in 3.1.

3.3. Staffing with experience in the administration of a RetroDUR program including:

3.3.1 Medical Director,

3.3.2 One or more pharmacists, one of which has specialty certification in mental health agents. One of these assigned pharmacists must attend quarterly DUR Board meetings and make presentations regarding RetroDUR activity and proposals for population based educational interventions for Medicaid prescribers

3.3.3 A database analyst

3.3.4 A Help Desk, available from 9:00 am to 5:00 pm ET, for answering inquiries from members, prescribers, or pharmacy providers regarding the Lock-In Program and any other inquiries about the RetroDUR Program.

4. MANDATORY REQUIREMENTS

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

4.1.1 The Vendor shall develop West Virginia specific therapeutic criteria within ninety (90) calendar days of the contract award. The criteria must meet the following requirements:

4.1.1.1 The Vendor's therapeutic criteria shall reflect current drug policies and programs (including prior authorized products and criteria for approval) and patterns of use. The Vendor's therapeutic criteria must take into account newly marketed drugs and must be updated monthly for this purpose at no cost to the Bureau's pharmacy program.

4.1.1.2 The Vendor shall reference literature documentation and make such documentation available, within ten (10) business days, in printed form upon request by providers and others at no additional cost to the Bureau.

4.1.1.3 The Vendor shall develop the therapeutic criteria with attention given to types of diseases, therapeutic classes of drugs, and specific problems most often associated, or implicated in, cases of inappropriate drug therapy so that clinically significant alerts will be generated. The Vendor's therapeutic criteria shall be utilized to screen for potential therapeutic problems.

Targeted disease categories shall include, but not be limited to:

- 4.1.1.3.1 Cardiovascular
- 4.1.1.3.2 Endocrine
- 4.1.1.3.3 Psychiatric Disorder
- 4.1.1.3.4 Gastrointestinal Disorders
- 4.1.1.3.5 Arthritis
- 4.1.1.3.6 Asthma
- 4.1.1.3.7 Chronic Obstructive Pulmonary Disease
- 4.1.1.3.8 Diabetes
- 4.1.1.3.9 Antineoplastics

4.1.1.4 The Vendor shall develop criteria to screen for problems most often associated with inappropriate drug therapy which shall include, but not be limited to: ;

- 4.1.1.5.1 Over and under -utilization;
- 4.1.1.5.2 Drug(s) contraindicated by diagnosis;
- 4.1.1.5.3 Drug/drug interactions;
- 4.1.1.5.4 Duplication therapy;
- 4.1.1.5.5 Therapeutic appropriateness;
- 4.1.1.5.6 Appropriate use of generic drugs;
- 4.1.1.5.7 Incorrect drug dosage or duration of therapy;
- 4.1.1.5.8 Clinical abuse and misuse;
- 4.1.1.5.9 Iatrogenic complications;
- 4.1.1.5.10 Treatment failure

4.1.1.5 The Vendor's therapeutic criteria shall allow for ongoing adjustments to be made by the DUR Board and/or the Retrospective Drug Utilization Committee. The Vendor shall implement adjustments prior to the next generation of profiles, or within two weeks of notification by the BMS Pharmacy Program, whichever is longer.

4.1.1.6 The Vendor shall maintain a complete listing of the West Virginia Medicaid therapeutic criteria and update as often as new clinical information regarding the criteria becomes available.

4.1.1.7 The Vendor shall provide a hardcopy listing of therapeutic criteria within ten (10) business days of request by the Bureau's Pharmacy Program.

4.1.1.8 The Vendor's system shall rank criteria by clinical significance to reduce the number of alerts likely to be false positives or clinically insignificant.

4.1.1.9 The Vendor shall provide recommendations monthly to the Bureau's Pharmacy Program for clinical edits and prior authorization criteria based on the findings in the retrospective therapeutic review of profiles that would be beneficial to the health care of the Medicaid member, cost effective to the State, or both. These recommendations should be made by e-mail.

4.1.1.10 The Vendor shall be able to read the Long Term Care (LTC) indicator(s) in order to distinguish LTC members from community-based members. The Vendor shall include LTC beneficiaries in the retrospective DUR therapeutic criteria reviews

4.1.1.11 The Vendor shall update the DUR manuals to reflect the changes and additions to the therapeutic criteria, in addition to the lock-in algorithms.

4.1.1.12 The Vendor shall maintain an archive of exception profiles for the duration of the contract.

4.1.2 The Vendor shall design a RetroDUR computer system utilizing West Virginia specific therapeutic criteria for both member profile generation and a Lock-in program and begin operation within ninety (90) calendar days of the contract award. The Vendor's RetroDUR system shall be able to:

- Utilize file extracts from the West Virginia Medicaid Medical Management System (MMIS)
- Read all available medical diagnoses codes, procedure codes and pharmacy history,
- Utilize all physician specialty codes listed for specific prescribers,
- Differentiate between an adjudicated claim, a voided claim, and a rejected claim when reviewing the patient's drug history

- Read and utilize demographic information for members and providers, including, but not limited to, the member's county code, county of service, county of residence, and the Medicare eligibility indicator code.

4.1.2.1 The Vendor's system shall be able to incorporate changes within ten (10) business days from the time changes are made to the MMIS system or when the BMS Pharmacy Program determines additional fields should be added to the format, in order to capture required data to review.

4.1.2.2 The Vendor shall be responsible for coordinating file layouts from the MMIS vendor to populate the Vendor's RetroDUR system and a mutually acceptable method of transferring the files once weekly.

4.1.2.3 The Vendor shall provide a RetroDUR system with the capability of producing all member profiles and reports required herein.

4.1.2.4 The Vendor's Retrospective DUR system shall assess drug and diagnostic data against explicit predetermined standards including, but not limited to, monitoring for:

- therapeutic appropriateness,
- over-utilization
- under-utilization,
- incorrect drug dosage or duration of therapy

The Vendor shall scan Medicaid members' medical and pharmacy claims histories, applying the DUR Board-approved therapeutic criteria, to identify members whose drug use indicates a significant level of risk for drug induced or exacerbated outcomes.

4.1.2.5 The Vendor's system shall allow flexibility in formatting and production of patient and provider profiles to impart educational information to prescribers and pharmacy providers. The Vendor's system shall be able to establish the total number of profiles generated, and to select various demographics such as (but not limited to) specific criteria exceptions for certain patient populations and have the capability to read up to six (6) provider specialty codes and their corresponding effective dates and end dates.

4.1.2.6 The Vendor's system shall have the capability of suppressing profile generation for previously identified criteria after the initial flagging, for a period of time specified by the Bureau. This feature is to prevent providers from receiving repeated alerts for the same or similar situations.

4.1.2.7 The Vendor's system shall allow for interactive selection of population-based interventions, provider profiling options, and population and patient-specific intervention tracking reports. The Vendor shall present potential population-based educational interventions, based on the review of data and therapeutic criteria from the Vendor's RetroDUR system, to the DUR Board at each quarterly Board meeting.

4.1.2.8 The Vendor's system shall be able to differentiate between Medicaid members whose medical and pharmacy benefits are reimbursed by Fee for Service payment or Managed Care Organizations.

4.1.2.9 The Vendor shall generate Medicaid patient profiles monthly based on therapeutic criteria, high risk patient profiles, and provider profiles (prescribers and pharmacy providers) in hard or electronic copy for RetroDUR.

4.1.2.10 The Vendor shall generate no less than 350 member profiles. The profiles should be reviewed against the therapeutic criteria and cover all age groups, including LTC members. The balance between members in Fee for Service and managed care shall be determined by the Bureau.

4.1.2.11 The profiles for review shall be made available for the Pharmacy Program's monthly RetroDUR Committee meeting and generated no more than three(3) business days before mailing. The profiles will be shipped to the Bureau and returned to the Vendor at no additional cost to the Bureau.

4.1.2.12 The Vendor's system shall generate patient and provider cases monthly by weighting and ranking mechanisms, which have been approved prior to use by the BMS Pharmacy program, to sort exceptions by potential seriousness.

4.1.2.13 The profiles developed by the Vendor's system must contain at least eighteen (18) contiguous months of claims history, representing a summarized review of all drug information and diagnoses for which claims were reimbursed. The Vendor shall be able to

differentiate between a claim that was voided or cancelled and a paid claim.

4.1.2.14 The Vendor's system shall maintain patient and provider confidentiality in all aspects of developing and handling patient history profiles, as well as all input claims history data. The Vendor shall handle and store claims data and patient and provider profiles in accordance with 42 Code of Federal Regulations part 431, Subpart F, regarding confidentiality of information concerning applicants and beneficiaries of public assistance, and 42 Code of Federal Regulations Part 2, regarding confidentiality of alcohol and drug abuse patient records (see Attachment A).

4.1.3 The Vendor shall communicate the results of patient profile reviews within thirty (30) calendar days by letter to prescribers and/or pharmacy providers for Fee-for-Service members. The cost of mailing shall be included in the Vendor's quotation. All letters to Medicaid prescribers and pharmacy providers must be signed by the Vendor's medical director. The Vendor's retrospective DUR program shall provide ongoing interventions for physicians and pharmacists targeted toward therapy problems or individual patients identified in the course of DUR review activities.

4.1.4 The Vendor shall design at least six (6) educational population- based interventions or other targeted provider interventions to be modifiable per the Bureau and DUR Board's requirements per year. The interventions shall be performed every two months. The Vendor shall make any such modifications to wording or formats, specified by the BMS Pharmacy program and DUR Board, within thirty (30) calendar days of the request by the Bureau, at the Vendor's expense. The total cost of the design, production and mailing of these interventions to targeted prescribers or pharmacy providers shall be included in the Vendor's quote. There are approximately 7,000 active prescribers and 700 pharmacy providers enrolled in the West Virginia Medicaid Program.

4.1.5 The Vendor shall establish and maintain a Pharmacy Lock-in Program for Medicaid beneficiaries who utilize multiple pharmacies and/or prescribers for controlled substances within ninety (90) calendar days of the contract award . The purpose of the Lock-In Program shall be to improve patient care by coordinating the activities of various health care providers, to integrate the pharmacist into the drug therapy management process, and to improve patient outcomes.

4.1.5.1 The member will be correctly identified by application of a utilization algorithm and clinical review. The Vendor shall accept beneficiary names from the Bureau and accept and process these candidates for immediate lock-in. The

eligible member will be required to select one provider for pharmacy services and the Vendor will notify the beneficiary that Medicaid will deny claims for pharmacy services submitted by any other pharmacy provider.

All members on Subuxone or Subutex must be locked into one pharmacy and incorporated into the Lock-In Program. The Vendor shall call the Pharmacy Provider the member has chosen within thirty (30) calendar days and explain the lock-in program and obtain agreement from the Pharmacy Provider to participate as the lock-in Pharmacy provider for the member. The Vendor shall provide all communications by mail to the members, prescribers and pharmacy providers for the lock-in program within thirty (30) calendar days of the members' choice of a pharmacy. The total cost of production and mailing of the letters regarding the lock-in program to members, prescribers and pharmacy providers shall be included in the Vendor's quote.

4.1.5.2 The Vendor shall maintain a toll-free telephone Help Desk for Medicaid prescribers, pharmacy providers and members to answer inquiries about the RetroDUR Program, including the Lock-in program, and any communications that may have been received by them. The Help Desk shall be available for at least a consecutive eight hour period coinciding with regular business hours, from Monday through Friday. The Vendor shall maintain the member Lock-in beneficiary and provider list and supply a file of this information to the BMS MMIS vendor daily for an automated lock-in process. The Vendor shall work with the BMS MMIS vendor to coordinate file layouts and transfer of files through a secure ftp site.

4.1.6 Prior to implementing the system, the Vendor shall provide a list of every office director, owner, partner, key employees, or other person with primary management or supervisory responsibilities, and any person who has a critical influence on or substantive control over a transaction with the State of West Virginia, whether or not employed by the Vendor. The list shall include full names, including maiden names and first and middle names where applicable. Additions or deletions to the list of names shall be reported voluntarily and automatically to the Pharmacy Program within one month of the change or addition. The Vendor shall not employ or contract with any individual or entity named on the federally excluded provider list.

4.1.7 The Vendor shall provide a RetroDUR Committee, made up of a minimum of three actively participating pharmacists and one additional member who is a physician, pharmacist, nurse practitioner or physician assistant. The RetroDUR Committee shall review the member medication profiles described in Section 4.1.2.10 in person with the

Pharmacy Services clinical staff at a regularly scheduled monthly meeting. Any costs incurred for provision of this Committee must be included in the Vendor's proposal.

4.1.8 The Vendor shall establish both a reporting system for established standard periodic reports and have the capability of *ad hoc* reporting. The Vendor's system shall allow for generation of reports to include, but not be limited to:

- Provider report cards;
- Drug/drug class utilization and utilization patterns;
- Diseases and disease categories;
- Member history and profiles;
- Sorting providers by prescribed drugs, specialty, patient volume, diagnosis codes, procedure codes, number of medications per patient, etc.;
- Sorting members by diagnoses, age, sex, drug use, provider, number of prescriptions, etc.;
- Ranking by utilization, volume, dollars paid, etc.;
- Reports by Managed Care plan.

4.1.8.1 Monthly reports-The Vendor shall provide the following RetroDUR summary reports monthly, at least three (3) calendar days prior to the RetroDUR Committee meeting, to the Pharmacy Services Program for review and approval. These reports shall be mailed to the Bureau for inclusion in the RetroDUR Committee members' monthly meeting packets. The content fields of the Vendor's summary reports shall be mutually identified and agreed upon. Monthly reports are to include, but not be limited to:

- Provider response log updates
- Provider profiling (physician and pharmacy provider)
- Profile review outcome summary
- Case summary
- Statistical activity summary report to include but not be limited to distribution of beneficiaries, number of cases reviewed, number of letters generated, summary of distribution of cases by problem types and follow-up data
- Report of outlier and errant claims by pharmacy providers

4.1.8.2 Quarterly Activity Reports-The Vendor shall submit, by e-mail and hard copy, each quarterly report within fifteen (15) calendar days following the applicable quarterly period. The quarterly reports are to include, but not be limited to:

- Patient profiles review outcome reports by population, including Fee-for-Service and Managed Care members
- Activity statistical report
- Case distribution by problem type
- Trend summary of major therapeutic categories of interest
- Outcomes reports (six month post intervention)-The Vendor shall provide an outcome report for review at DUR Board meetings.
- Outcomes reports (six month post intervention). The Vendor shall provide outcomes reports of all population based educational interventions and present them at the appropriate quarterly DUR Board meeting.

4.1.8.3 Annual Reports-The Vendor shall submit at least the following, data by May 1 of each calendar year for CMS annual reports (this information shall be submitted electronically to the Bureau):

- Outcomes and utilization summary reports
- Population-based intervention outcomes
- Savings generated by the RetroDUR Program
- All requirements specified by the Centers for Medicare and Medicaid (CMS) Annual Report no later than May 1 of each year to comply with Section 1927 (g)(3)(d) of the Social Security Act that requires each state to submit an annual report to CMS on the operation of its Medicaid DUR Program. The Vendor shall include all necessary data for the descriptions of the nature and scope of the RetroDUR program, a summary of the interventions used and an assessment of the education programs, and an assessment of the RetroDUR program's impact on quality of care, as well as any cost savings generated in the program. Additionally, the Vendor shall assist the Bureau in a description of DUR Board activities as it pertains to RetroDUR activities. The report format must be such that the Bureau will be able to add other sections to the electronic report to complete the document to CMS.

4.1.8.4 *Ad Hoc* Reporting-*Ad hoc* reports will be made available by e-mail to the Bureau within 72 hours of the Bureau's request. The Vendor's inquiry and reporting system shall have the ability to query for both a follow-up on previously identified situations, as well as to perform user-defined *ad hoc* reports. The Vendor will utilize this tool to perform sophisticated analyses of activity to develop documents and to develop additional reports to add to scheduled reports as requested by the BMS Pharmacy Program. The inquiry component of the Vendor's reporting system must:

4.1.8.4.1 Allow Vendor to select, compare and report on the data by any element or combination of elements in the data, by claim types, by date paid or date of service, by provider types, provider specialties, or billing or performing providers.

4.1.8.4.2 Allow Vendor to easily specify arithmetic, algebraic and statistical calculations such as subtotals, totals, percentages, ratios, percentiles, selections by less than, equal to or greater than criteria, unduplicated counts, regression analyses, and frequency distributions.

4.1.8.4.3 Allow Vendor to connect different categories of services based on specified criteria.

4.1.8.4.4 Allow Vendor to determine data trends over time and create standard report runs for these analyses.

4.1.8.4.5 Allow Vendor to save inquiry steps for later use by themselves and other users. The system must include a library of already-built query and run parameters which users can select, copy, and modify.

4.1.8.4.6 Allow non-technical users to create inquiries and groups of defined data elements to be use in inquiries. These must be provided in a desk top format for use by the Bureau staff members. The Vendor must provide on-site training for BMS staff for use of the desk top application for *ad hoc* queries.

4.1.8.4.7 Provide drill-down capable access to any reference tables provided in reports.

4.1.8.4.8 The Vendor must have the capability to export the results of inquiries into common desktop applications.

4.1.8.4.9 Have episode of care analysis which allows the Vendor to identify member and prescriber target events and to define an episode in terms of time.

4.1.8.4.10 Have capability to request comparisons of Medicaid claims activity against clinical and non-clinical standards or norms, including state approved national guidelines selected for this purpose.

4.1.8.4.11 Have capability to archive or store reports.

4.1.9 The Vendor shall produce a quarterly newsletter detailing BMS Pharmacy Policies, Drug Utilization Review Board actions, drug information and other relevant information to Medicaid prescribers and pharmacy providers. These newsletters must be mailed to Medicaid prescribers (approx.. 7000) and pharmacy providers (approx.. 700), and be available electronically on the Bureau for Medical Services website at:
http://www.dhhr.wv.gov/bms/Pharmacy/Pages/default.aspx.
The total cost of production and mailing must be included in the Vendor's quote.

4.1.10 The Vendor must provide support for quarterly DUR Board meetings including, but not limited to: meeting attendance and presentations regarding proposed population-based educational interventions and pharmacy profile review outcome reports and potential population-based educational interventions based on BMS therapeutic criteria exceptions and other relevant data. The Vendor shall also provide DUR Board meeting minutes, by e-mail, within ten (10) calendar days after each quarterly meeting. All costs associated with this support are to be included in the vendor's quote.

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 overall Vendor's Total Bid, as shown on the Pricing Page. Only the Yearly total for Year 1 will be awarded in the initial contract, with Year 2 and Year 3 added upon mutually agreed upon change orders for renewal in each of the subsequent years.

5.2 Pricing Page: Vendor should complete the Pricing Page by providing the Monthly cost for each service (data collection, member profiles and lock-in program) and deliverables (reports and educational programs for providers) indicated in the table in the Pricing Page. Bidders should multiply each Monthly cost bid by 12 to calculate the Yearly cost. The Vendor should also provide the Total Monthly and Yearly costs of all five services and deliverables combined that are listed in the table. The Vendor should note that all mailing costs and monthly amounts paid to RetroDUR Committee members should be included in the Vendor's price quotation. No costs can be passed on to the Bureau outside the Vendor's submitted quote for RetroDUR services. 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 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 a flat fee 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: _____

REQUEST FOR QUOTATION

BMS14096

Retrospective Drug Utilization Review Services

Pricing Page

Cost information below as detailed in the Request for Quotation. Cost should be clearly marked. Cost must be broken out by the following categories. This will be a fixed cost contract, based on a per year basis.

	YEAR 1			OPTIONAL YEAR 2			OPTIONAL YEAR 3		
Description of Services	**Monthly**		Yearly	**Monthly**		Yearly	**Monthly**		Yearly
Data Collection	$	x12	$	$	x12	$	$	x12	$
(Member Profiles)	$	x12	$	$	x12	$	$	x12	$
Educational Programs for Providers (Newsletters, Educational Population-Based Interventions, Member Profile Review Letters	$	x12	$	$	x12	$	$	x12	$
Retrospective Drug Utilization Review Reports	$	x12	$	$	x12	$	$	x12	$
Lock-In Program (including letters to members, prescribers and pharmacy providers) and Help Desk	$	x12	$	$	x12	$	$	x12	$
Totals	$	x12	$	$	x12	$	$	x12	$

VENDOR'S TOTAL BID (3 Year Price) _____

RFQ#BMS14096 Attachment A

SUBCHAPTER A—GENERAL PROVISIONS

PART 1 [RESERVED]

PART 2—CONFIDENTIALITY OF ALCOHOL AND DRUG ABUSE PATIENT RECORDS

Subpart A—Introduction

Sec.

Subpart B—General Provisions

Subpart C—Disclosures With Patient's Consent

Subpart D—Disclosures Without Patient Consent

Subpart E—Court Orders Authorizing Disclosure and Use

AUTHORITY: Sec. 408 of Pub. L. 92-255, 86 Stat. 79, as amended by sec. 303 (a), (b) of Pub L. 93-282, 83 Stat. 137, 138; sec. 4(c)(5)(A) of Pub. L. 94-237, 90 Stat. 244; sec. 111(c)(3) of Pub. L. 94-581, 90 Stat. 2852; sec. 509 of Pub. L. 96-88, 93 Stat. 695; sec. 973(d) of Pub. L. 97-35, 95 Stat. 598; and transferred to sec. 527 of the Public Health Service Act by sec. 2(b)(16)(B) of Pub. L. 98-24, 97 Stat. 182 and as amended by sec. 106 of Pub. L. 99-401, 100 Stat. 907 (42 U.S.C. 290ee-3) and sec. 333 of Pub. L. 91-616, 84 Stat. 1853, as amended by sec. 122(a) of Pub. L. 93-282, 88 Stat. 131; and sec. 111(c)(4) of Pub. L. 94-581, 90 Stat. 2852 and transferred to sec. 523 of the Public Health Service Act by sec. 2(b)(13) of Pub. L. 98-24, 97 Stat. 181 and as amended by sec. 106 of Pub. L. 99-401, 100 Stat. 907 (42 U.S.C. 290dd-3), as amended by sec. 131 of Pub. L. 102-321, 106 Stat. 368, (42 U.S.C. 290dd-2).

SOURCE: 52 FR 21809, June 9, 1987, unless otherwise noted.

Subpart A—Introduction

§ 2.1 Statutory authority for confidentiality of drug abuse patient records.

The restrictions of these regulations upon the disclosure and use of drug abuse patient records were initially authorized by section 408 of the Drug Abuse Prevention, Treatment, and Rehabilitation Act (21 U.S.C. 1175). That section as amended was transferred by Pub. L. 98-24 to section 527 of the Public Health Service Act which is codified

at 42 U.S.C. 290ee-3. The amended statutory authority is set forth below:

§ 290EE–3. CONFIDENTIALITY OF PATIENT RECORDS.

(a) *Disclosure authorization*

Records of the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of any drug abuse prevention function conducted, regulated, or directly or indirectly assisted by any department or agency of the United States shall, except as provided in subsection (e) of this section, be confidential and be disclosed only for the purposes and under the circumstances expressly authorized under subsection (b) of this section.

(b) *Purposes and circumstances of disclosure affecting consenting patient and patient regardless of consent*

(1) The content of any record referred to in subsection (a) of this section may be disclosed in accordance with the prior written consent of the patient with respect to whom such record is maintained, but only to such extent, under such circumstances, and for such purposes as may be allowed under regulations prescribed pursuant to subsection (g) of this section.

(2) Whether or not the patient, with respect to whom any given record referred to in subsection (a) of this section is maintained, gives his written consent, the content of such record may be disclosed as follows:

(A) To medical personnel to the extent necessary to meet a bona fide medical emergency.

(B) To qualified personnel for the purpose of conducting scientific research, management audits, financial audits, or program evaluation, but such personnel may not identify, directly or indirectly, any individual patient in any report of such research, audit, or evaluation, or otherwise disclose patient identities in any manner.

(C) If authorized by an appropriate order of a court of competent jurisdiction granted after application showing good cause therefor. In assessing good cause the court shall weigh the public interest and the need for disclosure against the injury to the patient, to the physician-patient relationship, and to the treatment services. Upon the granting of such order, the court, in determining the extent to which any disclosure of all or any part of any record is necessary, shall impose appropriate safeguards against unauthorized disclosure.

(c) *Prohibition against use of record in making criminal charges or investigation of patient*

Except as authorized by a court order granted under subsection (b)(2)(C) of this section, no record referred to in subsection (a) of this section may be used to initiate or substantiate any criminal charges against a patient or to conduct any investigation of a patient.

(d) *Continuing prohibition against disclosure irrespective of status as patient*

The prohibitions of this section continue to apply to records concerning any individual who has been a patient, irrespective of whether or when he ceases to be a patient.

(e) *Armed Forces and Veterans' Administration; interchange of records; report of suspected child abuse and neglect to State or local authorities*

The prohibitions of this section do not apply to any interchange of records—

(1) within the Armed Forces or within those components of the Veterans' Administration furnishing health care to veterans, or

(2) between such components and the Armed Forces.

The prohibitions of this section do not apply to the reporting under State law of incidents of suspected child abuse and neglect to the appropriate State or local authorities.

(f) *Penalty for first and subsequent offenses*

Any person who violates any provision of this section or any regulation issued pursuant to this section shall be fined not more than $500 in the case of a first offense, and not more than $5,000 in the case of each subsequent offense.

(g) *Regulations; interagency consultations; definitions, safeguards, and procedures, including procedures and criteria for issuance and scope of orders*

Except as provided in subsection (h) of this section, the Secretary, after consultation with the Administrator of Veterans' Affairs and the heads of other Federal departments and agencies substantially affected thereby, shall prescribe regulations to carry out the purposes of this section. These regulations may contain such definitions, and may provide for such safeguards and procedures, including procedures and criteria for the issuance and scope of orders under subsection (b)(2)(C) of this section, as in the judgment of the Secretary are necessary or proper to effectuate the purposes of this section, to prevent circumvention or evasion thereof, or to facilitate compliance therewith.

(Subsection (h) was superseded by section 111(c)(3) of Pub. L. 94-581. The responsibility of the Administrator of Veterans' Affairs to write regulations to provide for confidentiality of drug abuse patient records under Title 38 was moved from 21 U.S.C. 1175 to 38 U.S.C. 4134.)

§ 2.2 Statutory authority for confidentiality of alcohol abuse patient records.

The restrictions of these regulations upon the disclosure and use of alcohol

abuse patient records were initially authorized by section 333 of the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970 (42 U.S.C. 4582). The section as amended was transferred by Pub. L. 98-24 to section 523 of the Public Health Service Act which is codified at 42 U.S.C. 290dd-3. The amended statutory authority is set forth below:

§ 290DD-3. CONFIDENTIALITY OF PATIENT RECORDS

(a) *Disclosure authorization*

Records of the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of any program or activity relating to alcoholism or alcohol abuse education, training, treatment, rehabilitation, or research, which is conducted, regulated, or directly or indirectly assisted by any department or agency of the United States shall, except as provided in subsection (e) of this section, be confidential and be disclosed only for the purposes and under the circumstances expressly authorized under subsection (b) of this section.

(b) *Purposes and circumstances of disclosure affecting consenting patient and patient regardless of consent*

(1) The content of any record referred to in subsection (a) of this section may be disclosed in accordance with the prior written consent of the patient with respect to whom such record is maintained, but only to such extent, under such circumstances, and for such purposes as may be allowed under regulations prescribed pursuant to subsection (g) of this section.

(2) Whether or not the patient, with respect to whom any given record referred to in subsection (a) of this section is maintained, gives his written consent, the content of such record may be disclosed as follows:

(A) To medical personnel to the extent necessary to meet a bona fide medical emergency.

(B) To qualified personnel for the purpose of conducting scientific research, management audits, financial audits, or program evaluation, but such personnel may not identify, directly or indirectly, any individual patient in any report of such research, audit, or evaluation, or otherwise disclose patient identities in any manner.

(C) If authorized by an appropriate order of a court of competent jurisdiction granted after application showing good cause therefor. In assessing good cause the court shall weigh the public interest and the need for disclosure against the injury to the patient, to the physician-patient relationship, and to the treatment services. Upon the granting of such order, the court, in determining the extent to which any disclosure of all or any part of any record is necessary, shall impose appropriate safeguards against unauthorized disclosure.

(c) *Prohibition against use of record in making criminal charges or investigation of patient*

Except as authorized by a court order granted under subsection (b)(2)(C) of this section, no record referred to in subsection (a) of this section may be used to initiate or substantiate any criminal charges against a patient or to conduct any investigation of a patient.

(d) *Continuing prohibition against disclosure irrespective of status as patient*

The prohibitions of this section continue to apply to records concerning any individual who has been a patient, irrespective of whether or when he ceases to be a patient.

(e) *Armed Forces and Veterans' Administration; interchange of record of suspected child abuse and neglect to State or local authorities*

The prohibitions of this section do not apply to any interchange of records—

(1) within the Armed Forces or within those components of the Veterans' Administration furnishing health care to veterans, or

(2) between such components and the Armed Forces.

The prohibitions of this section do not apply to the reporting under State law of incidents of suspected child abuse and neglect to the appropriate State or local authorities.

(f) *Penalty for first and subsequent offenses*

Any person who violates any provision of this section or any regulation issued pursuant to this section shall be fined not more than $500 in the case of a first offense, and not more than $5,000 in the case of each subsequent offense.

(g) *Regulations of Secretary; definitions, safeguards, and procedures, including procedures and criteria for issuance and scope of orders*

Except as provided in subsection (h) of this section, the Secretary shall prescribe regulations to carry out the purposes of this section. These regulations may contain such definitions, and may provide for such safeguards and procedures, including procedures and criteria for the issuance and scope of orders under subsection(b)(2)(C) of this section, as in the judgment of the Secretary are necessary or proper to effectuate the purposes of this section, to prevent circumvention or evasion thereof, or to facilitate compliance therewith.

(Subsection (h) was superseded by section 111(c)(4) of Pub. L. 94-581. The responsibility of the Administrator of Veterans' Affairs to write regulations to provide for confidentiality of alcohol abuse patient records under Title 38 was moved from 42 U.S.C. 4582 to 38 U.S.C. 4134.)

§ 2.3 Purpose and effect.

(a) *Purpose.* Under the statutory provisions quoted in §§ 2.1 and 2.2, these regulations impose restrictions upon the disclosure and use of alcohol and drug abuse patient records which are maintained in connection with the performance of any federally assisted alcohol and drug abuse program. The regulations specify:

(1) Definitions, applicability, and general restrictions in subpart B (definitions applicable to § 2.34 only appear in that section);

(2) Disclosures which may be made with written patient consent and the form of the written consent in subpart C;

(3) Disclosures which may be made without written patient consent or an authorizing court order in subpart D; and

(4) Disclosures and uses of patient records which may be made with an authorizing court order and the procedures and criteria for the entry and scope of those orders in subpart E.

(b) *Effect.* (1) These regulations prohibit the disclosure and use of patient records unless certain circumstances exist. If any circumstances exists under which disclosure is permitted, that circumstance acts to remove the prohibition on disclosure but it does not compel disclosure. Thus, the regulations do not require disclosure under any circumstances.

(2) These regulations are not intended to direct the manner in which substantive functions such as research, treatment, and evaluation are carried out. They are intended to insure that an alcohol or drug abuse patient in a federally assisted alcohol or drug abuse program is not made more vulnerable by reason of the availability of his or her patient record than an individual who has an alcohol or drug problem and who does not seek treatment.

(3) Because there is a criminal penalty (a fine—see 42 U.S.C. 290ee-3(f), 42 U.S.C. 290dd-3(f) and 42 CFR 2.4) for violating the regulations, they are to be construed strictly in favor of the potential violator in the same manner as a criminal statute (see *M. Kraus & Brothers* v. *United States*, 327 U.S. 614, 621–22, 66 S. Ct. 705, 707–08 (1946)).

§ 2.4 Criminal penalty for violation.

Under 42 U.S.C. 290ee-3(f) and 42 U.S.C. 290dd-3(f), any person who violates any provision of those statutes or these regulations shall be fined not more than $500 in the case of a first offense, and not more than $5,000 in the case of each subsequent offense.

§ 2.5 Reports of violations.

(a) The report of any violation of these regulations may be directed to the United States Attorney for the judicial district in which the violation occurs.

(b) The report of any violation of these regulations by a methadone program may be directed to the Regional Offices of the Food and Drug Administration.

Subpart B—General Provisions

§ 2.11 Definitions.

For purposes of these regulations:

Alcohol abuse means the use of an alcoholic beverage which impairs the physical, mental, emotional, or social well-being of the user.

Drug abuse means the use of a psychoactive substance for other than medicinal purposes which impairs the physical, mental, emotional, or social well-being of the user.

Diagnosis means any reference to an individual's alcohol or drug abuse or to a condition which is identified as having been caused by that abuse which is made for the purpose of treatment or referral for treatment.

Disclose or disclosure means a communication of patient indentifying information, the affirmative verification of another person's communication of patient identifying information, or the communication of any information from the record of a patient who has been identified.

Informant means an individual:

(a) Who is a patient or employee of a program or who becomes a patient or employee of a program at the request of a law enforcement agency or official; and

(b) Who at the request of a law enforcement agency or official observes one or more patients or employees of

the program for the purpose of reporting the information obtained to the law enforcement agency or official.

Patient means any individual who has applied for or been given diagnosis or treatment for alcohol or drug abuse at a federally assisted program and includes any individual who, after arrest on a criminal charge, is identified as an alcohol or drug abuser in order to determine that individual's eligibility to participate in a program.

Patient identifying information means the name, address, social security number, fingerprints, photograph, or similar information by which the identity of a patient can be determined with reasonable accuracy and speed either directly or by reference to other publicly available information. The term does not include a number assigned to a patient by a program, if that number does not consist of, or contain numbers (such as a social security, or driver's license number) which could be used to identify a patient with reasonable accuracy and speed from sources external to the program.

Person means an individual, partnership, corporation, Federal, State or local government agency, or any other legal entity.

Program means:

(a) An individual or entity (other than a general medical care facility) who holds itself out as providing, and provides, alcohol or drug abuse diagnosis, treatment or referral for treatment; or

(b) An identified unit within a general medical facility which holds itself out as providing, and provides, alcohol or drug abuse diagnosis, treatment or referral for treatment; or

(c) Medical personnel or other staff in a general medical care facility whose primary function is the provision of alcohol or drug abuse diagnosis, treatment or referral for treatment and who are identified as such providers. (See §2.12(e)(1) for examples.)

Program director means:

(a) In the case of a program which is an individual, that individual;

(b) In the case of a program which is an organization, the individual designated as director, managing director, or otherwise vested with authority to act as chief executive of the organization.

Qualified service organization means a person which:

(a) Provides services to a program, such as data processing, bill collecting, dosage preparation, laboratory analyses, or legal, medical, accounting, or other professional services, or services to prevent or treat child abuse or neglect, including training on nutrition and child care and individual and group therapy, and

(b) Has entered into a written agreement with a program under which that person:

(1) Acknowledges that in receiving, storing, processing or otherwise dealing with any patient records from the progams, it is fully bound by these regulations; and

(2) If necessary, will resist in judicial proceedings any efforts to obtain access to patient records except as permitted by these regulations.

Records means any information, whether recorded or not, relating to a patient received or acquired by a federally assisted alcohol or drug program.

Third party payer means a person who pays, or agrees to pay, for diagnosis or treatment furnished to a patient on the basis of a contractual relationship with the patient or a member of his family or on the basis of the patient's eligibility for Federal, State, or local governmental benefits.

Treatment means the management and care of a patient suffering from alcohol or drug abuse, a condition which is identified as having been caused by that abuse, or both, in order to reduce or eliminate the adverse effects upon the patient.

Undercover agent means an officer of any Federal, State, or local law enforcement agency who enrolls in or becomes an employee of a program for the purpose of investigating a suspected violation of law or who pursues that purpose after enrolling or becoming employed for other purposes.

[52 FR 21809, June 9, 1987, as amended by 60 FR 22297, May 5, 1995]

§2.12 Applicability.

(a) *General*—(1) *Restrictions on disclosure.* The restrictions on disclosure in

these regulations apply to any information, whether or not recorded, which:

(i) Would identify a patient as an alcohol or drug abuser either directly, by reference to other publicly available information, or through verification of such an identification by another person; and

(ii) Is drug abuse information obtained by a federally assisted drug abuse program after March 20, 1972, or is alcohol abuse information obtained by a federally assisted alcohol abuse program after May 13, 1974 (or if obtained before the pertinent date, is maintained by a federally assisted alcohol or drug abuse program after that date as part of an ongoing treatment episode which extends past that date) for the purpose of treating alcohol or drug abuse, making a diagnosis for that treatment, or making a referral for that treatment.

(2) *Restriction on use.* The restriction on use of information to initiate or substantiate any criminal charges against a patient or to conduct any criminal investigation of a patient (42 U.S.C. 290ee-3(c), 42 U.S.C. 290dd-3(c)) applies to any information, whether or not recorded which is drug abuse information obtained by a federally assisted drug abuse program after March 20, 1972, or is alcohol abuse information obtained by a federally assisted alcohol abuse program after May 13, 1974 (or if obtained before the pertinent date, is maintained by a federally assisted alcohol or drug abuse program after that date as part of an ongoing treatment episode which extends past that date), for the purpose of treating alcohol or drug abuse, making a diagnosis for the treatment, or making a referral for the treatment.

(b) *Federal assistance.* An alcohol abuse or drug abuse program is considered to be federally assisted if:

(1) It is conducted in whole or in part, whether directly or by contract or otherwise by any department or agency of the United States (but see paragraphs (c)(1) and (c)(2) of this section relating to the Veterans' Administration and the Armed Forces);

(2) It is being carried out under a license, certification, registration, or other authorization granted by any department or agency of the United States including but not limited to:

(i) Certification of provider status under the Medicare program;

(ii) Authorization to conduct methadone maintenance treatment (see 21 CFR 291.505); or

(iii) Registration to dispense a substance under the Controlled Substances Act to the extent the controlled substance is used in the treatment of alcohol or drug abuse;

(3) It is supported by funds provided by any department or agency of the United States by being:

(i) A recipient of Federal financial assistance in any form, including financial assistance which does not directly pay for the alcohol or drug abuse diagnosis, treatment, or referral activities; or

(ii) Conducted by a State or local government unit which, through general or special revenue sharing or other forms of assistance, receives Federal funds which could be (but are not necessarily) spent for the alcohol or drug abuse program; or

(4) It is assisted by the Internal Revenue Service of the Department of the Treasury through the allowance of income tax deductions for contributions to the program or through the granting of tax exempt status to the program.

(c) *Exceptions*—(1) *Veterans' Administration.* These regulations do not apply to information on alcohol and drug abuse patients maintained in connection with the Veterans' Administration provisions of hospital care, nursing home care, domiciliary care, and medical services under title 38, United States Code. Those records are governed by 38 U.S.C. 4132 and regulations issued under that authority by the Administrator of Veterans' Affairs.

(2) *Armed Forces.* These regulations apply to any information described in paragraph (a) of this section which was obtained by any component of the Armed Forces during a period when the patient was subject to the Uniform Code of Military Justice except:

(i) Any interchange of that information within the Armed Forces; and

(ii) Any interchange of that information between the Armed Forces and

those components of the Veterans Administration furnishing health care to veterans.

(3) *Communication within a program or between a program and an entity having direct administrative control over that program.* The restrictions on disclosure in these regulations do not apply to communications of information between or among personnel having a need for the information in connection with their duties that arise out of the provision of diagnosis, treatment, or referral for treatment of alcohol or drug abuse if the communications are

(i) Within a program or

(ii) Between a program and an entity that has direct administrative control over the program.

(4) *Qualified Service Organizations.* The restrictions on disclosure in these regulations do not apply to communications between a program and a qualified service organization of information needed by the organization to provide services to the program.

(5) *Crimes on program premises or against program personnel.* The restrictions on disclosure and use in these regulations do not apply to communications from program personnel to law enforcement officers which—

(i) Are directly related to a patient's commission of a crime on the premises of the program or against program personnel or to a threat to commit such a crime; and

(ii) Are limited to the circumstances of the incident, including the patient status of the individual committing or threatening to commit the crime, that individual's name and address, and that individual's last known whereabouts.

(6) *Reports of suspected child abuse and neglect.* The restrictions on disclosure and use in these regulations do not apply to the reporting under State law of incidents of suspected child abuse and neglect to the appropriate State or local authorities. However, the restrictions continue to apply to the original alcohol or drug abuse patient records maintained by the program including their disclosure and use for civil or criminal proceedings which may arise out of the report of suspected child abuse and neglect.

(d) *Applicability to recipients of information*—(1) *Restriction on use of information.* The restriction on the use of any information subject to these regulations to initiate or substantiate any criminal charges against a patient or to conduct any criminal investigation of a patient applies to any person who obtains that information from a federally assisted alcohol or drug abuse program, regardless of the status of the person obtaining the information or of whether the information was obtained in accordance with these regulations. This restriction on use bars, among other things, the introduction of that information as evidence in a criminal proceeding and any other use of the information to investigate or prosecute a patient with respect to a suspected crime. Information obtained by undercover agents or informants (see §2.17) or through patient access (see §2.23) is subject to the restriction on use.

(2) *Restrictions on disclosures—Third party payers, administrative entities, and others.* The restrictions on disclosure in these regulations apply to:

(i) Third party payers with regard to records disclosed to them by federally assisted alcohol or drug abuse programs;

(ii) Entities having direct administrative control over programs with regard to information communicated to them by the program under §2.12(c)(3); and

(iii) Persons who receive patient records directly from a federally assisted alcohol or drug abuse program and who are notified of the restrictions on redisclosure of the records in accordance with §2.32 of these regulations.

(e) *Explanation of applicability*—(1) *Coverage.* These regulations cover any information (including information on referral and intake) about alcohol and drug abuse patients obtained by a program (as the terms "patient" and "program" are defined in §2.11) if the program is federally assisted in any manner described in §2.12(b). Coverage includes, but is not limited to, those treatment or rehabilitation programs, employee assistance programs, programs within general hospitals, school-based programs, and private practitioners who hold themselves out as

providing, and provide alcohol or drug abuse diagnosis, treatment, or referral for treatment. However, these regulations would not apply, for example, to emergency room personnel who refer a patient to the intensive care unit for an apparent overdose, unless the primary function of such personnel is the provision of alcohol or drug abuse diagnosis, treatment or referral and they are identified as providing such services or the emergency room has promoted itself to the community as a provider of such services.

(2) *Federal assistance to program required.* If a patient's alcohol or drug abuse diagnosis, treatment, or referral for treatment is not provided by a program which is federally conducted, regulated or supported in a manner which constitutes Federal assistance under § 2.12(b), that patient's record is not covered by these regulations. Thus, it is possible for an individual patient to benefit from Federal support and not be covered by the confidentiality regulations because the program in which the patient is enrolled is not federally assisted as defined in § 2.12(b). For example, if a Federal court placed an individual in a private for-profit program and made a payment to the program on behalf of that individual, that patient's record would not be covered by these regulations unless the program itself received Federal assistance as defined by § 2.12(b).

(3) *Information to which restrictions are applicable.* Whether a restriction is on use or disclosure affects the type of information which may be available. The restrictions on disclosure apply to any information which would identify a patient as an alcohol or drug abuser. The restriction on use of information to bring criminal charges against a patient for a crime applies to any information obtained by the program for the purpose of diagnosis, treatment, or referral for treatment of alcohol or drug abuse. (Note that restrictions on use and disclosure apply to recipients of information under § 2.12(d).)

(4) *How type of diagnosis affects coverage.* These regulations cover any record of a diagnosis identifying a patient as an alcohol or drug abuser which is prepared in connection with the treatment or referral for treatment of alcohol or drug abuse. A diagnosis prepared for the purpose of treatment or referral for treatment but which is not so used is covered by these regulations. The following are not covered by these regulations:

(i) Diagnosis which is made solely for the purpose of providing evidence for use by law enforcement authorities; or

(ii) A diagnosis of drug overdose or alcohol intoxication which clearly shows that the individual involved is not an alcohol or drug abuser (e.g., involuntary ingestion of alcohol or drugs or reaction to a prescribed dosage of one or more drugs).

[52 FR 21809, June 9, 1987; 52 FR 42061, Nov. 2, 1987, as amended at 60 FR 22297, May 5, 1995]

§ 2.13 Confidentiality restrictions.

(a) *General.* The patient records to which these regulations apply may be disclosed or used only as permitted by these regulations and may not otherwise be disclosed or used in any civil, criminal, administrative, or legislative proceedings conducted by any Federal, State, or local authority. Any disclosure made under these regulations must be limited to that information which is necessary to carry out the purpose of the disclosure.

(b) *Unconditional compliance required.* The restrictions on disclosure and use in these regulations apply whether the holder of the information believes that the person seeking the information already has it, has other means of obtaining it, is a law enforcement or other official, has obtained a subpoena, or asserts any other justification for a disclosure or use which is not permitted by these regulations.

(c) *Acknowledging the presence of patients: Responding to requests.* (1) The presence of an identified patient in a facility or component of a facility which is publicly identified as a place where only alcohol or drug abuse diagnosis, treatment, or referral is provided may be acknowledged only if the patient's written consent is obtained in accordance with subpart C of these regulations or if an authorizing court order is entered in accordance with subpart E of these regulations. The regulations permit acknowledgement of the presence of an identified patient in a facility or part of a facility if the

facility is not publicy identified as only an alcohol or drug abuse diagnosis, treatment or referral facility, and if the acknowledgement does not reveal that the patient is an alcohol or drug abuser.

(2) Any answer to a request for a disclosure of patient records which is not permissible under these regulations must be made in a way that will not affirmatively reveal that an identified individual has been, or is being diagnosed or treated for alcohol or drug abuse. An inquiring party may be given a copy of these regulations and advised that they restrict the disclosure of alcohol or drug abuse patient records, but may not be told affirmatively that the regulations restrict the disclosure of the records of an identified patient. The regulations do not restrict a disclosure that an identified individual is not and never has been a patient.

§ 2.14 Minor patients.

(a) *Definition of minor.* As used in these regulations the term "minor" means a person who has not attained the age of majority specified in the applicable State law, or if no age of majority is specified in the applicable State law, the age of eighteen years.

(b) *State law not requiring parental consent to treatment.* If a minor patient acting alone has the legal capacity under the applicable State law to apply for and obtain alcohol or drug abuse treatment, any written consent for disclosure authorized under subpart C of these regulations may be given only by the minor patient. This restriction includes, but is not limited to, any disclosure of patient identifying information to the parent or guardian of a minor patient for the purpose of obtaining financial reimbursement. These regulations do not prohibit a program from refusing to provide treatment until the minor patient consents to the disclosure necessary to obtain reimbursement, but refusal to provide treatment may be prohibited under a State or local law requiring the program to furnish the service irrespective of ability to pay.

(c) *State law requiring parental consent to treatment.* (1) Where State law requires consent of a parent, guardian, or other person for a minor to obtain alcohol or drug abuse treatment, any written consent for disclosure authorized under subpart C of these regulations must be given by both the minor and his or her parent, guardian, or other person authorized under State law to act in the minor's behalf.

(2) Where State law requires parental consent to treatment the fact of a minor's application for treatment may be communicated to the minor's parent, guardian, or other person authorized under State law to act in the minor's behalf only if:

(i) The minor has given written consent to the disclosure in accordance with subpart C of these regulations or

(ii) The minor lacks the capacity to make a rational choice regarding such consent as judged by the program director under paragraph (d) of this section.

(d) *Minor applicant for services lacks capacity for rational choice.* Facts relevant to reducing a threat to the life or physical well being of the applicant or any other individual may be disclosed to the parent, guardian, or other person authorized under State law to act in the minor's behalf if the program director judges that:

(1) A minor applicant for services lacks capacity because of extreme youth or mental or physical condition to make a rational decision on whether to consent to a disclosure under subpart C of these regulations to his or her parent, guardian, or other person authorized under State law to act in the minor's behalf, and

(2) The applicant's situation poses a substantial threat to the life or physical well being of the applicant or any other individual which may be reduced by communicating relevant facts to the minor's parent, guardian, or other person authorized under State law to act in the minor's behalf.

§ 2.15 Incompetent and deceased patients.

(a) *Incompetent patients other than minors—(1) Adjudication of incompetence.* In the case of a patient who has been adjudicated as lacking the capacity, for any reason other than insufficient age, to manage his or her own affairs, any consent which is required under these regulations may be given by the

guardian or other person authorized under State law to act in the patient's behalf.

(2) *No adjudication of incompetency.* For any period for which the program director determines that a patient, other than a minor or one who has been adjudicated incompetent, suffers from a medical condition that prevents knowing or effective action on his or her own behalf, the program director may exercise the right of the patient to consent to a disclosure under subpart C of these regulations for the sole purpose of obtaining payment for services from a third party payer.

(b) *Deceased patients*—(1) *Vital statistics.* These regulations do not restrict the disclosure of patient identifying information relating to the cause of death of a patient under laws requiring the collection of death or other vital statistics or permitting inquiry into the cause of death.

(2) *Consent by personal representative.* Any other disclosure of information identifying a deceased patient as an alcohol or drug abuser is subject to these regulations. If a written consent to the disclosure is required, that consent may be given by an executor, administrator, or other personal representative appointed under applicable State law. If there is no such appointment the consent may be given by the patient's spouse or, if none, by any responsible member of the patient's family.

§ 2.16 Security for written records.

(a) Written records which are subject to these regulations must be maintained in a secure room, locked file cabinet, safe or other similar container when not in use; and

(b) Each program shall adopt in writing procedures which regulate and control access to and use of written records which are subject to these regulations.

§ 2.17 Undercover agents and informants.

(a) *Restrictions on placement.* Except as specifically authorized by a court order granted under § 2.67 of these regulations, no program may knowingly employ, or enroll as a patient, any undercover agent or informant.

(b) *Restriction on use of information.* No information obtained by an undercover agent or informant, whether or not that undercover agent or informant is placed in a program pursuant to an authorizing court order, may be used to criminally investigate or prosecute any patient.

[52 FR 21809, June 9, 1987; 52 FR 42061, Nov. 2, 1987]

§ 2.18 Restrictions on the use of identification cards.

No person may require any patient to carry on his or her person while away from the program premises any card or other object which would identify the patient as an alcohol or drug abuser. This section does not prohibit a person from requiring patients to use or carry cards or other identification objects on the premises of a program.

§ 2.19 Disposition of records by discontinued programs.

(a) *General.* If a program discontinues operations or is taken over or acquired by another program, it must purge patient identifying information from its records or destroy the records unless—

(1) The patient who is the subject of the records gives written consent (meeting the requirements of § 2.31) to a transfer of the records to the acquiring program or to any other program designated in the consent (the manner of obtaining this consent must minimize the likelihood of a disclosure of patient identifying information to a third party); or

(2) There is a legal requirement that the records be kept for a period specified by law which does not expire until after the discontinuation or acquisition of the program.

(b) *Procedure where retention period required by law.* If paragraph (a)(2) of this section applies, the records must be:

(1) Sealed in envelopes or other containers labeled as follows: "Records of [insert name of program] required to be maintained under [insert citation to statute, regulation, court order or other legal authority requiring that records be kept] until a date not later than [insert appropriate date]"; and

(2) Held under the restrictions of these regulations by a responsible person who must, as soon as practicable

after the end of the retention period specified on the label, destroy the records.

§ 2.20 Relationship to State laws.

The statutes authorizing these regulations (42 U.S.C. 290ee-3 and 42 U.S.C. 290dd-3) do not preempt the field of law which they cover to the exclusion of all State laws in that field. If a disclosure permitted under these regulations is prohibited under State law, neither these regulations nor the authorizing statutes may be construed to authorize any violation of that State law. However, no State law may either authorize or compel any disclosure prohibited by these regulations.

§ 2.21 Relationship to Federal statutes protecting research subjects against compulsory disclosure of their identity.

(a) *Research privilege description.* There may be concurrent coverage of patient identifying information by these regulations and by administrative action taken under: Section 303(a) of the Public Health Service Act (42 U.S.C. 242a(a) and the implementing regulations at 42 CFR part 2a); or section 502(c) of the Controlled Substances Act (21 U.S.C. 872(c) and the implementing regulations at 21 CFR 1316.21). These "research privilege" statutes confer on the Secretary of Health and Human Services and on the Attorney General, respectively, the power to authorize researchers conducting certain types of research to withhold from all persons not connected with the research the names and other identifying information concerning individuals who are the subjects of the research.

(b) *Effect of concurrent coverage.* These regulations restrict the disclosure and use of information about patients, while administrative action taken under the research privilege statutes and implementing regulations protects a person engaged in applicable research from being compelled to disclose any identifying characteristics of the individuals who are the subjects of that research. The issuance under subpart E of these regulations of a court order authorizing a disclosure of information about a patient does not affect an exercise of authority under these research privilege statutes. However, the research privilege granted under 21 CFR 291.505(g) to treatment programs using methadone for maintenance treatment does not protect from compulsory disclosure any information which is permitted to be disclosed under those regulations. Thus, if a court order entered in accordance with subpart E of these regulations authorizes a methadone maintenance treatment program to disclose certain information about its patients, that program may not invoke the research privilege under 21 CFR 291.505(g) as a defense to a subpoena for that information.

§ 2.22 Notice to patients of Federal confidentiality requirements.

(a) *Notice required.* At the time of admission or as soon thereafter as the patient is capable of rational communication, each program shall:

(1) Communicate to the patient that Federal law and regulations protect the confidentiality of alcohol and drug abuse patient records; and

(2) Give to the patient a summary in writing of the Federal law and regulations.

(b) *Required elements of written summary.* The written summary of the Federal law and regulations must include:

(1) A general description of the limited circumstances under which a program may acknowledge that an individual is present at a facility or disclose outside the program information identifying a patient as an alcohol or drug abuser.

(2) A statement that violation of the Federal law and regulations by a program is a crime and that suspected violations may be reported to appropriate authorities in accordance with these regulations.

(3) A statement that information related to a patient's commission of a crime on the premises of the program or against personnel of the program is not protected.

(4) A statement that reports of suspected child abuse and neglect made under State law to appropriate State or local authorities are not protected.

(5) A citation to the Federal law and regulations.

(c) *Program options.* The program may devise its own notice or may use the

sample notice in paragraph (d) to comply with the requirement to provide the patient with a summary in writing of the Federal law and regulations. In addition, the program may include in the written summary information concerning State law and any program policy not inconsistent with State and Federal law on the subject of confidentiality of alcohol and drug abuse patient records.

(d) *Sample notice.*

CONFIDENTIALITY OF ALCOHOL AND DRUG ABUSE PATIENT RECORDS

The confidentiality of alcohol and drug abuse patient records maintained by this program is protected by Federal law and regulations. Generally, the program may not say to a person outside the program that a patient attends the program, or disclose any information identifying a patient as an alcohol or drug abuser *Unless:*

(1) The patient consents in writing;

(2) The disclosure is allowed by a court order; or

(3) The disclosure is made to medical personnel in a medical emergency or to qualified personnel for research, audit, or program evaluation.

Violation of the Federal law and regulations by a program is a crime. Suspected violations may be reported to appropriate authorities in accordance with Federal regulations.

Federal law and regulations do not protect any information about a crime committed by a patient either at the program or against any person who works for the program or about any threat to commit such a crime.

Federal laws and regulations do not protect any information about suspected child abuse or neglect from being reported under State law to appropriate State or local authorities.

(See 42 U.S.C. 290dd-3 and 42 U.S.C. 290ee-3 for Federal laws and 42 CFR part 2 for Federal regulations.)

(Approved by the Office of Management and Budget under control number 0930–0099)

§ 2.23 Patient access and restrictions on use.

(a) *Patient access not prohibited.* These regulations do not prohibit a program from giving a patient access to his or her own records, including the opportunity to inspect and copy any records that the program maintains about the patient. The program is not required to obtain a patient's written consent or other authorization under these regulations in order to provide such access to the patient.

(b) *Restriction on use of information.* Information obtained by patient access to his or her patient record is subject to the restriction on use of his information to initiate or substantiate any criminal charges against the patient or to conduct any criminal investigation of the patient as provided for under § 2.12(d)(1).

Subpart C—Disclosures With Patient's Consent

§ 2.31 Form of written consent.

(a) *Required elements.* A written consent to a disclosure under these regulations must include:

(1) The specific name or general designation of the program or person permitted to make the disclosure.

(2) The name or title of the individual or the name of the organization to which disclosure is to be made.

(3) The name of the patient.

(4) The purpose of the disclosure.

(5) How much and what kind of information is to be disclosed.

(6) The signature of the patient and, when required for a patient who is a minor, the signature of a person authorized to give consent under § 2.14; or, when required for a patient who is incompetent or deceased, the signature of a person authorized to sign under § 2.15 in lieu of the patient.

(7) The date on which the consent is signed.

(8) A statement that the consent is subject to revocation at any time except to the extent that the program or person which is to make the disclosure has already acted in reliance on it. Acting in reliance includes the provision of treatment services in reliance on a valid consent to disclose information to a third party payer.

(9) The date, event, or condition upon which the consent will expire if not revoked before. This date, event, or condition must insure that the consent will last no longer than reasonably necessary to serve the purpose for which it is given.

(b) *Sample consent form.* The following form complies with paragraph (a) of this section, but other elements may be added.

1. I (name of patient) ☐ Request ☐ Authorize:
2. (name or general designation of program which is to make the disclosure)

3. To disclose: (kind and amount of information to be disclosed)

4. To: (name or title of the person or organization to which disclosure is to be made)

5. For (purpose of the disclosure)

6. Date (on which this consent is signed)

7. Signature of patient

8. Signature of parent or guardian (where required)

9. Signature of person authorized to sign in lieu of the patient (where required)

10. This consent is subject to revocation at any time except to the extent that the program which is to make the disclosure has already taken action in reliance on it. If not previously revoked, this consent will terminate upon: (specific date, event, or condition)

(c) *Expired, deficient, or false consent.* A disclosure may not be made on the basis of a consent which:

(1) Has expired;

(2) On its face substantially fails to conform to any of the requirements set forth in paragraph (a) of this section;

(3) Is known to have been revoked; or

(4) Is known, or through a reasonable effort could be known, by the person holding the records to be materially false.

(Approved by the Office of Management and Budget under control number 0930-0099)

§ 2.32 Prohibition on redisclosure.

Notice to accompany disclosure. Each disclosure made with the patient's written consent must be accompanied by the following written statement:

This information has been disclosed to you from records protected by Federal confidentiality rules (42 CFR part 2). The Federal rules prohibit you from making any further disclosure of this information unless further disclosure is expressly permitted by the written consent of the person to whom it pertains or as otherwise permitted by 42 CFR part 2. A general authorization for the release of medical or other information is NOT sufficient for this purpose. The Federal rules restrict any use of the information to criminally investigate or prosecute any alcohol or drug abuse patient.

[52 FR 21809, June 9, 1987; 52 FR 41997, Nov. 2, 1987]

§ 2.33 Disclosures permitted with written consent.

If a patient consents to a disclosure of his or her records under § 2.31, a program may disclose those records in accordance with that consent to any individual or organization named in the consent, except that disclosures to central registries and in connection with criminal justice referrals must meet the requirements of §§ 2.34 and 2.35, respectively.

§ 2.34 Disclosures to prevent multiple enrollments in detoxification and maintenance treatment programs.

(a) *Definitions.* For purposes of this section:

Central registry means an organization which obtains from two or more member progams patient identifying information about individuals applying for maintenance treatment or detoxification treatment for the purpose of avoiding an individual's concurrent enrollment in more than one program.

Detoxification treatment means the dispensing of a narcotic drug in decreasing doses to an individual in order to reduce or eliminate adverse physiological or psychological effects incident to withdrawal from the sustained use of a narcotic drug.

Maintenance treatment means the dispensing of a narcotic drug in the treatment of an individual for dependence upon heroin or other morphine-like drugs.

Member program means a detoxification treatment or maintenance treatment program which reports patient identifying information to a central registry and which is in the same State as that central registry or is not more than 125 miles from any border of the State in which the central registry is located.

(b) *Restrictions on disclosure.* A program may disclose patient records to a central registry or to any detoxification or maintenance treatment program not more than 200 miles away for the purpose of preventing the multiple enrollment of a patient only if:

(f) The disclosure is made when:

(i) The patient is accepted for treatment;

(ii) The type or dosage of the drug is changed; or

(iii) The treatment is interrupted, resumed or terminated.

(2) The disclosure is limited to:

(i) Patient identifying information;

(ii) Type and dosage of the drug; and

(iii) Relevant dates.

(3) The disclosure is made with the patient's written consent meeting the requirements of §2.31, except that:

(i) The consent must list the name and address of each central registry and each known detoxification or maintenance treatment program to which a disclosure will be made; and

(ii) The consent may authorize a disclosure to any detoxification or maintenance treatment program established within 200 miles of the program after the consent is given without naming any such program.

(c) *Use of information limited to prevention of multiple enrollments.* A central registry and any detoxification or maintenance treatment program to which information is disclosed to prevent multiple enrollments may not redisclose or use patient identifying information for any purpose other than the prevention of multiple enrollments unless authorized by a court order under subpart E of these regulations.

(d) *Permitted disclosure by a central registry to prevent a multiple enrollment.* When a member program asks a central registry if an identified patient is enrolled in another member program and the registry determines that the patient is so enrolled, the registry may disclose—

(1) The name, address, and telephone number of the member program(s) in which the patient is already enrolled to the inquiring member program; and

(2) The name, address, and telephone number of the inquiring member program to the member program(s) in which the patient is already enrolled. The member programs may communicate as necessary to verify that no error has been made and to prevent or eliminate any multiple enrollment.

(e) *Permitted disclosure by a detoxification or maintenance treatment program to prevent a multiple enrollment.* A detoxification or maintenance treatment program which has received a disclosure under this section and has determined that the patient is already enrolled may communicate as necessary with the program making the disclosure to verify that no error has been made and to prevent or eliminate any multiple enrollment.

§2.35 Disclosures to elements of the criminal justice system which have referred patients.

(a) A program may disclose information about a patient to those persons within the criminal justice system which have made participation in the program a condition of the disposition of any criminal proceedings against the patient or of the patient's parole or other release from custody if:

(1) The disclosure is made only to those individuals within the criminal justice system who have a need for the information in connection with their duty to monitor the patient's progress (e.g., a prosecuting attorney who is withholding charges against the patient, a court granting pretrial or posttrial release, probation or parole officers responsible for supervision of the patient); and

(2) The patient has signed a written consent meeting the requirements of §2.31 (except paragraph (a)(8) which is inconsistent with the revocation provisions of paragraph (c) of this section) and the requirements of paragraphs (b) and (c) of this section.

(b) *Duration of consent.* The written consent must state the period during which it remains in effect. This period must be reasonable, taking into account:

(1) The anticipated length of the treatment;

(2) The type of criminal proceeding involved, the need for the information in connection with the final disposition of that proceeding, and when the final disposition will occur; and

(3) Such other factors as the program, the patient, and the person(s) who will receive the disclosure consider pertinent.

(c) *Revocation of consent.* The written consent must state that it is revocable upon the passage of a specified amount of time or the occurrence of a specified,

ascertainable event. The time or occurrence upon which consent becomes revocable may be no later than the final disposition of the conditional release or other action in connection with which consent was given.

(d) *Restrictions on redisclosure and use.* A person who receives patient information under this section may redisclose and use it only to carry out that person's official duties with regard to the patient's conditional release or other action in connection with which the consent was given.

Subpart D—Disclosures Without Patient Consent

§ 2.51 Medical emergencies.

(a) *General Rule.* Under the procedures required by paragraph (c) of this section, patient identifying information may be disclosed to medical personnel who have a need for information about a patient for the purpose of treating a condition which poses an immediate threat to the health of any individual and which requires immediate medical intervention.

(b) *Special Rule.* Patient identifying information may be disclosed to medical personnel of the Food and Drug Administration (FDA) who assert a reason to believe that the health of any individual may be threatened by an error in the manufacture, labeling, or sale of a product under FDA jurisdiction, and that the information will be used for the exclusive purpose of notifying patients or their physicians of potential dangers.

(c) *Procedures.* Immediately following disclosure, the program shall document the disclosure in the patient's records, setting forth in writing:

(1) The name of the medical personnel to whom disclosure was made and their affiliation with any health care facility;

(2) The name of the individual making the disclosure;

(3) The date and time of the disclosure; and

(4) The nature of the emergency (or error, if the report was to FDA).

(Approved by the Office of Management and Budget under control number 0930-0099)

§ 2.52 Research activities.

(a) Patient identifying information may be disclosed for the purpose of conducting scientific research if the program director makes a determination that the recipient of the patient identifying information:

(1) Is qualified to conduct the research;

(2) Has a research protocol under which the patient identifying information:

(i) Will be maintained in accordance with the security requirements of § 2.16 of these regulations (or more stringent requirements); and

(ii) Will not be redisclosed except as permitted under paragraph (b) of this section; and

(3) Has provided a satisfactory written statement that a group of three or more individuals who are independent of the research project has reviewed the protocol and determined that:

(i) The rights and welfare of patients will be adequately protected; and

(ii) The risks in disclosing patient identifying information are outweighed by the potential benefits of the research.

(b) A person conducting research may disclose patient identifying information obtained under paragraph (a) of this section only back to the program from which that information was obtained and may not identify any individual patient in any report of that research or otherwise disclose patient identities.

[52 FR 21809, June 9, 1987, as amended at 52 FR 41997, Nov. 2, 1987]

§ 2.53 Audit and evaluation activities.

(a) *Records not copied or removed.* If patient records are not copied or removed, patient identifying information may be disclosed in the course of a review of records on program premises to any person who agrees in writing to comply with the limitations on redisclosure and use in paragraph (d) of this section and who:

(1) Performs the audit or evaluation activity on behalf of:

(i) Any Federal, State, or local governmental agency which provides financial assistance to the program or is

authorized by law to regulate its activities; or

(ii) Any private person which provides financial assistance to the program, which is a third party payer covering patients in the program, or which is a peer review organization performing a utilization or quality control review; or

(2) Is determined by the program director to be qualified to conduct the audit or evaluation activities.

(b) *Copying or removal of records.* Records containing patient identifying information may be copied or removed from program premises by any person who:

(1) Agrees in writing to:

(i) Maintain the patient identifying information in accordance with the security requirements provided in §2.16 of these regulations (or more stringent requirements);

(ii) Destroy all the patient identifying information upon completion of the audit or evaluation; and

(iii) Comply with the limitations on disclosure and use in paragraph (d) of this section; and

(2) Performs the audit or evaluation activity on behalf of:

(i) Any Federal, State, or local governmental agency which provides financial assistance to the program or is authorized by law to regulate its activities; or

(ii) Any private person which provides financial assistance to the program, which is a third part payer covering patients in the program, or which is a peer review organization performing a utilization or quality control review.

(c) *Medicare or Medicaid audit or evaluation.* (1) For purposes of Medicare or Medicaid audit or evaluation under this section, audit or evaluation includes a civil or administrative investigation of the program by any Federal, State, or local agency responsible for oversight of the Medicare or Medicaid program and includes administrative enforcement, against the program by the agency, of any remedy authorized by law to be imposed as a result of the findings of the investigation.

(2) Consistent with the definition of program in §2.11, program includes an employee of, or provider of medical services under, the program when the employee or provider is the subject of a civil investigation or administrative remedy, as those terms are used in paragraph (c)(1) of this section.

(3) If a disclosure to a person is authorized under this section for a Medicare or Medicaid audit or evaluation, including a civil investigation or administrative remedy, as those terms are used in paragraph (c)(1) of this section, then a peer review organization which obtains the information under paragraph (a) or (b) may disclose the information to that person but only for purposes of Medicare or Medicaid audit or evaluation.

(4) The provisions of this paragraph do not authorize the agency, the program, or any other person to disclose or use patient identifying information obtained during the audit or evaluation for any purposes other than those necessary to complete the Medicare or Medicaid audit or evaluation activity as specified in this paragraph.

(d) *Limitations on disclosure and use.* Except as provided in paragraph (c) of this section, patient identifying information disclosed under this section may be disclosed only back to the program from which it was obtained and used only to carry out an audit or evaluation purpose or to investigate or prosecute criminal or other activities, as authorized by a court order entered under §2.66 of these regulations.

Subpart E—Court Orders Authorizing Disclosure and Use

§ 2.61 Legal effect of order.

(a) *Effect.* An order of a court of competent jurisdiction entered under this subpart is a unique kind of court order. Its only purpose is to authorize a disclosure or use of patient information which would otherwise be prohibited by 42 U.S.C. 290ee–3, 42 U.S.C. 290dd–3 and these regulations. Such an order does not compel disclosure. A subpoena or a similar legal mandate must be issued in order to compel disclosure. This mandate may be entered at the same time as and accompany an authorizing court order entered under these regulations.

(b) *Examples.* (1) A person holding records subject to these regulations receives a subpoena for those records: a response to the subpoena is not permitted under the regulations unless an authorizing court order is entered. The person may not disclose the records in response to the subpoena unless a court of competent jurisdiction enters an authorizing order under these regulations.

(2) An authorizing court order is entered under these regulations, but the person authorized does not want to make the disclosure. If there is no subpoena or other compulsory process or a subpoena for the records has expired or been quashed, that person may refuse to make the disclosure. Upon the entry of a valid subpoena or other compulsory process the person authorized to disclose must disclose, unless there is a valid legal defense to the process other than the confidentiality restrictions of these regulations.

[52 FR 21809, June 9, 1987; 52 FR 42061, Nov. 2, 1987]

§ 2.62 Order not applicable to records disclosed without consent to researchers, auditors and evaluators.

A court order under these regulations may not authorize qualified personnel, who have received patient identifying information without consent for the purpose of conducting research, audit or evaluation, to disclose that information or use it to conduct any criminal investigation or prosecution of a patient. However, a court order under § 2.66 may authorize disclosure and use of records to investigate or prosecute qualified personnel holding the records.

§ 2.63 Confidential communications.

(a) A court order under these regulations may authorize disclosure of confidential communications made by a patient to a program in the course of diagnosis, treatment, or referral for treatment only if:

(1) The disclosure is necessary to protect against an existing threat to life or of serious bodily injury, including circumstances which constitute suspected child abuse and neglect and verbal threats against third parties;

(2) The disclosure is necessary in connection with investigation or prosecution of an extremely serious crime, such as one which directly threatens loss of life or serious bodily injury, including homicide, rape, kidnapping, armed robbery, assault with a deadly weapon, or child abuse and neglect; or

(3) The disclosure is in connection with litigation or an administrative proceeding in which the patient offers testimony or other evidence pertaining to the content of the confidential communications.

(b) [Reserved]

§ 2.64 Procedures and criteria for orders authorizing disclosures for noncriminal purposes.

(a) *Application.* An order authorizing the disclosure of patient records for purposes other than criminal investigation or prosecution may be applied for by any person having a legally recognized interest in the disclosure which is sought. The application may be filed separately or as part of a pending civil action in which it appears that the patient records are needed to provide evidence. An application must use a fictitious name, such as John Doe, to refer to any patient and may not contain or otherwise disclose any patient identifying information unless the patient is the applicant or has given a written consent (meeting the requirements of these regulations) to disclosure or the court has ordered the record of the proceeding sealed from public scrunity.

(b) *Notice.* The patient and the person holding the records from whom disclosure is sought must be given:

(1) Adequate notice in a manner which will not disclose patient identifying information to other persons; and

(2) An opportunity to file a written response to the application, or to appear in person, for the limited purpose of providing evidence on the statutory and regulatory criteria for the issuance of the court order.

(c) *Review of evidence: Conduct of hearing.* Any oral argument, review of evidence, or hearing on the application must be held in the judge's chambers or in some manner which ensures that patient identifying information is not disclosed to anyone other than a party to the proceeding, the patient, or the person holding the record, unless the patient requests an open hearing in a

manner which meets the written consent requirements of these regulations. The proceeding may include an examination by the judge of the patient records referred to in the application.

(d) *Criteria for entry of order.* An order under this section may be entered only if the court determines that good cause exists. To make this determination the court must find that:

(1) Other ways of obtaining the information are not available or would not be effective; and

(2) The public interest and need for the disclosure outweigh the potential injury to the patient, the physician-patient relationship and the treatment services.

(e) *Content of order.* An order authorizing a disclosure must:

(1) Limit disclosure to those parts of the patient's record which are essential to fulfill the objective of the order;

(2) Limit disclosure to those persons whose need for information is the basis for the order; and

(3) Include such other measures as are necessary to limit disclosure for the protection of the patient, the physician-patient relationship and the treatment services; for example, sealing from public scrutiny the record of any proceeding for which disclosure of a patient's record has been ordered.

§ 2.65 Procedures and criteria for orders authorizing disclosure and use of records to criminally investigate or prosecute patients.

(a) *Application.* An order authorizing the disclosure or use of patient records to criminally investigate or prosecute a patient may be applied for by the person holding the records or by any person conducting investigative or prosecutorial activities with respect to the enforcement of criminal laws. The application may be filed separately, as part of an application for a subpoena or other compulsory process, or in a pending criminal action. An application must use a fictitious name such as John Doe, to refer to any patient and may not contain or otherwise disclose patient identifying information unless the court has ordered the record of the proceeding sealed from public scrutiny.

(b) *Notice and hearing.* Unless an order under § 2.66 is sought with an order under this section, the person holding the records must be given:

(1) Adequate notice (in a manner which will not disclose patient identifying information to third parties) of an application by a person performing a law enforcement function;

(2) An opportunity to appear and be heard for the limited purpose of providing evidence on the statutory and regulatory criteria for the issuance of the court order; and

(3) An opportunity to be represented by counsel independent of counsel for an applicant who is a person performing a law enforcement function.

(c) *Review of evidence: Conduct of hearings.* Any oral argument, review of evidence, or hearing on the application shall be held in the judge's chambers or in some other manner which ensures that patient identifying information is not disclosed to anyone other than a party to the proceedings, the patient, or the person holding the records. The proceeding may include an examination by the judge of the patient records referred to in the application.

(d) *Criteria.* A court may authorize the disclosure and use of patient records for the purpose of conducting a criminal investigation or prosecution of a patient only if the court finds that all of the following criteria are met:

(1) The crime involved is extremely serious, such as one which causes or directly threatens loss of life or serious bodily injury including homicide, rape, kidnapping, armed robbery, assault with a deadly weapon, and child abuse and neglect.

(2) There is a reasonable likelihood that the records will disclose information of substantial value in the investigation or prosecution.

(3) Other ways of obtaining the information are not available or would not be effective.

(4) The potential injury to the patient, to the physician-patient relationship and to the ability of the program to provide services to other patients is outweighed by the public interest and the need for the disclosure.

(5) If the applicant is a person performing a law enforcement function that:

(i) The person holding the records has been afforded the opportunity to be

represented by independent counsel; and

(ii) Any person holding the records which is an entity within Federal, State, or local government has in fact been represented by counsel independent of the applicant.

(e) *Content of order.* Any order authorizing a disclosure or use of patient records under this section must:

(1) Limit disclosure and use to those parts of the patient's record which are essential to fulfill the objective of the order;

(2) Limit disclosure to those law enforcement and prosecutorial officials who are responsible for, or are conducting, the investigation or prosecution, and limit their use of the records to investigation and prosecution of extremely serious crime or suspected crime specified in the application; and

(3) Include such other measures as are necessary to limit disclosure and use to the fulfillment of only that public interest and need found by the court.

[52 FR 21809, June 9, 1987; 52 FR 42061, Nov. 2, 1987]

§2.66 Procedures and criteria for orders authorizing disclosure and use of records to investigate or prosecute a program or the person holding the records.

(a) *Application.* (1) An order authorizing the disclosure or use of patient records to criminally or administratively investigate or prosecute a program or the person holding the records (or employees or agents of that program or person) may be applied for by any administrative, regulatory, supervisory, investigative, law enforcement, or prosecutorial agency having jurisdiction over the program's or person's activities.

(2) The application may be filed separately or as part of a pending civil or criminal action against a program or the person holding the records (or agents or employees of the program or person) in which it appears that the patient records are needed to provide material evidence. The application must use a fictitious name, such as John Doe, to refer to any patient and may not contain or otherwise disclose any patient identifying information unless the court has ordered the record of the proceeding sealed from public scrutiny or the patient has given a written consent (meeting the requirements of §2.31 of these regulations) to that disclosure.

(b) *Notice not required.* An application under this section may, in the discretion of the court, be granted without notice. Although no express notice is required to the program, to the person holding the records, or to any patient whose records are to be disclosed, upon implementation of an order so granted any of the above persons must be afforded an opportunity to seek revocation or amendment of that order, limited to the presentation of evidence on the statutory and regulatory criteria for the issuance of the court order.

(c) *Requirements for order.* An order under this section must be entered in accordance with, and comply with the requirements of, paragraphs (d) and (e) of §2.64 of these regulations.

(d) *Limitations on disclosure and use of patient identifying information.* (1) An order entered under this section must require the deletion of patient identifying information from any documents made available to the public.

(2) No information obtained under this section may be used to conduct any investigation or prosecution of a patient, or be used as the basis for an application for an order under §2.65 of these regulations.

§2.67 Orders authorizing the use of undercover agents and informants to criminally investigate employees or agents of a program.

(a) *Application.* A court order authorizing the placement of an undercover agent or informant in a program as an employee or patient may be applied for by any law enforcement or prosecutorial agency which has reason to believe that employees or agents of the program are engaged in criminal misconduct.

(b) *Notice.* The program director must be given adequate notice of the application and an opportunity to appear and be heard (for the limited purpose of providing evidence on the statutory and regulatory criteria for the issuance of the court order), unless the application asserts a belief that:

(1) The program director is involved in the criminal activities to be investigated by the undercover agent or informant; or

(2) The program director will intentionally or unintentionally disclose the proposed placement of an undercover agent or informant to the employees or agents who are suspected of criminal activities.

(c) *Criteria.* An order under this section may be entered only if the court determines that good cause exists. To make this determination the court must find:

(1) There is reason to believe that an employee or agent of the program is engaged in criminal activity;

(2) Other ways of obtaining evidence of this criminal activity are not available or would not be effective; and

(3) The public interest and need for the placement of an undercover agent or informant in the program outweigh the potential injury to patients of the program, physician-patient relationships and the treatment services.

(d) *Content of order.* An order authorizing the placement of an undercover agent or informant in a program must:

(1) Specifically authorize the placement of an undercover agent or an informant;

(2) Limit the total period of the placement to six months;

(3) Prohibit the undercover agent or informant from disclosing any patient identifying information obtained from the placement except as necessary to criminally investigate or prosecute employees or agents of the program; and

(4) Include any other measures which are appropriate to limit any potential disruption of the program by the placement and any potential for a real or apparent breach of patient confidentiality; for example, sealing from public scrutiny the record of any proceeding for which disclosure of a patient's record has been ordered.

(e) *Limitation on use of information.* No information obtained by an undercover agent or informant placed under this section may be used to criminally investigate or prosecute any patient or as the basis for an application for an order under §2.65 of these regulations.

PART 2a—PROTECTION OF IDENTITY—RESEARCH SUBJECTS

Sec.

AUTHORITY: Sec. 3(a), Pub. L. 91-513 as amended by sec. 122(b), Pub. L. 93-282; 84 Stat. 1241 (42 U.S.C. 242a(a)), as amended by 88 Stat. 132.

SOURCE: 44 FR 20384, Apr. 4, 1979, unless otherwise noted.

§2a.1 Applicability.

(a) Section 303(a) of the Public Health Service Act (42 U.S.C. 242a(a)) provides that "[t]he Secretary [of Health and Human Services] may authorize persons engaged in research on mental health, including research on the use and effect of alcohol and other psychoactive drugs, to protect the privacy of individuals who are the subject of such research by withholding from all persons not connected with the conduct of such research the names or other identifying characteristics of such individuals. Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals." The regulations in this part establish procedures under which any person engaged in research on mental health including research on the use and effect of alcohol and other psychoactive drugs (whether or not the research is federally funded) may, subject to the exceptions set forth in paragraph (b) of this section, apply for such an authorization of confidentiality.

(b) These regulations do not apply to:

(1) Authorizations of confidentiality for research requiring an Investigational New Drug exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) or to approved new drugs, such as methadone, requiring continuation of long-

(2) As expeditiously as the enrollee's health condition requires, but no later than 3 working days after the agency receives, from the MCO or PIHP, the case file and information for any appeal of a denial of a service that, as indicated by the MCO or PIHP—

(i) Meets the criteria for expedited resolution as set forth in §438.410(a) of this chapter, but was not resolved within the timeframe for expedited resolution; or

(ii) Was resolved within the timeframe for expedited resolution, but reached a decision wholly or partially adverse to the enrollee.

(3) If the State agency permits direct access to a State fair hearing, as expeditiously as the enrollee's health condition requires, but no later than 3 working days after the agency receives, directly from an MCO or PIHP enrollee, a fair hearing request on a decision to deny a service that it determines meets the criteria for expedited resolution, as set forth in §438.410(a) of this chapter.

(g) The public must have access to all agency hearing decisions, subject to the requirements of subpart F of this part for safeguarding of information.

[44 FR 17932, Mar. 29, 1979, as amended at 67 FR 41095, June 14, 2002]

§ 431.245 Notifying the applicant or recipient of a State agency decision.

The agency must notify the applicant or recipient in writing of—

(a) The decision; and

(b) His right to request a State agency hearing or seek judicial review, to the extent that either is available to him.

§ 431.246 Corrective action.

The agency must promptly make corrective payments, retroactive to the date an incorrect action was taken, and, if appropriate, provide for admission or readmission of an individual to a facility if—

(a) The hearing decision is favorable to the applicant or recipient; or

(b) The agency decides in the applicant's or recipient's favor before the hearing.

[57 FR 56506, Nov. 30, 1992]

FEDERAL FINANCIAL PARTICIPATION

§ 431.250 Federal financial participation.

FFP is available in expenditures for—

(a) Payments for services continued pending a hearing decision;

(b) Payments made—

(1) To carry out hearing decisions; and

(2) For services provided within the scope of the Federal Medicaid program and made under a court order.

(c) Payments made to take corrective action prior to a hearing;

(d) Payments made to extend the benefit of a hearing decision or court order to individuals in the same situation as those directly affected by the decision or order;

(e) Retroactive payments under paragraphs (b), (c), and (d) of this section in accordance with applicable Federal policies on corrective payments; and

(f) Administrative costs incurred by the agency for—

(1) Transportation for the applicant or recipient, his representative, and witnesses to and from the hearing;

(2) Meeting other expenses of the applicant or recipient in connection with the hearing;

(3) Carrying out the hearing procedures, including expenses of obtaining the additional medical assessment specified in §431.240 of this subpart; and

(4) Hearing procedures for Medicaid and non-Medicaid individuals appealing transfers, discharges and determinations of preadmission screening and annual resident reviews under part 483, subparts C and E of this chapter.

[44 FR 17932, Mar. 29, 1979, as amended at 45 FR 24882, Apr. 11, 1980; 57 FR 56506, Nov. 30, 1992]

Subpart F—Safeguarding Information on Applicants and Recipients

SOURCE: 44 FR 17934, Mar. 29, 1979, unless otherwise noted.

§ 431.300 Basis and purpose.

(a) Section 1902(a)(7) of the Act requires that a State plan must provide

safeguards that restrict the use or disclosure of information concerning applicants and recipients to purposes directly connected with the administration of the plan. This subpart specifies State plan requirements, the types of information to be safeguarded, the conditions for release of safeguarded information, and restrictions on the distribution of other information.

(b) Section 1137 of the Act, which requires agencies to exchange information in order to verify the income and eligibility of applicants and recipients (see § 435.940ff), requires State agencies to have adequate safeguards to assure that—

(1) Information exchanged by the State agencies is made available only to the extent necessary to assist in the valid administrative needs of the program receiving the information, and information received under section 6103(l) of the Internal Revenue Code of 1954 is exchanged only with agencies authorized to receive that information under that section of the Code; and

(2) The information is adequately stored and processed so that it is protected against unauthorized disclosure for other purposes.

[51 FR 7210, Feb. 28, 1986]

§ 431.301 State plan requirements.

A State plan must provide, under a State statute that imposes legal sanctions, safeguards meeting the requirements of this subpart that restrict the use or disclosure of information concerning applicants and recipients to purposes directly connected with the administration of the plan.

§ 431.302 Purposes directly related to State plan administration.

Purposes directly related to plan administration include—

(a) Establishing eligibility;

(b) Determining the amount of medical assistance;

(c) Providing services for recipients; and

(d) Conducting or assisting an investigation, prosecution, or civil or criminal proceeding related to the administration of the plan.

§ 431.303 State authority for safeguarding information.

The Medicaid agency must have authority to implement and enforce the provisions specified in this subpart for safeguarding information about applicants and recipients.

§ 431.304 Publicizing safeguarding requirements.

(a) The agency must publicize provisions governing the confidential nature of information about applicants and recipients, including the legal sanctions imposed for improper disclosure and use.

(b) The agency must provide copies of these provisions to applicants and recipients and to other persons and agencies to whom information is disclosed.

§ 431.305 Types of information to be safeguarded.

(a) The agency must have criteria that govern the types of information about applicants and recipients that are safeguarded.

(b) This information must include at least—

(1) Names and addresses;

(2) Medical services provided;

(3) Social and economic conditions or circumstances;

(4) Agency evaluation of personal information;

(5) Medical data, including diagnosis and past history of disease or disability; and

(6) Any information received for verifying income eligibility and amount of medical assistance payments (see § 435.940ff). Income information received from SSA or the Internal Revenue Service must be safeguarded according to the requirements of the agency that furnished the data.

(7) Any information received in connection with the identification of legally liable third party resources under § 433.138 of this chapter.

[44 FR 17934, Mar. 29, 1979, as amended at 51 FR 7210, Feb. 28, 1986; 52 FR 5975, Feb. 27, 1987]

§ 431.306 Release of information.

(a) The agency must have criteria specifying the conditions for release and use of information about applicants and recipients.

(b) Access to information concerning applicants or recipients must be restricted to persons or agency representatives who are subject to standards of confidentiality that are comparable to those of the agency.

(c) The agency must not publish names of applicants or recipients.

(d) The agency must obtain permission from a family or individual, whenever possible, before responding to a request for information from an outside source, unless the information is to be used to verify income, eligibility and the amount of medical assistance payment under section 1137 of this Act and §§ 435.940 through 435.965 of this chapter.

If, because of an emergency situation, time does not permit obtaining consent before release, the agency must notify the family or individual immediately after supplying the information.

(e) The agency's policies must apply to all requests for information from outside sources, including governmental bodies, the courts, or law enforcement officials.

(f) If a court issues a subpoena for a case record or for any agency representative to testify concerning an applicant or recipient, the agency must inform the court of the applicable statutory provisions, policies, and regulations restricting disclosure of information.

(g) Before requesting information from, or releasing information to, other agencies to verify income, eligibility and the amount of assistance under §§ 435.940 through 435.965 of this chapter, the agency must execute data exchange agreements with those agencies, as specified in § 435.945(f).

(h) Before requesting information from, or releasing information to, other agencies to identify legally liable third party resources under § 433.138(d) of this chapter, the agency must execute data exchanges agreements, as specified in § 433.138(h)(2) of this chapter.

[44 FR 17934, Mar. 29, 1979, as amended at 51 FR 7210, Feb. 28, 1986; 52 FR 5975, Feb. 27, 1987]

§ 431.307 Distribution of information materials.

(a) All materials distributed to applicants, recipients, or medical providers must—

(1) Directly relate to the administration of the Medicaid program;

(2) Have no political implications except to the extent required to implement the National Voter Registration Act of 1993 (NVRA) Pub. L. 103-931; for States that are exempt from the requirements of NVRA, voter registration may be a voluntary activity so long as the provisions of section 7(a)(5) of NVRA are observed;

(3) Contain the names only of individuals directly connected with the administration of the plan; and

(4) Identify those individuals only in their official capacity with the State or local agency.

(b) The agency must not distribute materials such as "holiday" greetings, general public announcements, partisan voting information and alien registration notices.

(c) The agency may distribute materials directly related to the health and welfare of applicants and recipients, such as announcements of free medical examinations, availability of surplus food, and consumer protection information.

(d) Under NVRA, the agency must distribute voter information and registration materials as specified in NVRA.

[44 FR 17934, Mar. 29, 1979, as amended at 61 FR 58143, Nov. 13, 1996]

Subparts G–L [Reserved]

Subpart M—Relations With Other Agencies

§ 431.610 Relations with standard-setting and survey agencies.

(a) *Basis and purpose.* This section implements—

(1) Section 1902(a)(9) of the Act, concerning the designation of State authorities to be responsible for establishing and maintaining health and other standards for institutions participating in Medicaid; and

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: West Virginia Department of Health and Human Resources, Bureau for Medical Services

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 13
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: _____

Name of Agency: West Virginia Department of Health and Human Resources
Bureau for Medical Services

Describe the PHI (do not include any actual PHI). If not applicable, please indicate the same.

All [types of PHI listed on App. A] in paper, electronic, verbal or any other form.
Including, but not limited to:
Member name, date of birth, Medicaid Identification number, prescription claims, medical claims including out-patient services and hospitalizations, emergency room visits, procedures and diagnos codes

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)

RFQ No. BMS14096

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** _____

Rev. 07/12

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:** _____