



LARRY HOGAN
Governor

BOYD K. RUTHERFORD
Lieutenant Governor

DAVID R. BRINKLEY
Secretary

MARC L. NICOLE
Deputy Secretary

**Amendment #4 to Request for Proposals (RFP)
NO. F10B640005R
Department of Budget & Management
Pharmacy Benefit Management Services and Pharmacy Benefits
Purchasing Pool Management
May 20, 2016**

This Amendment is being issued to amend and clarify certain information contained in the above named RFP. All information contained herein is binding on all Offerors who respond to this RFP. Specific parts of the RFP have been amended. The following changes/additions are listed below. New language has been double underlined and marked in bold (ex. **new language**), and language deleted has been marked with a strikeout (ex. ~~language deleted~~).

1. AMEND the Key Information Summary Sheet as follows:

Proposal Due (Closing) Date and Time: ~~May 12, 2016~~ June 7, 2016, at 2:00 p.m. Local Time

2. AMEND Section 1.2.5 of “Abbreviations and Definitions” as follows:

1.2.5 Brand Drug – ~~The innovator drug product submitted to the Federal Drug Administration for approval. A Brand Drug is a drug produced and distributed with patent protection.~~ **A drug that is approved by the U.S. Food and Drug Administration, and is produced, distributed under an original new drug application (NDA) or marketed by a cross-licensed producer/distributor operating under the NDA. A Brand Drug can be an innovator multisource drug that is originally marketed under an original NDA approved by the US Food and Drug Administration.**

3. AMEND Section 1.2.39 of “Abbreviations and Definitions” as follows:

1.2.39 Generic Drug – ~~A drug produced and distributed without patent protection. The Generic Drug may still have a patent on the formulation but not on the active ingredient.~~ **A generic drug is a single-source or multi-source drug available to pharmacy providers from at least one manufacturer and, per the FDA Orange Book, is rated as therapeutically equivalent to the reference drug. It is produced, and marketed under an abbreviated new drug application (ANDA) approved by the FDA. Single source generics are classified as generics and considered as generics for all purposes under the Contract resulting from this RFP.**

4. AMEND Section 1.2.76 of “Abbreviations and Definitions” as follows:

Specialty Drug —~~High cost medication that has unique uses for the treatment of complex or chronic diseases, requires special dosing or administration, involves significant patient education and monitoring, requires special storage and handling, is typically biologic in nature, and is typically prescribed by a specialist provider.~~ For FA-1 Commercial, Specialty Drug means a biologic, biosimilar, biogeneric, biobetter, or non-biologic pharmaceutical that equals or exceeds \$1,000 per claim (as determined by the amount of the discounted ingredient cost plus dispensing fee); and meets one or more of the following conditions: 1) is used to treat complex, chronic conditions, 2) requires special handling and storage, or 3) involves a significant degree of patient education, monitoring, and management. For FA-2 EGWP, a Specialty Drug is determined in accordance with applicable CMS regulations and guidance.

5. AMEND Section 3.3.3.3 c “Incident Response Requirement” as follows:

3.3.3.3 (c) The Contractor shall notify the Contract Manager within ~~two (2) hours~~ 1 Business Day if there is a threat to the Contractor and/or subcontractor's systems as it pertains to the use, disclosure, and security of the Department’s Sensitive Data.

6. AMEND the Table in Section 3.1 as follows:

Employee Status	Number of Employees	Number of Dependents	Number of Members Participants
Active	62,625	76,239	138,864
SLEOLA	1,419	2,523	3,942
Satellite	2,220	2,343	4,563
Direct Pay	1,281	955	2,236
Non-Medicare Retiree	12,229	11,204	23,433
Medicare Retiree (EGWP)	28,913	9,565	38,478
Total	108,687	102,829	211,516

7. AMEND Section 5.3 “Financial Proposal Evaluation Criteria” as follows:

Section 5.3 All Qualified Offerors (see Section 5.5.2.4) will be ranked from the lowest (most advantageous) to the highest (least advantageous) price based on the Total Proposal Price within the stated guidelines set forth in this RFP and as submitted on **Attachment F** - Financial Proposal Form.

For FA1-Attachment F, the “Total for the Duration of the Contract” found in Column L and Row ~~99~~ 137 will be multiplied by .95 for the F-4 Tab (Pricing for Fewer than 150,000 Purchasing Pool Participants) and by .05 for the F-5 Tab (Pricing for More than 149,999 Purchasing Pool Participants) and the products added together to arrive at a weighted total as displayed in the F-7 Tab for FA-1 Attachment F. For FA2-Attachment F, the EGWP Total for Contract Years 1 and 2 found in Column G, Row ~~99~~ 137 will be multiplied by .95 for the F-4 Tab (Pricing for Fewer than 150,000 Purchasing Pool Participants) and by .05 (Pricing for More than 149,999 Purchasing Pool Participants) and the products added together to arrive at a weighted total as displayed in the F-7 Tab for FA-2 Attachment F. The weighted totals for FA-1 Attachment F and FA-2 Attachment F will be added to arrive at the Offeror’s Total Proposal Price, by which an Offeror’s Financial Proposal will be evaluated.

8. AMEND the FA1 Technical Proposal Attachment P for Functional Areas 1 and 2 as indicated in the separately attached document “FA1 Attachment P Pharmacy Technical Proposal Amendment 3.” Offerors are to submit their FA1 Attachment P responses using the aforementioned amended file. Changes include the following:

- To modify Compliance Checklist (CC) Item 69;
- To modify Compliance Checklist (CC) Item-88.c;
- To modify CC Item-89;
- To strike the reference to the “State Pharmacy Access Act shown in Section IV” in Question 45;
- To delete Performance Guarantee (PG)-10;
- To modify PG-19;
- To modify PG-20;
- To modify PG-21; and
- To modify PG-22.

9. AMEND the Financial Forms, Attachments F FA1 and FA2, as indicated in the separately attached Excel spreadsheets labeled “(Amendment 3) FA1_Attachment F Commercial and Maryland Rx Purchasing Pool” and “(Amendment 3) FA2_Attachment F_EGWP. These forms replace the Financial Forms issued with the RFP and must be used in submission of an Offeror’s Financial Proposal. Changes include the following:

- To eliminate Exclusive Network Pricing;
- To modify Instructions 7 and 8 on Tab F-1.
- To change Tabs F-4 and F-5 to allow the Offeror to provide separate guarantees based on how Specialty Drugs are dispensed.
- To change terminology related to Participants and Members to reflect the definitions of those terms in Section 1.2.

10. AMEND Attachment K, HIPAA Business Associate Agreement as follows:

ATTACHMENT K - HIPAA BUSINESS ASSOCIATE AGREEMENT

BUSINESS ASSOCIATE AGREEMENT

This Business Associate Agreement (the “Agreement”) is made by and between the Department of Budget and Management (herein known as “Covered Entity”) and _____ (Name of Contractor) (hereinafter known as “Business Associate”). Covered Entity and Business Associate shall collectively be known herein as the “Parties.”

WHEREAS, Covered Entity has a business relationship with Business Associate that is memorialized in a separate agreement (the “Underlying Agreement”) pursuant to which Business Associate may be considered a “business associate” of Covered Entity as defined in the Health Insurance Portability and Accountability Act of 1996 including all pertinent privacy regulations (45 C.F.R. Parts 160 and 164) and security regulations (45 C.F.R. Parts 160, 162, and 164), as amended from time to time, issued by the U.S. Department of Health and Human Services as either have been amended by Subtitle D of the Health Information Technology for Economic and Clinical Health Act (the “HITECH Act”), as Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009 (Pub. L. 111–5) (collectively, “HIPAA”); and

WHEREAS, the nature of the contractual relationship between Covered Entity and Business Associate may involve the exchange of Protected Health Information (“PHI”) as that term is defined under HIPAA; and

WHEREAS, for good and lawful consideration as set forth in the Underlying Agreement, Covered Entity and Business Associate enter into this Agreement for the purpose of ensuring compliance with the requirements of HIPAA and the Maryland Confidentiality of Medical Records Act (Md. Ann. Code, Health-General §§ 4-301 *et seq.*) (“MCMRA”); and

WHEREAS, this Agreement supersedes and replaces any and all Business Associate Agreements the Covered Entity and Business Associate may have entered into prior to the date hereof;

NOW THEREFORE, the premises having been considered and with acknowledgment of the mutual promises and of other good and valuable consideration herein contained, the Parties, intending to be legally bound, hereby agree as follows:

Definitions.

- A. Catch-all definition. The following terms used in this Agreement, whether capitalized or not, shall have the same meaning as those terms in the HIPAA Rules: Breach, Data Aggregation, Designated Record Set, Disclosure, Health Care Operations, Individual, Minimum Necessary, Notice of Privacy Practices, Protected Health Information, Required by Law, Secretary, Security Incident, Subcontractor, Unsecured Protected Health Information, and Use.
- B. Specific definitions:
1. Business Associate. “Business Associate” shall generally have the same meaning as the term “business associate” at 45 C.F.R. 160.103, and in reference to the party to this agreement, shall mean (**Insert Name of Contractor**).
 2. Covered Entity. “Covered Entity” shall generally have the same meaning as the term “covered entity” at 45 C.F.R. § 160.103, and in reference to the party to this agreement, shall mean the Department of Budget and Management.
 3. HIPAA Rules. “HIPAA Rules” shall mean the Privacy, Security, Breach Notification, and Enforcement Rules at 45 C.F.R. Parts 160 and Part 164.
 4. Protected Health Information (“PHI”). Protected Health Information or “PHI” shall generally have the same meaning as the term “protected health information” at 45 C.F.R. § 160.103.

PERMITTED Uses AND Disclosures of PHI by Business Associate.

- A. Business Associate may only use or disclose PHI as necessary to perform the services set forth in the Underlying Agreement or as required by law.
- B. Business Associate agrees to make uses and disclosures and requests for PHI consistent with the minimum PHI necessary to accomplish the services required by the Contract ~~Covered Entity’s policies and procedures regarding minimum necessary use of PHI.~~
- C. Business Associate may not use or disclose PHI in a manner that would violate Subpart E of 45 C.F.R. Part 164 if done by Covered Entity.
- D. Business Associate may, if directed to do so in writing by Covered Entity, create a limited data set, as defined at 45 CFR 164.514(e)(2), for use in public health, research, or health care operations. Any such limited data sets shall omit any of the identifying information listed in 45 CFR § 164.514(e)(2). Business Associate will enter into a valid, HIPAA-compliant Data Use Agreement, as described in 45

CFR § 164.514(e)(4), with the limited data set recipient. Business Associate will report any material breach or violation of the data use agreement to Covered Entity ~~immediately~~ **within 1 Business Day** after it becomes aware of any such material breach or violation.

- E. Except as otherwise limited in this Agreement, Business Associate may disclose PHI for the proper management and administration, or legal responsibilities of the Business Associate, provided that disclosures are Required By Law, or Business Associate obtains reasonable assurances from the person to whom the information is disclosed that it will remain confidential and used or further disclosed only as Required By Law or for the purpose for which it was disclosed to the person, and the person notifies the Business Associate of any instances of which it is aware in which the confidentiality of the information has been breached.
- F. The Business Associate shall not directly or indirectly receive remuneration in exchange for any PHI of an Individual pursuant to §§ 13405(d)(1) and (2) of the HITECH Act. This prohibition does not apply to the State's payment of Business Associate for its performance pursuant to the Underlying Agreement.
- G. The Business Associate shall comply with the limitations on marketing and fundraising communications provided in §13406 of the HITECH Act in connection with any PHI of Individuals.

Duties of Business Associate Relative to PHI.

- A. Business Associate agrees that it will not use or disclose PHI other than as permitted or required by the Agreement or as Required by Law;
- B. Business Associate agrees to use appropriate administrative, technical and physical safeguards to protect the privacy of PHI.
- C. Business Associate agrees to use appropriate safeguards, and comply with Subpart C of 45 C.F.R. Part 164 with respect to electronic PHI, to prevent use or disclosure of PHI other than as provided for by the Agreement;
- D. Business Associate agrees to Report to Covered Entity any use or disclosure of PHI not provided for by the Agreement of which it becomes aware, including breaches of unsecured PHI as required by 45 C.F.R. § 164.410, and any Security Incident of which it becomes aware without reasonable delay, and in no case later than fifteen calendar days after the use or disclosure. **For purposes of reporting under this Agreement, in order to determine whether a particular situation is a reportable "Security Incident," the Business Associate may rely upon HIPAA and its related laws for guidance to render that determination;**
- E. If the use or disclosure amounts to a breach of unsecured PHI, the Business Associate shall ensure its report:
 - a. Is made to Covered Entity without unreasonable delay and in no case later than fifteen (15) calendar days after the incident constituting the Breach is first known, except where a law enforcement official determines that a notification would impede a criminal investigation or cause damage to national security. For purposes of clarity for this Section III.D.1, Business Associate must notify Covered Entity of an incident involving the acquisition, access, use or disclosure of PHI in a manner not permitted under 45 C.F.R. Part E within fifteen (15) calendar days after an incident even if Business Associate has not conclusively determined within that time that the incident constitutes a Breach as defined by HIPAA;
 - b. Includes the names of the Individuals whose Unsecured PHI has been, or is reasonably believed to have been, the subject of a Breach;

- c. Is in substantially the same form as **ATTACHMENT K-1** attached hereto; and
- d. Includes a draft letter for the Covered Entity to utilize to notify the affected Individuals that their Unsecured PHI has been, or is reasonably believed to have been, the subject of a Breach that includes, to the extent possible:
 - i) A brief description of what happened, including the date of the Breach and the date of the discovery of the Breach, if known;
 - ii) A description of the types of Unsecured PHI that were involved in the Breach (such as full name, Social Security number, date of birth, home address, account number, disability code, or other types of information that were involved);
 - iii) Any steps the affected Individuals should take to protect themselves from potential harm resulting from the Breach;
 - iv) A brief description of what the Covered Entity and the Business Associate are doing to investigate the Breach, to mitigate losses, and to protect against any further Breaches; and
 - v) Contact procedures for the affected Individuals to ask questions or learn additional information, which shall include a toll-free telephone number, an e-mail address, website, or postal address.
- F. To the extent permitted by the Underlying Agreement, Business Associate may use agents and subcontractors. In accordance with 45 C.F.R. §§ 164.502(e)(1)(ii) and 164.308(b)(2) shall ensure that any subcontractors that create, receive, maintain, or transmit PHI 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, Business Associate must enter into Business Associate Agreements with subcontractors as required by HIPAA;
- G. Business Associate agrees it will make available PHI in a designated record set to the Covered Entity, or, as directed by the Covered Entity, to an individual, **within 10 calendar days after receiving a written request from Covered Entity or an individual**, as necessary to satisfy Covered Entity's obligations under 45 C.F.R. § 164.524, including, if requested, a copy in electronic format;
- H. Business Associate agrees it will make any amendment(s) to PHI in a designated record set **within 10 Business Days after receiving a written request from Covered Entity or an individual**, as directed or agreed to by the Covered Entity pursuant to 45 C.F.R. § 164.526, or take other measures as necessary to satisfy Covered Entity's obligations under 45 C.F.R. § 164.526;
- I. **Within 10 business days after receiving a written request from Covered Entity or an individual**, Business Associate agrees to maintain and make available the information required to provide an accounting of disclosures to the Covered Entity or, as directed by the Covered Entity, to an individual, as necessary to satisfy Covered Entity's obligations under 45 C.F.R. § 164.528;
- J. To the extent the Business Associate is to carry out one or more of Covered Entity's obligation(s) under Subpart E of 45 C.F.R. Part 164, comply with the requirements of Subpart E that apply to the Covered Entity in the performance of such obligation(s);
- K. Business Associate agrees to make its internal practices, books, and records, including PHI, available to the Covered Entity and/or the Secretary for purposes of determining compliance with the HIPAA Rules.

- L. Business Associate agrees to mitigate, to the extent practicable, any harmful effect that is known to Business Associate of a use or disclosure of PHI by Business Associate in violation of the requirements of this Agreement.

IV. TERM AND TERMINATION

- A. Term. The Term of this Agreement shall be effective as of the effective date of the Contract entered into following the solicitation for Pharmacy Benefits Management Services and Purchasing Pool Management, Solicitation # F10B6400005R, and shall terminate when all of the PHI provided by Covered Entity to Business Associate, or the PHI created or received by Business Associate on behalf of Covered Entity, is destroyed or returned to Covered Entity, in accordance with the termination provisions in this Section IV, or on the date the Covered Entity terminates for cause as authorized in paragraph (b) of this Section, whichever is sooner. If it is impossible to return or destroy all of the PHI provided by Covered Entity to Business Associate, or the PHI created or received by Business Associate on behalf of Covered Entity, Business Associate's obligations under this contract shall be ongoing with respect to that information, unless and until a separate written agreement regarding that information is entered into with Covered Entity.
- B. Termination for Cause. Upon Covered Entity's knowledge of a material breach of this Agreement by Business Associate, Covered Entity shall:
1. Provide an opportunity for Business Associate to cure the breach or end the violation and, if Business Associate does not cure the breach or end the violation within the reasonable time specified by Covered Entity, terminate this Agreement; or
 2. Immediately terminate this Agreement if Business Associate has breached a material term of this Agreement and Covered entity determines or reasonably believes that cure is not possible.
- C. Effect of Termination.
1. Upon termination of this Agreement, for any reason, Business Associate shall return or, if agreed to by Covered Entity, destroy all PHI received from Covered Entity, or created, maintained, or received by Business Associate on behalf of Covered Entity, that the Business Associate still maintains in any form. **If return or destruction of the PHI is impossible or significantly infeasible, Business Associate may discuss this matter with the Covered Entity to reach the appropriate resolution.** Business Associate shall retain no copies of the PHI. This provision shall apply to PHI that is in the possession of subcontractors or agents of Business Associate.
 2. Should Business Associate make an intentional or grossly negligent Breach of PHI in violation of this Agreement or HIPAA or an intentional or grossly negligent disclosure of information protected by the MCMRA, Covered Entity shall have the right to immediately terminate any contract, other than this Agreement, then in force between the Parties, including the Underlying Agreement.
- D. Survival. The obligations of Business Associate under this Section shall survive the termination of this agreement.

V. CONSIDERATION

Business Associate recognizes that the promises it has made in this Agreement shall, henceforth, be detrimentally relied upon by Covered Entity in choosing to continue or commence a business relationship with Business Associate.

VI. REMEDIES IN EVENT OF BREACH

Business Associate hereby recognizes that irreparable harm ~~will~~may result to Covered Entity, and to the business of Covered Entity, in the event of breach by Business Associate of any of the covenants and assurances contained in this Agreement. As such, in the event of breach of any of the covenants and assurances contained in Sections II or III above, Covered Entity shall be entitled to enjoin and restrain Business Associate from any continued violation of Sections II or III. Furthermore, in the event of breach of Sections II or III by Business Associate, Covered Entity is entitled to reimbursement and indemnification from Business Associate for Covered Entity's reasonable attorneys' fees and expenses and costs that were reasonably incurred as a proximate result of Business Associate's breach. The remedies contained in this Section VI shall be in addition to, not in lieu of, any action for damages and/or any other remedy Covered Entity may have for breach of any part of this Agreement or the Underlying Agreement or which may be available to Covered Entity at law or in equity.

VII. MODIFICATION; AMENDMENT

This Agreement may only be modified or amended through a writing signed by the Parties and, thus, no oral modification or amendment hereof shall be permitted. The Parties agree to take such action as is necessary to amend this Agreement from time to time as is necessary for Covered Entity to comply with the requirements of the HIPAA rules and any other applicable law.

VIII. INTERPRETATION OF THIS AGREEMENT IN RELATION TO OTHER AGREEMENTS BETWEEN THE PARTIES

Should there be any conflict between the language of this Agreement and any other contract entered into between the Parties (either previous or subsequent to the date of this Agreement), the language and provisions of this Agreement shall control and prevail unless the parties specifically refer in a subsequent written agreement to this Agreement by its title and date and specifically state that the provisions of the later written agreement shall control over this Agreement.

IX. COMPLIANCE WITH STATE LAW

The Business Associate acknowledges that by accepting the PHI from Covered Entity, it becomes a holder of medical information under the MCMRA and is subject to the provisions of that law. If the HIPAA Privacy or Security Rules and the MCMRA conflict regarding the degree of protection provided for PHI, Business Associate shall comply with the more restrictive protection requirement.

X. MISCELLANEOUS

- A. Ambiguity. Any ambiguity in this Agreement shall be resolved to permit Covered Entity to comply with the Privacy and Security Rules.
- B. Regulatory References. A reference in this Agreement to a section in the HIPAA Rules means the section as in effect or as amended.
- C. Notice to Covered Entity. Any notice required under this Agreement to be given Covered Entity shall be made in writing to:

Name: **Anne Timmons**
Address: **Maryland Department of Budget and Management
Employee Benefits Division
301 W. Preston Street, Room 510
Baltimore, MD 21201**
Email: **Anne.timmons@maryland.gov**
Phone: **(410) 767-4787**

D. Notice to Business Associate. Any notice required under this Agreement to be given Business Associate shall be made in writing to:

Address: _____

Attention: _____
Phone: _____

E. Survival. Any provision of this Agreement which contemplates performance or observance subsequent to any termination or expiration of this contract shall survive termination or expiration of this Agreement and continue in full force and effect.

F. Severability. If any term contained in this Agreement is held or finally determined to be invalid, illegal, or unenforceable in any respect, in whole or in part, such term shall be severed from this Agreement, and the remaining terms contained herein shall continue in full force and effect, and shall in no way be affected, prejudiced, or disturbed thereby.

G. Terms. All of the terms of this Agreement are contractual and not merely recitals and none may be amended or modified except by a writing executed by all parties hereto.

H. Priority. This Agreement supersedes and renders null and void any and all prior written or oral undertakings or agreements between the parties regarding the subject matter hereof.

IN WITNESS WHEREOF and acknowledging acceptance and agreement of the foregoing, the Parties affix their signatures hereto.

COVERED ENTITY:

BUSINESS ASSOCIATE:

By: _____

By: _____

Name: _____

Name: _____

Title: _____

Title: _____

Date: _____

Date: _____

Issued and authorized by

<signed>
Rachel Hershey
Procurement Officer