



LARRY HOGAN  
Governor

BOYD K. RUTHERFORD  
Lieutenant Governor

DAVID R. BRINKLEY  
Secretary

MARC L. NICOLE  
Deputy Secretary

**QUESTIONS AND RESPONSES # 5**  
**PROJECT NO. F10B640005R**  
**Department of Budget & Management**  
**Pharmacy Benefit Management Services and Pharmacy Benefits**  
**Purchasing Pool Management**  
**June 6, 2016**

Ladies/Gentlemen:

This List of Questions and Responses #5, questions #73 through #84, is being issued to clarify certain information contained in the above named RFP.

In most instances the Department's response to the submitted questions merely serves to clarify the existing requirements of the RFP. Sometimes, however, in submitting questions potential Offerors may make statements or express interpretations of contract requirements that may be inconsistent with the Department's intent. To the extent that the Department recognizes such an incorrect interpretation, the provided answer will note that the interpretation is erroneous and either state that the question is moot once the correct interpretation is explained or provide the answer based upon the correct interpretation.

No provided answer to a question may in and of itself change any requirement of the RFP. If it is determined that any portion of the RFP should be changed based upon a submitted question, the actual change may only be implemented via a formal amendment to the RFP. In this situation the answer provided will reference the amendment containing the RFP change.

**Questions and Answers**

*Notice to Offerors: The Department is working to address several additional vendor questions. Consequently, the Department anticipates releasing another Q&A and associated amendment and has extended the Proposal Due Date to provide notice of these forthcoming documents and in anticipation of their release. Please see Amendment 6, Item #1.*

*73. Section 5.4 of Attachment A – Contract states, “[t]he Contractor shall not affix any restrictive markings upon any data, documentation, or other materials provided to the State [under the Contract] ...” Based on the other provisions of Contract Article 5 (Rights to Records), Bidder is understanding this to relate to markings intending to impose restrictions on the use of such materials, such as copyright marks. Can the State confirm that the Contractor may appropriately mark documents that contain information that the Contractor asserts in good faith to be exempt from disclosure under the Maryland Public Information Act, consistent with Article 8 (Confidential or Proprietary Information and Documentation) of the Contract, with the*

*understanding that permitting such markings would not bind the State to agree with the Contractor's assertions?*

**RESPONSE:** The Department confirms that the Contractor may appropriately mark documents that contain information that the Contractor asserts in good faith to be exempt from disclosure under the Maryland Public Information Act, consistent with Article 8 of the Contract, with the understand that permitting such markings would not bind the Department to agree to the Contractor's assertions.

*74. Attachment A – Contract: Bidder expects that in providing services the Contractor will provide the State with a significant amount of pre-existing intellectual property and also materials that are offered to Contractor's book of business clients generally. Accordingly, will the State agree to modify the terms of Article 6 (Exclusive Use) of Attachment A – Contract as follows (changes noted in bold italics):*

*6.1 The State shall have the exclusive right to use, duplicate, and disclose any data, information, documents, records, or results, in whole or in part, in any manner for any purpose whatsoever, that may be created or generated by the Contractor **specifically** in connection with this Contract. If any material, including software, is capable of being copyrighted, the State shall be the copyright owner and Contractor may copyright material connected with this project only with the express written approval of the State.*

*6.2 Except as may otherwise be set forth in this Contract, Contractor shall not use, sell, sub-lease, assign, give, or otherwise transfer to any third party any other information or material provided to Contractor by the Department or developed by Contractor **specifically** relating to the Contract, except that Contractor may provide said information to any of its officers, employees and subcontractors who Contractor requires to have said information for fulfillment of Contractor's obligations hereunder. Each officer, employee and/or subcontractor to whom any of the Department's confidential information is to be disclosed shall be advised by Contractor of and bound by confidentiality and intellectual property terms substantively equivalent to those of this Contract.*

**RESPONSE:** The Department has amended Provision 6 of the State Contract. Please see Amendment 6, Item 1.

*75. Regarding Section 25 (Right to Audit) of Attachment A – Contract, Subsection 25.2 states that the Contractor must provide the State access to records for verification of Contract compliance upon three business days' prior notice. While Bidder can gather and provide for the State's review many specific individual records related to the Contract upon such short prior notice, it may not be feasible to gather many other records necessary for a comprehensive audit upon such short notice. For instance, scanned images of mail pharmacy prescriptions are generally stored offline and offsite after the prescription is no longer valid and retrieval can take several days to several weeks. Similarly, gathering and loading comprehensive claims experience files for audit purposes can take several days to a few weeks depending on the age of the claims. Can the State confirm that for comprehensive systematic audits of claims experience and/or rebates, it will, to the greatest extent feasible, provide more prior notice than three*

*business days to permit the Contractor to efficiently and completely gather the appropriate records?*

**RESPONSE:** The Department confirms that for the comprehensive systematic audits of claims experience and/or rebates it will provide at least three days' prior notice and, if reasonably feasible, more notice of such audits.

*76. Regarding Section 25 (Right to Audit) of Attachment A – Contract, because the range of documents subject to audit by the State includes some competitively sensitive documents of the Contractor, such as manufacturer rebate contracts and retail pharmacy network contracts, will the State agree that: 1) independent auditors must sign a confidentiality agreement, reasonably acceptable to the Contractor, prior to performing any audit services; and 2) the State or its auditor will agree that such agreements [sic] will be reviewed at a mutually agreed-upon site and the State or its independent auditor shall not retain copies of such very competitively sensitive documents after the audit?*

**RESPONSE:** The Department's independent auditors sign its standard confidentiality agreement, in the form of RFP Attachment J, the Non-Disclosure Agreement, which is available for inspection in the RFP Wrap document. Among other protections, the Non-Disclosure Agreement requires the return of confidential information and the permanent deletion of all confidential electronic records. The Department has an interest in keeping the confidential documents of its contractors confidential in order to ensure their continued participation in the Department's contracting process and the State's reputation as a sound business partner.

*77. FA-1-CC81: Can the State please advise how many lawsuits it has experienced over the last five years related to denial of benefits due to a Drug Utilization Review decision (i.e., suits of the nature that the Contractor will be required to provide a defense for pursuant to CC-81)?*

**RESPONSE:** The Department has experienced no lawsuits in the past five years related to denial of benefits due to Drug Utilization Review decision.

*78. Attachment J – Non-Disclosure Agreement: Bidder provided an executed copy of Attachment J in accordance with the RFP requirements. Attachment J requires, in part, that the names of any employees of the Contractor and its subcontractors that receive Confidential Information must be added to Attachment J-1 (and such staff presumably must sign Attachment J-1 based on its format) as needed from time to time. For purposes of responding to the RFP, relatively few Bidder staff require access to Confidential Information and the management of Attachment J-1 is easily achieved. In the event that Bidder is selected through this RFP, the number of Bidder's staff and its subcontractor staff that would have access to one or more aspects of Confidential Information to provide the services would grow exponentially into the thousands of persons. For instance, all customer service staff available to assist State plan members would have the ability to look up elements of Confidential Information; any Bidder staff processing prior authorizations, appeals, or clinical programs would have access to certain Confidential Information; mail pharmacy and specialty pharmacy employees would have access to Confidential Information; and subcontractor staff performing ID card printing, retail pharmacy help desk services, and retail pharmacy auditing functions would all have access to Confidential Information—just to name a few. With this many individuals having access to Confidential Information, management of Attachment J-1 could become quite infeasible. In addition, Attachment J requires that original copies of Confidentiality Agreements executed by all such*

*staff and subcontractor staff be provided to the State. Again, obtaining and providing this volume of original Confidentiality Agreements to the State will be unduly burdensome to both the Contractor and the State. All Bidder employees are required to sign confidentiality agreements upon hire, and subcontractor staff are subject to similar requirements. Will the State agree that obtaining these agreements and permitting the review of a reasonable sample of such agreements by the State will satisfy the requirements of Attachment J with respect to Contractor and subcontractor staff? If not, can the State please confirm that it expects literally thousands of contractor and subcontractor staff to execute separate confidentiality agreements and for those to be provided to the State?*

**RESPONSE:** The Department agrees that Contractor and subcontractor employees do not personally need to sign Attachment J-1, provided the Contractor understands it is responsible for the performance of the agreement. See Amendment 6, Item 3. The Contractor's subcontractors, however, will still need to execute Non-Disclosure Agreements (NDAs); and those NDAs will need to be provided to the State, pursuant to Provision 9 of the NDA. The awarded Contractor may execute the amended version of the NDA.

*79. Regarding Attachment K – HIPAA Business Associate Agreement: For purposes of managing and improving the performance or outcomes of their plans, PBM clients generally seek benchmarking data on the performance of their plan as compared to a PBM's overall population of clients and certain subsections of that population. To provide this information, PBMs must engage in data aggregation, which is not generally permitted for covered entities. Accordingly, and understanding that, as stated in response to bidder questions 59-68, the State reserves the right to revisit the terms of Attachment K prior to execution, will the State agree to modify Section C of the Permitted Uses and Disclosures of PHI by Business Associate section of Attachment K as follows (changes noted in bold italics)?*

*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, **except that Business Associate may use and disclose PHI to provide Data Aggregation services to Plan as permitted by 45 CFR 164.504(e)(2)(i)(B).***

**RESPONSE:** The Department has added similar language. Please see Amendment 6, Item 4.

*80. Regarding Attachment K – HIPAA Business Associate Agreement: Section E of the Permitted Uses and Disclosures of PHI by Business Associate section of Attachment K permits the Business Associate to Disclose PHI for the proper management and administration, or legal responsibilities of the Business Associate, under certain circumstances. There are also circumstances where a Business Associate must use PHI for the proper management and administration, or legal responsibilities of the Business Associate and, in compliance with the minimum necessary rule, where the Business Associate is capable of addressing such proper management and administration, or legal responsibilities internally, rather than through disclosure to a third party, it should do so. Accordingly, and understanding that, as stated in response to bidder questions 59-68, the State reserves the right to revisit the terms of Attachment K prior to execution, will the State agree to modify Section E of the Permitted Uses and Disclosures of PHI by Business Associate section of Attachment K as follows (changes noted in bold italics)?*

*E. Except as otherwise limited in this Agreement, Business Associate **may use PHI for the proper management and administration, or legal responsibilities of the Business Associate, and 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.***

**RESPONSE:** This addition is acceptable. Please see Amendment 6, Item 5.

*81. Regarding Attachment K – HIPAA Business Associate Agreement: As part of the services typically provided by a PBM, the PBM will process coordination of benefit claims that are submitted to it by Medicaid, the Veteran’s Administration or other payer of last resort. In addition, other Covered Entities may contact the PBM from time to time seeking PHI of plan members. For example, a hospital emergency room may contact the PBM from an ID card carried by an unconscious patient to determine which, if any, prescription drugs may have been prescribed to such patient. Also, representatives of plan members with proper authorization may request PHI of such plan member from time to time. To efficiently and timely address such requests, Bidder typically has permission to use or disclose PHI for such purposes. Accordingly, and understanding that, as stated in response to bidder questions 59-68, the State reserves the right to revisit the terms of Attachment K prior to execution, will the State agree to modify the Permitted Uses and Disclosures of PHI by Business Associate section of Attachment K to add a new Subsection H as follows?*

*H. Business Associate may use and disclose PHI to respond to requests for PHI either accompanied by an authorization that meets the requirements of 45 CFR 164.508 or from a covered entity or health care provider in accordance with 45 CFR 164.506(c).*

**RESPONSE:** The Department has added similar language. Please see Amendment 6, Item 6.

*82. Regarding Attachment K – HIPAA Business Associate Agreement: As modified in Amendment 4, Section D of the Duties of Business Associate Relative to PHI section of Attachment K states in part that “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, ... without **reasonable** delay, and in no case later than fifteen calendar days after the use or disclosure” [emphasis added]. Can the State confirm that the word “reasonable” should be the word “unreasonable” in this provision?*

**RESPONSE:** The Department can confirm this is a typographical error. Please see Amendment 6, Item 2, for correction.

*83. CC-46: The Contractor agrees prescriptions purchased via mail order will never be more expensive than those obtained via retail pharmacies. Because PBMs do not control the price of usual and customary (U&C) retail pharmacy claims, would the State allow these claims to be excluded from the requirement?*

**RESPONSE:** This requirement was included to ensure mail order pricing was equal to or better than retail pricing, particularly for generic drugs with MAC pricing at retail. Since the PBM does not control the U&C retail pricing, the Department agrees that U&C retail pharmacy claims would be excluded from this requirement. Please see Amendment 6, Item 8.

84. (Amendment 4) FA2 \_Attachment F\_EGWP Final.xlsx:

*Please advise where in the spreadsheet we should show pricing for tertiary networks (e.g., home infusion, long-term-care facilities).*

**RESPONSE:** The Department has reviewed the claims data and determined that less than 2% of total prescriptions came through a tertiary network in the data provided. Due to the low prevalence of these claims, the Department anticipates they will have a de minimis impact on the guarantees provided by the PBMs. For pricing purposes, Offerors should include these tertiary networks into the overall discount and rebate guarantees.