DEPARTMENT OF
BUDGET & MANAGEMENT

LARRY HOGAN
Governor

BOYD K. RUTHERFORD
Lieutenant Governor

DAVID R. BRINKLEY
Secretary

MARC L. NICOLE
Deputy Secretary

QUESTIONS AND RESPONSES # 3
PROJECT NO. F10B6400005R
Department of Budget & Management
Pharmacy Benefit Management Services and Pharmacy Benefits
Purchasing Pool Management
May 20, 2016

Ladies/Gentlemen**:**

This List of Questions and Responses #3, questions #10 and #14 through #68, 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

The Department has amended its answer to Question 10 released on April 15, 2016. Offerors are advised to rely on the amended answer below in preparing its proposal.

10. Section 3.9 requires the PBM to have a SOC-2, Type 2 Audit performed annually. Section 3.9.8 provides: "If the Contractor, including any relevant subcontractor, currently has an annual information security assessment performed that includes the operations, systems, and repositories of the Information Functions and/or Processes being provided to the Department under the Contract, and if that assessment generally conforms to the content and objective of the Guidance, the Department will determine in consultation with appropriate State government technology and audit authorities whether the Contractor's and any relevant subcontractor's current information security assessments are acceptable in lieu of the SOC 2 Report(s)."

The Health Information Trust Alliance (HITRUST) Common Security Framework (CSF) was created for the healthcare industry and the sensitive patient information we manage. HITRUST's CSF rationalizes health-relevant regulations, standards, best practices and risk related events (such as cyber threats and breach data) into a single overarching security framework. The CSF is fully mapped to ISO 27001, and HITRUST has broad overlap with ISO 27001 while maintaining an in-depth focus on the controls that are most critical for healthcare providers. In July 2014, HITRUST and the American Institute of CPAs (AICPA) announced a collaboration to streamline and simplify the process of leveraging the CSF and CSF Assurance programs for the AICPA's Service Organization Control SOC reporting, the accounting standards for reporting service organization controls. This approach provides healthcare organizations that must comply with HIPAA or other regulatory requirements the ability to leverage one comprehensive, scalable and up-to-date framework relevant to their organization type. We currently have an annual SOC-1, Type 2, and HITRUST CSF reviews. Please confirm that SOC-1, Type 2 and HITRUST certification together are acceptable in lieu of the SOC-2 report.

AMENDED RESPONSE TO QUESTION 10: **For the first Contract Year only,** the ~~The~~ HITRUST Certification in conjunction with the SOC 1 Type 2 Report would be an acceptable alternative to the SOC 2 Type 2 Report pursuant to RFP Section 3.9.8, provided that the Offeror's SOC 1 audit and HITRUST Certification are current and provided that the Offeror, if awarded the Contract, maintains its HITRUST Certification throughout ~~the life~~ **that year** of the Contract. Certification means that an independent, qualified Common Security Framework assessor has performed an assessment according to HITRUST's Common Security Framework and has issued a report of the audit results, and the report has been accepted and approved by HITRUST.

If an Offeror proposes a combination of the HITRUST Certification and SOC 1 Type 2 Report to meet the requirements of RFP Section 3.9 **for the first year of the Contract**, then all of the requirements of Section 3.9 respective to the SOC 2 Type 2 Audit and Report will apply to the Offeror's HITRUST Certification and SOC 1 Type 2 Audit and Report. ~~Additionally, the Offeror must agree to maintain its HITRUST Certification and, if awarded the Contract, provide by May 1 of each Contract year, per RFP Section 3.9.1, both evidence that it has successfully retained its HITRUST Certification and also a copy of its SOC 1 Type 2 Report and associated audit corrective action documentation.~~

After the first Contract Year, the Contractor must submit a SOC 2 Type 2 audit report annually in accordance with the provisions of Section 3.9. The Contractor's SOC2 Type 2 report may be based on the HITRUST CSF control requirements. See https://hitrustalliance.net/soc2/ **for more information.**

14. RFP Requirement 3.3.3.3(c) says: The Contractor shall notify the Contract Manager within two (2) hours 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.

We detect (and stop) hundreds of attempts each day for unauthorized access to information in our systems. To verify that there is an actual threat and to identify which data is targeted and which client(s) that belongs to takes significantly longer than two hours. We are sure that the State does not want to be bombarded with warnings that turn out to be false or irrelevant, which would happen if we have only two hours to notify the State. In addition, with a two hour

timeframe, there would often be no one at the State to receive the notices because many could be sent after hours. Please change two hours to one Business Day to facilitate providing accurate and timely notice of relevant problems.

RESPONSE: The Department has revised this requirement. Please see Amendment 4, Item 5.

15. State of Maryland PBM RFP Section 1.2 Definitions, Brand Drug and Generic Drug 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. 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.

The industry does not have a single definitive source for brand/generic classifications. Whether a PBM uses Medi-Span or First DataBank (FDB) for determining the brand-generic status of a drug, not all drugs fit cleanly in a brand-generic category. Medi-Span, for example, provides a "multisource" indicator but states this is not meant to be used as a brand generic determinant. In addition, a particular drug can move back and forth between generic and brand status in either the Medi-Span or FDB classification systems. CMS requires that members be given at least six months' notice of any increase in copays, so using any brand-generic classification system that does not allow some adjustment of brand-generic status will violate CMS requirements. To meet CMS requirements, as well as to avoid member disruption, and to ensure predictability and stability in adjudication, we utilize a Brand-Generic Algorithm across our entire book of business to apply FDB indicators in a systematic way. Please modify the definitions of Brand Drug and Generic Drug to allow use of the PBM's CMS-compliant process. We suggest the following language:

Brand Drug – A drug adjudicated by the Contractor as a Brand Drug through application of indicators from an independent source such as Medi-Span or First Databank.

Generic Drug – A drug adjudicated by the Contractor as a Generic Drug through application of indicators from an independent source such as Medi-Span or First Databank

RESPONSE: The Department will not adopt the suggested definitions, but it has revised the definitions of Brand Drug and Generic Drug. See Amendment 4, Items 2 and 3 respectively.

16. RFP 1.2 (Amendment 1) Definition 76. Specialty Drug. Amendment 1 added the following definition: 76. Specialty Drug – A 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 biological in nature, and is typically prescribed by a specialist provider.

This definition as written requires specialty drugs to meet all the listed criteria. Many specialty drugs do not meet all of the criteria. For example:

- *Copaxone –Injectable drug for multiple sclerosis; not a biologic*
- *Synvisc – injectable for arthritis; not treating a complex condition; not a biologic (true for all hyaluronic acid injections)*
- *Bravelle- injectable for infertility; not treating a complex chronic condition; not a biologic (true for all infertility)*

- *Gleevec – oral oncology; does not require special storage or handling*
- *Tecfidera – oral for multiple sclerosis; does not require special storage or handling*
- *Vikiera Pak – oral for Hepatitis C; does not require special storage or handling*
- *Some generic specialty drugs are not high cost.*

In addition, Limited Distribution or Exclusive Distribution drugs are not included in this definition. Please revise the definition of specialty drugs to read:

Specialty Drug - A medication that meets one or more of the following criteria:

- *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,*
- *Subject to limited or exclusive distribution,*
- *Is biological in nature, or*
- *Is typically prescribed by a specialist provider.*

RESPONSE: The Department will not adopt the suggested definition, but it has revised the definition of "Specialty Drug." See Amendment 4, Item 4.

17. Sections 1.33 MBE Goals and 1.41 VBE Goals. For meeting MBE and VBE goals, must the work done under these subcontracts be performed exclusively for this contract or can some portion be performed for other business of the bidder? For example, if we retain a VBE printer to produce materials, the State's account may not require enough materials to meet the entire goal, and finding some other function to subcontract with another VBE would cause us to need to spend far more in total than is needed to meet the goal, and that cost would need to be built into the fees charged to the State. If we could meet most of the goal through materials directly related to the State's contract and use the VBE subcontractor to produce materials for other contracts, we could meet or exceed the State's goal for VBE subcontracting without wasteful spending that increases the cost of services to the State.

RESPONSE: Work performed by MBE and VSBE subcontractors attributable to other contracts may not be counted toward fulfillment of the Contractor's MBE and VSBE participation commitment on the State Contract for which the MBE and VSBE participation commitment is made. To count toward MBE or VSBE participation under the Contract, the MBE or VSBE subcontractor's work must be attributable to the Contract.

18. Attachment P – Pharmacy Technical Proposal. Q-45 – states, "Are you willing to solicit a more aggressive pharmacy network? If yes, describe how the process would work, taking into account the State Pharmacy Access Act shown in Section IV, and what the expected result would be."

Upon review of the RFP, we do not see reference to the State Pharmacy Access Act within the proposal and have not seen any reference to this Act through internet research. Will the State please provide additional clarification as to the State Pharmacy Access Act referenced in this question?

RESPONSE: The reference to "the State Pharmacy Access Act shown in Section IV" in Attachment P – Pharmacy Technical Proposal Q-45 has been struck. See Amendment 4, Item 8.

19. *CC-5. The Contractor will accept electronic transfer of eligibility data in a format indicated by the State or Participating Pool Participant and including cloud based transfers.*

To ensure the security of sensitive member and client data, we use means that we can verify are secure, and we offer a variety of different options and formats. We are not familiar with "cloud-based transfers" of eligibility, and therefore cannot verify their security, reliability, or accuracy. Please revise this requirement to read: The Contractor will accept electronic transfer of eligibility data in an industry-standard format or other mutually agreeable format.

RESPONSE: The Department will not revise this requirement.

20. CC-88.c and PG-22 – Rebate Payments. CC-88.c requires the PBM "to reimburse the State no less than the guaranteed rebate yield on a quarterly basis to be paid no later than 90 days following the end of the reporting period. Payment must include all rebates received for the quarter up to 10 Business Days before the rebate payment is due to the State. An annual reconciliation will occur no later than 120 days following the end of the fiscal year.

PG 22 says the PBM "Agrees to reimburse the State all rebates received on a quarterly basis to be paid no later than 90 days following the end of the reporting period. Payment must include all rebates received for the quarter up to 10 Business Days before the rebate payment is due to the State. An annual reconciliation will occur no later than 120 days following the end of the fiscal year."

The requirement to pay the guaranteed rebates conflicts with the requirement to pay all rebates received up to 10 Business Days before the payment is due. Our rebate payment system allows payment of either the guaranteed rebates or the amount actually collected up to 50 days before the payment date. This system is designed to be SOC-compliant so modifying this process has significant and costly risks for complying with the other State requirements, as well as other regulations such as Sarbanes-Oxley. Because rebates are received for all clients and allocation among hundreds of clients requires strict controls, we cannot set up a special process to allocate only State of Maryland payments received up to 10 business days before the payment date. Please modify CC-88.c and PG-22 to require payment of either minimum guaranteed rebates or rebates received up to 50 days before the payment is due.

RESPONSE: The Department has revised this requirement. Please see Amendment 4, Item 8.

21. PG-9, Financial Accuracy. Financial Accuracy measures the gross dollars paid incorrectly (overpayments plus underpayments) subtracted from total paid claim dollars, divided by total paid claim dollars within the audit sample.

This guarantee implies that audit results will be extrapolated from a sample. CMS requires errors be corrected by adjusting every erroneous claim to ensure the highest possible accuracy, and we apply the same process to our commercial business to achieve the same accuracy. Using the total adjustments divided by total claim dollars will provide the most accurate measure of financial accuracy. Please revise this PG to delete "within the audit sample."

RESPONSE: The question suggests an inconsistency between the performance guarantee measurement on the basis of a sample of claims and a CMS requirement that all errors must be corrected. The Department does not see a discrepancy because the performance guarantee would be measured by an independent auditor based on a sample of claims, a practice which does not conflict with any CMS requirements. Accordingly, the Department will not revise this performance guarantee.

22. PG-12, Employee Satisfaction. This guarantee is "Measured through a random sample of 10% of all members enrolled in each respective Plan and assessed by the State's annual Customer Satisfaction Survey."

Please confirm that this means a client-specific survey done by the PBM. Our survey methodology surveys only members who have actually used the pharmacy benefit to ensure that ratings are related to the member's experience with us rather than general feelings about the plan. Additionally, because survey response rates vary, we survey enough members to get a statistically significant response, which may be less or more than 10% of total members. Please revise the language of PG-12 to require a statistically valid sample of utilizing members.

RESPONSE: No, this performance guarantee refers to the annual customer satisfaction survey conducted by the Employee Benefits Division. The Performance Guarantee will not be revised.

23. PG-19 - Mail Order Dispensing Turnaround Time-For Prescriptions not requiring intervention. PG-19 requires: 95% of prescriptions dispensed within 2 Business Days and 100% within 4 Business Days.

We strive to dispense all prescriptions as fast as possible. It is not realistic that 100% of prescriptions can be dispensed in 4 business days without disruption or inconvenience to the member. For example, in circumstances where a drug is out of stock, we would need to return the script to the member unfilled, which violates the terms of this PG. Even if the PG were modified or interpreted as allowing dispensing or return of the script in 4 business days, it would result in lower member satisfaction than a more flexible approach. For example, in an out of stock situation where we expect new supplies within a few days, we would still need to return the script within four business days unfilled rather than being able to dispense the order when if we expect the new supplies on the fifth or sixth day, which most members would prefer compared to starting the process over at our pharmacy or another pharmacy. Please revise this PG to require 95% of prescriptions dispensed with two business days and delete the 100% requirement.

RESPONSE: The Department has revised part of this performance guarantee. See Amendment 4, Item 8.

24. PG-20 - Mail Order Dispensing Turnaround Time-For Prescriptions requiring intervention. 95% of prescriptions dispensed within 4 Business Days and 100% within 7 Business Days Dispense or return all.

Requiring 100% of scripts to be dispensed or returned in 7 Business Days will result in lower member satisfaction than allowing the PBM the flexibility to continue to try to clear up the problem. For example, we sometimes have difficulty reaching a provider to clear up a potential clinical problem. If a prescriber is on vacation until the sixth day and then cannot give an immediate approval, we would need to return the script unfilled rather than wait for the prescriber to approve a day or two later after having the chance to do additional research. Please revise this PG to require 95% of prescriptions dispensed with four business days and delete the 100% requirement.

RESPONSE: The Department has revised part of this performance guarantee. See Amendment 4, Item 8.

25. **PG-21 Paper Rx Claims Turnaround**
PG-21 requires for paper claims that 95% of prescriptions reimbursed within 10 Business Days and 100% within 15 Business Days, and applies to both commercial and EGWP claims.

For EGWP paper claims, CMS requires that 100% of paper claims be processed within 14 calendar days, which in almost all cases is a higher standard than is requested in this PG. To ensure compliance with regulatory requirements, we request that this standard be changed in regard to application to the EGWP (and not for the commercial plan) to 100% of paper claims be processed in accordance with CMS standards.

RESPONSE: The Department has revised this performance guarantee. See Amendment 4, Item 8.

26. FA 1 Attachment P-1: Plan Information III. Pharmacy Delivery Systems. Describe the proposed geographical service area. Are you asking for the breadth of locations of pharmacies within each network proposed (e.g., all 50 states, number of pharmacies per state)?

RESPONSE: Offerors are to respond with a detailed breakout of their proposed network so that the Department can determine whether the Offeror provides an adequate level of access for current and future participants. A break out by state would be an appropriate response for this purpose.

27. FA 1 Attachment P-1: Plan Information III. Pharmacy Delivery Systems. Provide a map of the proposed geographical service area. Label as "Response FA 1 Attachment P-1: Service Area Map." Our broadest network is made up of more than 60,000 pharmacies. Would a map of the U.S. color-coded for locations where we have pharmacies suffice? Please clarify what you are looking for.

RESPONSE: A map of the U.S. color coded to indicate locations where an Offeror has pharmacies would suffice; however, the map would need to represent the network that the Offeror is proposing and provide some indication of the number of pharmacies within each state.

28. FA 1 Attachment P-1: Plan Information III. Pharmacy Delivery Systems. Provide the website address (URL) for your provider directory and its password, if necessary. Our online provider directory is based on address/ZIP code lookup. Will the URL for this lookup tool suffice?

RESPONSE: Yes, the URL will be acceptable. As stated above, if the website requires a password, an Offeror must include the password in its response.

29. Participants' Access to Providers. The State would like to determine the availability of pharmacy providers to its employee population. Prepare GeoAccess® GeoNetworks® report(s) for the Pharmacy network that you are proposing, using census data provided by The State and the parameters in the table below. Provide access for the proposed network in two ways: 1) all employees currently in the Pharmacy Plan and 2) all employees. Note that it is important that you follow the exact parameters. Report output is required for those with access and those without access, based upon the stipulated parameters. The report output should show the average distance to each Pharmacy. See the section entitled "FA 1 Attachment P-5: Access to Pharmacies" for the required format of the output. In addition to the hard copy report, the data must be supplied in electronic format that has read/write capabilities. Do not send the data in a read-only file.

Please clarify what the values signify under the headers in the Census file, particularly Census Member Status, Census member plan, and Census Member Pharmacy Tier. What column and values correspond to each of the following:

- *all employees/Non-Medicare retirees currently in the Pharmacy Plan;*
- *all employees/Non-Medicare retirees;*
- *all Medicare retirees and spouses currently in the Pharmacy Plan; and*
- *all Medicare retirees and spouses?*

RESPONSE: The census file provides information on all State participants eligible for the pharmacy program. The "current member status" represents an employee's status as defined in the RFP Wrap document (active, satellite, direct pay, etc.). Under "census member plan," the Offeror will be able to identify which eligible members have enrolled in Pharmacy coverage. The "census member tier" identifies what family tier the employee elected during enrollment (single, double, or family). The Offeror will need to filter this data file by the necessary fields to arrive at the desired totals listed above.

30. FA-1- Technical Proposal- Compliance Checklist Item CC-14- The language in the question is confusing since if a Call Center Representative is not immediately available, the time stated to the member will be the approximate time until there is a Call Center Representative available to speak. Can the language be clarified as such: During call center hours, as indicated above, the customer service phone intake system should be an automatic answering system that picks up within 30 seconds and directs Participants into a queue that will provide member a wait time until serviced, with an available opt-out to a live representative at any time during the automatic answering system call tree options.

RESPONSE: No, the Department will not revise this requirement. The expectation is that the call will be answered within 30 seconds by a call center representative during call center hours.

31. FA-1- CC-58- Is the State able to provide a copy of the current Eligibility Format in order to review programming costs associated with administering State's current layout?

RESPONSE: The Department is unable to accommodate this request because it is implementing a new human resources system and does not yet have the layout to be used for 2018. Providing the current layout would not be helpful as it is expected to change significantly.

32. FA-1- CC-80- Formulary- Does State of Maryland currently utilize a formulary which employs exclusions of select non-formulary products in therapeutic categories which are covered in the State's plan design as a means to increase formulary compliance?

RESPONSE: Yes, but exclusions of non-formulary products are employed in order to achieve rebate yield more than formulary compliance. The current formulary is available here: http://dbm.maryland.gov/benefits/Documents/2016%20Express%20Scripts%20National%20Preferred%20Formulary.pdf .

33. FA-1- CC-81- Where the RFP requires that the Contractor assumes fiduciary responsibility for defense of any DUR decisions, can DUR decisions be clarified to be any clinical decisions made as it relates to Utilization Management programs that are implemented such as Step Therapy, Prior Authorization, and Appeals?

RESPONSE: The Department will not revise this requirement.

34. FA-1- CC-89- RFP asks for billing to be done on a weekly basis. Contractor's system is able to invoice clients four (4) times a month. Would State accept invoices four (4) times a month instead of weekly?

RESPONSE: Yes, the Department can accept invoices 4 times per month. See Amendment 4, Item 8.

35. Retail Network- Does the State of Maryland currently exclude any pharmacies from the Retail Network available to members?

RESPONSE: No. The State intentionally has an open network.

36. Scoring- Can the State of Maryland provide detail on how each factor in the RFP such as Financials, Technicals, etc., will be scored?

RESPONSE: The Department does not use scoring in its evaluation of Offeror proposals. Instead, the Department establishes an overall ranking of Offeror proposals based on a merger of Technical and Financial Proposal rankings, which are given equal weight in accordance with Section 5.5.3 of the RFP. Technical Proposals are ranked in accordance with the evaluation criteria listed in RFP Section 5.2 based upon consideration of the Offerors' Technical Proposals, cure letter responses, and oral presentations. Following the ranking of Technical Proposals, financial rankings of the Offerors will be determined in accordance with the manner described in Section 5.3 See Amendment 4, Item 7 for revised Section 5.3. The overall ranking merges the Technical and Financial rankings to arrive at an award recommendation of the Proposal reflecting the overall best value to the Department.

37. FA 1 Attachment P-6: Compliance Checklist. CC-69: The Contractor will provide, on a monthly basis, a full file of all claim activity to the State's data warehouse vendor. This file will include member Social Security numbers and will be in the format specified in Attachment G: Claims Data Record Layout.

Please advise where we can find Attachment G.

RESPONSE: The language has been updated. Please see Amendment 4, Item 8.

38. Do you have an estimate of how many benefit fairs you expect to have, given the 100% attendance requirement?

RESPONSE: There are approximately 130 employee benefit fairs during Open Enrollment and approximately another 150 wellness events throughout the year for a total of approximately 280 events requiring the Contractor's attendance per Contract year.

39. *FA1, Attachment P, Q-17 regarding economic impact cautions bidders to not include financial information in response to this question. Does this restriction also apply to other responses in the technical proposal? Is "financial information" limited to the items presented in the pricing section (i.e., Attachment F)? Or does it include book-of-business or client-specific savings results/projections? If it includes savings information, can we reference this information in the technical proposal and include it in the pricing section?*

RESPONSE: The Offeror may not include any financial information in its Technical Proposal that would divulge any pricing information contained in its Financial Proposal. Offerors' Technical Proposals will be evaluated first and independently from Offerors' Financial Proposals; consequently, to ensure a separate and independent technical evaluation, any and all pricing information related to the Offeror's Financial Proposal must be presented exclusively in the Offeror's Financial Proposal in the specified format. In this sense, the prohibition on including "financial information" referenced in FA 1, Attachment P, Q-17, is limited to the financial information presented in the Offeror's Financial Proposal. General financial information not related to the Offeror's Financial Proposal, e.g., contract values for clients listed as references, savings projections from proposed Offeror programs (provided such projections do not include information from which one could derive the Offeror's pricing), and financial statements showing the Offeror's fiscal integrity, may be included in an Offeror's Technical Proposal and in some cases is requested as part of the Offeror's Technical Proposal response.

40. The term "Specialty Drug" is defined in Amendment 1. We do not see a definition of "specialty pharmacy" in the RFP. In FA1 Attachment F, Tab F-2, Item F-3(g) [Row 22], and in the pricing worksheets on Tab F-4 "Specialty Pharmacy" is capitalized implying that it is defined. FA1 Attachment F, Tab F-2, Item F-3 [Row 27], uses the term "specialty pharmacies", not capitalized.

In general, specialty pharmacy pricing guarantees apply only to Specialty Drugs dispensed through the PBM's owned or subcontracted specialty pharmacy, and not through retail stores, which are independent contractors. Please clarify if the Specialty Pharmacy pricing guarantees on Tab F-4 are to apply to only to Specialty Drug claims dispensed through the PBM's owned or subcontracted specialty pharmacy, or should include both retail Specialty Drug claims and PBM-owned/subcontracted Specialty Drug claims.

RESPONSE: For the specialty guarantees, please see Amendment 4, Item 9 for Attachments FA1 and FA2, tabs F-4 and F-5. These tabs now allow for the Offeror to provide separate guarantees dependent upon how drugs are dispensed.

41. FA1 Attachment F, Tab F-2, Item F-4 says "Each distinct pricing guarantee will be measured and reconciled on a component (e.g. retail brand, retail generic, mail order brand,

mail order generic, and specialty) basis only and guaranteed on a dollar for dollar basis with 100% of any shortfalls recouped by the State. Surpluses in one component may not be utilized to offset deficits in another component." Item F-6 says "Rebate guarantees are based on minimums. 100% of rebates will be passed through to the State of Maryland." FA-2 Attachment F Tab F-2 has the same terms at Items F-5 and F-7. The examples in F-4/F-5 for pricing guarantee components are all related to ingredient cost discounts; rebates are not specified.

Typically rebate guarantees are considered to be a single pricing component. Please confirm that rebate guarantees for retail, mail, and specialty are considered one component to be reconciled in aggregate, and are not considered three different pricing components.

RESPONSE: Rebates for retail, mail, and specialty will be measured independently of each other. For example, retail rebates and mail order rebates will be viewed as individual guarantees; a surplus in the retail rebates will not be able to offset any shortfalls in the mail order.

42. Minimum Qualifications. With regard to providing references, if an Offeror has many large clients, it may not be feasible to gather contact information for all of them. As proof of an Offeror's ability to meet the minimum qualifications, will you accept the requested information for a selection of clients that shows that we meet the qualifications?

RESPONSE: Yes, an Offeror may use information from a selection of its clients in submitting the required proof as stated in Sections 2.1.2, 2.2.2, 2.3.2, 2.4.2, 2.5.2, and 2.6.2, of meeting the stated Minimum Qualifications listed in Sections 2.1.1, 2.2.1, 2.3.1, 2.4.1, 2.5.1, and 2.6.1.

43. Attachment P Technical Proposal—Compliance Checklist. CC-21 The Contractor agrees to have an annual audit performed by an independent audit firm of its handling of the Department's critical functions and/or sensitive information, which is identified as Insurance Claims Processing Services (collectively referred to as the "Information Functions and/or Processes"). Such audits shall be performed in accordance with audit guidance: Reporting on Controls at a Service Organization Relevant to Security, Availability, Processing Integrity, Confidentiality, or Privacy (SOC 2) as published by the American Institute of Certified Public Accountants (AICPA) and as updated from time to time, or according to the most current audit guidance promulgated by the AICPA or similarly-recognized professional organization, as agreed to by the Department, to assess the security of outsourced client functions or data (collectively, the "Guidance"). Copies of such audits will be provided to DBM annually.

Please clarify the scope and timing expected.

RESPONSE: The Offeror is instructed to review Section 3.9 of the RFP Wrap document for timing and scope of the SOC 2 Type 2 audit requirement. Specifically, Section 3.9.1 requires the Contractor to submit to the Contract Manager an audit report covering the preceding calendar year by May 1 of each contract year. Section 3.9.2 requires that the SOC 2 Audit report on the Contractor's and any relevant subcontractor's system(s) and the suitability of the design and operating effectiveness of controls of the Information Functions and/or Processes to meet the requirements of the Contract, including the Security Requirements identified in Section 3.3, relevant to the following trust principles: Processing Integrity, Security, Availability, Confidentiality, and Privacy.

44. Confirm if the Performance Guarantee 11 (Claims Standards Processing Time) that 95 percent of all claims adjudicated within 10 business days and 98 percent of all claims within 20 business days apply to electronic claims, paper claims or both.

RESPONSE: Performance Guarantee 11 applies to both electronic claims and paper claims.

45. Will you provide the State's annual Customer Satisfaction Survey that is referenced in performance guarantee 12?

RESPONSE: The survey document cannot be provided. Only contractors receive a copy and then of their results only.

46. Please confirm that PG-13 and PG-14 (Certificate/Evidence of Coverage Document) apply to the EGWP line of business only (and not commercial).

RESPONSE: Confirmed. PG-13 and PG-14 apply to the FA-2 (EGWP) only and not FA-1 (commercial).

47. For the network disruption, we found several discrepancies between the census data and the exhibits for the State of Maryland. After applying the fillers for each exhibit report, we found that:

- *There are multiple states with the same county name that have been combined in the totals. One of the counties on the exhibit (all four sections), Harford didn't have the correct count.*

Question: Is this correct or should the totals only include members from the state of Maryland?

- *After Geocoding and Place Naming the ZIP codes, we compared what they had on the census (member state and member county) and they do not match.*

Question: Do you want us to summarize by their state/county or the ZIP and how it was geocoded?

RESPONSE: All Offerors will need to develop tables that count employees by the counties listed. For each table the following filters will need to be included utilizing the data provided:

1. Census Member Plan
2. Census Member Relationship
3. Census Member Status

For Commercial FA1

When asked for the Employees that currently have Rx coverage please filter your table as follows:

1. Census Member Plan: Commercial
2. Census Member Relationship: EE
3. Census Member Status: Active, Direct Pay, Retiree With Medicare, Retiree Without Medicare, Satellite, and SLEOLA

When asked for all Employees eligible for Rx coverage please filter your table as follows:

1. Census Member Plan: Commercial and No Rx
2. Census Member Relationship: EE
3. Census Member Status: Active, Direct Pay, Retiree With Medicare, Retiree Without Medicare, Satellite, and SLEOLA

For EGWP FA2
When asked for the Medicare Retirees that currently have Rx coverage through the EGWP please filter your table as follows:

4. Census Member Plan: EGWP
5. Census Member Relationship: EE, Spouse, and Blank
6. Census Member Status: EGWP

When asked for the Medicare Retirees eligible for Rx coverage through the EGWP please filter your table as follows:

4. Census Member Plan: EGWP
5. Census Member Relationship: EE, Spouse, and Blank
6. Census Member Status: EGWP, Retiree with Medicare, Retiree without Medicare

48. Regarding the EGWP claims data, the data does not have mail or retail indicator. Please provide a mail indicator.

RESPONSE: Offerors are instructed to see "Attachment Q Claims Repricing Files Key." Using this file Offerors can determine mail or retail based on the pharmacy indicator. Additionally, "claim process type" shows the mail/retail indicator. Retail claims are "1," mail claims are "2," and paper claims are "3."

49. Regarding the EGWP claims data, there is no unique member identifier. There is a cardholder identifier but members and their beneficiaries could have the same card. There is a relationship identifier but it is only 1 throughout all rows. Please provide a unique member ID, or clarification of the relationship identifier "1" (which assumes that there are no beneficiaries).

RESPONSE: The EGWP repricing file only includes 1 in the relationship code as each member has an individual card under Medicare. For the Commercial file, offerors can use the relationship code to determine spouse or dependent status.

50. Regarding the EGWP claims data, please explain why data in December 2015 is very light. Less than 75% scripts than previous months.

RESPONSE: The data is on a paid basis through December 2015. As such the 2015 claims data is not fully incurred and may be a little lighter in the latter months of 2015.

51. Regarding the EGWP claims data, there are 45,000 unique cardholder IDs in the data for 2015. Please explain why this is greater than the expected number of EGWP members.

RESPONSE: The 45,000 number represents all EGWP members; which consists of Medicare eligible retirees, Medicare eligible spouses that elected Rx coverage, and active employees with End Stage Renal Disease. Medicare eligibility may be the result of age or disability.

52. Regarding question CC-70 in bold text: The Contractor agrees to deliver the required management information reporting in a format specified by the State that provides utilization, claims reporting, rebates, and administrative services data by subgroup to the State of Maryland. The required subgroups are: Active, Satellite, Direct Pay, State retirees under 65, and State retirees 65 and over. The Contractor also agrees to provide monthly claims and enrollment in these specified subgroups. Question: Please define what administrative services data the State is looking for.

RESPONSE: Desired administrative services information includes information on any services that are rendered by the PBM for that particular population. These services could include paper claim processing, drug utilization review, utilization management, and any other services provided under the Contract as necessary or as requested.

53. *Regarding question CC-76g: The Contractor will provide full disclosure quarterly reports of drug intervention, drug substitution and drug repackaging that occurs directly or indirectly in connection with the State Plan and the Maryland Rx Program, including at least the following:*
i.) drug name, dosage, strength and NDC code of the drug prior to substitution, intervention or repackaging;
ii.) drug name, dosage, strength and NDC code of the drug after substitution, intervention or repackaging;
iii.) the price of each drug;
iv.) therapeutic basis or cost savings for the intervention or substitution;
v.) the manufacturer of each drug;
vi.) the labeler or packager of each drug;
vii.) the aggregate number of interventions, substitutions or repackaging during the reporting period; and whether the Contractor has received any compensation from any source related to any drug intervention or substitution.
Question: Please confirm if this request is about mail order services?

RESPONSE: Where applicable, the Contractor is required to report the requested information from any/all dispensing channels.

54. FA2 throughout the compliance checklist and questionnaire references FA1. For example, in FA2 Q. 25 references the Customer Services questions the Customer Services questions in FA1. Please confirm where EGWP responses for items references in FA1 should be provided.

RESPONSE: EGWP responses are to be included in FA2 Attachment P. As many of the services for FA2 mirror those as in FA1, the FA2 Attachment P was designed so that Offerors could respond more efficiently. Where services overlap between FA1 and FA2, Offerors are just being asked to confirm they will provide the same services for FA2 as they have agreed to in FA1.

55. Requirement 2.4.1 states: The Offeror must provide proof of registration and/or certification as required by the following State laws: a) Certification as a Private Review Agent under Md. Ann. Code, Insurance Art., Title 15, subtitle 10B. This certification may be held by either the Offeror or the entity that performs utilization review, as defined in Md. INSURANCE Code Ann. § 15-10B-01 (n), on behalf of the Offeror; and b) Registration as a Pharmacy Benefits Manager under Md. Ann. Code, Insurance Art., Title 15, subtitle 16 and the required disclosure report as described in Md. Ann. Code, Insurance Art. § 15-1623. Registration must be held by the legal entity of the Offeror itself. For the purposes of meeting this qualification, registration may not be held by any other legal entity, including subsidiaries.

We carry out certain functions through corporate affiliates. In particular, one of our corporate affiliates holds a pharmacy benefit management license from the state of Maryland and a separate corporate affiliate holds a contract with CMS that authorizes that entity to perform EGWP services. Requirement 2.4.1 requires that the "Offeror" be the entity that holds the pharmacy benefit management license from the state of Maryland. Given that requirement and

CMS requirements that EGWP services be provided by the entity holding the CMS contract, is it acceptable to define "Offeror" as multiple corporate affiliates. All such entities would be parties to the ultimate contract. In the alternative, if the Offeror can only be the entity that holds the pharmacy benefit management license with the state of Maryland, will the state of Maryland accept contract language that specifically authorizes corporate affiliates to carry out various duties required by the contract, including invoicing and receipt of payment.

RESPONSE: The Offeror is defined in the RFP Wrap Section 1.2 as "an entity that submits a Proposal in response to this RFP." The Offeror as the entity responsible for submitting the Proposal must itself be the PBM manager, as stated in Section 2.4.1. The Offeror must also meet the other Minimum Qualifications unless the qualification expressly states that another entity may meet that qualification on behalf of the Offeror. See Answer to Q&A #1, Question 6. For example, the Minimum Qualification stated in Section 2.5.1 allows either the Offeror or its proposed subcontractor, which may or may not be a corporate affiliate, to hold a contract with CMS as a Medicate Part D Prescription Drug Plan. Additionally, Section 1.1.4 allows the Offeror to use subcontractors to provide services under the Contract. Under these provisions, in the example stated in the question, the Offeror would need to be the entity registered as the PBM. The Offeror as the PBM registrant may propose to have an affiliate hold the CMS contract to provide the EGWP services and the Offeror may propose to use other subcontractors or corporate affiliates to provide other services under the Contract.

56. *Performance Guarantee 10 says:*

PG-10	*Claims Standards* *Payment Accuracy Measures the number of incorrect drafts of payments made on behalf of the State, subtracted from the total draft or payment transactions, divided by the total draft or payment transactions.*	*97% of claims with benefit payments are processed accurately.*	*Quarterly Plan Performance Measurement Report Card (Report Card to be submitted by the Offeror).* *Measured by the State's independent auditor as part of the annual claims audit. Criteria as defined by the State's independent auditor. Measured to two (2) decimal places.* *Frequency of report: Quarterly*	*2% of admin fees if below 97% but at least 95%. 4% of admin fees if less than 95%.*

This PG is between PG-9 which calls for 99% of claim dollars being processed accurately, and which we believe refers to all claims, and PG-11 which calls 95% of all claims to be adjudicated within 10 business days, which we believe must relate to only paper claims because about 99% of claims are adjudicated within seconds on line. The PG-10 reference to incorrect drafts of payments sounds like it is measuring the number of checks or remittances to pharmacies that have incorrect amounts, or it could relate to checks to members. In any event, we have never seen a request for measure of the percentage of checks/remittances. In addition, auditing of actual pharmacy remittances would be nearly impossible because we pay pharmacies for claims for all clients in batch remittances so they contain confidential information of many clients. Is PG-10 supposed to refer to the actual claims processed incorrectly, which is a commonly requested PG? If yes, we request the State revise the PG to change "drafts of payments" and

"draft or payment transactions" to read "claims", and also to clarify that it will be the percentage of all claims processed in error claims as measured by the agreed upon final results of the State's annual claims audit. If not, please clarify what the State is asking for.

RESPONSE: Please see Amendment 4, Item 8. This PG was included as an oversight and has been deleted.

57. Contractor agrees that it will comply with the Living Wage law by paying all Covered Employees the applicable Living Wage. Section 32 of Attachment A authorizes the State to withhold payment of an invoices if Contractor fails to submit all records to the Commissioner of Labor and Industry as required under COMAR 21.11.10.05. Section 1.34 of the Request for Proposal also states that failure to comply with that regulation could result in a breach of the Contract. COMAR 21.11.10.05 gives the Commissioner broad authority require (sic) Contractor to "submit data, in a form acceptable to the Commissioner". Please confirm that if Contractor submits payroll records for the all Covered Employees, the State will not exercise its right to assert breach or withhold payment of invoices.

RESPONSE: The Department cannot limit the authority of the Commissioner to request information from the Contractor. However, the Department is not likely to assert breach or withhold payment if the Contractor is cooperating with the Department in regard to its duties under the Living Wage law.

58. Amendment 1 FA1 Attachment 1 Commercial and MarylandRx, Tab F-4 is for <150,000 Participants and Tab F-5 is for >149,999 Participants. Participant is defined in Amendment 1 as "59. Participant – Each individual covered by a plan (Members and Dependents)." The table on RFP page 33 shows about 173,000 commercial members currently (211,516 total Members less 38,478 EGWP Members, with "Members" appearing to be the number of Employees and Dependents, rather than "53. Member" as defined in Amendment 1). This would put the State over the F-4 count immediately. All other Administrative Fee pricing is done PEPM (Definition 62). Should the lives breaks on Tabs F-4 and F-5 be per Employee (which is not defined, but which we think is intended to be the same as "53. Member" in Amendment 1, and that the last column in the table on RFP page 33 should refer to "Number of Participants") rather than Participants as in Definition 59?

RESPONSE: The table and price form labels have been changed to reflect the defined terms of "Member" and "Participant" more accurately. See Amendment 4, Items 6 and 9. "Member" refers to a covered employee **and** his or her covered household. "Participant" refers to any individual covered by a plan.

59. In reference to ATTACHMENT K – HIPAA BUSINESS ASSOCIATE AGREEMENT Section B, would the State consider changing the following language:

"Business Associate agrees to make uses and disclosures and requests for PHI consistent with Covered Entity's policies and procedures regarding minimum necessary use of PHI."
to:
Business Associate agrees to make uses and disclosures and requests for PHI consistent with the minimum PHI necessary to accomplish the services.

RESPONSE: Please see Amendment 4, Item 10 for changes to the HIPAA Business Associate Agreement. Because HIPAA laws are developing on an ongoing basis, it will be necessary to fully evaluate the terms of BAA at the time of execution. The Department reserves the right to amend the BAA to comport with HIPAA and its related laws as they stand at the time of execution of the BAA.

60. In reference to ATTACHMENT K – HIPAA BUSINESS ASSOCIATE AGREEMENT Section D, would the State consider changing the following language:

"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 after it becomes aware of any such material breach or violation."
to:
"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 promptly after it becomes aware of any such material breach or violation."

RESPONSE: Please see Amendment 4, Item 10 for changes to the HIPAA Business Associate Agreement. Because HIPAA laws are developing on an ongoing basis, it will be necessary to fully evaluate the terms of BAA at the time of execution. The Department reserves the right to amend the BAA to comport with HIPAA and its related laws as they stand at the time of execution of the BAA.

61. In reference to ATTACHMENT K – HIPAA BUSINESS ASSOCIATE AGREEMENT Section D, would the State consider changing the following language:

"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."
to:
"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, a reportable "Security Incident" shall not include unsuccessful or inconsequential incidents that do not represent a material threat to confidentiality, integrity or availability of PHI (such as scans, pings, or unsuccessful attempts to penetrate computer networks);"

RESPONSE: Please see Amendment 4, Item 10 for changes to the HIPPA Business Associate Agreement. Because HIPAA laws are developing on an ongoing basis, it will be necessary to fully evaluate the terms of BAA at the time of execution. The Department reserves the right to amend the BAA to comport with HIPAA and its related laws as they stand at the time of execution of the BAA.

62. In reference to ATTACHMENT K – HIPAA BUSINESS ASSOCIATE AGREEMENT Section G, would the State consider changing the following language:

"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, as necessary to satisfy Covered Entity's obligations under 45 C.F.R. § 164.524, including, if requested, a copy in electronic format;"
to:
"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 ten business 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;

RESPONSE: Please see Amendment 4, Item 10 for changes to the HIPAA Business Associate Agreement. Because HIPAA laws are developing on an ongoing basis, it will be necessary to fully evaluate the terms of BAA at the time of execution. The Department reserves the right to amend the BAA to comport with HIPAA and its related laws as they stand at the time of execution of the BAA.

63. In reference to ATTACHMENT K – HIPAA BUSINESS ASSOCIATE AGREEMENT Section H, would the State consider changing the following language:

"Business Associate agrees it will make any amendment(s) to PHI in a designated record set 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;"
to:
"Business Associate agrees it will make any amendment(s) to PHI in a designated record set within ten business days after receiving a written request from Covered Entity or an individual as directed or agreed to by the Covered Entity or an individual 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;"

RESPONSE: Please see Amendment 4, Item 10 for changes to the HIPAA Business Associate Agreement. Because HIPAA laws are developing on an ongoing basis, it will be necessary to fully evaluate the terms of BAA at the time of execution. The Department reserves the right to amend the BAA to comport with HIPAA and its related laws as they stand at the time of execution of the BAA.

64. In reference to ATTACHMENT K – HIPAA BUSINESS ASSOCIATE AGREEMENT Section I, would the State consider changing the following language:

"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;"
to:
"Within ten 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;"

RESPONSE: Please see Amendment 4, Item 10 for changes to the HIPAA Business Associate Agreement. Because HIPAA laws are developing on an ongoing basis, it will be necessary to fully evaluate the terms of BAA at the time of execution. The Department reserves the right to amend the BAA to comport with HIPAA and its related laws as they stand at the time of execution of the BAA.

65. In reference to ATTACHMENT K – HIPAA BUSINESS ASSOCIATE AGREEMENT Section B.2, would the State consider changing the following language:

"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 time specified by Covered Entity, terminate this Agreement; or"
to:
"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"

RESPONSE: Please see Amendment 4, Item 10 for changes to the HIPAA Business Associate Agreement. Because HIPAA laws are developing on an ongoing basis, it will be necessary to fully evaluate the terms of BAA at the time of execution. The Department reserves the right to amend the BAA to comport with HIPAA and its related laws as they stand at the time of execution of the BAA.

66. In reference to ATTACHMENT K – HIPAA BUSINESS ASSOCIATE AGREEMENT Section C.1, would the State consider changing the following language:

"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. 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."
to:
"Within thirty (30) days after 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 not feasible, Business Associate may retain the PHI subject to section IV(A). 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."

RESPONSE: Please see Amendment 4, Item 10 for changes to the HIPAA Business Associate Agreement. Because HIPAA laws are developing on an ongoing basis, it will be necessary to fully evaluate the terms of BAA at the time of execution. The Department reserves the right to amend the BAA to comport with HIPAA and its related laws as they stand at the time of execution of the BAA.

67. In reference to ATTACHMENT K – HIPAA BUSINESS ASSOCIATE AGREEMENT Section C.2, would the State consider removal of the following language:

"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."

RESPONSE: No, the Department will not remove this language.

68. In reference to ATTACHMENT K – HIPAA BUSINESS ASSOCIATE AGREEMENT, would the State consider changing the following language:

"Business Associate hereby recognizes that irreparable harm will 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…"
to:
"Business Associate hereby recognizes that irreparable harm 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..."

RESPONSE: Please see Amendment 4, Item 10 for changes to the HIPAA Business Associate Agreement. Because HIPAA laws are developing on an ongoing basis, it will be necessary to fully evaluate the terms of BAA at the time of execution. The Department reserves the right to amend the BAA to comport with HIPAA and its related laws as they stand at the time of execution of the BAA.

Issued and authorized by

<signed>
Rachel Hershey
Procurement Officer