DEPARTMENT OF
BUDGET & MANAGEMENT

LARRY HOGAN
Governor

BOYD K. RUTHERFORD
Lieutenant Governor

DAVID R. BRINKLEY
Secretary

MARC L. NICOLE
Deputy Secretary

QUESTIONS AND RESPONSES # 6
PROJECT NO. F10B6400005R
Department of Budget & Management
Pharmacy Benefit Management Services and Pharmacy Benefits
Purchasing Pool Management
June 13, 2016

Ladies/Gentlemen**:**

This List of Questions and Responses #6, questions #85 through #89, 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

85. Amendment 4, Items 2 and 3 amends the definitions of Brand Drug and Generic Drugs, RFP Sections 1.1.5 and 1.2.39, to depend on whether a drug is marketed under a New Drug Application (NDA) or Abbreviated New Drug Application (ANDA). These definitions will cause confusion and inconsistency for members and cannot be applied in all cases. For example:

- *There are some drugs still on the market that pre-date the NDA/ANDA structure. These claims would need to be rejected under this definition because the RFP requires that all claims be included in the guarantees but they cannot fit within the definition of either Brand or Generic.*

- *Some drugs, including some common ones such as atorvastatin (Lipitor) have both an "authorized generic" (AG) and one or more unauthorized Generics, commonly called "true generics" (TG). An AG is licensed by the Brand manufacturer and marketed*

under the original NDA. These are typically priced like other Generic drugs after additional manufacturers launch generic products. TGs are marketed under an ANDA. The definitions as amended would require that the member be charged a brand copay for AG atorvastatin and a generic copay for TG atorvastatin, even though the member and/or pharmacy may have no idea of the difference. They would also need to be accounted for under separate pricing guarantees even though are both are priced like generics.

The definitions of Brand and Generic generally have two main purposes: First to determine the member copay; second to allow for consistent evaluation and reconciliation of pricing guarantees. Our claims system adjudicates claims based on a well-defined process that minimizes member disruption and provides uniform, consistent copays for members, plans, and providers. Every PBM must necessarily apply some formula or ad hoc adjustment to address this problem because there is no single industry-standard method for determining brand or generic status. If the State is primarily concerned with pricing, we suggest that the RFP allow PBMs to use their standard processes for adjudicating Brand and Generics, but that AWP discount guarantees be based on a reconciliation of claims to the Medi-Span MNOY indicator. MNOY is not suitable for adjudicating claims, but is an independently set indicator that will allow for an equal pricing evaluation for all bidders and a consistent method for reconciling discount guarantees. If the State does not accept reconciling AWP discounts using MNOY, we request that the State allow a detailed discussion with bidders during the RFP process about how they will address classification of Brand and Generic drugs.

RESPONSE: The Department has revised the definitions of Brand Drug and Generic Drug. Please see Amendment 7, Items 2 and 3.

86. Amendment 4, Item 4, amends the definition of Specialty Drug, RFP Section 1.2.76, to require that Specialty Drugs be at least $1,000 per claim. There are several concerns with this requirement:

- *Many Specialty generics, are under $1,000 per claim. We expect the number of generic Specialty Drugs to increase significantly during the term of the contract. The revised Financial Proposal forms require a guaranteed discount for Specialty Generics, and this guarantee would be largely nullified by the $1,000 minimum.*

- *We expect the price of more branded Specialty Drugs to be under $1,000 per claim as more competition among Specialty brand products increases. For example, PSCK-9 Inhibitors are already under $1,000 per script because there are competing brands. This minimum may cause us to be unable to dispense lower cost Specialty brands from our Specialty Pharmacy, which would inconvenience members and could result in lower quality care.*

- *The strict minimum price could cause some claims for a single specific drug to be counted as non-Specialty, while other claims for the same drug are Specialty. For example, the cost could vary by the days' supply needed, or could vary by the strength/dose of the drug in the script.*

While we understand that the State is concerned about how different bidders' may define Specialty Drugs differently and have different Specialty Drug lists, this minimum price requirement adds significant, and to some extent hard to foresee, complexity into complying with the contract. We request that the State remove the minimum cost requirement from this

definition or allow a detailed discussion with bidders about how to define Specialty Drugs to develop ways to meet all parties' concerns.

RESPONSE: The Department has revised the definition of Specialty Drug. See Amendment 7, Item 9.

87. In Amendment 4, Items 6 and 7, the State corrected the Member/Participant Count and changed the Financial Proposal worksheets, including the items noted here:

Amendment 4, FA 1, Attachment F, F-1 Instructions says:

3. Attachment F - 4 and F - 5: Financial Proposal

Your offer and all pricing during the term of the contract must comply with all of the following instructions:

1. *Administrative fees, rebates, and discounts shown on Attachment F-4 are specific to the State of Maryland for less than 150,000 participants including those in the State's Purchasing Pool. Administrative fees, rebates, and discounts shown on Attachment F-5 are specific to the State of Maryland when the State's Purchasing Pool reaches 150,000 participants.*
2. *The offeror is to provide pricing for both F-4 and F-5 dependent upon the total number of participants within the State's Purchasing Pool. When the States reaches 150,000 participants in the Purchasing Pool, improved terms represented in Attachment F-5 will become the new pricing arrangement.*

The F-1 instructions appear to indicate that the State's own membership is included in the Pool for the purpose of calculating which Financial Proposal is applicable. While Administrative Fees are calculated on the basis of 79,774 Employees, the applicable Financial Proposal is calculated on the basis of Participants, with 95% of the financial weighting on the <150,000 Participants pricing (Amendment 4, Item 7). According to the table in the RFP, the State alone has over 150,000 Participants currently in the Commercial program, so the <150,000 pricing would never be applicable unless there is a very large decrease in the State's employee population. Please indicate whether the Financial Proposals should be based on greater or less than 150,000 Employees (as opposed to Participants), or if the F-4 and F-5 should exclude the State's own members (which makes it very unlikely that the F-5 pricing would ever be implemented), or revise the amount of Participants applicable to each Financial Proposal.

RESPONSE: The Financial Proposal Tabs F4 and F5 are based on Members (i.e., households). Please see Amendment 7, Items 4, 5, 6, and 7 for clarification to the defined terms Member and Participants. See Amendment 7, Item 11, for the amended FA-1 and FA-2 Financial Forms.

88. Amendment #6 clarified that the Non-Disclosure Agreement (NDA) needs to be signed only by the Contractor and its subcontractors, not by individuals. However, it is not clear if we need to produce signed NDAs for all subcontractors with the proposal, or only upon contract award. The language at the top of Attachment J about "Contractor has been awarded" seems to indicate that this does not need to be done with the proposal submission, but bidders needed to sign the form to get claims data. Please confirm that forms do not need to be attached to the Proposals at submission.

RESPONSE: Signed NDAs or substantially similar agreements that are in no event less restrictive than the Department's NDA would need to be submitted by subcontractors upon Contract award, pursuant to RFP Section 5.6. Subcontractor-signed NDA forms, or substantially similar agreements, do not need to be submitted with Offeror Proposals.

89. Attachment J, the Non-Disclosure Agreement (NDA), indicates that subcontracts must have terms substantially similar to this Agreement, in no event less restrictive than as set forth in this Agreement. If our existing subcontractor agreements have terms that meet this requirement, Please confirm that we can produce a copy of the relevant portion of the existing subcontractor agreements instead of having each subcontractor execute Attachment J.

RESPONSE: In lieu of submitting Attachment J executed by subcontractors, the recommended awardee, upon notice of recommendation for Contract award, can produce executed subcontractor agreements that are substantially similar and in no event less restrictive than the Department's NDA, pursuant to Section 9 of the NDA.