REQUEST FOR PROPOSALS FOR

Specialty Pharmacy Drug Program

ISSUING OFFICE

Department of Public Welfare
Office of Administration
Bureau of Financial Operations
Division of Procurement
Room 402 Health and Welfare Building
625 Forster Street
Harrisburg, PA 17120

On behalf of

Office of Medical Assistance Programs

RFP NUMBER
10-13

DATE OF ISSUANCE

February 24, 2014
REQUEST FOR PROPOSALS FOR
Specialty Pharmacy Drug Program

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## CALENDAR OF EVENTS

The Commonwealth will make every effort to adhere to the following schedule:

<table>
<thead>
<tr>
<th>Activity</th>
<th>Responsibility</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deadline to submit Questions via email to <a href="mailto:RA-pwrfpquestions@pa.gov">RA-pwrfpquestions@pa.gov</a>.</td>
<td>Potential Offerors</td>
<td>March 14, 2014</td>
</tr>
<tr>
<td>Answers to Potential Offeror questions posted to the DGS website</td>
<td>Issuing Office</td>
<td>March 28, 2014</td>
</tr>
<tr>
<td>(<a href="http://www.dgsweb.state.pa.us/RTA/Search.aspx">http://www.dgsweb.state.pa.us/RTA/Search.aspx</a>) no later than this date.</td>
<td></td>
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</tr>
<tr>
<td>Please monitor website for all communications regarding the RFP.</td>
<td>Potential Offerors</td>
<td>Ongoing</td>
</tr>
<tr>
<td>Sealed proposal must be received by the Issuing Office at Department of</td>
<td>Offerors</td>
<td>April 4, 2014 2:00 p.m.</td>
</tr>
<tr>
<td>Public Welfare Division of Procurement Room 402 Health and Welfare Building 625 Forster Street Harrisburg, Pennsylvania 17120</td>
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PART I

GENERAL INFORMATION

I-1. Purpose. This request for proposals (RFP) provides to those interested in submitting proposals for the subject procurement (“Offerors”) sufficient information to enable them to prepare and submit proposals for the Department of Public Welfare’s (DPW or Department) consideration on behalf of the Commonwealth of Pennsylvania (“Commonwealth”) to satisfy a need for Specialty Pharmacy Drug Program provider services (“Project”).

I-2. Issuing Office. The Department of Public Welfare, Office of Administration (“Issuing Office”) has issued this RFP on behalf of DPW’s Office of Medical Assistance Programs (“OMAP”). The sole point of contact in the Commonwealth for this RFP shall be Michelle Herring RA-pwrfpquestions@pa.gov, the Project Officer for this RFP. Please refer all inquiries to the Project Officer.

I-3. Scope. This RFP contains instructions governing the requested proposals, including the requirements for the information and material to be included; a description of the service to be provided; requirements which Offerors must meet to be eligible for consideration; general evaluation criteria; and other requirements specific to this RFP.

I-4. Problem Statement Through this Request for Proposals (RFP), the Department seeks to select two Offerors to serve as the Department’s preferred providers of specialty pharmacy services for Medical Assistance (MA) recipients in the Fee-for-Service delivery system statewide. Additional detail is provided in Part IV of this RFP.

I-5. Type of Agreement. It is proposed that if the Department enters into provider agreements as a result of this RFP, they will be a fee-for-service agreements containing the Standard Contract Terms and Conditions as shown in Appendix A and the DPW Addendum to Standard Contract Terms and Conditions as shown in Appendix B, including all riders and the Business Associates Addendum in Appendix L. The Department, in its sole discretion, may undertake negotiations with Offerors whose proposals, in the judgment of the Department, show them to be qualified, responsible and capable of performing the Project.

I-6. Rejection of Proposals. The Department may, in its sole and complete discretion, reject any proposal received as a result of this RFP.

I-7. Incurring Costs. The Department is not liable for any costs the Offerors incur in preparation and submission of its proposal, in participating in the RFP process or in anticipation of award of agreements.

I-8. Pre-proposal Conference. There will be no pre-proposal conference for this RFP. If there are any questions, please forward them to the Project Officer in accordance with Section I-9.

I-9. Questions & Answers. If an Offeror has any questions regarding this RFP, the Offeror must submit the questions by email (with the subject line “RFP 10-13 Question”) to the
Project Officer named in Part I, Section I-2 of the RFP. If the Offeror has questions, they must be submitted via email no later than the date indicated on the Calendar of Events. The Offeror shall not attempt to contact the Project Officer by any other means. The Department shall post the answers to the questions on the DGS website by the date stated on the Calendar of Events. An Offeror who submits a question after the deadline date for receipt of questions indicated on the Calendar of Events assumes the risk that its proposal will not be responsive or competitive because the Commonwealth is not able to respond before the proposal receipt date or in sufficient time for the Offeror to prepare a responsive or competitive proposal. When submitted after the deadline date for receipt of questions indicated on the Calendar of Events, the Project Officer may respond to questions of an administrative nature by directing the questioning Offeror to specific provisions in the RFP. To the extent that the Department decides to respond to a non-administrative question after the deadline date for receipt of questions indicated on the Calendar of Events, the answer must be provided to all Offerors through an addendum.

All questions and responses as posted on the DGS website are considered as an addendum to, and part of, this RFP in accordance with RFP Part I, Section I-10. Each Offeror shall be responsible to monitor the DGS website for new or revised RFP information. The Department shall not be bound by any verbal information nor shall it be bound by any written information that is not either contained within the RFP or formally issued as an addendum by the Department. The Department does not consider questions to be a protest of the specifications or of the solicitation.

I-10. Addenda to the RFP. If the Department deems it necessary to revise any part of this RFP before the proposal response date, the Department will post an addendum to the DGS website at http://www.dgsweb.state.pa.us/RTA/Search.aspx. It is the Offeror’s responsibility to periodically check the website for any new information or addenda to the RFP. Answers to the questions asked during the Questions & Answers period also will be posted to the website as an addendum to the RFP.

I-11. Response Date. To be considered for selection, hard copies of proposals must arrive at the Issuing Office on or before the time and date specified in the RFP Calendar of Events. The Department will not accept proposals via email or facsimile transmission. Offerors who send proposals by mail or other delivery service should allow sufficient delivery time to ensure timely receipt of their proposals. If, due to inclement weather, natural disaster, or any other cause, the Commonwealth office location to which proposals are to be returned is closed on the proposal response date, the deadline for submission will be automatically extended until the next Commonwealth business day on which the office is open, unless the Issuing Office otherwise notifies Offerors. The hour for submission of proposals shall remain the same. The Department will reject, unopened, any late proposals.

I-12. Proposals. To be considered, Offerors should submit a complete response to this RFP to the Issuing Office, using the format provided in Part II, providing one (1) original and five (5) paper copies of the Technical Submittal; and one (1) original and one (1) paper copy of the Cost Submittal. In addition to the paper copies of the proposal, Offerors shall submit two (2) complete and exact copies of the entire proposal (Technical and Cost submittals, along with all requested documents) on CD-ROM or Flash drive in Microsoft Office or Microsoft Office-compatible format. Additionally, on the two CD-ROM or Flash drives, include separate folders
which contain a complete and exact copy of the entire technical (excluding financial capability) submittal in PDF (portable document format). To the extent that an Offeror designates information as confidential or proprietary or trade secret protected in accordance with Part I, Section I-17, the Offeror must also include one (1) redacted version of the Technical Submittal, excluding Financial Capability on CD-ROM or Flash Drive, in Microsoft Office or Microsoft Office-compatible format. Except as provided in this section, the electronic copy must be a mirror image of the paper copy and any spreadsheets must be in Microsoft Excel. The Offerors may not lock or protect any cells or tabs. The CD or Flash drive should clearly identify the Offeror and include the name and version number of the virus scanning software that was used to scan the CD or Flash drive before it was submitted. Offerors should ensure that there is no costing information in the technical submittal. Offerors should not reiterate technical information in the cost submittal.

Each Offeror submitting a proposal specifically waives any right to withdraw or modify it, except that the Offeror may withdraw its proposal by written notice received at the Issuing Office’s address for proposal delivery prior to the exact hour and date specified for proposal receipt. An Offeror or its authorized representative may withdraw its proposal in person prior to the exact hour and date set for proposal receipt, provided the withdrawing person provides appropriate identification and signs a receipt for the proposal. An Offeror may modify its submitted proposal prior to the exact hour and date set for proposal receipt only by submitting a new sealed proposal or sealed modification which complies with the RFP requirements.

I-13. Economy of Preparation. Offerors should prepare proposals simply and economically, providing a straightforward, concise description of the Offeror’s ability to meet the requirements of the RFP.

I-14. Alternate Proposals. The Department has identified the basic approach to meeting its requirements, allowing Offerors to be creative and propose their best solution to meeting these requirements. The Department will not accept alternate proposals.

I-15. Discussions for Clarification. Offerors may be required to make an oral or written clarification of their proposals to the Department to ensure thorough mutual understanding and Offeror responsiveness to the solicitation requirements. The Project Officer will initiate requests for clarification. Clarifications may occur at any stage of the evaluation and selection process prior to agreement execution.

I-16. Prime Contractor Responsibilities. The agreements will require the selected Offerors to assume responsibility for all services offered in its proposal whether it produces them itself or
by subcontract. The Department will consider the selected Offerors to be the sole point of contact with regard to contractual matters.

I-17. Proposal Contents.

A. Confidential Information. The Commonwealth is not requesting, and does not require, confidential proprietary information or trade secrets to be included as part of Offerors’ submissions in order to evaluate proposals submitted in response to this RFP. Accordingly, except as provided herein, Offerors should not label proposal submissions as confidential or proprietary or trade secret protected. Any Offeror who determines that it must divulge such information as part of its proposal must submit the signed written statement described in subsection c. below and must additionally provide a redacted version of its proposal in accordance with Part I, Section I-13, which removes only the confidential proprietary information and trade secrets, for required public disclosure purposes.

B. Commonwealth Use. All material submitted with the proposal shall be considered the property of the Commonwealth of Pennsylvania and may be returned only at the Department’s option. The Commonwealth has the right to use any or all ideas not protected by intellectual property rights that are presented in any proposal regardless of whether the proposal becomes part of an agreement. Notwithstanding any Offeror copyright designations contained on proposals, the Commonwealth shall have the right to make copies and distribute proposals internally and to comply with public record or other disclosure requirements under the provisions of any Commonwealth or United States statute or regulation, or rule or order of any court of competent jurisdiction.

C. Public Disclosure. After the award of a contract pursuant to this RFP, all proposal submissions are subject to disclosure in response to a request for public records made under the Pennsylvania Right-to-Know-Law, 65 P.S. § 67.101, et seq. If a proposal submission contains confidential proprietary information or trade secrets, a signed written statement to this effect must be provided with the submission in accordance with 65 P.S. § 67.707(b) for the information to be considered exempt under 65 P.S. § 67.708(b)(11) from public records requests. If financial capability information is submitted in response to Part II of this RFP such financial capability information is exempt from public records disclosure under 65 P.S. § 67.708(b)(26).


A. While not required, the Department may conduct discussions with Offerors for the purpose of obtaining “best and final offers.” To obtain best and final offers from Offerors, the Department may do one or more of the following, in any combination and order:

1. Schedule oral presentations;

2. Request revised proposals; and,
3. Enter into pre-selection negotiations.

B. The following Offerors will not be invited by the Department to submit a Best and Final Offer:

1. Those Offerors, which the Department has determined to be not responsible or whose proposals the Department has determined to be not responsive.

2. Those Offerors, which the Department has determined in accordance with Part III, Section III-5, from the submitted and gathered financial and other information, do not possess the financial capability, experience or qualifications to assure good faith performance of the agreements.

3. Those Offerors whose score for their technical submittal of the proposal is less than 70% of the total amount of technical points allotted to the technical criterion.

The Department may further limit participation in the best and final offers process to those remaining responsible Offerors which the Department has, within its discretion, determined to be within the top competitive range of responsive proposals.

C. The Evaluation Criteria found in Part III, Section III-4, shall also be used to evaluate the Best and Final offers.

I-19. News Releases. Offerors shall not issue news releases, Internet postings, advertisements or any other public communications pertaining to this Project without prior written approval of the Issuing Office, and then only in coordination with the Department.

I-20. Restriction of Contact. From the issue date of this RFP until the Department selects proposals for award, the Project Officer is the sole point of contact concerning this RFP. Any violation of this condition may be cause for the Department to reject the offending Offeror’s proposal. If the Department later discovers that the Offeror has engaged in any violations of this condition, the Department may reject the offending Offeror’s proposal or rescind its agreement award. Offerors must agree not to distribute any part of their proposals beyond the Issuing Office. An Offeror who shares information contained in its proposal with other Commonwealth personnel and/or competing Offeror personnel may be disqualified.

I-21. Department Participation. Offerors shall provide all services, supplies, facilities, and other support necessary to complete the identified work, except as otherwise provided in this Part I, Section I-21. The Department’s primary participation will include the following:

- Managing the Specialty Pharmacy Drug Program
- Controlling utilization of specialty medications through the Preferred Drug List (PDL) and Prior Authorization
- Reviewing requests for Benefit Limit Exceptions (automated approvals and manual reviews)
- Facilitating the selected Offerors’ communications with other contractors, providers and Commonwealth offices
- Monitoring the performance of the selected Offerors.

I-22. Term of Agreement. The term of the agreements will commence on the Effective Date and will end two (2) years from the Effective Date. Subject to the performance of the selected Offerors and other considerations, the Department may renew the agreement for three (3) additional one-year periods. The Issuing Office will fix the Effective Date after the agreements have been fully executed by the selected Offerors and by the Commonwealth and all approvals required by Commonwealth contracting procedures have been obtained. The selected Offerors shall not start the performance of any work prior to the Effective Date and the Commonwealth shall not be liable to pay the selected Offerors for any service or work performed or expenses incurred before the Effective Date.

I-23. Offeror’s Representations and Authorizations. By submitting its proposal, each Offeror understands, represents, and acknowledges that:

A. All of the Offeror’s information and representations in the proposal are material and important, and the Department may rely upon the contents of the proposal in awarding the agreements.

B. The Offeror has arrived at the price(s) and amounts in its proposal independently and without consultation, communication, or agreement with any other Offeror or potential Offeror.

C. The Offeror has not disclosed the price(s), the amount of the proposal, nor the approximate price(s) or amount(s) of its proposal to any other firm or person who is an Offeror or potential Offeror for this RFP, and the Offeror shall not disclose any of these items on or before the proposal submission deadline specified in the Calendar of Events of this RFP.

D. The Offeror has not attempted, nor will it attempt, to induce any firm or person to refrain from submitting a proposal on this agreement, or to submit a proposal higher than its proposal, or to submit any intentionally high or noncompetitive proposal or other form of complementary proposal.

E. The Offeror makes its proposal in good faith and not pursuant to any agreement or discussion with, or inducement from, any firm or person to submit a complementary or other noncompetitive proposal.

F. To the best knowledge of the person signing the proposal for the Offeror, the Offeror, its affiliates, subsidiaries, officers, directors, and employees are not currently under investigation by any governmental agency and have not in the last four (4) years been convicted or found liable for any act prohibited by State or Federal law in any jurisdiction, involving conspiracy or collusion with respect to bidding or proposing on any public agreement, except as the Offeror has disclosed in its proposal.

G. To the best of the knowledge of the person signing the proposal for the Offeror and except as the Offeror has otherwise disclosed in its proposal, the Offeror has no
outstanding, delinquent obligations to the Commonwealth including, but not limited to, any state tax liability not being contested on appeal or other obligation of the Offeror that is owed to the Commonwealth.

H. The Offeror is not currently under suspension or debarment or has not been precluded from participation in a health care program by the Commonwealth, any other state or the federal government, and if the Offeror cannot so certify, then it shall submit along with its proposal a written explanation of why it cannot make such certification.

I. The Offeror has not made, under separate agreement with the Department, any recommendations to the Department concerning the need for the services described in its proposal or the specifications for the services described in the proposal.

J. Each Offeror, by submitting its proposal, authorizes Commonwealth agencies to release to the Commonwealth information concerning the Offeror’s Pennsylvania taxes, unemployment compensation and workers’ compensation liabilities.

K. Until the selected Offerors receive fully executed and approved written agreements from the Issuing Office, there is no legal and valid agreement, in law or in equity, and the Offerors shall not begin to perform.


A. Agreement Negotiations. The Department will notify all Offerors in writing of the Offerors selected for agreement negotiations after the Department has determined, taking into consideration all of the evaluation factors, the proposals that are the most advantageous to the Department.

B. Award. Offerors whose proposals are not selected will be notified when agreement negotiations have been successfully completed and the Department has received the final negotiated agreements signed by the selected Offerors.

C. Debriefing Conferences. Offerors whose proposals are not selected will be notified of the names of the selected Offerors and given the opportunity to be debriefed. The debriefing will not compare the Offeror with other Offerors, other than the position of the Offeror’s proposal in relation to all other Offerors’ proposals. An Offeror’s exercise of the opportunity to be debriefed does not constitute the filing of a protest.

I-25. Use of Electronic Versions of this RFP. This RFP is being made available by electronic means. If an Offeror electronically accepts the RFP, the Offeror acknowledges and accepts full responsibility to insure that no changes are made to the RFP. In the event of a conflict between a version of the RFP in the Offeror’s possession and the Issuing Office’s version of the RFP, the Issuing Office’s version shall govern.
PART II

PROPOSAL REQUIREMENTS

Offerors must submit their proposals in the format, including heading descriptions, outlined below. To be considered, the proposal must respond to all requirements in this RFP. Offerors should provide any other information thought to be relevant, but not applicable to the enumerated categories, as an appendix to the Proposal. All cost data relating to this proposal should be kept separate from and not included in the Technical Submittal. Each Proposal shall consist of the following two separately sealed submittals:

A. Technical Submittal, which shall be a response to RFP Part II, Sections II-1 through II-9. Offerors must format their technical responses using the following guide:

- Tab 1: Table of Contents
- Tab 2: Statement of the Problem
- Tab 3: Management Summary
- Tab 4: Work Plan/Work Statement Questionnaire
- Tab 5: Prior Experience
- Tab 6: Personnel
- Tab 7: Training
- Tab 8: Financial Capability
- Tab 9: Objections to Standard Terms and Conditions
- Tab 10: Corporate Reference Questionnaire (Appendix E)
- Tab 11: Personnel Reference Questionnaire (Appendix F)
- Tab 12: Trade Secret/Confidential Proprietary Notice (Appendix J)
- Tab 13: Lobbying Certification and Disclosure Forms (Appendix K)
- Tab 14: Business Associate Addendum (Appendix L)
- Tab 15: Domestic Workforce Utilization Certification (Appendix M)

B. Cost Submittal, in response to RFP Part II, Section II-10.

C. Proposals must follow the following format:

1. Pages must be 8.5 by 11 inches with right and left margins of one (1) inch; and be double-sided.
2. Must use Arial or Times New Roman font with a size of twelve (12).
3. Tab and Section headings, show in Part II-A, General Proposal Requirements, MUST be used.
4. Each page of the proposal must include a page number and identification of the Offeror in the page footer.
5. Materials provided in any Appendix must be specifically referenced by page number(s) in the body of the proposal.
6. Exceptions for paper and font size are permissible for project schedule (Microsoft Project) or for graphical exhibits and material in appendices which may be printed on white paper with dimensions of 11 by 17 inches.
The Department may request additional information which, in the Department’s opinion, is necessary to assure that the Offeror’s competence, number of qualified employees, business organization, and financial resources are adequate to perform according to the RFP.

The Department may make investigations as deemed necessary to determine the ability of the Offeror to perform the Project, and the Offeror shall furnish to the Issuing Office all requested information and data. The Department may reject any proposal if the evidence submitted by, or investigation of, such Offeror fails to satisfy the Department that such Offeror is properly qualified to carry out the obligations of the RFP and to complete the Project as specified.

II-1. Statement of the Problem. (Limit: Two pages) State in succinct terms the following: (1) the Offeror’s understanding of the services and related requirements of this RFP; (2) the Offeror’s qualifications for the work required in this RFP; and (3) the Offeror’s overall approach to this project. The statement of the problem should discuss specific issues and risks associated with the project and should include proposed solutions for each. The Offeror’s response should demonstrate that the Offeror fully understands the scope of work, the Offeror’s responsibilities, and how the Offeror will determine the effective management of the project.

II-2. Management Summary. (Limit two pages) Include a narrative description of the proposed effort and a list of the items to be delivered or services to be provided. The summary will condense and highlight the contents of the Technical proposal in a manner that allows a broad understanding of the entire Technical submittal. If the Offeror is proposing to subcontract any work included within the project, the Offeror should identify the subcontractor and describe the scope of work to be subcontracted.

II-3. Emergency Preparedness. (Limit two pages) Include a narrative description of the Offeror’s plan to maintain operations during an emergency. State in succinct terms the following: (1) how the Offeror anticipates a crisis will impact operations; and (2) the Offeror’s plan to respond to an emergency and ensure continuity of operations. Use the description in Part IV-3.A. of this RFP as your reference point.

II-4. Work Plan. Describe in narrative form your technical plan for accomplishing the work. Structure your response consistent with the Work Statement Questionnaire and use the task descriptions in Part IV of this RFP as your reference point. Modifications of the task descriptions are permitted; however, reasons for changes should be fully explained. Indicate the number of person hours allocated to each task. If more than one approach is apparent, comment on why you chose this approach.

Work Statement Questionnaire

1. Maintain an Inventory of Specialty Pharmacy Drug and Ancillary Medical Supplies and Equipment. (Part IV, Section IV-4, Task 1) (Limit: Twenty pages excluding the list required in 1.a)
   a. Provide a list of the contracted manufacturers, wholesalers and distributors of specialty pharmacy drugs with whom the Offeror has a contractual relationship.
Include the following items, as listed in Section IV-4, Task 1.a (Manufacturer, Wholesaler, and Distributor Relationships):

i. Name of manufacturer, wholesaler, or distributor

ii. Product

iii. Length of relationship and remaining term of agreement

iv. Scope of agreement (general description of products and services)

v. Limitations and exclusions

b. Service expectations and standards (turnaround time) Describe the Offeror’s approach to the assay management program, including the program goals, allowed percent variances, the process for assay management, and length of experience with assay management. Describe the steps the Offeror will take in the event that it does not have a factor product in the inventory that matches the prescribed product.

c. Describe how the Offeror guarantees the pedigree of the clotting factor to avoid any type of product mishandling or tampering.

d. Describe how the Offeror plans to select vendors for drugs, medical supplies and equipment to be provided to MA recipients, including product quality assessment.

e. Include a list of ancillary medical supplies and equipment the Offeror will provide for the administration of specialty drugs and home infusion therapy, including supplies for the treatment of prevention of bleeding episodes.

f. Identify all specialty pharmacy drugs included in Appendix D, Specialty Pharmacy Drug Program, for which:

i. Access to a supply of drugs is subject to exclusive distribution rights of which the Offeror is not part of the network. For these drugs, explain how the Offeror will access a supply when prescribed for an MA recipient.

ii. A local entity, such as a pharmacy, will supply drugs and under which circumstances.

iii. A manufacturer, wholesaler, or distributor will provide specialty pharmacy drugs to MA recipients in times of short supply.

g. Describe the Offeror’s policy for product recalls.

h. Provide the Offeror’s total purchasing volume and stratified annual purchasing volume.
i. Identify the Offeror’s stock out rates for the drugs identified in Appendix D, Specialty Pharmacy Drug Program, and describe its policies and procedures for providing drugs that are out of stock.

j. Describe the Offeror’s policies to manage product returns and products deemed “undeliverable.”

k. Describe the Offeror’s policies and procedures for the procurement and storage of all products with a short shelf life and those requiring special handling.

2. Operate a Specialty Pharmacy Dispensing and Delivery System. (Part IV, Section IV-4, Task 2) (Limit: Twenty pages)

a. Describe how the Offeror will operate an efficient, accurate and responsive ordering and refill process in compliance with the Task 2 requirements, including detail about:

   i. Operating a call center for providers and MA recipients, including hours of operation. The submittal should specifically address accommodations for MA recipients who have Limited English Proficiency or who are hearing impaired.

   ii. Capability to receive prescriptions and requests for refills. Describe all formats the Offeror will use.

b. Identify each location of and how the Offeror will ensure adequate staffing for its pharmacies, central distribution centers, any additional distribution sites and call centers and the adequacy of staffing patterns at these locations.

c. Describe how the Offeror will process prescriptions, dispense specialty pharmacy drugs and submit claims, including detail about how the Offeror will:

   i. Conform to accepted standards of practice and quality of service and MA Program regulations, policies and procedures.

   ii. Provide prescribed medications, or in the case of inadequate supply, policies and procedures to change the order.

   iii. Validate prior authorization of prescriptions by the Department, as necessary.

   iv. Submit accurate claims using the PROMISe™ on-line claims adjudication system, and coordinate benefits with other coverage of MA recipients.

   v. Coordinate benefits when the MA recipient has other private or public coverage.

   vi. Assure that “clean” prescriptions are turned around within two (2) business days.
d. Describe the Offeror’s dispensing policies and procedures related to in-home inventory of factor product for bleeding disorder therapy; refills; emergency prescriptions and emergency refills; replacement costs of damaged prescription drugs and medical supplies and equipment; dispensing of drugs with short expiration dates; waste management; educational interventions with prescribers; and “dosing.”

e. Describe how the Offeror will operate an efficient, accurate and responsive distribution and delivery system. Include descriptions for the following:

   i. Reflections of “best practices” and precisely how the Offeror will ensure that MA recipients receive their specialty pharmacy drug(s) when and where needed.

   ii. Steps in distribution and delivery to the site of administration. Include an explanation of how the Offeror will inform dispensing providers and MA recipients regarding the expected timeframes for receipt of delivered items; standard shipping methods and practices used by the Offeror; the name of delivery vendor(s) and delivery services provided by each vendor; provisions for timely delivery, proper handling and security of drug delivered.

   iii. Average turn-around time for a prescription.

   iv. Distribution system back-up system and disaster recovery strategy and process.

   v. Training related to distribution, delivery, handling and storage of specialty pharmacy drugs offered by the Offeror to prescribers, hospital discharge planners, providers administering a specialty pharmacy drug, office staff and MA recipients and their families.

   vi. Distribution of all products with a short shelf life and those requiring special handling.

3. **Provide a Clinical Support System. (Part IV, Section IV-4, Task 3) (Limit: Fifteen pages)**

   a. Provide an overview of the Offeror’s clinical support system with examples of how the model reflects “best practices” in managing care.

   b. Provide a detailed description of the Offeror’s therapy management programs, including documentation on the following program components:

      i. Individualized education, guidance, counseling and ongoing communication with both MA recipients and providers to support therapy management.

      ii. Optimal compliance with and adherence to drug regimens including the Offeror’s definition of compliance and how it relates to therapy management.

      iii. Care collaboration and coordination.
a) Improved therapeutic outcomes and how they are monitored and measured.

b) For individuals with hemophilia: maximized bleed prevention, maximized treatment reduction, maximized avoidance of emergency room use, management of patient compliance and care coordination with Hemophilia Treatment Centers and other providers of blood factor products.

c) For residents of long term care facilities, proposed methods to improve care coordination and care management.

c. Describe how the Offeror will operate a clinical call center for MA recipients, including descriptions of call center staffing, hours of operations, call center tracking and reporting, and policies and procedures for accommodating MA recipients with Limited English Proficiency or hearing impairments.

d. Describe how the Offeror plans to coordinate in-home nursing services with a home health agency enrolled in the MA Program when needed.

e. Describe how the Offeror plans to review interventions and the amount of clotting factor used, compare the results with goals for the individual patient’s care, assess if the response to therapy is adequate, and alert treating physicians to changes in the patient’s bleeding pattern, clotting factor usage, or life style issues that may require changes to the treatment regimen.

4. Respond to General Inquiries and Complaints. (Part IV, Section IV-4, Task 4) (Limit: Three pages)

a. Describe the Offeror’s process for responding to providers’ and recipients’ general inquiries and complaints. Include specific processes for responding to general inquiries and complaints through a call center and those received through written communications (See Task 2.a). Describe other communication methods the Offeror will use for inquiries and complaints, if any.

b. Describe the Offeror’s proposed process for tracking and reporting all general inquiries and complaints received, as well as their outcomes, to the Department.

c. Describe how the Offeror will assist the Department to address inquiries and complaints about the Specialty Pharmacy Program.

5. Policies and Procedures. (Part IV, Section IV-4, Task 6) (Limit: Three pages and three examples of policies and procedures)

a. Provide the Offeror’s proposed policies and procedures for:

   i. Quality control and quality assurance
ii. Communications with prescribers and MA recipients

iii. Admitting new MA recipients into the program and assessing their needs as they relate to the therapy management program

b. Describe how the Offeror will ensure that its staff understands and implements policies and procedures on a day-to-day, ongoing basis.

c. Describe how the Offeror will update any of the policy and procedures as approved by the Department to be current with new technologies, including how quickly it will implement updated guidelines after the Department approves them.

6. Communication and Education. (Part IV, Section IV-4, Task 7) (Limit: Five pages and three examples)

a. Describe how the Offeror plans to develop and produce materials for providers and MA recipients, including how the Offeror will work with the Department to publish communication materials and to comply with Department requirements for materials.

b. Provide no more than three (3) examples of education and information material developed by the Offeror for MA recipients and providers, or similar populations if necessary, that address either training or informational materials about Specialty Pharmacy Drug Programs, therapy management programs or in-home nursing or information and instructions on submitting prescriptions and requesting refills.

c. Describe the Offeror’s plan to identify and provide appropriate educational interventions for “outlier” prescribers.

d. Describe how the Offeror will provide a link to its website to be posted on the Department’s Specialty Pharmacy Drug Program website to ensure MA recipients’ easy access to the selected Offeror’s program information.

e. Provide an assurance that the Offeror will agree to provide educational information about specialty pharmacy drugs, when requested by the Department.

7. Coordination with the Department and Other Contractors and Providers. (Part IV, Section IV-4, Task 8) (Limit: Five pages)

a. Describe how the Offeror will coordinate and collaborate with the Department and other contractors and providers to achieve Department goals and objectives and care coordination for MA recipients for the Specialty Pharmacy Program.

8. Plan for Transition to the Preferred Provider and Continuity of Care. (Part IV, Section IV-3, Task 9) (Limit: Four pages)

a. Submit the Offeror’s proposed plan to transition individuals who are currently in the Specialty Pharmacy Drug Program, and individuals who are currently receiving their
specialty drugs from a non-preferred provider to the Specialty Pharmacy Drug Program that will ensure uninterrupted continuity of care and a seamless transition to the selected preferred provider.

b. Describe the Offeror’s proposed plan to transition newly eligibles MA recipients from the Specialty Pharmacy Drug Program to the MA recipient’s chosen HealthChoices managed care organization to ensure uninterrupted continuity of care and a seamless transition.

9. Perform Quality Assurance Monitoring. (Part IV, Section IV-4, Task 10) (Limit: Four pages)

Describe how the Offeror will monitor the quality of all components of the Specialty Pharmacy Drug Program operations. Include a description of outcomes measures the Offeror recommends using to measure overall program effectiveness and specifically how it will monitor the dispensing and delivery system of the Specialty Pharmacy Drug Program, the responsiveness of the provider/member call center, the accessibility of specialty pharmacy drug providers to MA recipients, evaluate the therapy management program, and comply with Department requirements for claims submissions. Describe the process the selected Offeror will use to make recommendations to the Department for potential improvement to the Specialty Pharmacy Drug Program, as necessary.

10. Perform Environmental Scanning. (Part IV, Section IV-4, Task 11) (Limit: Four pages)

a. Describe how the Offeror will identify and report on trends and practices in specialty pharmacy and home infusion therapy.

b. Describe how the Offeror will use information from its environmental scanning, operational and clinical experience, and reports and data it generates to recommend to the Department the following:

i. New specialty pharmacy drugs to be added to the scope of products covered under the Specialty Pharmacy Drug Program.

ii. Requirements for utilization management such as prior authorization of existing or new specialty pharmacy drugs, including utilization review guidelines, quantity limits when applicable, and predicted savings.

iii. Requirements for the Department’s Prospective Drug Utilization Review (Pro DUR) program and Pro DUR alerts to the pharmacist as they relate to specialty pharmacy drugs.
11. **Information Technology (IT) and Management Information System (MIS).** (Part IV, Section IV-4, Task 12) (Limit: Three pages)

   a. Describe the Offeror’s telecommunications and information technology system capabilities that will enable it to fulfill all obligations required by this RFP and a final agreement. Address the Offeror’s ability to meet all minimum IT and MIS requirements outlined in **Part IV, Task 12** of this RFP.

   b. Explain whether the Offeror’s current MIS is ready to operate according to the requirements of this RFP. If the Offeror’s MIS requires modifications or updates, describe the necessary modifications and updates and the Offeror’s plan for completion.

   c. Describe the current capability of the Offeror’s MIS to provide required reports and any system modifications or updates to the Offeror’s MIS that will be necessary.

   d. Describe security measures in the Offeror’s MIS to prevent the unauthorized use of, or access to, data. Include, at minimum, information about how the proposed MIS will comply with Health Insurance Portability and Accountability Act (HIPAA) requirements and other Federal and State confidentiality requirements.

12. **Implementation Schedule.** (Part IV, Section IV-4, Task 13) (Limit: Four pages)

   Submit an operational implementation schedule for the Specialty Pharmacy Drug Program that includes the implementation milestones that the Offeror must accomplish to successfully implement the program on time.

13. **Reports and Project Control.** (Part IV, Section IV-5) (Limit: Six pages and three examples)

   a. Describe how the Offeror will meet the reporting requirements established in **Part IV, Section IV-5** (Reports and Project Control) for status reports, trigger reports, ad hoc reports, problem identification reports and reports to assist in the ongoing evaluation of the Specialty Pharmacy Drug Program.

   b. Describe additional reports the Offeror would recommend developing to monitor the success of the Specialty Pharmacy Drug Program. Provide examples of existing reports that the Offeror has developed for past clients.

14. **Monitoring, Performance Standards and Corrective Action Plans.** (Part IV, Section IV-6) (Limit: Five pages)

   a. Submit the Offeror’s plan for monitoring its own performance throughout the Agreement term and complying with the Department’s monitoring process and performance standards. Identify operational areas that the Offeror anticipates may require substantial oversight.
b. Describe how the Offeror will track and report pharmacy staffing levels, successful product recalls, medication delivery statistics, inquiry and complaint statistics, drug substitution practices, standards of practice and quality standards, claims submission statistics, accurate medication dispensing and turnaround time of “clean” prescriptions.

c. Describe how the Offeror will monitor any subcontractors and provide oversight of any work products or onsite participation.

II-5. Prior Experience

a. **Corporate Background.** The Offeror must describe the corporate history and relevant experience of the Offeror and any subcontractors. This section must detail information on the ownership of the company (names and percent of ownership), the date the company was established, the date the company began operations, the physical location of the company, and the current size of the company. The Offeror must provide a corporate organizational chart as part of this section.

Offerors must identify any current contracting or subcontracting relationship(s) that may result in a conflict of interest with the requirements of this RFP. Offerors must also abide by the Department’s conflict of interest standards identified in Appendix A, Standard Contract Terms and Conditions and Appendix B, Department of Public Welfare Addendum to Standard Terms and Conditions.

b. **Prior Corporate Experience.** The Offeror must describe experience providing specialty pharmacy services to government agencies, health plans, and insurers. Include experience in operating specialty pharmacy drug programs. Experience shown should be work done by individuals who will be assigned to this project as well as that of the company. Studies or projects referred to must be identified and the name of the customer shown, including the name, address, and telephone number of the responsible official of the customer, company, or agency who may be contacted.

At a minimum, this section of the proposal must include a description of the Offeror’s experience in:

i. Maintaining inventories of specialty pharmacy drugs and ancillary medical supplies and equipment.

ii. Operating a specialty pharmacy dispensing and delivery system, specifically detailing experiences with Medicaid programs, providers and recipients, if any.

iii. Operating provider and member call centers to make and receive requests for prescriptions and refills, and to respond to general inquiries and complaints.

iv. Operating a clinical support system, including therapy management programs and a clinical call center.

v. Assay management, including length of experience and cost savings.
vi. Assessing patient adherence and compliance.

vii. Operating patient assistance programs that include individualized education, guidance, support and ongoing communication.

viii. Educating providers and members on topics such as specialty pharmacy drugs, therapy management programs and in-home nursing services.

ix. Evaluating specialty drug programs and developing recommendations for new specialty pharmacy drugs, requirements for prior authorization, quantity limits and requirements for prospective and retrospective drug utilization review (DUR).

x. Providing government agencies, health plans or insurers with relevant statistics on specialty pharmacy program data.

xi. Using IT systems to exchange information with clients.

The Offeror must provide evidence of the Offeror’s and its subcontractor(s), as applicable, accreditation(s) from either the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) or URAC (formerly known as the Utilization Review Accreditation Commission), including the expiration date of the certification.

c. **Cost Savings.** The Offeror must describe how the Offeror has reduced expenditures for other customers by providing services similar to those described by this RFP. The Offeror should identify customers and provide the following:

   i. A description of how the Offeror reduced expenditures for specialty pharmaceuticals and therapy management programs, while maintaining access for individuals to medically necessary supplies and services, including the dollar amount and percentage of the expenditure reduction.

   ii. A description of the method by which the Offeror quantified the reductions in expenditures.

d. **References.** The Offeror must provide a list of at least three (3) relevant contracts (non-DPW) within the past three (3) years to serve as corporate references. This list shall include the following for each reference:

   i. Name of contractor

   ii. Type of contract

   iii. Contract description, including type of service provided

   iv. Total contract value
v. Contracting officer’s name and telephone number

vi. Role of subcontractor(s) (if any)

vii. Time period in which service was provided

The Offeror must submit Appendix E, Corporate Reference Questionnaire, directly to the contacts listed. The references should return completed questionnaires in sealed envelopes to the Offeror. The Offeror must include these sealed references with its Technical Submittal.

The Offeror must also submit letters of support from the hemophilia program directors at two (2) of the state-recognized hemophilia programs in Pennsylvania. These letters must include statements describing the level of service that the Offeror provides to members with bleeding disorder and how well the Offeror works with those programs to resolve problems that arise. If the Offeror has not serviced members with bleeding disorder within the Commonwealth of Pennsylvania, the Offeror may provide the two letters of support from two other Federally-funded hemophilia treatment centers in the United States where the Offeror has serviced members.

II-6. Personnel. The Offeror must provide a detailed staffing plan for the proposed project team. Indicate the responsibilities each project team member will have in this project. Provide an organizational chart of the proposed project team members who will be engaged in the work. Identify by name any subcontractors the Offeror intends to use, the services and tasks included in the scope of this RFP they will perform and provide copies of all proposed subcontracted arrangements (excluding any cost information) as an appendix to the Technical Submittal. Subcontracts must be submitted to and approved by the Department prior to the effective date of a selected Offeror’s Specialty Pharmacy Drug Program agreement.

For the key personnel positions specified in Part IV, Section IV-3.D. (Staffing Requirements for Key Personnel), the Offeror must provide the number and amount of time stated in terms of full-time equivalents, for such positions to be devoted to this project. For the Project Manager, Clinical Pharmacist and Clinical Call Center Manager, include the following information:

a. Employees’ and any subcontractors’ names and, through a resume or similar document, their education and experience in specialty pharmacy drug programs, and how these employees meet the qualifications specified in Part IV, Section IV-3.D. (Staffing Requirements for Key Personnel).

b. How long each individual has been with the Offeror's company or, if the individual is a subcontractor, the length of experience working with the subcontractor.

c. Where each key individual will be physically located during the time he or she is engaged in the work.
The Offeror must provide the name, address and telephone number of at least three (3) professional references (non-DPW) for the Project Manager designated by the Offeror.

The Offeror must submit Appendix F, Key Personnel Professional Reference Questionnaire, directly to the references listed and include the completed Key Personnel Professional Reference Questionnaire with its Technical Submittal. The Department may contact references other than those identified by the Offeror.

For the Pharmacy Staff and Clinical Call Center Staff, the Offeror must provide job descriptions, including minimum education and training requirements of staff the Offeror will use to operate the Specialty Pharmacy Program.

The Offeror must disclose any ownership interests that its project team members who will be engaged in the project have in specialty pharmaceutical companies or companies that may present a conflict of interest with the requirements of this RFP.

**Key Staff Diversions or Replacement.** Once key staff is approved by DPW, a selected Offeror may not divert or replace key personnel without approval of the DPW Contract Administrator except as provided in the following procedures. The selected Offeror must provide notice of a proposed diversion or replacement to the DPW Contract Administrator at least thirty (30) days in advance and provide the name, qualifications, and background check of the person who will replace the diverted or removed staff. The DPW Contract Administrator will notify the Offeror within ten (10) days of the diversion notice whether the proposed diversion is acceptable and if the replacement is approved.

Divert or diversion is defined as the transfer of personnel by a selected Offeror or its subcontractor to another assignment within the control of either the Offeror or subcontractor. Advance notification and approval does not include changes in key personnel due to resignations, death and disability, dismissal for cause or dismissal as a result of the termination of a subcontract or any other causes that is beyond the control of a Selected Offeror or its subcontractor. DPW must approve the replacement staff.

The DPW Contract Administrator may request that a Selected Offeror remove its person from this project at any time. In the event that person is removed from the project, the Selected Offeror will have ten (10) days to fill the vacancy with a person acceptable in terms of experience and skills, subject to the DPW Contract Administrator’s approval.

**II-7. Financial Capability.** Describe your company’s financial stability and economic capability to perform the agreement requirements. Provide your company’s financial statements (audited, if available) for the past three fiscal years. Financial statements must include the company’s Balance Sheet and Income Statement or Profit/Loss Statements. Also include a Dun & Bradstreet comprehensive report, if available. If your company is a publicly traded company, please provide a link to your financial records on your company website in lieu of providing hardcopies. The Commonwealth may request additional information it deems necessary to evaluate an Offeror’s financial capability.
II-8. Objections and Additions to Standard Contract Terms and Conditions. The Offeror will identify which, if any, of the terms and conditions (contained in Appendix A and Appendix B) it would like to negotiate and what additional terms and conditions the Offeror would like to add to the standard terms and conditions. The Offeror’s failure to make a submission under this paragraph will result in its waiving its right to do so later, but the Department may consider late objections and requests for additions if to do so, in the Department’s sole discretion, would be in the best interest of the Commonwealth. The Department may, in its sole discretion, accept or reject any requested changes to the standard terms and conditions. The Offeror shall not request changes to the other provisions of the RFP, nor shall the Offeror request to completely substitute its own terms and conditions for Appendix A or B. All terms and conditions must appear in one integrated agreement. The Department will not accept references to the Offeror’s, or any other, online guides or online terms and conditions contained in any proposal.

Regardless of any objections set out in its proposal, the Offeror must submit its proposal, including the cost proposal, on the basis of the terms and conditions set out in Appendix A and Appendix B. The Department will reject any proposal that is conditioned on the negotiation of the terms and conditions set out in Appendix A or B or to other provisions of the RFP.

II-9. Domestic Workforce Utilization Certification. Complete and sign the Domestic Workforce Utilization Certification contained in Appendix M of this RFP. Offerors who seek consideration for this criterion must submit in hardcopy the signed Domestic Workforce Utilization Certification Form in the same sealed envelope with the Technical Submittal.

II-10. Cost Submittal. The information requested in this Part II, Section II-8 shall constitute the Cost Submittal. The Cost Submittal shall be placed in a separate sealed envelope within the sealed proposal, separated from the technical submittal. The total proposed cost shall be broken down into the following components:

a. Proposed agreement rate for the specialty drugs. The Offeror shall base the proposed agreement rate for the specialty drugs on a percentage of Average Wholesale Price (AWP) for each Generic Sequence Number (GSN) covered under the scope of the RFP and as listed in Appendix G.

    The Offeror shall also include the Wholesale Acquisition Price (WAC) for each Generic Sequence Number (GSN) that is equivalent to the proposed AWP. In the event that a specific drug does not have a WAC listed by a nationally recognized pricing service, the Department will make payment for the drug based upon the proposed AWP.

The accepted agreement rates for the specialty drugs will be an all inclusive rate, including but not limited to costs associated with all tasks and requirements listed in Part IV Work Statement.

Offerors should not include any assumptions in their Cost Submittals. If the Offeror includes assumptions in its Cost Submittal, the Department may reject the proposal. Offerors should direct in writing to the Department pursuant to Part I, Section I-9, of this RFP any questions about whether a cost or other component is included or applies. All Offerors will then have the benefit of the Department’s written answer so that all proposals are submitted on the same basis.
The selected Offerors shall submit claims for the drug component using the PROMISe™ on-line point of sale claims processing system for drug claims. The selected Offerors must submit claims in accordance with the MA Program billing requirements and procedures.

The Department will pay the selected Offerors the lower of the selected Offeror’s accepted agreement rate or the Department’s payment methodology set by state regulation as described in Part IV, Section IV-2. 4. for work satisfactorily performed after execution of a written agreement and the start of the agreement term, in accordance with agreement requirements, and only after the Department has issued a notice to proceed.
PART III

CRITERIA FOR SELECTION

III-1. Mandatory Responsiveness Requirements. To be eligible for selection, a proposal must be:

A. Timely received from an Offeror;

B. Properly signed by the Offeror.

III-2. Technical Nonconforming Proposals. The two (2) Mandatory Responsiveness Requirements set forth in Section III-1 above (A-B) are the only RFP requirements that the Commonwealth will consider to be non-waivable. The Department may, in its sole discretion, (1) waive any other technical or immaterial nonconformities in an Offeror’s proposal, (2) allow the Offeror to cure the nonconformity, or (3) consider the nonconformity in the scoring of the Offeror’s proposal.

III-3. Evaluation. The Department has selected a committee of qualified personnel to review and evaluate timely submitted proposals. The Issuing Office will notify in writing of the Department’s selections for negotiation the responsible Offerors whose proposals are determined to be the most advantageous to the Commonwealth as determined by the Department after taking into consideration all of the evaluation factors.

III-4. Evaluation Criteria. The following criteria will be used in evaluating each proposal:

A. Technical: The Department has established the weight for the Technical criterion for this RFP as 60% of the total points. The evaluation committee will evaluate the technical proposal, including, but not limited to, the following in order of importance:

   i. Soundness of Approach: The evaluation committee will evaluate the soundness of the Offeror’s approach. The proposal should demonstrate a sound and cost efficient approach for operating the Specialty Pharmacy Drug Program, which will result in access to quality care in clinically appropriate settings, therapy management, care coordination, and patient compliance in a cost-effective and accountable manner.

   ii. Contractor Qualifications: The evaluation committee will evaluate the quality, comprehensiveness and volume of the Offeror’s corporate specialty drug qualifications.

   iii. Personnel Qualification and Organization: The evaluation committee will evaluate the adequacy of the staffing plan, the organization of the Offeror’s key personnel and the individual qualifications and responsibilities of the Offeror’s key personnel
iv. Statement of the Problem: The evaluation committee will evaluate the Offeror’s understanding of the problems presented in the RFP, including the Offeror’s understanding of the Department’s goal and objectives for the Specialty Pharmacy Drug Program.

The final Technical scores are determined by giving the maximum number of technical points available to the proposal with the highest raw technical score. The raw technical scores of the remaining proposals are scored using the following formula:

\[
\text{Raw Technical Score of Proposal being scored (B)} \times \frac{C}{A}
\]

B. **Cost:** The Issuing Office has established the weight for the Cost criterion for this RFP as 40% of the total points. The cost criterion is rated by giving the proposal with the lowest total cost the maximum number of Cost points available. The cost submittals of the remaining proposals are then scored using a proportional percentage model.

C. **Domestic Workforce Utilization:** Any points received for the Domestic Workforce Utilization criterion are bonus points in addition to the total points for this RFP. The maximum bonus points for this criterion are 3% of the total points for this RFP. To the extent permitted by the laws and treaties of the United States, each proposal will be scored for its commitment to use domestic workforce in the fulfillment of the contract. Maximum consideration will be given to those Offerors who will perform the contracted direct labor exclusively within the geographical boundaries of the United States or within the geographical boundaries of a country that is a party to the World Trade Organization Government Procurement Agreement. Those who propose to perform a portion of the direct labor outside of the United States and not within the geographical boundaries of a party to the World Trade Organization Government Procurement Agreement will receive a correspondingly smaller score for this criterion. Offerors who seek consideration for this criterion must submit in hardcopy the signed Domestic Workforce Utilization Certification Form in the same sealed envelope with the Technical Submittal. The certification will be included as a contractual obligation when the contract is executed.

**III-5. Offeror Responsibility.** To be responsible, an Offeror must submit a responsive proposal and possess the capability to fully perform the agreement requirements in all respects and the integrity and reliability to assure good faith performance of the agreement.

In order for an Offeror to be considered responsible for this RFP and therefore eligible for selection for best and final offers or selection for agreement negotiations:

A. The total score for the technical submittal of the Offeror’s proposal must be greater than or equal to 70% of the available technical points; and
B. The Offeror’s financial information must demonstrate that the Offeror possesses the financial capability to assure good faith performance of the agreement. The Department will review the Offeror’s previous three financial statements, any additional information received from the Offeror, and any other publicly-available financial information concerning the Offeror, and assess each Offeror’s financial capacity based on calculating and analyzing various financial ratios, and comparison with industry standards and trends.

An Offeror which fails to demonstrate sufficient financial capability to assure good faith performance of the agreement as specified herein may be considered by the Department, in its sole discretion, for Best and Final Offers or agreement negotiation contingent upon such Offeror providing agreement performance security for the first agreement year cost proposed by the Offeror in a form acceptable to the Department. Based on the financial condition of the Offeror, the Department may require a certified or bank (cashier’s) check, letter of credit, or a performance bond conditioned upon the faithful performance of the agreement by the Offeror. The required performance security must be issued or executed by a bank or surety company authorized to do business in the Commonwealth. The cost of the required performance security will be the sole responsibility of the Offeror and cannot increase the Offeror’s cost proposal or the agreement cost to the Commonwealth.

Further, the Issuing Office will award an agreement only to an Offeror determined to be responsible in accordance with the most current version of Commonwealth Management Directive 215.9, Contractor Responsibility Program.

III-6. Final Ranking and Award.

A. After any best and final offer process conducted, the Issuing Office will combine the evaluation committee’s final technical scores and the final cost scores, in accordance with the relative weights assigned to these areas as set forth in this Part.

B. The Issuing Office will rank responsible Offerors according to the total overall score assigned to each, in descending order.

C. The Issuing Office may select for agreement negotiations the Offerors with the highest overall scores; PROVIDED, HOWEVER, THAT AN AWARD MAY NOT BE MADE TO AN OFFEROR WHOSE PROPOSAL RECEIVED THE LOWEST TECHNICAL SCORE AND HAD THE LOWEST COST SCORE OF THE RESPONSIVE PROPOSALS RECEIVED FROM RESPONSIBLE OFFERORS. IN THE EVENT SUCH A PROPOSAL ACHIEVES THE HIGHEST OVERALL SCORE, IT MAY BE ELIMINATED FROM CONSIDERATION AND AWARD MAY BE MADE TO THE OFFEROR WITH THE NEXT HIGHEST OVERALL SCORE.

D. The Issuing Office has the discretion to reject all proposals or cancel the request for proposals, at any time prior to the time an agreement is fully executed, when it is in the best interests of the Commonwealth. The reasons for the rejection or cancellation shall be made part of the agreement file.
PART IV
WORK STATEMENT

IV-1. Objectives

A. General. Through this Request for Proposals (RFP), the Department seeks to select two Offerors to serve as the Department’s preferred providers of specialty pharmacy services for Medical Assistance (MA) recipients in the Fee-for-Service delivery system statewide.

The Department’s goal for the Specialty Pharmacy Drug Program is to maintain access to quality care for MA recipients who have a medical need for specialty pharmacy drugs, appropriate ancillary items and services and clinical supports in the Fee-for-Service delivery system while at the same time, enhancing administrative efficiencies.

B. Specific. The Department’s objectives in administering a Specialty Pharmacy Drug Program are as follows:

1. To operate an efficient and effective Specialty Pharmacy Drug Program as an alternative to the traditional Fee-for-Service model.

2. To offer MA recipients a choice of specialty pharmacy preferred providers.

3. To provide a reliable and convenient dispensing and delivery system for providers and MA recipients that facilitates care in clinically appropriate settings.

4. To provide a clinical support system designed to optimize therapy management, care coordination, and patient compliance.

5. To provide cost-effective services through an accountable Specialty Pharmacy Drug Program.

IV-2. Nature and Scope of the Project

For purposes of this RFP, the Department is broadly defining specialty pharmacy drugs as drugs that require a set of services for access not typically provided in a traditional outpatient pharmacy setting. Specialty pharmacy drugs are generally biotechnical in nature and include, but are not limited to drugs that are:

- Injectables
- Infusibles
- Environmentally sensitive and require special handling
- Typically administered on a chronic basis to treat long-term diseases
- Either self-administered in the home or provider-administered in the home, clinic, or physician’s office
- Usually high cost and associated with complex dosing regimens, frequently requiring patient education, monitoring and clinical supports.

The specific drugs that are included in the scope of this RFP are listed in **Appendix D, Specialty Pharmacy Drug Program**.

Through this RFP, the Department intends to enact an agreement with organizations that have experience in the distribution of specialty pharmacy drugs as defined above to providers and MA recipients, the assessment of patient adherence and compliance, and the operation of patient assistance programs that include individualized education, guidance, support and ongoing communication, while offering deeply discounted pricing.

If requested by the Department, the selected Offerors must assist the Department with the expansion of the Specialty Pharmacy Drug Program to include the following: HealthChoices, the MA mandatory managed care program; other Department offices such as, but not limited to, the Office of Mental Health and Substance Abuse Services, the Office of Children, Youth and Families, and the Office of Developmental Programs; and other State offices.

**A. Population Served**

The Department’s Specialty Pharmacy Drug Program has been in operation in the Fee-for-Service program in 42 counties in the northern half of the state since January 12, 2009. By March 2013, the Department expanded its risk-based, mandatory managed care program statewide. Since the expansion of the managed care program, approximately 500,000 MA program recipients statewide continue to receive their health care services through the Fee-for-Service delivery system. Of that number, approximately 100,000 recipients will be required to secure their specialty drugs, listed in **Appendix D**, from one of the Department’s preferred providers through the Specialty Pharmacy Drug Program. The Fee-for-Service population includes the following:

a. “Dual eligible” adults (individuals 21 years of age and older determined eligible for both the MA Program and Medicare);

b. Residents of long term care facilities;

c. Adults and children determined eligible for MA who are awaiting enrollment in a physical health managed care organization (typically 4 to 6 weeks);

d. Residents of state-operated facilities (i.e. Intermediate Care Facilities), transitional care homes, and Juvenile Detention Centers;

e. Individuals enrolled in the Autism Capitated Assistance Program; and

f. Non-citizens whose coverage is limited to emergency medical conditions.
**Exempted Populations** - Dual eligibles, for the most part, receive their prescription drug coverage under Medicare Part B and Part D and will be exempt from participation in the Specialty Pharmacy Drug Program. MA recipients who have other public or private, commercial third-party coverage that is the primary source of payment for pharmacy services are also exempt from participation in the Specialty Pharmacy Drug Program. If the Fee-for-Service recipient’s other public or private, commercial third-party coverage does not provide coverage of a medically necessary specialty pharmacy drug and the MA Fee-for-Service Program is the primary source of payment, the Fee-for-Service MA recipient will be required to secure that drug from one of the Department’s preferred providers.

**Coordination of Benefits** – When Fee-for-Service MA recipients have other public or private, commercial third-party coverage that is the primary source of payment for pharmacy services, and the selected Offerors dispense the drug (specialty or non-specialty) and bills the primary source of payment, the selected Offerors must coordinate benefits and submit a claim to the Department as secondary payer. The selected Offerors may not bill the MA recipient for the balance of the prescription cost. The MA program, as secondary payer, will pay the lower of the amount the MA recipient owes or:

1. The difference between the amount paid by the primary source of payment and the negotiated rate for a specialty drug, or
2. The difference between the amount paid by the primary source of payment and the MA Program payment rate for a non-specialty drug.

Over 1.7 million MA recipients receive services through the risk-based, mandatory managed care delivery system which includes coverage of pharmacy services. Managed care enrollees will continue to receive their pharmacy services from their managed care organizations and will not be included in the population served.

**B. Scope of Pharmacy Benefit**

The specific drugs that are included in the scope of this RFP are listed in Appendix D, Specialty Pharmacy Drug Program. The Department may modify this list as new specialty drugs become available in the market place or in response to the recommendations of the selected Offerors based upon the findings in their environmental scanning.

**C. Amount and Duration of Pharmacy Benefit**

All adult MA Program recipients twenty-one (21) years of age and older have a limit of six (6) prescriptions per month. The Department has criteria and procedures for prescribing providers to request an exception to the limit of six (6) prescriptions per month which were published in a Medical Assistance Bulletin located on the Department’s website at: [http://www.dpw.state.pa.us/ucmprd/groups/webcontent/documents/bulletin_admin/d_005824.pdf](http://www.dpw.state.pa.us/ucmprd/groups/webcontent/documents/bulletin_admin/d_005824.pdf)
The Department determined that most specialty drugs meet the criteria for an exception to the limit of six (6) prescriptions per month and approval of an exception to the limit for those specialty drugs is automated at the pharmacy point-of-sale.

The Department provides coverage for an original prescription and multiple refills. Multiple refills cannot exceed six (6) months from the time the original prescription is filled or five (5) refills, whichever comes first.

Quantity limits consist of a 34-day supply or 100 units, whichever is greater, unless otherwise specified by the Department. In addition, certain drugs and therapeutic drug classes, including some specialty pharmacy drugs, are subject to daily dose quantity limits identified by the Department. Prior Authorization is required when quantities exceed those limits. The current list of drugs with maximum daily dose quantity limits can be found at: http://www.dpw.state.pa.us/publications/bulletinsearch/bulletinselected/index.htm?bn=09-11-58&o=N&po=OMAP&id=12/30/2011

The limits on the pharmacy benefit will apply to specialty pharmacy drugs. See 55 Pa. Code § 1121.53 for the current regulations relating to limitations on payment for pharmacy services.

D. MA Program Payment

In the Fee-for-Service delivery system, payment is made on a per-service basis for health care services provided to eligible MA recipients.

The Department bases its payment for compensable drugs on the lower of the estimated acquisition cost (EAC) or the State Maximum Allowable Cost (State MAC). The Department expects the Offeror to propose agreement rates in the Cost Submittal and the following payment methodology represents the maximum the Department will pay for a specialty drug.

For brand name drugs, the EAC established by the Department as one of the following:

1. The lowest WAC listed for the drug in available nationally recognized pricing services, plus 3.2%.

2. If WAC data are not available from a nationally recognized pricing service, the lowest AWP listed for the drug in available nationally recognized pricing services, minus 14%.

3. If both WAC and AWP cost data are available for the drug from a nationally recognized pricing service, the lower of the two amounts.

For generic drugs, the EAC established by the Department as one of the following:
1. The lowest WAC listed for the drug in available nationally recognized pricing services

2. If WAC data are not available from a nationally recognized pricing service, the lowest AWP listed for the drug in available nationally recognized pricing services, minus 25%.

3. If both WAC and AWP cost data are available for the drug from a nationally recognized pricing service, the lower of the two amounts.

The State MAC for multisource drugs established by the Department at the lower of the following:

1. The upper payment limit established by the Centers for Medicare and Medicaid Services (CMS).

2. Provided that the generic product is available at the price established by the Department from at least two wholesalers:
   a. If the generic product is available from more than one manufacturer, the base price of 150% of the lowest acquisition cost for the generic product, unless 150% of the lowest acquisition cost is not at least 120% of the second lowest acquisition cost, in which case the base price will be set at 120% of the second lowest acquisition cost.
   b. If the generic product is available from only one manufacturer, the base price is 120% of the acquisition cost for the generic product.

The Department pays a $2.00 dispensing fee for both brand name and generic drugs, and a $3 dispensing fee for a compounded prescription, to pharmacies. Dispensing physicians and certified registered nurse practitioners do not receive a dispensing fee. Also, the current Specialty Pharmacy Drug Program preferred providers do not receive a dispensing fee for specialty drugs dispensed under the Specialty Pharmacy Drug Program.

The selected Offerors will be required to submit claims for specialty pharmacy drugs using the 11-digit National Drug Code (NDC) and must submit claims through the PROMISETM On-Line Claims Adjudication System.

See 55 Pa. Code § 1121.55 relating to method of payment and § 1121.56 relating to drug cost determination. Payment to the selected Offerors for all non-specialty drugs delivered to a MA recipient will be based on these regulations. Payment to the selected Offerors for all specialty drugs will be based on negotiated rates but will not exceed the payment methodology set by these regulations.

The Department currently covers the ancillary and nursing services for home infusion therapy under the home health agency services benefit.
E. Co-Payments

The requirements for MA recipient co-payments will not apply to specialty pharmacy drugs.

For all non-specialty drugs dispensed by the specialty pharmacy preferred providers, children under the age of eighteen (18) years, pregnant women and residents of long term care facilities are exempt from co-payments for pharmacy services. All other MA recipients must pay a $3.00 co-payment per prescription for brand name drugs, including multi-source brand name drugs; and $1.00 per prescription for generic drugs. The following drugs are excluded from the co-payment requirement for all categories of recipients, except General Assistance adults:

1. Drugs, including immunizations, dispensed by a physician or a certified registered nurse practitioner.

2. Specific drugs identified by the Department in the following categories:

   a. Antihypertensive agents
   b. Antidiabetic agents
   c. Anticonvulsants
   d. Cardiovascular preparations
   e. Antipsychotic agents, except those that are also schedule C-IV antianxiety agents
   f. Antineoplastic agents
   g. Antiglaucoma drugs
   h. Antiparkinson drugs
   i. Drugs for which the only approved indication is the treatment of acquired immunodeficiency syndrome (AIDS)

The selected Offerors will be responsible for collecting the cost sharing for non-specialty drugs delivered to the MA recipient’s home unless exempt by current regulations.

See 55 Pa. Code § 1101.63(b) for the current regulations relating to co-payments for MA services.

F. Utilization Controls

1. Preferred Drug List

   The Department has a Preferred Drug List (PDL). Preferred drugs within particular drug classes are included on the PDL based on clinical effectiveness,
safety and outcomes. When all drugs within a class are therapeutically equivalent, then the cost of the drug, including rebates, is also considered.

Drugs included in the therapeutic class of drugs subject to the PDL and not included on the PDL are considered non-preferred. Non-preferred drugs are available when medically necessary but require prior authorization.

The scope of therapeutic classes of drugs subject to the PDL includes some of the drugs listed in Appendix D, Specialty Pharmacy Drug Program. The most recent version of the PDL, listing the therapeutic classes of drugs included on the PDL and the products that are preferred or non-preferred can be found at www.providersynergies.com/services/documents/PAM_PDL.pdf

2. Prior Authorization

The Department requires prior authorization of the following drugs in the Fee-for-Service delivery system:

   i. Brand name drugs when an A-rated generic is available

   ii. Prescriptions for drugs when the quantity exceeds the established quantity limit

   iii. Non-preferred drugs

   iv. Certain drugs designated by the Department as requiring prior approval to ensure the clinical health and safety of the MA recipient

   v. Early refills

   vi. Therapeutic duplication

The Department will maintain its responsibility for the development and implementation of pharmacy prior authorization requirements and guidelines to determine medical necessity, in consultation with the Department’s Pharmacy and Therapeutics Committee and Drug Utilization Review (DUR) Board. The Department will also continue to operate its Pharmacy Call Center.

Only the prescribing provider can submit the request for prior authorization to the Pharmacy Call Center. The procedures for a prescribing provider to request prior authorization of a prescription are located on the Department’s website at: http://www.dpw.state.pa.us/provider/doingbusinesswithdpw/pharmacieservices/pharmacypriorauthorizationgeneralrequirements/index.htm. These procedures will continue to apply with the following exceptions:

- The specialty pharmacy preferred provider may contact the Pharmacy Call Center to request approval of a prescription that denies for an early refill
The Pharmacy Call Center will e-mail a notice of approval of a request for prior authorization of a prescription for a specialty drug to the specialty pharmacy preferred provider designated by the MA recipient or the prescribing provider. The selected Offerors will provide an e-mail address dedicated to receiving notices of approved requests for prior authorization of prescriptions for specialty drugs.

3. **Drug Utilization Review (DUR)**

The Department has a DUR program for covered outpatient drugs. The objective of the DUR program is to assure that prescriptions are appropriate, medically necessary and are not likely to result in adverse medical results. The DUR also serves to enhance the quality of patient care by educating prescribers, pharmacists and MA recipients on the appropriateness of care provided to MA recipients.

The PROMISE™ on-line claims adjudication system includes a Prospective DUR (Pro DUR) system that checks all pharmacy claims, including claims for specialty pharmacy drugs, at the point of sale for the following:

i. Therapeutic appropriateness  
ii. Over-utilization  
iii. Appropriate use of generic drugs  
iv. Therapeutic duplication  
v. Drug-disease contraindications  
vi. Drug-drug interactions  
vii. Incorrect drug dosage  
viii. Clinical abuse/misuse

Selected Offerors are required to respond to Pro DUR alerts and take appropriate action when submitting claims for specialty pharmacy drugs through the PROMISE™ On-Line Claims Adjudication System.

**G. Emergency Supplies**

The Department will allow a pharmacist to dispense an emergency supply of the prescribed medication without prior authorization if in the professional judgment of the pharmacist, the MA recipient has an immediate need for the medication, such as the recipient cannot take any other alternative medication during the time the prior authorization is being obtained. In such emergency situations, the pharmacy may dispense a five-day supply of the prescribed medication without prior authorization, unless the pharmacist determines that taking the prescribed medication either alone or along with other medication(s) that the MA recipient may be taking would jeopardize the health and safety of the MA recipient.
While the need for an emergency supply does not typically occur for specialty pharmacy drugs, the selected Offerors may dispense and submit claims for a five-day supply of a specialty pharmacy drug if that situation does occur.

H. MA Program Pharmaceutical Volume and Expenditures

Table 1 provides statistics on specialty pharmacy drugs provided to MA recipients in the Fee-for-Service delivery system beginning January 1, 2013 through June 30, 2013. The number of MA Recipients who received a specialty drug in the Fee-for-Service delivery system decreased from January to June due to the transition of MA recipients from Fee-for-Service to mandatory managed care which includes coverage of pharmacy services. See Appendix H, Specialty Pharmacy Drug Service Summary, for Fee-for-Service claims and cost information for MA recipients statewide by GC3 code and National Drug Code (NDC) for the period January through June 2013.

<table>
<thead>
<tr>
<th>Month</th>
<th>Number of MA Recipients Receiving Specialty Drugs</th>
<th>Total Number of Prescriptions for Specialty Drugs</th>
<th>Total Specialty Drug Expenditures</th>
</tr>
</thead>
<tbody>
<tr>
<td>January</td>
<td>1,989</td>
<td>2,516</td>
<td>$4,600,606</td>
</tr>
<tr>
<td>February</td>
<td>1,871</td>
<td>2,300</td>
<td>$4,023,403</td>
</tr>
<tr>
<td>March</td>
<td>895</td>
<td>1,121</td>
<td>$892,472</td>
</tr>
<tr>
<td>April</td>
<td>866</td>
<td>1,125</td>
<td>$919,868</td>
</tr>
<tr>
<td>May</td>
<td>751</td>
<td>960</td>
<td>$915,093</td>
</tr>
<tr>
<td>June</td>
<td>372</td>
<td>424</td>
<td>$466,099</td>
</tr>
</tbody>
</table>

A listing of pharmacy services information is available on the Department's website at: http://www.dpw.state.pa.us/provider/doingbusinesswithdpw/pharmacyservices/index.htm

I. Act 207 of 2012

The provisions in Act 207 of 2012 enable Medical Assistance program recipients to access their specialty drugs at a retail pharmacy as long as the retail pharmacy is willing to accept the same pricing, terms, conditions and requirements that the Department establishes for its Specialty Pharmacy Drug Program preferred providers. To date, no pharmacy enrolled in the Medical Assistance program has requested to participate as a Specialty Pharmacy Drug Program provider.
IV-3. Requirements

A. Emergency Preparedness.

To support continuity of operations during an emergency, the Commonwealth needs a strategy for maintaining operations for an extended period of time. One part of this strategy is to ensure that essential contracts and agreements that provide critical business services to the Commonwealth or the individuals it serves have planned for such an emergency and put contingencies in place to provide needed goods and services.

1. Describe how you anticipate such a crisis will impact your operations.

2. Describe your emergency response continuity of operations plan. Please attach a copy of your plan, or at a minimum, summarize how your plan addresses the following aspects of pandemic preparedness:

   a) Employee training (describe your organization’s training plan, and how frequently your plan will be shared with employees)

   b) Identified essential business functions and key employees (within your organization) necessary to carry them out

   c) Contingency plans for:

      i.) How your organization will handle staffing issues when a portion of key employees are incapacitated due to illness.

      ii.) How employees in your organization will carry out the essential functions if contagion control measures prevent them from coming to the primary workplace.

   d) How your organization will communicate with staff and suppliers when primary communications systems are overloaded or otherwise fail, including key contacts, chain of communications (including suppliers), etc.

   e) How and when your emergency plan will be tested, and if the plan will be tested by a third-party.

B. General Requirements

1. The selected Offerors must be enrolled in the MA Program as a pharmacy provider and must comply with all MA Program requirements. The Specialty Pharmacy Drug Program agreement will serve as an extension of the Provider Agreement for Pharmacy and Medical Suppliers. Each subcontractor must enroll as a provider in the MA Program and comply with all MA Program requirements.
2. The selected Offerors must have a current accreditation from the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), or URAC (formerly known as the Utilization Review Accreditation Commission) and maintain such accreditation throughout the course of the agreement. All individuals or entities with whom the selected Contractor subcontracts must meet all accreditation and quality standards required by the RFP.

3. The selected Offerors, and all subcontractors, must comply with all applicable Federal and State statutes and regulations and the 1915(b) Waiver approved by the Centers for Medicare and Medicaid Services (CMS). The Department will maintain responsibility for securing approval of all necessary State Plan Amendments and the 1915(b) Waiver.

4. The selected Offerors are liable for the cost of any prescription for a specialty pharmacy drug and any ancillary medical supplies and equipment until the shipment is accepted by the person designated to receive it. The Department defines delivery as drugs accepted by the designated MA recipient, or proffered by a courier at the site of administration, on the date specified, by the prescribing provider or MA Program recipient.

5. The selected Offerors must maintain a business site within the Commonwealth of Pennsylvania.

C. General Staffing Requirements

Appropriately qualified individuals as specified below must support the Department’s administration of the Specialty Pharmacy Drug Program.

1. The selected Offerors must retain personnel that perform all work required to meet the Department’s goals, objectives and requirements.

2. The selected Offerors must use personnel that are performing satisfactorily at the appropriate skill levels specified in the final agreement.

3. The selected Offerors must relieve any Offeror staff or staff of the Offerors’s subcontractors from any further work under the agreement if:
   a. The individual staff member or subcontractor’s staff member has been excluded from participation in any federal funded health care program.
   b. The individual staff member or subcontractor’s staff member does not perform at the applicable skill level specified in this RFP, the selected Offerors’s proposal, the approved work plan, and the final agreement.
c. The individual staff member or subcontractor’s staff member does not deliver work that conforms to the performance standards stated in the final agreement.

The selected Offerors shall immediately notify the Department’s Contract Administrator of the discharge of any of the selected Offeror’s staff or subcontractors assigned to this agreement, and such staff shall be forthwith relieved of any further work under this agreement.

D. Staffing Requirements for Key Personnel

1. At a minimum, the selected Offerors’ key personnel must include the following positions:

   a. **Project Manager.** The Project Manager will serve as the primary contact person for the Department. The Project Manager must have at least one year of previous experience managing large specialty pharmacy drug distribution systems, including home infusion therapy and clinical support systems. The Project Manager must be available to the Department via telephone or email during the Department’s regular business hours and in an emergency during non-business hours. Project Manager responsibilities must include:

      i. Ensuring compliance with administrative policies and procedures, MA Program requirements and the Agreement.

      ii. Administering program operations and performance.

      iii. Overseeing development of status reports and ad hoc reports, if any, submitted to the Department.

   b. **Clinical Pharmacist.** The Clinical Pharmacist will serve as the primary clinical contact for the Department. The Clinical Pharmacist must have a Pennsylvania pharmacy license and previous experience in specialty pharmacy drug care management, home infusion therapy and related diagnoses. The Clinical Pharmacist must have knowledge of the management of all conditions for which specialty drugs are prescribed and dispensed. For example, the Clinical Pharmacist must be knowledgeable about hematological disorders, including pediatric hematological disorders, with emphasis on bleeding disorders. Clinical Pharmacist responsibilities must include:

      i. Ensuring compliance with clinical and program policies and procedures.

      ii. Monitoring pharmacy dispensing and distribution system operations and performance.
iii. Overseeing the development of clinical status reports and ad hoc reports submitted to the Department.

c. **Clinical Call Center Manager.** The Clinical Call Center Manager must have at least one year of previous experience in managing a specialty pharmacy call center and will manage the day-to-day call center operations. Clinical Call Center Manager responsibilities must include:

   i. Overseeing Clinical Call Center staff training.

   ii. Analyzing Clinical Call Center reports to identify areas for improvement and implementing improvement processes.

   iii. Overseeing the auditing and assurance of Call Center staff’s compliance with Department policies and generally accepted standards of practice.

   iv. Overseeing the development of quality control reports and ad hoc reports submitted to the Department.

   v. Managing the efficient use of call center staff resources.

d. **Clinical Call Center Staff.** Clinical Call Center Staff must have at least one (1) year of prior experience with, or equivalent experience with, specialty pharmacy drugs and home infusion therapy and related diagnoses. Clinical Call Center Staff responsibilities must include:

   i. Answering incoming calls from patients and providers.

   ii. Providing drug information.

   iii. Counseling on self-administration techniques.

   iv. Counseling on product storage and handling.

   v. Counseling on adherence to drug regimen.

   vi. Counseling on management of side effects.

   vii. Adhering to Department-approved policies and procedures when answering incoming calls for inquiries and complaints and referring callers to appropriate Offeror staff or Department staff, as needed.

   viii. Documenting and tracking all inquiries to the Call Centers via software.
e. **Pharmacy Staff.** All pharmacists must have a Pennsylvania pharmacist license. Pharmacy Staff must have prior experience with specialty pharmacy drugs and home infusion therapy and related diagnoses such as knowledge of the management of all pediatric hematological disorders with emphasis on bleeding disorders, or equivalent experience. In the event that any specialty pharmacy drug is dispensed from a pharmacy outside of Pennsylvania, at least one staff pharmacist must have a Pennsylvania pharmacy license. Pharmacy Staff responsibilities must include:

i. Assessing that the diagnosis is appropriate for the drug therapy and that the dose is appropriate for the patient and treatment regimen.

ii. Dispensing specialty pharmacy drugs with complex dosing regimens, including prescription renewals.

iii. Assay managing anti-hemophiliac agents.

iv. Providing patient counseling, education and monitoring; providing clinical interventions; and managing adverse events.

v. Assessing responses to therapy, patient compliance, and ongoing review of drug regimens and communicating with prescribers and other members of the Offeror’s patient support system.

vi. Determining remaining doses on hand (if any) to avoid waste and manage inventory.

2. The selected Offerors must arrange, at their own expense, for a background check for all key personnel. Background checks are to be conducted as follows:


b. Via the List of Excluded Individuals/Entities (LEIE), a data base of all individuals or entities that have been excluded nationwide from participation in any federal health care program found at [http://www.dpw.state.pa.us/learnaboutdpw/fraudandabuse/medichecklist/P_039955](http://www.dpw.state.pa.us/learnaboutdpw/fraudandabuse/medichecklist/P_039955).
The background check must be conducted prior to the effective date of the Specialty Pharmacy Drug Program agreement and on an annual basis thereafter.

3. In the unlikely event that the selected Offerors, or the subcontractors’ personnel may, for any reason, work directly with children, the selected Offerors must arrange, at their own expense, for a child abuse clearance for all of those personnel, including subcontractors’ personnel. Clearances are to be conducted via the Pennsylvania Child Abuse History Clearance procedures found at http://www.dpw.state.pa.us/ucmprd/groups/webcontent/documents/form/s_001762.pdf.

IV-4. Tasks

Task 1: Maintain an Inventory of Specialty Pharmacy Drug and Ancillary Medical Supplies and Equipment

The selected Offerors will be required to maintain an inventory of specialty pharmacy drugs and ancillary medical supplies and equipment for home infusion therapy, sufficient to meet the needs of the MA recipient population for whom those drugs, supplies and equipment are prescribed and authorized. The selected Offerors will be responsible for the following tasks:

a. Manufacturer, Wholesaler, and Distributor Relationships. The selected Offeror must provide, and update as necessary, a list of manufacturers, wholesalers, and distributors of the drugs listed in Appendix D, Specialty Pharmacy Drug Program, with whom the selected Offeror has a contractual relationship, addressing the items listed below:

   i. Name of manufacturer, wholesaler, or distributor
   
   ii. Product
   
   iii. Length of relationship and remaining term of agreement
   
   iv. Scope of agreement (general description of products and services)
   
   v. Limitations and exclusions
   
   vi. Service expectations and standards (turnaround time)

b. Assay Inventory. The selected Offerors must maintain a consistent inventory of clotting factor with a range of assays to support assay management.

The selected Offerors must document its assay management program, including the program goals, allowed percent variances, and the process for assay management. The documentation must describe the steps the selected Offeror
will take to provide the prescribed product in the event that it does not have a factor product in inventory that matches the prescription.

c. **Guaranteed Pedigree.** The selected Offerors must guarantee the pedigree of all specialty drugs including clotting factor.

If a specialty drug is purchased from any source other than a manufacturer, the selected Offerors must develop and maintain policies and procedures for how it guarantees the pedigree of the drug to avoid any type of product mishandling or tampering.

d. **Ancillary Medical Supplies and Equipment List.** The selected Offerors must provide the ancillary medical supplies and equipment required for administration of specialty drugs and home infusion therapy, including supplies for the treatment of prevention of bleeding episodes.

The selected Offerors must develop and maintain a list of the ancillary medical supplies and equipment to be provided.

e. **Vendor Selection and Product Assessment.** The selected Offerors must develop and maintain a vendor selection procedure for drugs, medical supplies and equipment, including product quality assessment.

f. **Limitations on Access to Supply.** The selected Offerors must identify all drugs included in Appendix D, Specialty Pharmacy Drug Program, for which:

i. Access to a supply of the drugs is subject to constraints such as exclusive distribution rights and the selected Offeror is not part of the exclusive distribution network and how the selected Offeror will access a supply when prescribed for an MA recipient.

ii. The selected Offerors will use a local entity such as a pharmacy to provide the drug(s) and the circumstances when that would occur, (e.g., very time sensitive).

iii. The selected Offeror has a preferred agreement with a manufacturer, wholesaler, or distributor to support MA recipients in times of short supply.

g. **Product Recall.** The selected Offerors must develop and maintain policies for product recalls.

h. **Purchasing Volume.** The selected Offerors must identify its total purchasing volume and stratified annual purchasing volume.

i. **Stock-Out Rates and Out of Stock Process.** The selected Offerors must identify its stock out rates for the drugs listed in Appendix D, Specialty Pharmacy Drug Program.
Program, and develop and maintain a policy and procedures for providing drugs that are out of stock.

j. **Returns/Undeliverable Medications.** The selected Offerors must develop and maintain policies to manage product returns and products deemed “undeliverable” by either the MA recipient or the selected Offeror.

k. **Short-Dated and Temperature-Sensitive Medications.** The selected Offerors must develop and maintain policies and procedures related to the procurement and storage of all products with a short shelf life and those requiring special handling.

**Task 2: Operate a Specialty Pharmacy Dispensing and Delivery System**

The selected Offerors must provide reliable and convenient dispensing and delivery systems for providers and MA recipients that facilitate care in clinically appropriate settings.

The selected Offerors must demonstrate its capacity to accept, dispense, and deliver patient-specific requests for specialty pharmacy drugs in a manner that is responsive to both prescribers and MA recipients, complies with MA Program regulations and requirements and requirements of the Pennsylvania Board of Pharmacy, and minimizes the potential for waste. The selected Offerors will be responsible for performing the following tasks and the proposal must describe how the selected Offeror will perform these tasks.

a. **Operate an Efficient, Accurate and Responsive Ordering and Refill Process**
   
i. **Operate a Call Center for Providers and MA recipients.** The selected Offerors must serve as the single point of contact and maintain a distinct toll-free telephone line for prescribers of specialty pharmacy drugs, providers administering those drugs, hospital discharge planners, and MA recipients. This telephone line must be dedicated exclusively to provider and MA recipient requests for prescriptions and refills, including prescriptions or orders for ancillary medical supplies and equipment, provider and MA recipient inquiries regarding delivery of drugs, and other provider and MA recipient inquiries and complaints as described in Task 4. The selected Offerors must accommodate recipients who have Limited English Proficiency or who are hearing impaired.
   
   ii. **Call Centers Hours of Operation.** The selected Offerors’ call center (for providers and MA recipients) must be operational 24 hours per day, seven (7) days a week, including holidays. Selected Offerors are required to operate direct contact call centers during routine business hours, defined as Monday through Friday, 8:30 a.m. to 5:00 p.m. Selected Offerors may operate their call centers on an on-call basis after business hours, on weekends and holidays. Answering machines are not permitted.
   
   iii. **Receive prescriptions in alternative formats.** The selected Offerors must have the capacity to receive prescriptions and requests for refills in a
hard copy paper format, by telephone, fax, and electronically (e-prescribing).

iv. **Call Center Tracking.** The selected Offerors must have the capacity to track Call Center abandonment rates, average call wait times, average speed of answer, first call resolution, average call duration, and on-call response times for its toll free number.

b. **Ensure adequate staffing of pharmacies**

The selected Offerors must:

i. Provide a sufficient number of pharmacies, central distribution centers and any additional distribution sites necessary to meet the requirements of this RFP.

ii. Develop and maintain an adequate staffing plan for its pharmacies, distribution centers and sites, including staffing patterns that are adequate to meet the requirements of the Specialty Pharmacy Drug Program.

c. **Process Prescriptions, Dispense Specialty Pharmacy Drugs and Submit Claims**

i. When processing prescriptions and refills for specialty pharmacy drugs and dispensing those medications to MA recipients, the selected Offerors must:

a) Conform to accepted standards of practice and quality of service and MA Program regulations, policies and procedures.

b) Provide the prescribed medication in the dose ordered or, if inventory supply does not allow, coordinate with the other selected specialty pharmacy preferred provider to dispense the medication, and notify the prescriber or MA recipient who submitted the request for the prescription of the referral to the other selected specialty pharmacy preferred provider.

c) Verify MA recipient eligibility.

d) Validate that the prescription was prior authorized by the Department when prior authorization is required.

e) Submit accurate claims using the PROMISe™ On-line claims adjudication system.

f) Coordinate benefits – Because the MA Program is the payer of last resort and an MA recipient must exhaust his or her other coverage before the MA Program will pay the claim, if an MA recipient has
other private or public coverage, the selected Offerors must first submit a claim to the MA recipient’s other coverage before submitting a claim to the MA Program.

g) Turnaround “clean” prescriptions within two (2) business days or the “needs by date” specified by either the prescribing provider or the MA recipient.

ii. The selected Offerors must develop and maintain dispensing policies and procedures for each of the following:

a) In-home inventory of all specialty medications, including factor product for bleeding disorder therapy

b) Refills, including steps to address compliance and adherence, avoid stockpiling and address “dose creep.”

c) Emergency prescriptions and emergency refills.

d) Replacement costs of prescription drugs and medical supplies and equipment damaged during distribution and delivery.

e) Dispensing of drugs with short expiration dates.

f) Waste management.

g) Educational interventions with prescribers including prescribers whose prescribing practices are considered outliers.

h) Definition of “dosing.”

d. Operate an Efficient, Accurate and Responsive Distribution and Delivery System

The selected Offerors must implement and operate a distribution and delivery system that reflects “best practices” and optimizes distribution and delivery by ensuring that MA recipients receive their specialty pharmacy drug when and where it is needed. The system must provide the following, at a minimum:

i. Steps in distribution and delivery to the site of administration, including an MA recipient’s home, the prescribers’ offices, clinics, and outpatient infusion sites. Steps must include an explanation of how the selected Offeror will inform administering providers and MA recipients regarding the expected time frames for receipt of delivered items.

ii. Standard shipping methods and practices.

iii. Name of delivery vendor(s) and delivery services provided by each vendor.

v. The average turn-around time for a prescription (i.e., maximum response time from receipt of request to delivery of the drug).

vi. The distribution system back-up system.

vii. The distribution system disaster recovery strategy and process.

viii. Training offered by the selected Offerors to prescribers, hospital discharge planers, providers administering a specialty pharmacy drug, office staff and MA recipients and their families, related to distribution, delivery, handling and storage of specialty pharmacy drugs.

ix. Distribution of all products with a short shelf life and those requiring special handling.

Task 3: Provide a Clinical Support System

The selected Offerors must provide an integrated clinical support system designed to support drug administration and therapy management.

The selected Offerors’ clinical support systems must reflect “best practices” in managing care. The system must provide the following, at a minimum:

a. Therapy Management Programs. Therapy management programs by specialty class of drugs or individual drugs listed in Appendix D, with documented evidence of the following:

i. Individualized education, guidance, counseling and ongoing communication with both MA recipients and providers to support therapy management.

ii. Optimal compliance with and adherence to drug regimens including the selected Offeror’s definition of compliance and how it relates to therapy management.

iii. Care collaboration and coordination.

a) Improved therapeutic outcomes and how they are monitored and measured.

b) The therapeutic outcomes, monitoring and measurement for individuals with hemophilia must include the following:

i.) Maximized bleed prevention.

ii.) Maximized avoidance of emergency room use.

iii.) Minimized factor stockpiling.
iv.) Management of patient compliance.

v.) Care coordination with Hemophilia Treatment Centers and other providers of blood factor products.

c) The therapeutic outcomes, monitoring and measurement for individuals who are residents of long term care facilities must include proposed methods to improve care coordination and care management.

b. Clinical Call Center

i. Operate a Clinical Call Center for MA Recipients. The selected Offerors must maintain toll-free telephone lines for MA recipients of specialty pharmacy drugs. This telephone line must be used for patient questions about, but not limited to, drug information, product storage and handling, side effect management, injection assistance, adherence and compliance with drug regimens, and other issues related to the Specialty Pharmacy Drug Program. Clinical Call Center staff must answer incoming calls and provide appropriate and timely information and counseling.

The selected Offerors must operate a Clinical Call Center that accommodates MA recipients who have Limited English Proficiency or who are hearing impaired.

ii. Clinical Call Center Staffing and Hours of Operation. The selected Offerors’ call center must be operational 24 hours per day, seven (7) days a week, including holidays. Selected Offerors are required to operate direct contact call centers during routine business hours, defined as Monday through Friday, 8:30 a.m. to 5:00 p.m. Selected Offerors may operate their call centers on an on-call basis after business hours, on weekends and holidays. Answering machines are not permitted.

iii. Clinical Call Center Tracking and Reporting. The selected Offerors must have the capacity to track Call Center abandonment rates, average call wait times, average speed of answer, first call resolution, average call duration, and on-call response times for each toll free number.

c. Coordination of In-Home Nursing. The selected Offerors must coordinate in-home nursing services with a home health agency enrolled in the MA Program when needed.

4. Ongoing Hemophilia Assessment. The selected Offeror will review interventions and the amount of clotting factor used, compare the results with goals for the individual patient’s care, and assess if the response to therapy is adequate. If a discrepancy is evident, the Offeror will alert the treating physician to changes in the patient’s bleeding pattern, clotting factor usage, or lifestyle issues that may require changes to the treatment regimen.
Task 4: Respond to General Inquiries and Complaints

a. Each selected Offeror must maintain its own toll-free telephone line for recipients and providers to call with general inquiries and complaints (See Task 2.a.) The selected Offerors must also have the capacity to receive and respond to general inquiries and complaints submitted in writing, by fax or Internet.

b. The selected Offerors must respond to general inquiries and address complaints as soon as possible, but no later than two (2) business days. In situations where the general inquiry cannot be addressed by a selected Offeror (e.g., questions about eligibility for services), the selected Offeror must provide the caller with the telephone number of the Department contact which will be provided by the Department.

c. The selected Offerors must develop a system to track and report to the Department all general inquiries and complaints received, as well as the outcome of each general inquiry and complaint.

d. In instances where the Department receives a general inquiry or complaint about the Specialty Pharmacy Drug Program, the selected Offerors must coordinate with the Department to accept the forwarded call or follow-up with the caller to address the inquiry or complaint.

Task 5: Readiness Review Participation

The selected Offerors must participate in a readiness review that the Department may conduct prior to the effective date of the Specialty Pharmacy Drug Program agreements.

Task 6: Policies and Procedures

Each selected Offeror must submit for Department approval, the policies and procedures for all of the following:

a. Quality Control and Quality Assurance.

b. Provider/MA recipient call center.

c. Communications with prescribers and MA recipients (before dispensing a medication; informing the prescribing provider or the MA recipient of the requirement for prior authorization and the process to verify a prior authorization with the Department; regarding MA recipient-specific needs and interventions; updates on MA recipient’s progress and ongoing therapy; when an MA recipient is determined ineligible for MA on the date of service; etc.).

d. Process to admit new MA recipients into the program and assess their needs as they relate to the therapy management program.
e. Staffing of pharmacies and call centers.

f. Therapy management.

The selected Offerors must modify the policies and procedures as directed by the Department. The selected Offerors must review policies and procedures annually, and update them as directed by the Department. The Department may also require new or updated policies and procedures during the course of the Agreement.

The Department must approve in writing every new policy or procedure and any modification and/or addition to any existing policy or procedure before the selected Offerors may implement the policy or procedure.

**Task 7: Communication and Education**

The Department will develop materials to notify MA recipients and providers about the Specialty Pharmacy Drug Program, including but not limited to recipient notices, MA Bulletins, and a posting on the Department’s website describing the Program, including information about the selected Offerors and the Specialty Pharmacy Drug Program requirements and procedures. The selected Offerors must assist the Department in developing all communication materials for providers and MA recipients, including the Department’s website. In addition, each selected Offeror is responsible for the development, including updates and revisions, and cost of the following:

a. **Educational and Informational Materials.** The selected Offerors are required to develop materials for MA recipients and providers which provides information such as, but not limited to, the following:

   i. Training and patient kits or informational materials about:

      a) Admission into the Specialty Pharmacy Drug Program.

      b) Specialty pharmacy drugs and the Specialty Pharmacy Drug Program.

      c) Therapy management programs.

      d) Coordination with in-home nursing when necessary.

   ii. Information and instructions to submit prescriptions and request refills, inquire about distribution and delivery, including the status of the delivery, contact the Provider and MA Recipient Call Center and Clinical Call Center, and make general inquiries.

   iii. A presentation packet providing an overview of the Specialty Pharmacy Drug Program that can be used at stakeholder meetings and posted on the Department’s website.
b. **Educational Prescriber Interventions.** The selected Offerors must submit a plan to identify and provide appropriate educational interventions for “outlier” (overutilization, underutilization, inappropriate diagnoses, etc.) prescribers.

c. **Specialty Pharmacy Drug Program Website.** The Department will continue to maintain a Specialty Pharmacy Drug Program on its website. Each selected Offeror will provide a link to its website to be posted on the Department’s Specialty Pharmacy Drug Program website to ensure MA recipients’ easy access to the selected Offeror’s program information.

d. **Reading Level and Translation.** All materials for MA recipients and the MA recipient section of the website must be culturally sensitive, easily understood, written at no higher than a fourth grade reading level whenever possible, and include an English and Spanish version. MA recipient materials must include taglines in other languages identified by the Department and must be available in other languages upon request.

e. **Department Approval.** The selected Offerors must submit preliminary and final drafts of the materials, manuals and the website for the Department’s approval before implementation of the Specialty Pharmacy Drug Program.

f. The selected Offerors must provide educational information about specialty pharmacy drugs, when requested by the Department, to support activities required by the Department’s Retrospective Drug Utilization Review program (Retro DUR) related to clinical education of providers, analyses of provider prescribing patterns and provider profiling.

The Department may request the selected Offerors to develop and translate other materials related to the Specialty Pharmacy Drug Program, as necessary.

**Task 8: Coordination with the Department and Other Contractors and Providers.**

The selected Offerors must coordinate with the Department and the Department’s Contractors, as specified by the Department, to achieve the Department’s program goals and objectives.

a. **Coordination with the Department.** At a minimum, the selected Offerors must coordinate with the Department in the following ways:

i. Attend meetings with the Department and other Contractors, as requested by the Department and upon request, prepare and submit to the Department for approval, agendas, file notes, presentations and other deliverables identified by the Department to streamline coordination efforts.
ii. The selected Offerors must collaborate with the Department’s care management program to coordinate care for medically compromised MA recipients who are also being prescribed specialty pharmacy drugs.

iii. The selected Offerors must, when requested by the Department, attend and participate in the Department’s Pharmacy and Therapeutics Committee and Drug Utilization Review (DUR) Board meetings when specialty drugs are scheduled for review.

iv. The selected Offeror must review the scope of drugs covered under the Specialty Pharmacy Drug program and pricing of those drugs, at least annually, and more frequently when requested by the Department.

b. **Coordination with Other Contractors and Providers.** At a minimum, the selected Offerors must coordinate with other Contractors and providers in the following ways:

i. The selected Offerors must coordinate with the Department’s Claims Processor, currently Hewlett Packard Enterprise Services (HP), as needed to facilitate the on-line adjudication of pharmacy claims and submission of claims for any ancillary medical supplies and equipment through PROMISe™.

ii. The selected Offerors must coordinate with the Department when it is necessary to work with the Department’s MCOs and their panel of pharmacies and specialty pharmacy providers to ensure continuity of care for MA recipients transitioning from the Fee-for-Service delivery system to managed care.

iii. The selected Offerors must coordinate with other contractors and providers as required by the Department.

**Task 9: Plan for Transition to the Preferred Provider and Continuity of Care.**

The selected Offerors must develop a plan for transition to the preferred provider or to a HealthChoices managed care organization, and explain how the plan ensures continuity of care for the following MA recipients:

a. All MA recipients who continued to participate in the Specialty Pharmacy Drug Program in the Fee-for-Service Program in the 42 counties where it was originally in operation.

b. All children and adults who are currently receiving a specialty pharmacy drug from a non-preferred provider when the Specialty Pharmacy Drug Program is expanded to the 25 counties where the original program was not operational. These MA recipients may continue to receive their drug from the non-preferred provider for 60 days or the balance of the timeframe of the current prescription,
whichever is longer. All new prescriptions must be handled by one of the selected Offerors.

c. All MA recipients who are newly determined eligible for MA, are being prescribed a specialty drug, and who are receiving their pharmacy services under the Fee-for-Service delivery system while waiting for enrollment in a HealthChoices managed care organization.

Because MA recipients taking specialty pharmacy drugs will require special care during a transition of providers, the selected Offerors must submit for Departmental approval, before start-up of the new agreement, a detailed plan to transition individuals from the current Preferred Specialty Pharmacy Providers to the selected Offerors, and from the selected Offerors to the MA recipient’s HealthChoices managed care organization to ensure uninterrupted continuity of care and a seamless transition.

**Task 10: Perform Quality Assurance Monitoring.** The selected Offerors must monitor the quality of all components of its Specialty Pharmacy Drug Program operations.

The selected Offerors must participate with the Department and its Contractors in the ongoing evaluation of the Specialty Pharmacy Drug Program, including partnering with the Department in developing an outcomes analysis of the Program.

The selected Offerors must make recommendations to the Department for potential improvements to the Specialty Pharmacy Drug Program, as necessary.

**Task 11: Perform Environmental Scanning.** The selected Offerors must monitor and report on trends and practices in specialty pharmacy and home infusion therapy. Environmental scanning includes but is not limited to the following:

a. New products in the development pipeline, development status, and disease categories targeted

b. Trends by therapeutic class and trend drivers

c. New indications

d. Black box warnings

e. Changes or modifications in therapy management and treatment protocols

The Department may modify the list of drugs covered under the Specialty Pharmacy Drug Program and the selected Offerors also will make recommendations to the Department for changes in the scope of drugs covered under the RFP in response to changes in specialty pharmacy and home infusion therapy.

The selected Offerors must use information from its environmental scanning, operational and clinical experience, and reports and data it generates to recommend to the Department the following:
iv. New specialty pharmacy drugs to be added to the scope of products covered under the Specialty Pharmacy Drug Program.

v. Requirements for utilization management such as prior authorization of existing or new specialty pharmacy drugs, including quantity limits when applicable, and predicted savings. In addition, the selected Offerors must recommend utilization review guidelines based on nationally accepted, evidence-based clinical criteria to determine medical necessity of new specialty drugs and any modification to the current guidelines used by the Department’s pharmacy prior authorization reviewers to determine medical necessity.

vi. Requirements for the Department’s Prospective Drug Utilization Review (Pro DUR) program and Pro DUR alerts to the pharmacist as they relate to specialty pharmacy drugs.

**Task 12: Information Technology (IT) and Management Information System (MIS)**

a. **IT and MIS Requirements.** The selected Offerors must maintain its own MIS system to track drug product inventory; dispensing, distribution and delivery of special pharmaceutical drugs and ancillary supplies and equipment; provider and MA recipient communications; and Call Center inquiries and requests.

The selected Offerors must meet the following IT and MIS requirements:

i. Have Internet access for all Call Center staff.

ii. Have sufficient telecommunication capabilities to meet the requirements of this RFP and the final Agreement.

iii. Have the ability to submit claims using the on-line claims adjudication system in PROMIsedom.

iv. Have the ability to coordinate benefits when a Fee-for-Service MA recipient has other public or private, commercial third-party coverage that is the primary source of payment for pharmacy services.

v. Have the capability to receive, store, analyze and report on data sufficient to meet the requirements of this RFP and the final Agreement.

b. The selected Offerors and their subcontractors must have a HIPAA-compliant system with effective security measures to prevent the unauthorized use of, or access to, data. The selected Offerors and its subcontractors must maintain confidentiality and only use information from the Department to fulfill its contractual obligations.
Task 13: Implementation Schedule

The selected Offerors must provide the Department with an implementation schedule in electronic format.

a. The implementation schedule must identify major tasks, identify the work elements of each task, the resources assigned to the task, the time allotted to each element of the task and the deliverable items the selected Offeror will produce.

b. The selected Offerors must update, as required by the Department, and submit the detailed operational implementation schedule included in the proposals within ten (10) business days of the effective date of the Agreement.

Task 14: Turnover

Upon expiration or termination of the Agreement, the selected Offerors shall provide for a smooth and timely turnover of its services to the Department and its subsequent providers, as applicable. Specifically, the selected Offerors must:

a. Provide a final detailed turnover plan to be initiated four (4) months prior to the last day of the Agreement. Tasks and elements of tasks to be included in the turnover plan will be jointly identified by the Department’s Contract Administrator and the selected Offerors’ Project Managers.

b. Cooperate with the Department and supply the Department and its Providers and Contractors with all information required by the Department during the turnover process.

c. Pay all costs relating to the transfer of materials and responsibilities as a normal part of doing business with the Department.

IV-5. Reports and Project Control

The selected Offerors must continually monitor performance throughout the term of the agreements. The selected Offerors must establish and maintain a Department-approved system of records and reports for the Specialty Pharmacy Drug Program. Reports must provide accurate data and clear and concise narrative explanations. Reports should include charts and graphs to illustrate points. The Department will confer with the selected Offerors to determine Department-held data that the selected Offerors must routinely use to allow it to effectively meet its reporting obligations.

The selected Offerors must submit all specified reports electronically in Microsoft® Word™ or Microsoft Excel™ versions that are certified by Microsoft to be compatible with Windows 7.

In addition to the minimum reports and minimum content of those reports that the selected Offerors must submit to the Department as specified below, the selected Offerors must confer
with the Department to recommend additional reports or information that would be of use to the Department, and generate other relevant reports identified by the Department throughout the term of the agreements.

a. **Quarterly Status Report.** Beginning the week of the effective date of the agreements through the first three months of the statewide operation of the Specialty Pharmacy Drug Program, the selected Offerors must submit weekly status reports covering activities, problems and recommendations. During the first three (3) months of operation, the weekly status reports must also include the information outlined below. After the first three (3) months of operation, the selected Offerors must submit status reports with the information outlined below on a quarterly basis.

The initial quarterly reporting period will be from the Program Effective Date to the end of the calendar quarter in which the Program Effective Date occurs. After the initial reporting period, the selected Offerors will provide reports on a calendar quarter basis.

The status report must summarize all information for the reporting period and the year-to-date and provide analysis and commentary on the statistical data presented in the reports.

The status reports must include:

1. Therapy Management Statistics
   a) Adverse events
   b) Hemophilia-related information
      • The number of hemophilia patients being served as a percentage of the total number of MA recipients enrolled in the Offeror’s program
      • List of bleeds that required dispensing extra factor to control the bleed
      • Types of bleeds
      • Bleeds-related clinical interventions (Give specific examples with clinical and financial outcomes)
      • Dose assay management
         • MA Recipient Identification Number
         • Drug name
         • Ship date
         • Total quantity prescribed (in units)
         • Total quantity shipped (in units)
         • Variance in units
            o Variance %
         • Physician Name
         • Total assay variance
            o Variance %
         • Cost variance/savings
• MA Recipient Identification Number
• Ship date
• Projected cost for prescribed dose
• Total cost of units shipped
• Cost savings/variance
• Total cost variance
  o Cost variance %
c) Number and type of specialty provider clinical interventions
d) Description of examples of case studies with significant interventions and estimated savings
e) Hospitalizations
f) Emergency room visits
  • Avoidable and why
  • Not avoidable and why
g) Therapy compliance issues
h) Dispensing accuracy/dispensing errors
i) Number of medications delivered by “needs by” date
j) Medications possession ratio (MPR) by drug class (MPR is defined as the sum of the days' supply of medication divided by the number of days between the first fill and the last refill plus the days' supply of the last refill.)
k) Top 15 therapeutic classes
  • Therapeutic class
  • Total cost
    • A comparison to total cost in other state Medicaid programs and/or Medicaid MCOs for whom the selected Offeror provides specialty drugs
  • Average cost per prescription
    • A comparison to average cost per prescription for other state Medicaid programs and/or Medicaid MCOs for whom the selected Offeror provides specialty drugs
  • Number of fills
  • Percent of total cost
    • A comparison to the percent of total cost for other state Medicaid programs and/or Medicaid MCOs for whom the selected Offeror provides specialty drugs
  • Total cost change from previous calendar quarter
  • Total cost change from the same calendar quarter in the previous year
l) Top 20 drugs
  • Name of drug
  • Therapeutic class
  • Total cost
- A comparison to the total cost for other state Medicaid programs and/or Medicaid MCOs for whom the selected Offeror provides specialty drugs
- Average cost per prescription
  - A comparison to the average cost per prescription in other state Medicaid programs and/or Medicaid MCOs for whom the selected Offeror provides specialty drugs
- Number of fills
- Percent of total cost
  - A comparison to the percent of total cost for other state Medicaid programs and/or Medicaid MCOs for whom the selected Offeror provides specialty drugs
- Total cost change from previous calendar quarter
- Total cost change from the same calendar quarter in the previous year
m) Specialty patient demographics
n) Total prescription trend year-to-year
  - A comparison to the total prescription trend year-to-year for other state Medicaid programs and/or Medicaid MCOs for whom the selected Offeror provides specialty drugs
o) Total specialty utilization by drug, ranked by cost
p) Total specialty utilization by drug within therapeutic category (listed alphabetically)
q) Total specialty utilization by therapeutic category (ranked by cost)
r) Top 10 prescribers (ranked by total spend)
s) Number and description of delivery problems
t) List of MA recipients, names of the drugs, and the dates of the prescriptions that the selected Offeror was unable to process, including those where inventory supply did not allow for a prescription to be filled and required coordination with the other Contracted specialty pharmacy preferred provider to dispense the medication
u) Number of active MA recipients
v) Number of new MA recipients

2. Call Center performance statistics:
   a) Call abandonment rate
   b) Call waiting time
   c) Average speed for answering calls
   d) Percentage of calls answered in no more than 30 seconds or less
   e) Resolution during first call

3. Inquiry and complaint statistics:
   a) Number and type of inquiries and complaints from recipients
   b) Number and type of inquiries and complaints from providers
   c) Disposition or resolution of complaints and inquiries.
   d) Number of inquiries and complaints not responded to within the timeframe specified in the RFP.
4. Treatment Outcomes and Cost Savings of Therapy Management Programs - by specialty class of drugs or individual drug listed in Appendix D.
   a) Rate of adherence to treatment regimens
   b) Averted medical/pharmacy costs
   c) Attainment of treatment goals
5. Provide the prescribed medication in the dose ordered or, if inventory supply does not allow, coordinate with the other Contracted specialty pharmacy preferred provider to dispense the medication, and notify the prescriber or MA recipient who submitted the request for the prescription of the referral to the other Contracted specialty pharmacy provider.

b. Weekly Status Report.  List of MA recipients, names of the drugs, and the dates of the prescriptions that the selected Offeror was unable to process

c. Trigger Reports. The selected Offerors must submit to the Department a weekly report that identifies MA recipients who need immediate intervention. The Department’s pharmacy nurse case manager will provide feedback to the specialty pharmacy for follow up or will refer the MA recipient to the Department’s case management program. Reports must also list missed doses and the reason for the missed dose.

The following patients are currently referred to the Department through the Trigger Reports:
- Synagis patients
- Hemophilia patients reporting bleeds, central lines, joint damage, or pain
- Crohn’s Disease patients reporting flares or hospitalizations
- Multiple Sclerosis patients reporting depression symptoms
- Patients receiving long-acting injectable antipsychotics who have not received a scheduled dose
- HIV patients not compliant with therapy
- PAH patients not compliant with therapy
- Hepatitis B and C patients not compliant with therapy

The selected Offerors must identify to the Department all patients who would benefit from more intense care management and care coordination.

d. Ad Hoc Reports. The selected Offerors must develop and submit to the Department ad hoc reports, as requested by the Department. The Department will provide reasonable notice to the selected Offerors of the need for each ad hoc report. The selected Offerors must revise these reports, as requested by the Department.

e. Problem Identification Report. The selected Offerors must provide a report identifying problem areas on an “as required” basis, as determined by the Department. The report should describe the problem and its impact on the overall Specialty Pharmacy Drug Program and on each affected task. It should list possible courses of
action with advantages and disadvantages of each, and include the selected Offeror’s recommendations with supporting rationale.

f. **Ongoing Evaluation of the Specialty Pharmacy Drug Program.** The selected Offerors must participate with the Department and each other in the ongoing evaluation of the Specialty Pharmacy Drug Program, including partnering with the Department in developing an outcomes analysis of the Program. The selected Offerors must have the capability to receive, store, analyze and report on data sufficient to meet this requirement.

**IV-6. Monitoring, Performance Standards and Corrective Action Plans.**

a. **Department Monitoring.** The selected Offerors must cooperate with the Department when the Department monitors the selected Offerors’ performance.

During the first three (3) months of operation, the selected Offerors must hold weekly status meetings with the Department, or as otherwise directed by the Department. After the first three (3) months of operation, the selected Offerors must conduct, at a minimum, monthly status meetings with the Department, or as otherwise directed by the Department. The selected Offerors must develop the agenda and provide the agenda and status report to the Department at least three (3) business days prior to each meeting. The selected Offerors must record and prepare meeting minutes and provide minutes to the Department within five (5) business days after each meeting. The agenda and minutes are subject to the Department’s review and approval.

b. **Preferred Provider Monitoring.** The selected Offerors must monitor and report on their performance on an ongoing basis. See Section IV-5, Reports and Project Control, for reporting information.

c. **Performance Standards.** As part of the Department’s monitoring and evaluation, the Department will assess the selected Offerors’ performance according to the performance standards specified in Appendix I, Specialty Pharmacy Drug Program Performance Standards.

d. **Corrective Action Plans.** The Department will inform a selected Offeror when its performance does not comply with the agreement requirements. The selected Offerors must prepare and submit for Department approval a corrective action plan for each identified problem within the timeframe determined by the Department. The corrective action plan must include, but is not limited to:

i. Brief description of the Department’s findings.

ii. Specific steps the selected Offeror will take to correct the situation or reasons why it believes corrective action is not necessary.

iii. Name(s) and title(s) of responsible staff person(s).

iv. Timetable for performance of each corrective action step.
v. Monitoring the selected Offeror will perform to ensure that it takes the specified corrective action steps.

vi. Signature of a senior executive.

The selected Offerors must implement the corrective action plan within the timeframe specified by the Department. Failure by the selected Offeror to implement corrective action plans, as required by the Department, may result in further action by the Department.