

NYS SPECIALTY PHARMACY PROGRAM RFP
Questions & Answers - Set 3
January 21, 2009

The responses to questions included herein are the official responses by the State to questions posed by potential bidders and are hereby incorporated into the Request for Proposals (RFP) issued December 1, 2008. In the event of any conflict between the RFP and these responses, the requirements or information contained in these responses will prevail.

Q1. Will NYS accept any questions following the deadline?

A1. No.

Q2. If the bidder is unable to meet the Pass/Fail requirements, will the bidder be disqualified?

A2. Yes.

Q3. We are pursuing ACHC accreditation and hope to be fully accredited by July 2009; is this acceptable?

A3. Section E.5.a) pg. 43: This is a Pass/Fail requirement. The bidder must be accredited at the time of submitting its proposal.

Q4. When preparing answers to the RFP questions, do the actual questions need to precede the answers in the final version, or just the question numbers?

A4. Providing the section heading is sufficient.

Q5. Is the Letter of Transmittal the document in which the bidder should note any clarification or deviations to any of the requirements, attachments or appendices (i.e. Standard Clauses for all NYS contracts)? Or should the bidder submit a separate document outlining this information?

A5. The bidder should submit a separate document.

Q6. We are an out-of-state NY licensed pharmacy but have been denied enrollment as a NY Medicaid provider because we do not have a current brick and mortar location in NY. Are we eligible to participate in the Specialty Pharmacy Program?

A6. Yes; a NYS-licensed out-of-state pharmacy is eligible to enroll in New York Medicaid for the specific purpose of providing specialty pharmacy drugs through a contract with the NYS Specialty Pharmacy Program.

Q7. Is an out-of-state pharmacy eligible to enroll in NY Medicaid if covered services under the NYS Specialty Pharmacy are provided via mail order?

A7. Yes, a NYS licensed out-of-state pharmacy providing the majority of its services via mail order would be eligible to enroll in NY Medicaid for the specific purpose of providing specialty pharmacy drugs through a contract with NYS Specialty Pharmacy Program.

Q8. NYSDOH has a policy limiting reimbursement of out-of-state providers. Currently, the Medicaid "Information for All Providers - General Policy" sets out only 2 instances when an out-of-state provider will be reimbursed for services rendered to a NYS Medicaid enrollee. Will a specialty pharmacy, which fills some or all of its obligations from an out-of-state location, be reimbursed in situations other than the 2 limited instances described?

A8. Specialty pharmacies contracting through the NYS Specialty Pharmacy Program will serve as preferred providers for specialty drugs. The policy limiting reimbursement of out-of-state providers will not apply to specialty drugs provided through the NYS Specialty Pharmacy Program.

Q9. Can the specialty pharmacy continue to be an enrolled Medicaid provider at the termination of the contract?

A9. Pharmacies granted enrollment in the NY Medicaid program for the express purpose of the specialty pharmacy contract will need to re-apply for enrollment in NY Medicaid at the termination of the specialty pharmacy contract.

Q10. The specialty pharmacy must be a licensed pharmacy and wholesaler. Can NYS Specialty Pharmacy Procurement team comment on licensing requirements?

A10. No, the NYS Specialty Pharmacy Procurement team will not comment on licensing requirements. Questions regarding licensing requirements must be addressed to NYS Department of Education.

Q11. Please clarify the intent of NYS is to contract with three providers to provide specialty services, and not that each selected provider needs to enter into three contracts.

A11. The intent of NYS is to contract with three providers to provide select specialty pharmacy drugs.

Q12. The RFP states that NYS intends to enter into contracts with three specialty pharmacies. How does NYS plan to divide script volume between the pharmacies selected? Will eligible program participants have the option to choose which selected specialty pharmacy will fill their script(s)? In other words, will the three specialty pharmacy contractors be exclusive?

A12. NYS will NOT divide prescription volume between the selected specialty pharmacies. Medicaid enrollees retain their freedom of choice and will have the option to choose which specialty pharmacy they want to use to fill their specialty drug prescription(s).

Q13. NYS will be choosing three specialty pharmacy providers; how will a referral process work and how will NYS decide where the referrals will go?

A13. There will be no referral process; Medicaid enrollees retain their freedom of choice and will have the option to choose which specialty pharmacy they want to use to fill their specialty drug prescription(s).

Q14. Will the specialty medications be mandated to the three selected pharmacies?

A14. Yes; drugs on the specialty pharmacy drug list will only be available through the contracted specialty pharmacies for enrollees enrolled in FFS, MMC and FHP, unless an exclusion applies (see Section C.1c). Physician administered drugs only: These drugs are available to physicians, nurse practitioners and midwives as an option to the prescriber. Prescribers may use the specialty pharmacy or continue to buy and bill for their specialty drug needs.

Q15. Will the proposed services include or exclude retail pharmacies?

A15. Drugs and blood products listed in the RFP are exclusive to the three contracted specialty pharmacies and must be obtained through the Specialty Pharmacy Program.

Q16. Must a subcontractor be licensed as a New York State pharmacy and/or be enrolled in the NYS MA program as a pharmacy provider?

A16. Pg. 18, 5) Subcontracting. Yes. Each subcontractor must be licensed in NYS and must agree to comply with all NYS MA program requirements.

Q17. What level of “subcontracting” do we need to provide information?

A17. Section C.3.g) 5): Only those services within the scope of the RFP.

Q18. Our pharmacy utilizes another company for their home infusion nursing, would this be considered a “subcontracting” situation?

A18. Subcontracting only applies to services within the scope of the RFP. Nursing services are not included within the scope of this RFP. Covered nursing services are provided and billed on a fee-for-service basis by Medicaid enrolled providers and are not part of this RFP.

Q19. Are drugs provided by home infusion providers (specifically Synagis, IGG and Hemophilia Factor) included in the Specialty Pharmacy Program if they are provided by a home infusion provider?

A19. Drugs and blood products listed in the RFP are exclusive to the three contracted specialty pharmacies and must be obtained through the Specialty Pharmacy Program.

Q20. Is there an option for a home infusion provider to continue to provide both the drug and service components outside of the Specialty Pharmacy Program?

A20. The home infusion provider may continue to provide the service components but the drug must be obtained through the Specialty Pharmacy Program.

Q21. We have concerns regarding the timely, proper treatment of bleeding disorders, the need for ongoing education for patients with bleeding disorders, and the access to blood products for such patients. Would Medicaid consider exempting bleeding disorders from the RFP so pharmacies specializing in bleeding disorders can remain providers for Medicaid patients as long as they meet Medicaid established rates of reimbursement?

A21. The RFP specifically addresses the needs of the hemophilia population by requiring a special education program around managing the disease and requiring special blood product dispensing provisions (Section C.3.e); E.3.d)4)). Furthermore, the RFP requires that the contracted pharmacies have emergency procedures in place to provide specialty drugs, including blood products, or arrange for the provision of these specialty drugs, on an emergency basis (Section C.3.4). These procedures assure that patients have ready access to their medication if their prescriber determines that an immediate need exists. The contracted pharmacies are also required to provide educational information to the patient, as well as have a call center operational 24 hours/day, 7 days/week to respond to calls (Section C.3.c); C.3.i)1); E.3.d)4)). The patient's physician, as well as their care agency, remains available to also provide and reinforce educational information.

Q22. Would Medicaid consider amending the RFP so specialized pharmacies such as those for bleeding disorders can apply to continue providing service to Medicaid patients without requiring them to provide additional medications they don't already dispense?

A22. Based on the provisions in the RFP as referenced in response #10, the State believes the key concerns have been reasonably addressed in the RFP and an amendment to the RFP is not necessary.

Q23. Ribavirin usually ships with Peg Intron and Pegasys as an adjunctive therapy; however, Ribavirin is not on the specialty drug list. Can the selected specialty pharmacies be reimbursed if Ribavirin is dispensed to patients as an adjunctive drug to specialty hepatitis C drugs?

A23. Yes; covered adjunctive drugs are reimbursable.

Q24. Can the selected specialty pharmacies provide any drugs on the NYS Medicaid formulary and receive reimbursement?

A24. Yes. The selected pharmacy must enroll in the MA program as a pharmacy provider and can serve as both the preferred provider for specialty drugs and as a MA pharmacy provider. The selected pharmacy can dispense and submit claims through eMedNY for covered non-specialty drugs and be reimbursed at the standard Medicaid rate, as long as these products are provided in the same manner as required by the specialty pharmacy contract, i.e. signature required for delivery, no drop shipment of prescriptions, access to the 24/7 call center, etc., and will be subject to audit.

Q25. Does NYS have a limited days' supply program for any of the drugs on the specialty drug list? If so, what are the drugs and their respective limits?

A25. No, NYSDOH does not have a limited days' supply program. Drugs must be ordered in a quantity consistent with the health needs of the patient and sound medical practice.

Q26. Will the selected specialty pharmacies be able to bill per diem? How does NY Medicaid plan to reimburse providers for nursing services and ancillary equipment such as home infusion pumps and other non-standard supplies?

A26. Section C3.b) 1) Yes: Covered ancillary supplies, equipment and nursing services are provided and billed on a fee-for-service basis by Medicaid enrolled providers and is not part of this RFP. Medicaid enrolled providers of these services will submit claims through eMedNY online adjudication system. Fee schedules for Medicaid covered ancillary supplies, equipment and nursing services can be found at www.emedny.org/providermanuals/.

Q27. The New York State Medicaid program charges an enrollee a co-payment for most drugs and medical supply items dispensed from a pharmacy. Will the application and value of the co-pay be determined by the adjudicator or the specialty pharmacy?

A27. Providers must not reduce the amount charged on a Medicaid claim by the co-payment that is collected from a Medicaid enrollee. Each claim that requires a co-payment will have the co-payment automatically deducted from the final payment when the claim is approved for payment.

Further information can be found at:

http://www.emedny.org/ProviderManuals/Pharmacy/PDFS/Pharmacy_Policy_Guidelines.pdf

Q28. Will NYS provide the size of the exception population for co-pays as a percentage of the total enrollee population?

A28. No.

Q29. Bidders are asked to describe their policy and procedures for the procurement and storage of all products with short shelf-life and those requiring special handling. Is NYS looking for the bidder's standard procedures for the storage of all products with short shelf-life and/or special requirements? Does this question relate to storage within the bidder's facility once the specialty pharmacy has received the specialty drug product?

A29. Yes.

Q30. Will NYS perform prior authorizations?

A30. The prior authorization process will not change. For a description of prior authorization programs see Section B.1.a). Additional information can be found at <https://newyork.fhsc.com>.

Q31. Will dual-eligibles (individuals eligible for both Medicare and Medicaid) be required to get specialty pharmacy drugs from the contracted specialty pharmacies?

A31. Section C.1.b page 10: No; these individuals receive their primary prescription drug coverage through Medicare Part B and Part D and are excluded.

Q32. Can the enrollee get their first fill at retail pharmacy?

A32. No. First fills will be performed by the contracted specialty pharmacies

Q33. What will the message to the pharmacist at the retail pharmacy be if the specialty drug prescription is rejected?

A33. Claim will be denied and the pharmacy will receive the following message: non-SPP (Specialty Pharmacy Provider) billing for specialty drug.

Q34. Will NYS have the ability to accommodate data received through ePrescribing prior to the implementation date? What capacities are expected from the pharmacies under ePrescribing?

A34. No. The capacity to receive and accept prescriptions is as stated in Section C.d)1) pg.15.

Q35. Do supportive services (e.g., call center, data management, data housing, and coordination of nursing services) have to be performed in NYS?

A35. No. However supportive services must be located in the contiguous United States.

Q36. Define “emergency prescriptions and refills”.

A36. Emergency is defined as a medical or behavioral condition as determined by the prescriber or pharmacist, the onset of which is sudden, that manifests itself by symptoms of sufficient severity, including severe pain, and for which delay in beginning treatment prescribed by the patient’s health care provider would result in:

- a. placing the health or safety of the person afflicted with such condition or other person or persons in serious jeopardy;
- b. serious impairment to such person’s bodily functions;
- c. serious dysfunction of any bodily organ or part if such person;
- d. serious disfigurement of such person; or
- e. severe discomfort

Q37. Define “undeliverable”.

A37. An “undeliverable” prescription is any prescription that has been lost or damaged through distribution and delivery and any prescription where delivery has not been confirmed by signature of the enrollee, their designee, the provider or their designee.

Q38. Does NYS have an established criterion for determining resolution in first call?

A38. NYS will work with the selected pharmacies in developing a standard.

Q39. Is it acceptable to propose alternative Call Center performance standards based on the specialty pharmacy’s own systems and procedures/protocols?

A39. Alternative performance standards may be proposed as long as they, at minimum, meet or exceed the DOH standards as specified in the RFP listed in Section C. n) 3) pg 24 Performance Standards.

Q40. On page 38, question d) 1) a) V, we are asked to provide "Experience with physician offices, outpatient clinics, hospital discharge planners, in New York regions." We aren't clear what this question means in the context of contract relationships with manufacturers, wholesalers and distributors. Can you clarify?

A40. Explain your level of experience with any contractual relationship you have with physician offices, outpatient clinics, hospital discharge planners within the NY region.

Q41. Are there any performance guarantees that apply to hemophilia products only? Does NYS want bidders to propose such performances?

A41. The performance standards for all blood products and drugs can be found on Section C. n) 3) pg 24 Performance Standards

Q42. NYS requires final approval on all Policies and Procedures (P&P's). The pharmacy and accreditation requirements may make full compliance with NYS requirements impossible. Can we counter propose a deviation that states we will share our P&P's and discuss them to ensure that we are aligned with NYS's goals? Is this acceptable?

A42. Section C h) pg. 20: No. The State assures that it will not infringe on accreditation requirements; therefore, the specialty pharmacy is required to provide P&P's and the State will have final approval.

Q43. Although we have reviewed the RFP materials, we believe it possible that exceptions may be required based on NY's response to questions. Is it possible to state other exceptions with our response submission?

A43. Exceptions to the RFP proposal requirements should be noted within the bidder's proposal. The bidder's proposal will then be evaluated by the State accordingly. No exceptions will be made to any other sections of the RFP, including Method of Award, Administrative Information, and Attachments.

Q44. Will bidders be receiving detailed specialty claims data in order to more accurately price their respective bids?

A44. No. Bidders are provided utilization data in Attachment 2b and 2c.

Q45. The RFP states bidders must submit pricing for all drugs listed. What course of action should be taken by bidders in the event that a drug has an exclusive arrangement with a pharmacy and is unavailable to other pharmacies?

A45. Provide information as described in Section C.3.a) and provide the AWP -% discount in the Financial Response Form Attachment 6e.

Q46. Are all products to be quoted as AWP minus percentage?

A46. Yes

Q47. Are hemophilia products to be quoted as a discount of AWP and/or as per unit rate?

A47. They should be quoted at AWP minus %.

Q48. Will generic medications be paid out at AWP-25%?

A48. NYSDOH pharmacy reimbursement for generic equivalents to brand name drugs on the specialty pharmacy drug list will be the lower of contracted AWP discount, the federal upper limit (FUL), the estimated acquisition cost (EAC) of a drug to pharmacies, or the dispensing pharmacies usual and customary charged to the public. For more information about FUL, and EAC refer to Attachment 5, Pharmacy Reimbursement and Section C.1.c) pg.11.

Q49. Will the selected specialty pharmacies receive the generic specialty medication business?

A49. The list of specialty drugs will not be limited to the brand name products. When available the specialty pharmacy drug list will include all generic products with the same generic sequence number as brand products.

Q50. Is the generic utilization included in the SFY \$298 million of NYS specialty pharmacy spend? If so, can NYS break out the generic from the brand spend?

A50. Generic utilization found during the time period for the products on the specialty pharmacy drug list is provided.

Q51. Can bidders provide exception pricing for specific drugs that are exclusive or limited distribution (at discounts lower than 16.25%, provided that the aggregate pricing discounts 16.25% or greater)?

A51. No, bidding is for specific drugs and no aggregate pricing is allowed.

Q52. As a part of the financial offer that bidders submit to NYS for the Specialty Pharmacy Program, can bidders include additional standard performance guarantees to underline our commitment to providing quality service to NYS and its enrollees?

A52. No, the technical and financial proposals are evaluated separately. Any additional performance standards should be proposed in the technical portion of the proposal.

Q53. Are we required to bid on all items on the Bidder's Proposal Worksheet?

A53. Section C 2. pg. 12 and Section E 5. pg. 43: Yes.

Q54. The Bidder's Proposal Worksheet only allows a bidder to input one rate for all strengths and forms. Do we have the ability to offer different rates for different form/strengths for a particular drug?

A54. No.

Q55. What are the reimbursement rates for items not on the specialty drug list?

A55. Attachment 5 of the RFP explains NYS reimbursement methodology for drugs not on the specialty drug list.

Q56. How are new specialty drugs that are brought to the market added to the contract?

A56. See Section C.1.c) pg.11 and Section C.3.m) pg.23

Q57. What is the time frame for adding new drugs to the specialty drug list, and what are the pricing criteria for adding new drugs to the list?

A57. Section C1. c) Pg.11 and Section C3.m) pg.23

Q58. How does NYS intend to address the pending First Data Bank AWP litigation and the planned roll back of impacted NDC's?

A58. See Section C.1.c) pg.11.

Attachment 10 – Appendix A: Standard Clauses for NYS Contracts

Q59. We understand that the standard clauses that appear within Appendix 10 form the basis of any contract negotiated with the NYSDOH. Will additional language that relates specifically to the provision of specialty pharmacy services also be incorporated into the contract?

A59. No. Language incorporated into the contract relating specifically to the provision of specialty pharmacy services are contained within the RFP and the Questions and Answers.

Q60. Item 1- Executory Clause: We would like the NYSDOH to clarify the intent of this clause. In the event that the State of New York does not appropriate adequate funding to support the full cost of this Specialty Pharmacy Program as outlined in the RFP, does this mean that the NYSDOH will not pay the specialty pharmacy provider for any outstanding claims? What are the appropriate protocols for ensuring the health and safety of patients of life-sustaining specialty medications in those instances in which the NYSDOH does not have adequate funding or while the NYSDOH awaits monies to support the continuation of the program? How does the NYSDOH expect to bridge the gap in care for these patients? Is the NYSDOH asking the specialty pharmacy vendor to assume financial liability for these patients?

A60. The Specialty Pharmacy Program is not being supported through appropriated funds; selected pharmacies will bill Medicaid directly for specialty pharmacy drugs as Medicaid enrolled pharmacies.

Q61. Item 2 - Non-Assignment Clause: If work is performed by a wholly-owned subsidiary of the contractor (specialty pharmacy provider) is that considered a “subcontract” or “assignment” requiring prior written consent of the NYSDOH? Can our affiliates participate? What if our affiliate has different Medicaid number?

A61. Assignment is different from sub-contract. Assignment means you turn over the entire contract to another entity. Sub-contract means you contract with another entity (or subsidiary or affiliate) to perform a portion of the services for you.

You cannot assign this contract to another entity. However, you may subcontract with another entity, including an affiliate, subsidiary, etc., with prior consent of the State.

Q62. Item 3 - Comptroller’s Approval: How long will it take to obtain the comptroller’s signature and will the specialty pharmacy provider be expected to commence the program prior to receiving approval from the comptroller?

A62. The Comptroller has 90 days to review the contract, but generally approvals are received within 4 weeks. The specialty pharmacy provider will not commence the program prior to receiving approval from the Comptroller.

Q63. #10 requires the bidder to maintain records for 6 years, and there must be a “mutually agreeable and reasonable venue within New York... for the purpose of inspection, auditing and copying”. Is the intent/requirement to maintain records within the State of NY?

A63. It is the intent of the State to maintain records within the State of NY; however, the State acknowledges that for out-of-state providers, this presents a burden in light of conflicting pharmacy state laws which require dispensing records to remain with the dispensing pharmacy, etc. For those businesses with no offices or pharmacies within NYS, the State will allow such records to be maintained in the main offices of the Contractor's home state. All other requirements of section #10 apply.

Q64. Item 10 - Records: Does Public Disclosure only occur in conjunction with an audit or can we denote during the RFP and bid selection process those documents that the specialty pharmacy provider would like to protect as proprietary and confidential?

A64. After the contracts are approved, the contents of each of the bidder’s proposals shall be considered public information, with the exception of proprietary information identified by the bidder and approved by the State. If a bidder

believes that any information in its proposal constitutes a trade secret and wishes such information not to be disclosed if requested pursuant to the NYS Freedom of Information Law, Article 6 of the Public Officers Law, the bidder must submit a request for non-disclosure of trade secrets with its transmittal letter as outlined in the RFP in Section F, Administrative Information, 8. Disclosure of Proposal Contents. Any determination for withholding of material under the NYS Freedom of Information Law shall be made in the sole discretion of the Department.

Q65. Item 18 - Prohibition on Purchase of Tropical Hardwoods: Please clarify how this item is applicable to the services being requested as a part of the RFP process. Can this provision be intentionally omitted from the contract for specialty pharmacy services? Does this statement appear simply as a result of New York State Law, which requires that this provision appear within any and all contracts negotiated with any vendor regardless of services being provided?

A65. This is a NYS statutory requirement and cannot be omitted.

Q66. Item 19 – MacBride Fair Employment Principles: Please clarify how this item is applicable to the services being requested as a part of the RFP process. Can this provision be intentionally omitted from the contract for specialty pharmacy services? Does this statement appear simply as a result of New York State Law, which requires that this provision appear within any and all contracts negotiated with any vendor regardless of services being provided?

A66. This is a NYS statutory requirement and cannot be omitted.

Q67. Section 20 - Omnibus Procurement Act of 1992: What kinds of reasonable efforts is the NYSDOH looking for? Can you please provide additional clarification in the form of specific examples?

A67. Please check with the NYS Department of Economic Development for more information. The website address is www.empire.state.ny.us.

Q68. Item 22 – Purchase of Apparel: Please clarify how this item is applicable to the services being requested as a part of the RFP process. Can this provision be intentionally omitted from the contract for specialty pharmacy services? Does this statement appear simply as a result of New York State Law, which requires that this provision appear within any and all contracts negotiated with any vendor regardless of services being provided?

A68. This is a NYS statutory requirement and cannot be omitted.

Attachment 11 – Appendix D General Specifications

Q69. Item O - No Subcontracting: Can the specialty pharmacy provider subcontract with its own affiliated entities? What if these entities have separate Medicaid provider and tax ID numbers?

A69. Yes, the specialty pharmacy provider can subcontract with its own affiliated entities. Under the subcontract, the subcontractor would provide the service and bill the specialty pharmacy provider. The specialty pharmacy provider pays the subcontractor for the service, then bills to Medicaid.

Q70. Item R - Experience Requirements: This requirement states that “The Contractor shall submit evidence to the satisfaction of the Department that it possesses the necessary experience and qualifications to perform the type of services required under this contract and must show that it is currently performing similar services. The Contractor shall submit at least two references to substantiate these qualifications.” What is considered “evidence to the satisfaction”? Is this requirement be considered to be completed satisfactorily by responding to and submitting the information requested in Attachment 6a – TP Form-1 Summary of Corporate Experience and References?

A70. All evidence required to meet the experience requirements are being called for within the RFP proposal.

Q71. Item Z - Confidentiality Clauses (1): Can the NYSDOH provide an example of what is meant by “materials”? Does this relate to any marketing materials that the specialty pharmacy provider would use to help promote the use of the Specialty Pharmacy Program and appropriate patient use of the benefit that is in alignment with the objectives of the NYSDOH as opposed to documents and educational materials that we routinely send to patients to help ensure the proper use of medications and help prevent adverse events? Please provide an example of the types of documents that must contain the statement that appears within this item.

A71. Yes, this relates to marketing materials that the specialty pharmacy provider would use to promote the use of the Specialty Pharmacy Program and appropriate patient use of the benefit in alignment with the objectives of the NYSDOH.

Attachment 13 – Appendix H Health Insurance Portability and Accountability Act (HIPAA)

Q72. Page 28, 5.a.1- HIPPA Compliance/Confidentiality: Since we are a covered entity, we are already HIPPA compliant, and would not need to enter into the Business Associate Agreement (BAA). This requirement does not apply in this case. We would like to propose an exception to this in our response.

A72. The BAA is a required part of the contract, and no exceptions will be made.