

**NYS Medicaid Specialty Pharmacy Program
Questions and Answers**

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 August 31, 2009. In the event of any conflict between the RFP and these responses, the requirements or information contained in these responses will prevail.

Q1. Will 340B Hemophilia Treatment Center (HTC) factor programs be exempt from this RFP?

A1. Section C.1.b, Page 11: Yes. 340B Program Drugs that are billed through the 340B program are excluded from the Medicaid Specialty Pharmacy Program.

Q2. Please confirm if diabetic testing supplies will be covered in this procurement?

A2. No, diabetic testing supplies are not included in this RFP.

Q3. The numbering of pages for Attachment 3 Tables: Lists of Defined Specialty Drug Categories (ATT 3a), NY Medicaid Specialty Drug Utilization (ATT 3b), and Volume and Expenditures (ATT 3c) seems to be incorrect. Are pages 1 through 9 and 18 through 23 purposely omitted or is the RFP complete as is?

A3. Please disregard the numbering of pages for Attachment 3. The RFP is complete as issued. No pages have been omitted.

Q4. On page 28 of the RFP, the State has specified frequency of requested reports. However, it is not clear which reports are to be provided on a weekly, monthly, quarterly, or annual basis. Can you clarify?

A4. Section C.3.d, Page 28: Provides definitions for reporting time frames, and state expectations for reporting format. The frequency of reports has been outlined on Page 27: Sections C.3.a –Status Reports and C.3.b- Ad Hoc Reports.

Q5. On page 18 (2), we must resolve general inquires and complaints within 2 days from receipt. Does this apply to written, fax and oral?

A5. This requirement applies to all general inquiries and complaints.

Q6. On page 18 (3), How frequently does the issues and issues outcome report need to be provided?

A6. DOH will work with the selected pharmacies to develop a schedule.

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- Q7. Page 29, 7) Access to facility. As a practicing pharmacy engaged in the daily dispensing of advanced pharmaceuticals, free access to our facility during normal business hours may impede our ability to execute our regular business objectives. Is it acceptable to limit access to mutually agreeable timeframes and scope?**
- A7. NYS will work with the selected pharmacies to schedule access to facilities.
- Q8. Page 15: What is the State's definition for First Call resolution?**
- Q9. Section C. Detailed Specification, p. 15, par. 6: Does the DOH have established criteria for determining resolution in the first call or will the DOH work with the selected pharmacies in developing a standard?**
- A8. & A9. First call resolution is defined as properly addressing the provider or enrollees need the first time they call, thereby eliminating the need for the provider or enrollee to follow up with a second call.
- Q10. Page 17, item h. What are your expectations for training discharge planners, etc.? What is currently done to educate them?**
- A10. Section C.2.d.4.h, Page 17: Training related to distribution, delivery, handling and storage of specialty pharmacy drugs. DOH does not currently provide education to discharge planners.
- Q11. Under the Summary of Experience and References, it states that the bidders must complete form TP Form-1 for three (3) current or former clients who demonstrates the bidder's prior or current experience with the specific functions included in this RFP; and we will do so. Section 1), p.35**
However, in addition, in the last paragraph on p. 35, it states that the DOH is particularly interested in current or prior experience providing specialty pharmacy drugs and services for other Medicaid programs. If the bidder is presently providing similar services for any other state Medicaid programs, a TP Form-1, must be filled out for each State Medicaid program serviced. We plan to submit the 3 references stated above which may include a cross section of Medicaid and Commercial clients serviced; however, we service over 33 State Medicaid programs providing specialty pharmacy services at various levels of activity and patient count; do we need to provide a TP Form-1 for each of these 33 Medicaid clients?
- A11. Yes. Section F.2.c.1, Page 35.

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Q12. Is it allowable for us to use the TP Form-3 for the job descriptions for the Pharmacy Staff and Call Center Staff as required in 5) on p.37?

A12. It is not a requirement of the RFP, but it is allowable.

Q13. General thoughts regarding the format and page maximum requirements, it would be good to have some reasonable flexibility and clearer instructions on the guidelines for the answers; our goal is to provide a very good response with no risk of any pages being deleted and not considered due to being over limit; or for the risk of our response being viewed unfavorable due some technical interpretation as to the format.

A13. The proposal requirements in Section F will not be changed.

Q14. What is the current volume of specialty medications currently obtained by NYS Medicaid recipients from the Cystic Fibrosis Foundation's non-profit pharmacy?

A14. The DOH will not release specific provider information for purposes of this RFP.

Q15. The RFP states bidders are required to coordinate the provision of ancillary supplies, equipment, and nursing services. How does the DOH plan to reimburse providers for ancillary equipment such as home infusion pumps and other non-standard supplies? Some codes in question that don't appear on DME list on your website are K0445, E0779, A4222.

A15. Section C.2.b, Page 14: 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. Fee schedules for Medicaid covered ancillary supplies, equipment and nursing services can be found at <http://www.emedny.org/ProviderManuals/index.html>

Q16. Section B. Background, p. 8, par. 4: In the event a selected pharmacy receives an ineligibility notification from the Electronic Medicaid Eligibility Verification System (EMEVS) because the enrollee is on the Recipient Restriction Program, what communications should the pharmacy have with the enrollee to provide them an indication of denial of service?

A16. NYS will work with the selected pharmacies in developing a process to address restricted recipients.

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Q17. Section C. Detailed Specification, p. 9, par. 7: Are bidders expected to submit separate proposals for each of the categories (specialty products, cystic fibrosis, and human growth hormones)?

Q18. If bidders were to submit proposals for all categories, would bidders submit one proposal for specialty products, cystic fibrosis, and human growth hormones as well as complete Part III for Clotting Factor Products?

A17. & A18. One proposal may be submitted for all of the specialty drug categories. However, the bidder must indicate on the Cover Sheet (Attachment #1) each category they are proposing to provide. The submitted proposal will be reviewed individually for each category indicated by the bidder. Proposals for clotting factor products must complete Part III, in addition to Part I and Part II.

Q19. Section C. Detailed Specifications, p. 21, par. 7: Can the DOH further clarify “Direct Marketing” as it pertains to this RFP?

A19. Direct contact to the enrollee to solicit business is prohibited. Examples include, but are not limited to, flyers and telephone calls.

Q20. Section List of Specialty Drugs, p. 85: 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?

A20. Yes; covered adjunctive drugs are reimbursable.

Q21. Section List of Specialty Drugs, p. 85: Can the selected specialty pharmacies provide any drugs on the DOH Medicaid formulary and receive reimbursement?

A21. Yes. The selected pharmacies 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.

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Q22. Section List of Specialty Drugs, p. 85: Does the DOH 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?

A22. 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.

Q23. We are already in the process of being accredited by URAC and they are not listed as one of the three accreditations on the RFP. Are the three listed in the RFP the only ones that will be acceptable?

A23. Please see RFP Amendment #1. The DOH amended the list of acceptable accreditation entities and will accept URAC as a viable accrediting entity. A bidder that is fully accredited by URAC at the time of proposal submission will meet the accreditation requirement.

Q24. What is the process that will be followed to assign a recipient to one of the five specialty pharmacy providers that have been awarded the contract?

A24. Section C.1.a, Page 10: The DOH will not divide prescription volume between the selected specialty pharmacies nor will DOH provide specific data on enrollees currently utilizing specialty drugs. Medicaid enrollees retain their freedom of choice and will have the option to choose which specialty pharmacy(s) they want to use to fill their specialty drug prescription(s).

Q25. Section C. Detailed Specifications, p. 9, par. 3: The New York State Medicaid program charges an enrollee a co-payment for most drugs and medical supply items dispensed from a pharmacy: "Co-Payment policy, (including a description of those enrollees who are exempt from co-payments) and amounts can be found in Attachment 5" (9). Will the application and value of the co-pay be determined by the adjudicator or the specialty pharmacy?

A25. 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

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Q26. Can the NYSDOH confirm that the dispensing fees will remain \$3.50 for brand name claims and \$4.50 for generic drugs at the contract effective date?

A26. Medicaid pharmacy reimbursement and dispensing fees for prescription drugs is established in Section 367-a of NYS Social Services Law.

Q27. Residents in long term care facilities are often admitted to the facility under Medicare Part A, then switch to Medicaid or “pending” Medicaid billing after a designated time, and then may switch back to Part A again. Since this billing information changes so often and the long term care pharmacy is often not aware of the method of payment at the time of dispensing medication, how would one determine the correct billing for specialty drugs and which pharmacy can be used?

A27. Section C.1.c, Page 12: The selected pharmacy(s) will be required to submit claims for specialty drugs using the 11 digit National Drug Code (NDC) and National Council for Prescription Drug Program (NCPDP) format used by the Medicaid program at the time of submission. Claims must be submitted through the eMedNY online point-of-sale claims adjudication system, which will provide eligibility and copayment and reimbursement information.

Q28. We understand that patients will not be directed to any one provider. However, in order to determine appropriate staffing estimates, can you give us an estimate a Specialty provider may see, based on historical utilization?

Q29. How much was the drug expenditure for clotting factor products in the last 3 years?

A28 & A29. The expenditures for clotting factors products as well as the expenditures for specialty products, drugs for the treatment of cystic fibrosis, and human growth hormones are provided below. This material is provided for informational purposes only and is not a guarantee of performance or expenditures.

Pharmacy Expenditures for Clotting Factor Products

State Fiscal Year	Medicaid Paid Amount	Medicaid Claims	Beneficiaries
SFY07	24,654,659	1,250	108
SFY08	25,003,620	1,047	109
SFY09	34,854,889	1,236	126

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Pharmacy Expenditures for Specialty Products

State Fiscal Year	Medicaid Paid Amount	Medicaid Claims	Beneficiaries
SFY07	257,561,390	168,205	33,139
SFY08	251,078,945	152,356	27,785
SFY09	292,974,283	157,019	28,938

Pharmacy Expenditures for Drugs for Treatment of Cystic Fibrosis

State Fiscal Year	Medicaid Paid Amount	Medicaid Claims	Beneficiaries
SFY07	7,770,478	3,677	639
SFY08	7,914,336	3,587	625
SFY09	8,550,678	3,634	666

Pharmacy Expenditures for Human Growth Hormones

State Fiscal Year	Medicaid Paid Amount	Medicaid Claims	Beneficiaries
SFY07	33,128,963	8,376	1,532
SFY08	36,453,527	8,453	1,538
SFY09	40,578,846	8,477	1,575

Q30. Please confirm the number of beneficiaries that will require services?

A30. Attachment 3-Tables: See Attachment 3b NY Medicaid Specialty Drug Utilization and Attachment 3c Volume and Expenditures

Q31. Can you furnish utilization data based upon NDC, number of units dispensed, and zip code of patient?

A31. No.

Q32. Will selected pharmacy(s) receive a file of Physicians currently prescribing Specialty Medications for NYS Medicaid members? If so, when will selected pharmacy(s) receive the file?

A32. No.

Q33. Will the DOH release the NDC's of specialty medications related to your population's claim volume?

A33. No.

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Q34. Section H. Attachments, p. 81: Attachment 5 lists the co-pay exceptions categories. Can the DOH provide the size of the exception population as a percentage of the total enrollee population?

A34. No.

Q35. Will patients have the option of picking up the drug at an approved SP vendor or having it delivered to them?

A35. There is no requirement that the dispensing pharmacy be located in NYS or offer on-site pick up. However, if the dispensing pharmacy offers on-site pick up then the patient would have the option of picking up the drug or having it delivered to them.

Q36. The selected pharmacy (s) will be required to track the progress of the delivery, obtain a signature from the enrollee, a designated agent of the enrollee, or provider upon delivery, and make a contact with the enrollee or provider within 24 hours of post delivery date to confirm delivery. If we have delivery confirmation (signature of enrollee or their designee) from our delivery provider, do we still have to contact the enrollee within 24 hours to confirm (or reconfirm again) the delivery? Page 16, (3, b, II, iii)

A36. Yes. Contact within 24 hours of delivery is mandatory.

Q37. Currently, we do not universally impose a signature requirement on all shipments. Nor do we call post-fulfillment on all orders. Our concern is vendor delay; if the courier cannot acquire the recipient's signature, medication is generally shipped back to a central location, where it may spoil. Is it acceptable to ship with out signature requirement? Is it possible to pose a deviation from the phone call requirement?

A37. No. The requirement for signature at the time of delivery and a contact within 24 hours of delivery is mandatory.

Q38. Section C. Detailed Specifications, p. 16, par. 22: What process is in place if patient availability is confirmed, however, delivery of a specialty is not made to the patient because the patient is not at the specified location at the specified time? What process is in place for the DOH to reimburse the selected pharmacy?

A38. DOH will not reimburse for products that are not delivered.

Q39. We are able to bill Medicare Part D plans as a part of some of our contracts. Does that qualify as being enrolled in Medicare?

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A39. Section F.2, Page 33: No. A contract that includes participation in Medicare Part D plans does not meet the requirement for enrollment in Medicare. The bidder must be enrolled in Medicare at the time of proposal submission.

Q40. Could you tell me if you accept out-of-state specialty pharmacies as Medicaid providers for New York State?

Q41. Currently, New York Medicaid rules have an in-state brick and mortar requirement. Does this mean the new RFP continues to require pharmacy operations to be located in New York?

Q42. Does the dispensing pharmacy have to be located in the State of NY in order to receive reimbursement for all drugs in the program?

Q43. Section A. Introduction, p. 6, par. 1: Is an out-of-state pharmacy eligible to enroll in New York Medicaid if covered services under the NYS Specialty Pharmacy are provided via mail order?

A40.– A43. A New York State licensed out-of-state pharmacy is eligible to enroll in NY Medicaid for the specific purpose of providing specialty pharmacy drugs through a contract with the NYS Medicaid Specialty Pharmacy Program.

Q44. Does the provider need a physical location in New York?

A44. No, there is no requirement that the dispensing pharmacy be located in NYS.

Q45. 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?

A45. 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. Winning the bid will NOT automatically grant a pharmacy Medicaid provider status in the State of New York. Award of a contract is contingent upon meeting the Medicaid provider requirements and completed enrollment in the Medicaid program. A contract will not be executed if a pharmacy fails to enroll in Medicaid.

Q46. Is there a preference for a domestic business entity in NY Specialty Pharmacy Program?

A46. No.

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Q47. We would be interested in working with DOH in identifying a physical location in NY to distribute drugs and services to members that impact cost and outcome trends as a provider of SPP services. Are there underserved counties/cities that require a higher service level to reduce costs i.e. unnecessary hospitalization that you would suggest that we search for a site?

A47. DOH will not identify a location for a pharmacy. The pharmacy is required to provide services to enrollees across New York State.

Q48. The Pass/Fail Requirement, number 7, requires that the bidder be eligible to participate in the NYS Medicaid Program. Our pharmacy is not currently enrolled in the NYS Medicaid Program but we know of no reason why we shouldn't be eligible (we are contracted by approximately 30 Medicaid programs). How would we be graded on this pass/fail?

A48. Bidders that meet pass/fail requirements numbers 4, 5, and 6 stated in Section F, Method of Award, and are enrolled in Medicare will meet this pass/fail requirement.

Q49. Does the provider need to be enrolled in NYS Medicaid?

A49. Bidders do not need to be enrolled in the Medicaid program at the time of proposal submission, however, potential bidders must meet the requirements to enroll as a NYS Medicaid pharmacy provider at the time of proposal submission. The successful bidders will be required to enroll in the Medicaid program to receive a contract.

Q50. Is an out-of state pharmacy eligible to enroll in NY Medicaid if covered services under the NYS Specialty Pharmacy are provided via mail and the pharmacy indicates mail order and specialty pharmacy?

Q51. Would a NYS licensed out-of-state pharmacy, providing the majority of its services via mail order, be eligible to enroll in NY Medicaid for the specific purpose of providing specialty pharmacy drugs through a contract with NYS Specialty Pharmacy Program?

Q52. 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?

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Q53. Section A. Introduction, p. 6, par. 2: Is an out-of-state pharmacy eligible to enroll in New York Medicaid if providing more than 15% of the required covered services under the NYS Specialty Pharmacy Program is provided via mail order? If so, will the out-of-state pharmacy be reimbursed for services rendered to NYS Medicaid enrollees outside of the following circumstances: – The provider practices within the “common medical marketing area” of the enrollee's home LDSS as determined by the Local Professional Director – An emergency requires that the out-of-state provider render immediate care to an enrollee who is temporarily out-of-state.

A50.–A53. A NYS licensed out-of-state pharmacy providing services via mail would be eligible to enroll in NY Medicaid for the specific purpose of providing specialty pharmacy drugs through a contract with NYS Medicaid Specialty Pharmacy Program.

Q54. Residents of long term care facilities require different types of special packaging of medication. The facilities also require physician order forms and medication administration records reflecting all the resident's medication to be printed by the pharmacy for ordering and documentation purposes. Since this would not be possible for a separate specialty pharmacy to provide, would long term care residents be exempt?

A54. No. See Section C.1.b, Page 10: Medicaid Specialty Pharmacy Program Exclusions.

Q55. Could long term care residents be exempt?

A55. No. See Section C.1.b, Page 10: Medicaid Specialty Pharmacy Program Exclusions

Q56. Does a long term care pharmacy, that dispenses specialty drugs to its residents, qualify for the requirement of the bidder to be a specialty pharmacy with 5 years experience?

A56. Any pharmacy that meets all the requirements in the RFP would be eligible to participate in the NYS Medicaid Specialty Pharmacy program.

Q57. If a long term care pharmacy agrees to dispense specialty drugs, must the long term care pharmacy agree to dispense for all Medicaid enrollees, even if they are not residents of our contracted facilities?

A57. Specialty pharmacies contracting through the NYS Medicaid Specialty Pharmacy Program will serve as preferred providers for specialty drugs for all Medicaid enrollees.

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Q58. Is it mandatory that the drug be sent directly to a physician office or clinic for administration to the patient?

A58. Attachment 3a, Specialty Pharmacy Product List, Page 61-65: Drugs designated as “physician administered only” (denoted by asterisk*), are NOT eligible to be dispensed to the patient, and must be delivered directly to the prescriber for administration to the patient at the office.

Q59. Page 10, Physician Administered Drugs. Please provide a list of drugs that are available for physician administration.

A59. All drugs are eligible for physician administration.

Q60. Aside from Spanish, what other languages does the State anticipate for materials?

Q61. Section C. Detailed Specifications, p. 22, par. 13: Which alternate languages will be required for patient-directed communications? What will be the process for identifying languages for translation and notifying selected pharmacy(s) of the languages to be used for communications?

A60. & A61. Section C.2.i.3, Page 22: Spanish and English must be available. Enrollee materials must include taglines in other languages identified by the DOH and must be available in other languages upon request by DOH. DOH will work with contracted pharmacies to determine languages to be used.

Q62. Section C. Detailed Specifications, p. 16, par. 7: Which alternate languages will be required for prescription labels? What will be the process for identifying languages for translation and notifying selected pharmacy(s) of the languages to be used for prescription labels?

A62. Section C.2.d, Page 15: The selected pharmacy(s) must have the capacity to accept, dispense, and deliver patient-specific prescriptions for specialty pharmacy drugs in a manner that is responsive to both providers and enrollees. Alternate languages required would be based on the enrollees needs. As part of Section C.2.d.3, Process Prescriptions, Dispense Specialty Pharmacy Drugs and Submit Claims , the pharmacy should have the capacity and a process in place to identify enrollees with limited English proficiency on intake of prescription.

Q63. Page 22, Materials must meet a fourth grade reading level. Our materials are generally between 6th to 11th grade reading level. The very appearance of a medication name increases the reader’s grade

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level requirement. As a result, fourth grade reading level may reduce one's ability to describe treatment, etc. Is this acceptable?

A63. Section C.2.i.3, Page 22: Excluding the medication name, all materials must meet a fourth grade level whenever possible.

Q64. This question and the following questions pertain to the number of page numbers management for the various questions and required responses for the RFP. We understand the importance of staying within the page maximums, and the actions for not doing so. First question; on p. 36, for the General Operational Capacity and Experience sections d) 1) and 2), how many narrative pages are we allowed for the answer? There is no mention of the maximum.

A64. No page limit is imposed for this section.

Q65. This question pertains to the Part II of the proposal. This is where we are required to use TP Form-3 and TP Form-4; we are clear on when to use these forms – for the 4 key positions. However, we need to provide a narrative answer for 3. a) and b), p. 37 dealing with General Organizational Structure and Operations, and Personnel; how many pages are we allowed for an answer here?

A65. No page limit is imposed for this section.

Q66. Following the instructions dealing with TP Form-3 and TP Form-4, there is a requests for information in sections b) 3), 4) and 5), p. 37; how many pages are we allowed for the answers to 3) and 4)?

A66. No page limit is imposed for this section.

Q67. For the section 3. c), p. 37, Work Plan and Implementation Schedule, there is a required answer for our plans and such, but there is no mention of the number of pages allowed for the answer. How many pages are we allowed? The pages allowed for the Detailed Work Plan is clear, but the other sections were not.

A67. No page limit is imposed for this section. Where page limits are imposed, any excess pages will be removed and not scored.

Q68. For the Part I – Corporate Qualifications Response; start with section 2. a) 1), p. 33, it said we are allowed 3 pages maximum. This is not clear at all; do we have 3 pages for a) 1), and then 3 pages for 2), and then 3 pages for 3), and then 3 pages for 4)?

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A68. The 3 page maximum applies to the entire response for **Corporate Structure and Organization**

Q69. **Likewise, when we move to the Subcontractor section b) on page 34, there is no mention of the page maximum limits; how many pages are we allowed for subcontractors?**

A69. No page limit is imposed for this section.

Q70. **Can you tell me which pricing data base you are referencing for clotting factor products found in Attachment 6, Pharmacy Reimbursement, and Page 2?**

A70. Section C.1.c, Page 11: Medicaid currently utilizes a NY State established maximum allowable cost as the basis for reimbursement (Attachment 6). Attachment 6, Page 2: Pharmacy reimbursement for clotting factor products under the New York State Medicaid program currently utilizes a New York State established maximum allowable cost.

Q71. **Will the RFP be using AWP-%, or another methodology for the hemophilia (clotting factor) products?**

A71. Section C.1.c, Page 11: The bidders must agree to a fixed contracted guaranteed discount off AWP for **each** distinct clotting factor product covered under the scope of this RFP, as specified in Attachment 7e Defined Specialty Drug Category Reimbursement.

Q72. **Per the recent litigation settled with FDB, they will not be referencing AWP's as of Sept. 26, 2009. They will be using Red Book pricing. Will your RFP be updated to use Red Book numbers?**

Q73. **What reimbursement methodology do you plan to use as a result of the First Data Bank AWP settlement?**

Q74. **Is the baseline AWP discount provided in the current RFP applicable to the program at the time the program begins or have you adjusted the discount to reflect the settlement?**

Q75. **Are the discount rates noted in the RFP going to be adjusted for the 4% reduction in AWP effective 9/26/09?**

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Q76. Section B. Background, p. 8, par. 8: How does the DOH intend to address the pending First DataBank AWP litigation and the planned rollback of impacted AWP NDCs?

Q77. Attachment 7e: Will the AWP discounts outlined in attachment 7e be adjusted to account for the FDB AWP settlement?

Q78. Section c) Specialty Pharmacy Reimbursement, Page 12, Paragraph 2 -----Given that AWP changes have gone into effect as of Sept. 26, 2009 (lowering rates approximately 2%), does the DOH propose to make a modification prior to the award to reflect consistent margins prior and post the AWP change? Any other clarifying information on the reimbursement rates would be appreciated.

A72.– A78. Section C.1.c, Page 12. The DOH continues to use First DataBank as its source of AWP and there have been no changes to reimbursement methodology.

Q79. Are all drugs listed in attachment 3A and 3B included in the required pricing methodology?

A79. Attachment 3A contains the lists of drugs included in each defined specialty drug category, specialty drug products, cystic fibrosis products, human growth hormone products, and clotting factor products. Section C.1.c, page 11: Each distinct pricing methodology applies to the products in the corresponding drug product list.

Attachment 3B provides drug utilization for all products.

Q80. Would the state consider any exceptions by drug to the 18.5% reimbursement rate on specialty drugs, human growth hormone, or cystic fibrosis drugs?

Q81. The proposed reimbursement levels may result in medications that are dispensed at or below the pharmacy's cost. Will there be a process in place to address this?

A80. & A81. No. Section C.5, Page 42: This is a Pass/Fail requirement. The bidder must agree to the single fixed contracted guaranteed discounts off of Average Wholesale Price (AWP) for each defined specialty drug category that the bidder is proposing to provide.

Q82. In terms of reimbursement, how will the State address new medications as they come to market?

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A82. Section C.1.c, Page 11: Specialty pharmacy reimbursement for each defined specialty drug category under the scope of this RFP, including but not limited to drugs listed in Attachment 3a, and for all product updates made by DOH will be applied.

Q83. Please comment on S 6146 legislation as it pertains to reimbursement. It appears that reimbursement is moving over to a WAC methodology. How will this affect the Specialty Pharmacy RFP?

A83. DOH will not comment on proposed legislative changes.

Q84. In the RFP, for Hemophilia products, an AWP - % is referenced for each product. What will be the reimbursement methodology be for the Hemophilia products?

A84. Section C.1.c, Page 11: The bidders must agree to a fixed contracted guaranteed discount off AWP for **each** distinct clotting factor product covered under the scope of this RFP, as specified in Attachment 7e Defined Specialty Drug Category Reimbursement.

Q85. Is the Project Manager to be dedicated only to the State? i.e., the Project Manager only has one account, this specialty program.

Q86. Please expand on the statement “The RFP requires that a dedicated Project Manager be employed solely to conduct the Medicaid Specialty Pharmacy Program contract management activities”. Page 18, (g)

Q87. Section 2. General Tasks, g) Staffing Requirements, Page 18, Paragraph 2 -----The RFP specifies that a Project Manager be “employed solely to conduct the SP contract management activities.” Especially with multiple vendors, does the DOH still require that the project manager be SOLELY dedicated to the contract, or, can the project manager also support other clients?

A85.- A87. Section C.2.g.6, Page 19: The Project Manager will serve as the primary contact person for the DOH and is dedicated solely to overseeing and managing the selected specialty pharmacy’s contract responsibilities.

Q88. Page 16. Ratio of pharmacists to technician. What is the State’s definition of a technician?

A88. The DOH will not comment on NYS Department of Education definitions. This must be addressed to NYS Department of Education, Office of the Professions.

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Q89. Can the Project Manager and the Clinical Care Coordinator be the same person? Page 19, (6 & 9)

A89. No. Section C.2.g, Page 18: The RFP requires that a dedicated Project Manager be employed solely to conduct the Medicaid Specialty Pharmacy Program contract management activities.

Q90. If a vendor has 2 facilities must each have a pharmacist in charge for NYS or will one be adequate to cover all facilities?

A90. A supervising pharmacist must be on staff at each location. Only one clinical pharmacist is required for all facilities. The selected vendors must maintain staffing patterns that are in compliance with New York State laws, rules and regulations.

Q91. Subcontractors section in b) 1) – 7) p. 34; please define some of the subcontractors that would fall into this list. Our company does and will perform all the patient care, call center, pharmacy, clinical, and other activities by our employees; we utilize FedEx and UPS for delivery services, some PRN nurses for training, and retain an IT firm for some support in that specific area. Will you require all seven items in this section for these type subcontractor arrangements? Please explain in more detail.

A91. Detailed information for subcontractors providing direct patient care services included in the scope of the RFP must be provided.

Q92. b) Subcontractors, page 34: There are certain businesses functions that a vendor may outsource that do not pertain directly to the services provided as a specialty pharmacy or that pertain to coordination of services. An example of such functions would include collaborating with a printing vendor for brochures and communications materials that are developed for patients and physicians. We assume that the subcontracting provisions do not apply to coordination of services or outsourcing of the services that do not pertain directly to the services we provide as a specialty pharmacy. We also assume that operations performed by a parent or subsidiary company on behalf of our company would not be classified as a subcontracted relationship. Please confirm

A92. Detailed information only needs to be provided for subcontractors providing direct patient care services included in the scope of the RFP. Subcontracting agreements will be required from separately incorporated entities.

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Q93. Page 26, Transition, item 3) must be willing to pay the cost to transition materials and responsibilities to new vendor. What costs are associated with such transition? Is this known?

A93. Section C.2.r.3, Page 26. These costs would be predicated on the transition plan provided, the number of enrollees served at the end of the contract, and the number of categories of drugs provided.

Q94. Section 2. General Tasks, r Transition, Page 26: Since there will likely be multiple vendors in the various categories, does the DOH accept that any transition plan is contingent upon selection by the enrollee and that any prospective transition planning is therefore not possible?

A94. Section C.2.r, Page 26: A transition plan is required. These costs would be predicated on the transition plan provided, the number of enrollees served at the end of the contract, and the number of categories of drugs provided.

Q95. May we counter propose language for performance standards and contract terms and conditions with our bid as part of an “Exceptions” section?

A95. No exceptions to performance standards and contract terms and conditions will be allowed.

Q96. F. Proposal Requirements, Page 32: The State has requested that the proposal be consecutively numbered; however, some exhibits that the State is requesting might be difficult to number. For example, communication materials such as a brochure or an annual report that already have numbered pages. Can you provide direction as to how to deal with these types of situations?

A96. Any exhibits, annual reports, or communication materials such as a brochure do not have to be re-numbered.

Q97. Vendor Responsibility III. Contract History- Questionnaire With regard to question 4.5., we would like further clarification on the information requested within this particular question. There are numerous instances in which we have selected to decline to bid an opportunity following the execution of intent to bid documentation. This question is fairly broad. Can NYSDOH please clarify the intent of this question to help us better provide the information requested?

A97. This question addresses withdrawing a bid **submitted** to a government entity **in lieu** of responding to an information request or subsequent to a

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Q98. VIII. Leadership Integrity Can NYSDOH please define what a “Business Entity Leader” is?

A98. A Business Entity Leader is defined as an officer, general partner, managing partner, and manager of an LLC, and/or director.

Q99. Appendix H: Under the Federal Health Insurance Portability and Accountability Act, our company would be considered a covered entity based on the relationship that we would enter into as a contracted entity for the services requested by the NYSDOH. Can NYSDOH please clarify its intention for selected bidders to complete a Business Associate Agreement?

A99. The Business Associate Agreement will be incorporated into the resulting contract as Appendix H.

Q100. Section G. Administrative, p.50, par 1-4: The RFP requirement regarding M/WBE Utilization requires the M/WBE Subcontracting amount be “stated in total dollars and as a percent of the total cost necessary to fulfill the RFP requirement.” Does total cost to fulfill only include the cost of administration, expenses, and services necessary to fulfill the contract? Please confirm that the “total cost to fulfill” does not include drug costs.

A100. The “total cost to fulfill” only includes the cost incurred by the selected contractor to fulfill the requirements of this RFP and does not include the drug costs.

Q101. Section G. Administrative, p. 50, par. 2: Can the DOH further clarify the definition of “contract activities” as it pertains to this requirement?

A101. Any activities that are conducted under the scope of this RFP.

Q102. In reviewing attachments 14 and 15 for Forms A and B, there appears to be conflicting instructions regarding these forms. For form A, it states that this report must be completed before work begins on a contract. But, then it states that typically, it is completed as a part of the original bid proposal. So, which do we do – submit prior to the work on the contract begins, or with the original bid? See attachments 14 and 15, Forms and instructions for Forms A and B.

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Furthermore, please provide some examples of the type of situation in which these forms would be required; most all of the work on this contract will be done with our employees aside for delivery services, a few PRN nurses for training, and some IT services.

A102. For purposes of responding to this RFP, Forms A and B are not required.

Q103. Can we request that our entire bid proposal be considered a “trade secret” to prevent it from becoming public information after the contract is approved? Page 46-47, (8).

A103. No. The Department does not except blanket trade secret claims by a commercial entity. Any person may request a record maintained by the Department and unless exempt from release in accordance with the New York Public Officers Law the record may be released by the Department. The New York Public Officers Law (POL) Section 87.2(d) authorizes an agency to withhold access to a record or portion thereof if the content is a trade secret.

The Department when reviewing a submitted record which may require trade secret protection determines whether disclosing the record or portion thereof would cause substantial injury to the competitive position of the commercial enterprise. Several factors are considered in determining if a trade secret claim is valid including: (1) the extend to which the information is known outside the business; (2) the extend to which it is known by a business' employee and other involved in the business; (3) the extent of the measures taken by a business and to its competitors to guard the secrecy of the information; (4) the value of the information to a business and to its competitors; (5) the amount of effort or money expended by a business in developing the information; and (6) the ease or difficulty with which the information could be properly acquired or duplicated by others. A commercial entity submitting records to the Department must be prepared to justify in detail their trade secret claims upon inquiry by the Department. A request for trade secret protection should be kept to a minimum based on the attendant circumstances and upon submission of materials the portion of the record containing a trade secret should be clearly marked as proprietary or trade secret.

Q104. Would you consider the addition of VIVITROL onto the “Specialty Pharmacy Drug List.

A104. No. The list of drugs for the NYS Medicaid Specialty Pharmacy Program has been finalized. However, as stated in the RFP, Section C.2.m, Page 24, DOH reserves the right to continually update the list of specialty drugs.