

**ADDENDUM #3 To ODJFS Diabetic Supplies and Rebate Program RFP#
JFS- R-1213-07-8035, Amended Timeline and Final Question and Answers
July 31, 2012**

2.1 Updated Procurement Timetable

ORIGINAL DATE	REVISED DATE	EVENT/ACTIVITY
July 2, 2012	NO CHANGE	ODJFS Releases RFP to Potential Manufacturers on DAS/ODJFS Web Sites; Q&A Period Opens - RFP becomes active - Manufacturers may submit inquiries for RFP clarification
July 16, 2012	NO CHANGE	Manufacturer Q&A Period Closes, 8 a.m. (for inquiries for RFP Clarification) - No further inquiries for RFP clarification will be accepted
July 19, 2012	JULY 31, 2012	ODJFS provides Final Manufacturer Question & Answer Document (estimated)
August 2, 2012	AUGUST 15, 2012	Deadline for Manufacturers to Submit Proposals to ODJFS (3 p.m.) - This is the proposal opening date, beginning the ODJFS process of proposal review LATE PROPOSALS WILL NOT BE CONSIDERED. THERE WILL BE NO EXCEPTIONS MADE.
August 30, 2012	SEPTEMBER 4, 2012 (ESTIMATED)	ODJFS Issues Contract Award Notification Letter (ESTIMATED) - Manufacturers that submitted proposals in response to this RFP will be sent letters stating whether their proposal was accepted for award of the contract
November 1, 2012	NO CHANGE	Implementation* (estimated-effective date of OAC 5101:3-9-02 as amended).

This concludes Addendum #1 to ODJFS RFP#: JFS-R-1213-07-8035

VENDOR QUESTIONS AND ANSWERS
Diabetic Supplies and Rebate Program
R-1213-07-8035
Q & A period: July 2, 2012-July 16, 2012

Final Question and Answer Document

FINAL

July 8, 2012 (Date of Inquiry)

Chris Metcalf

LifeScan

Inquiry Number: 25925

Q1. Page 36 of 37. Section 8.18 Mandatory Disclosures of Governmental Investigations. Question: What is meant by "adverse regulatory or adverse administrative governmental action?" These are very broad statements. Can manufacturers apply the standards under the Federal Awardee Performance Integrity & Information system, which defines these terms and applies a 5-year time frame?

A1. A company may be adversely affected by judgments, settlements, unanticipated costs or other effects of legal and administrative proceedings now pending or that may be instituted in the future, or from investigations by regulatory bodies or administrative agencies. An adverse outcome might result in administrative or civil proceedings, sanctions and the payment of fines and penalties.

July 9, 2012 (Date of Inquiry)

Aaron Vincent

ARKRAY USA

Inquiry Number: 25930

Q2. Question regarding Section 4.2 (Number of Participants) on page 14 of the RFP document.

Could you please share what number or percentage of the population of 250,000 are diabetic? How many of this group are currently using diabetic supplies?

A2. Between November 1, 2011, and April 30, 2012, 8,635 unique patients received blood glucose test strips through Ohio Medicaid. Approximately 29,000 consumers covered under this program have diabetes.

July 9, 2012 (Date of Inquiry)

Aaron Vincent

ARKRAY USA

Inquiry Number: 25932

Q3. Clarification question in regards to Section 4.4D, Rebates on Page 17. In regards to GNUP for diabetic test strips - the document states that test strips and lancets must have a consistent GNUP across package sizes and product types (e.g. all glucose test strips).

To clarify, does this mean that two different test strip products must have the same GNUP for a bottle of 50 strips, even if they use different meter platforms and test strip chemistry?

A3. Correct, all blood glucose test strips must have the same GNUP. If the meter uses strips to test for blood ketones or other functions, the GNUP for those strips may be different.

July 9, 2012 (Date of Inquiry)

Aaron Vincent
ARKRAY USA

Inquiry Number: 25936

Q4. Clarification question regarding Section 5.2 (C), Cost Proposal on Page 25 and Section 4.4 (D), Rebates on Page 17. This section states that once the rebate contracts are in place, reimbursement will change to the formula WAC + 7%. Manufacturers will then be invoiced for a rebate that is reimbursement (WAC + 7%) minus the GNUP. Three questions:

1) Is a dispensing fee also included in this reimbursement, and if so, is the dispensing fee going to be factored/included in the rebate?

A4. No dispensing fee is paid for diabetic supplies.

Q5. 2) Meters are expected to be GNUP = \$0.00. In some business relationships with pharmacies, we have provided free meters to the pharmacies. Usually when this occurs, the pharmacy can not submit the meter for reimbursement. Would ODJFS reimburse a pharmacy for a meter the pharmacy received for free? If so, would a rebate be expected from the manufacturer? Or is the expectation that pharmacies will always pay for meters?

A5. Medicaid providers are not permitted to bill for free goods, so no payment will be made or rebate invoiced.

Q6. 3) The RFP states the reimbursement rate of WAC + 7%. What expectations are there as far as whether this reimbursement rate might be increased/adjusted in the future? Accordingly, what notice would we receive as manufacturers?

A6. The pricing methodology is in Ohio Administrative Code and any changes to the methodology would fall under the rulemaking process. Any changes will be communicated to the selected manufacturer(s).

July 10, 2012 (Date of Inquiry)

Aaron Vincent
ARKRAY USA

Inquiry Number: 25936

Q7. Clarification question regarding Section 3.1, Mandatory Manufacturer Qualifications on Page 8: Regarding Part C - the financial audit requirement. Would a compiled financial statement/compilation report be satisfactory?

A7. No, ODJFS wants an independent audit of the current or previous year's financials.

July 12, 2012 (Date of Inquiry)

Rashelle Mason

Roche Diagnostics

Inquiry Number: 25966

Q8. (page 31, section 8.2) Can we have an opportunity to request to present our product portfolio to the P&T committee? If yes, what is the process and timeline?

A8. ODJFS anticipates that the contract award notification letter(s) will be sent to the selected manufacturer(s) prior to the next P & T Committee meeting in mid-October. If the state deems it necessary, clinical presentations will be scheduled with state staff.

Inquiry Number: 25967

Q9. (page 18 section E.1.A.2) It the .3 microliter sample of blood mandatory or just preferred, please elaborate?

A9. The .3 microliter sample of blood is mandatory for at least one meter proposed.

Inquiry Number: 25968

Q10. (page 18 section E.1.A.3) Is it a requirement to have at least one meter with a result time in less than 5 seconds?

A10. Yes, it is a requirement.

Inquiry Number: 25969

Q11. (page 3 Fiscal Soundness) Please explain the reason for the performance bond of 5%.

A11. The selected manufacturer must be in compliance with IRS and state and local regulations, and with no currently outstanding audit findings by these regulatory authorities as related to these processes. The provision of a 5% performance bond would indicate the vendor's fiscal soundness. The bond also ensures that in the event of vendor default the state would be able to use the bond to cover costs of finding a replacement vendor.

Inquiry Number: 25970

Q12. (page 5 and page 13 timeline) The timelines identified on these 2 pages are different, which one is correct?

A12. The timeline in Section 2.1 is correct, anticipating a start date of November 1. However, please refer to the updated timeline.

July 12, 2012 (Date of Inquiry)

Rashelle Mason

Roche Diagnostics

Inquiry Number: 25971

Q13. (page 8 sec 3.1.A) Please elaborate on 10 years experience, what type of experience are you looking for regarding activities?

A13. As stated in Section 3.1, manufacturers must have a minimum of 10 years experience in manufacturing or distributing diabetic supplies for the retail pharmacy and/or hospital market. Other required qualifications are described in Section 3.2.

Inquiry Number: 25972

Q14. (page 23 section G) Availability through retail and mail order pharmacies, what type of mail order pharmacies are you referring to? National DMEs? Can you give us some examples?

A14. The manufacturer's products should be available through all pharmacies participating with Ohio Medicaid that would like to provide diabetic supplies. The manufacturer must not require a limited distribution network.

Inquiry Number: 25973

Q15. (Attachment D) Will you be sending over Attachment D in an excel file for us to save to a CD?

A15. All documents posted to ODJFS' web page must be in PDF format. Please print Attachment D and fill in.

Inquiry Number: 25974

Q16. (page 16 section A) in regards to Marketing and Outreach, will ODJFS be willing to provide a list of their pharmacy providers including chain drug and independent pharmacies?

A16. Yes.

Rashelle Mason

Roche Diagnostics

Inquiry Number: 25975

Q17. (page 20 section F) In regards to Customer Service, Does ODJFS expect the Manufacturer to provide a dedicated customer line for Ohio Medicaid beneficiaries?

A17. No.

Inquiry Number: 25976

Q18. (page 16 section A) In regards to the educational materials, is it a requirement of offer educational material in Somali? If so, can you provide estimates of the size of the Somali speaking Medicaid populations?

A18. Yes, materials must be provided in English, Spanish and Somali. We cannot provide data at this time on the size of the Somali-speaking Medicaid population, but according to ODJFS' Refugee Services Section, 4335 Somali refugees have been resettled in Ohio in the last seven years, but this does not include Somali immigrants or Somali refugees who moved to Ohio from other states. As refugees, they are generally eligible for Medicaid for their first seven years in the U.S. If they become U.S. citizens or Lawful Permanent residents with 40 qualifying work quarters, they may receive Medicaid beyond their seven year limit.

July 12, 2012 (Date of Inquiry)

Rashelle Mason

Roche Diagnostics

Inquiry Number: 25977

Q19. (page 16 and section A) In regards to the technology and information delivery systems is it required to use formulary flash through Epocrates?

A19. This section gives examples of the marketing and outreach that ODJFS will require of the manufacturer. ODJFS will work with the selected manufacturer(s) to determine the exact marketing strategies.

Inquiry Number: 25978

Q20. (Attachment A.3.A) Does the Vendor Ohio Administrative Knowledge Systems (OAKS) apply to us and if yes, how? Please explain

A20. It is a requirement for all companies for which the State of Ohio does business.

Inquiry Number: 25979

Q22. (page 17 section D) What data is included in the states quarterly invoice? Rx level detail? Sent electronically in an Excel format?

A22. The data elements identified in Section 4.4.D. will be provided in the aggregate quarterly, similar to invoices for Medicaid drug rebates specified by CMS. The invoice will be in PDF format. In the event of rebate invoice disputes, ODJFS will provide claim-level detail in a format to be agreed upon by ODJFS and the manufacturer.

Inquiry Number: 25980

Q23. (page 17 section D) How does the manufacturer reimburse the state for rebate payments, via check or EFT wire?

A23. ODJFS can accept payments through either process.

Inquiry Number: 25981

Q24. (page 16 section A) How will ODJFS communicate to providers the Medicaid beneficiaries the preferred brand(s) in the program? For example, mailing? email communication?

A24. ODJFS will communicate information through the ODJFS website, provider communications and professional associations.

Inquiry Number: 25982

Q25. (page 9 section 3.2.A.3) In regards to our experience processing at least 500,000 transactions per year from order to product delivery. This question appears to be aimed at manufacturers that ship directly to the end consumer. Since we use retailers and DMEs to distribute our products we dont come close to filling 500k transactions per year. We have over 2 million consumers using ACCU-CHEK products but we do not process transactions for these customers. Most if not all Manufacturers of blood glucose testing supplies do not deliver direct to the consumer. Can you please explain the order to product delievery you are looking for?

A25. RFP Applicants should submit specific information that is most relevant to any distribution method that they currently utilize for their products. This information should clearly articulate the Applicant's distribution chain direct to consumer, distributor or any combination thereof.

July 13, 2012 (Date of Inquiry)

Glenda Schwem

Abbott Diabetes Care

Inquiry Number: 25994

Q26. This question references the Implementation Date of any awarded contract, the heading is entitled 2.1 Anticipated Procurement Timetable: The table states that any awarded contract will be implemented November 1, 2012. This appears to be different than stated later in the RFP. [4.3 Objectives and Administrative Structures, Milestones subsection, page 13] The Milestones states the PDSRB begins Sept 15, 2012 and that Ohio will require prior authorization for non-preferred products on October 1, 2012. What will be the start date of the awarded contract(s)? What date does the State expect

Manufacturers to use for the State's rebate eligibility? Will the State allow Medicaid recipients to use grandfathered manufacturer's product (a Manufacturer that is not selected as a Preferred Manufacturer)?

A26. The anticipated start date of the contract is November 1. The contract will specify the actual start date. ODJFS will allow a transition period of approximately one month.

Inquiry Number: 25995

Q27. This question references call center locations, the heading is entitled 4.4(F) Customer Support and Call Center Services, and is listed on page 20: Is it an automatic elimination from the RFP if a Call Center is located outside of the USA? Or is it an item that may not disqualify a Manufacturer but may not receive top scores?

A27. Page 20 of the RFP states that the customer support and call center services must be located within the United States; therefore, a vendor would be eliminated if the call center is not located within the United States.

Inquiry Number: 25996

Q28. This question references the mandatory requirement of 10 years in manufacturing diabetic supplies, the heading is entitled 3.1(A) Mandatory Manufacturer Qualifications: May the Manufacturer simply state in their proposal that they meet the requirement of having 10 years experience in manufacturing diabetic supplies? If not, please specify the exact type of documentation the State is requesting for this portion of the RFP.

A28. Yes. Additional information is required in Section 3.2 Organizational Experience and Capabilities.

Inquiry Number: 25997

Q29. This question references the minimum requirement of 3 years in providing rebates to health care plans, the heading is entitled 3.1(B) Mandatory Manufacturer Qualifications: For Manufacturers that have ten years of experience in diabetic supplies, it would be onerous to list every single contract executed. It would be onerous to list every currently active contract. There could also be confidentiality issues involved so the Manufacturer will have to contact their customer and obtain permission to disclose the contractual relationship. May the Manufacturer simply state in their proposal that they meet the requirement of having the minimum three years experience in providing rebates and list a few of the contracts that have been active for more than 12 months?

A29. Yes. Representations made in the proposal will be verified.

July 13, 2012 (Date of Inquiry)

Inquiry Number: 25998

Q30. May the Manufacturer simply explain in their proposal how their order processing system works and how products are distributed through various channels? Does the explanation need to be specific to Ohio? What type of documentation does the State wish to see?

A30. The explanation does not need to be specific to Ohio unless there are features unique to Ohio.

July 13, 2012 (Date of Inquiry)

Inquiry Number: 25999

Q31. This question references the minimum requirement of processing at least 500,000 transactions per year for at least three years: Please define what the State means by “transaction” as this can be interpreted several ways. Does this mean 500,000 orders each year or 500,000 line items total on orders each year? Is an order considered a separate transaction from a delivery? Does this mean 500,000 units of product? Is a rebate or a chargeback considered a transaction?

A31. The intent of this requirement is to insure that the manufacturer can meet the demand for this contract. Manufacturers should describe how products are distributed through the Applicant’s supply chain, such as test strips, meters, lancets and other supplies. RFP Applicants should submit specific information that is most relevant to any distribution method that they currently utilize for their products. This information should clearly articulate the Applicant’s distribution chain direct to consumer, distributor or any combination thereof and indicate the actual number of products being distributed by product type and description.

July 13, 2012 (Date of Inquiry)

Inquiry Number: 26000

Q32. This question references improvement in quality and health status of Ohio Medicaid consumers: Please define “health status” and the criteria the State uses to determine “improvement in quality.” What type of documentation is the State requesting under this provision of the RFP?

A32. The documentation regarding improvement in quality and health status is in Section 4.4 Specification of Deliverables and Proposed Work Plan. The Applicant should propose a method to demonstrate the improvement in quality and health status expected as a result of this contract. ODJFS will partner with the selected manufacturer(s) to identify criteria to measure improvement during the contract period.

July 13, 2012 (Date of Inquiry)

Inquiry Number: 26001

Q33. This question references information delivery systems, the heading is entitled 4.4 (A) Specifications of Deliverables: The RFP states that Manufacturers should provide information through multiple technology and information delivery systems. One listed item is Formulary Flash through Epocrates. Is the Epocrates software a mandatory requirement or is it an example?

A33. Epocrates is one example.

July 13, 2012 (Date of Inquiry)

Inquiry Number: 26002

- Q34.** This question references rebate payment terms, the heading is entitled 4.3(A)(3) Establish a Preferred Product/Rebate Program: The RFP states that rebates will be invoiced quarterly with payments due within 30 days after the invoice is issued. CMS uses a 38 day schedule for rebate payment. Will the State accept the CMS 38 day schedule for rebate payment?
- A34.** **The CMS requirement allows 38 days after the postmark date of an invoice. ODJFS anticipates sending invoices electronically eliminating the need for extra time for the mail.**

July 13, 2012 (Date of Inquiry)

Inquiry Number: 26003

- Q35.** This question references providing materials in the Somali language, the heading is entitled 4.4 (A) Marketing and Outreach: The State is asking for “translated materials” in Somali. What type of document(s) does the State feel need to be in Somali? A blood glucose meter instruction booklet is an obvious choice for translation, but what other type of document(s) does the State feel need to be in Somali?
Also, can the State be more specific about which Somali language is requested. The two common languages in Somalia are Arabic and three dialects/versions of Somali (Northern, Benadir, and Maay).
- A35.** **All documents related to this RFP will need to be translated into Somali. According to the ODJFS Refugee Services Section, materials are generally translated in Somali Somali ("regular"). There is also a Bantu population in Ohio and they may speak Maay Maay so it would be helpful to these Medicaid consumers if translations in both languages could be provided.**

July 13, 2012 (Date of Inquiry)

Inquiry Number: 26004

- Q36.** This question references samples of the diabetic testing supplies, the heading is entitled 4.4(E) Diabetic Supply Specifications: Samples of each meter the Manufacturer proposes, with corresponding test strips, must be included in the proposal. Is one sample of each type of meter sufficient or does the State require a specified number of meters? Is one 50-count vial of test strips adequate or does each meter need a separate vial of test strips? Does the State need control solutions, lancing devices, and lancets to be included as samples?
- A36.** **Manufacturers should provide one meter with a minimum of 10 test strips and control solution as described in Sections 4.4.E Diabetic Supply Specifications and 5.1 Proposal Submission Information. Samples of other products are not required. Please do not send lancets, syringes, needles or other materials requiring sharps disposal protocols.**

July 13, 2012 (Date of Inquiry)

Glenda Schwem

Abbott Diabetes Care

Inquiry Number: 26005

Q37. This question references the prohibition of services outside of the USA, the heading is entitled 8.23 Prohibition Against Services Performed Outside the US: Please define “Services.” Please specify how the State differentiates between a “service” and a “good.” What service does the State anticipate it is paying for outside of the USA under this RFP?
Does the State agree that the State will not be buying a product directly from the Manufacturer and that the State will receive only a rebate payment from the Manufacturer?

A37. Services are actions people perform, furnishing of labor, time, or effort. Goods are tangible things that can be consumed, touched, felt or seen. For purposes of this RFP, services included in the scope of work are marketing and outreach, account management, rebate payment processing, and customer support and call center services.
Although ODJFS will not be purchasing a product from the manufacturer, and instead receiving a rebate from the manufacturer or distributor, the selected manufacturer(s) must attest that all services related to the RFP will be performed in the United States.

July 13, 2012 (Date of Inquiry)

Inquiry Number: 26006

Q38. This question references work for hire, the heading is entitled Attachment, Contract for Services: Many portions of this Model Contract appear to be applicable to a work-for-hire situation in which the State would pay the Manufacturer for a deliverable. Will the State re-draft the Model Contract to eliminate the work-for-hire concept, deliverables, and ownership of deliverables? The contract should reflect that if a Medicaid recipient purchases the Manufacturer’s diabetic blood glucose testing strip from a pharmacy, then the State is eligible to submit utilization data for a Rebate from the Manufacturer. The Manufacturer does not grant the intellectual property rights to the State.

A38. The State is willing to modify the Model Contract as appropriate to address ownership and work-for-hire concerns. The deliverables will be drafted in a manner that states what is being provided by the vendor.

July 13, 2012 (Date of Inquiry)

Inquiry Number: 26007

Q39. This question references suspension, the heading is entitled Article IV Suspension and Termination (b) on the Contract for Services: Please define what a suspended contract is (as compared to a terminated contract).

A39. Suspension occurs when the State instructs the vendor to temporarily stop work on all or a portion of the deliverables but will want the contract to continue once the issue for the suspension has been resolved. Termination of a contract would not allow the continuation of the contract past the termination date

July 13, 2012 (Date of Inquiry)

Inquiry Number: 26008

- Q40.** This question references business associates requirements, the heading is entitled Article VIII Business Associate Requirements under HIPAA on the Contract for Services: Under what circumstances would the State provide Protected Health Information to the Manufacturer? There does not appear to be a need for the Manufacturer to receive any PHI.
- A40.** **The State wanted all vendors to be aware of the potential language that may be required. If the State determines that no protected health information will be provided to the vendor then this article would be deleted out of the model contract.**

July 13, 2012 (Date of Inquiry)

Inquiry Number: 26007

- Q41.** This question references Ethics Laws, the heading is Article IX Contractor Certification of Compliance with Special Conditions on the Contract for Services, Subsection 3: Can the State please publish the Governor's Executive Order 2011-03K pertaining to ethics for review by the Manufacturers?
- A41.** **The Governor's Executive Order 2011-03K can be viewed at:**
<http://www.governor.ohio.gov/Portals/0/pdf/executiveOrders/EO2011-03.pdf>

July 13, 2012 (Date of Inquiry)

Inquiry Number: 26007

- Q42.** This question references Managed Care Enrollment Center Services "the Program", the heading is entitled Article X Misc. Provisions, subsection F1: What is the referenced "Managed Care Enrollment Center Services ("the Program")?"
- A42.** **The document was posted merely as a model, and that was what was appropriate for this RFP. The title of that program is not applicable and will be removed from the actual contract.**

July 13, 2012 (Date of Inquiry)

Inquiry Number: 25994

- Q43.** This question references Problem Resolution Systems, the heading is entitled 1.4 Objectives of the Project, subsection 5: Please specify in detail what the State defines as an adequate "problem resolution system." Does a customer support center that answers questions about the diabetic testing supplies, provides diabetes education, provides any product replacement needed, and keeps records of the same meet the State's expectations of a "problem resolution system?"
- A43.** **Applicants should be able to demonstrate the ability to manage problems. This is addressed in Section 4.4.F Customer Support and Call Center Services.**

July 13, 2012 (Date of Inquiry)

Danielle Pezzella

Bayer HealthCare, LLC
Inquiry Number: 26011

Q44. a) How did ODJFS develop the RFP diabetes meter/test strip specifications? b) What patient care standards were utilized to determine the sample size and test time specifications? c) What constitutes partial credit as far as scoring evaluation is concerned?

A44. These specifications were determined using criteria from other state Medicaid programs that have implemented rebate programs for diabetic supplies. Applicants should include specifications for equipment and supplies to be used for this program. Applicants are expected to adhere to generally accepted patient care standards. Applicants must meet all specified criteria in the RFP and Technical Proposal Score Sheet. Where ODJFS may have identified some expected standard of performance, any offer of something below that standard could be awarded partial (or “partially meets”) credit. Offers of performance above that standard and which would be of use/value to the ODJFS program may be awarded a higher score for these criteria.

**THIS CONCLUDES THE QUESTION & ANSWER DOCUMENT
FOR ODJFS RFP#: R-1213-07-8035.**