

REQUEST FOR PROPOSALS

ADDENDUM # 1

ISSUED: 11/27/2012

RFP NUMBER: CSP902613
INDEX NUMBER: LDC100

The State of Ohio, through the Department of Administrative Services, Office of Procurement Services, on behalf of the Department of Mental Health, Department of Health, and State Universities, is requesting proposals for:

Supply of Pharmaceuticals to the State of Ohio and Related Services

Attached are page(s) 3, 19 through 23, and 62 to this Request for Proposal (RFP). Remove the corresponding page(s) from the existing RFP and replace with the attached.

Reason for Addendum. This addendum is issued to advise of the addition of Cooperative Purchasing clarification and related changes, and revision of the (Excel) Price Submission Report, as indicated herein. Actual changes are indicated on pages 3, 19, and 62, and the balance of affected pages are due to adjustments in formatting.

PROPOSAL DUE DATE: December 12, 2012 by 1:00 p.m.
OPENING LOCATION: Department of Administrative Services
General Services Bid Desk
4200 Surface Road
Columbus, Ohio 43228-1395

OPSC Formulary. The State's formulary (hereinafter "Formulary") currently contains over 2,000 items. A listing is provided herein via Web access. Refer to Attachment Eleven for the Web address to the formulary document. This list includes the OPSC Stock number, Item Description, Package Size, and Unit for each item. Any items stocked by OPSC must be recommended and approved by the Interdepartmental Pharmacy and Therapeutics (IP&T) Committee.

Currently, the breakdown of the usage of products on the State Formulary is:

Generic Products	91%
Brand Products	6%
Other Products	3%
TOTAL	100%

MINORITY SET ASIDE: The Ohio Revised Code Section 125.081 requires state agencies to purchase supplies or services from a certified Minority Business Enterprise (MBE). The goal for the value of these purchases exempted, or "set aside", for purposes of Revised Code Section 125.081, will be at least fifteen percent (15%) of the aggregate value of these purchases.

In the State of Ohio OPSC Formulary listing, items which are currently designated as MBE set aside are indicated, for reference. These items are either currently awarded or may potentially be awarded as MBE set aside items under various contract(s). The assortment of MBE items may change slightly, over time, with additions/deletions.

OBJECTIVES. The primary objective of this RFP is for DAS, on behalf of the State of Ohio, to contract with a pharmaceutical supplier with the experience, expertise, and resources in the pharmaceutical industry that fulfill the requirements, performance expectations, and deliverables as outlined in the Scope of Work (SOW). The intent of this RFP is to select a single supplier that can provide the best procurement solutions ensuring the highest quality products and services at an economical cost. It shall be the successful Offeror's obligation to ensure that personnel involved with this Project are qualified to perform their portions of the Work. The selected Contractor shall provide the State with pharmaceuticals and associated ancillary services that meet service level goals and provide data to support the services rendered.

Notable enhancements from previous pharmaceutical contracts:

1. A strategy to move from multiple sources toward a single source to attract superior service levels, and assist OPSC in maintaining an excellent fulfillment rate, better control of inventory, and the development of management reports that measure supply chain performance.
2. The leveraging of pharmaceutical spend, high generic utilization, single delivery point, and extended contract period to achieve better pricing and efficiencies.

Overview of the Project's Scope of Work. The SOW for the Project is provided in Attachment One, Part One of this RFP. This section only gives a summary of that work. If there is any inconsistency between this summary and the description of the Work, contained in Attachment One, Part One, the attachment will govern.

The overall goals of the project are to evaluate the following areas:

1. * Pricing: The Contractor shall offer excellent pricing as a result of the aggregation of purchased volume from a single source. Additionally, this contract will allow the State and the Contractor to competitively expand access beyond the existing customer base to include, but not limited to, Cooperative Purchasing Program participants (see link, Attachment Eleven).
2. Superior Service Level: The Contractor shall demonstrate its ability to fulfill the State's service expectations including, but are not limited to, fulfillment rate, frequency of delivery, and inventory management, including returns and recalls.
3. Ancillary Services: In order to measure supply chain performance, the Contractor shall demonstrate its ability to support the reporting requirements of the State, which include, but are not limited to, inventory management, contract management, and various ad hoc requirements.

The successful Offeror shall be responsible for performing the items identified in the Project Scope of Work, in accordance with the successful Offeror's Work Plan.

* Denotes change.

ATTACHMENT ONE: WORK REQUIREMENTS AND SPECIAL PROVISIONS
PART ONE: WORK REQUIREMENTS

This attachment describes the Project and what the Contractor must do to complete the Project satisfactorily. It also describes what the Offeror must deliver as part of the completed Project (the "Deliverables"), and it gives a detailed description of the Project's schedule.

I. SCOPE OF WORK

These specifications cover different types of drugs, vaccines, and pharmaceuticals for the State.

The Contractor must meet all RFP requirements and perform Work as defined in the Scope of Work.

1. APPLICABLE DOCUMENTS

- a. Applicable section(s) of Federal Food, Drug, and Cosmetic Act
- b. Applicable section(s) of the Code of Federal Regulations (CFR), Title 21
- c. Applicable section(s) of the Ohio Pure Food, Drug, and Cosmetic Law
- d. Approved Prescription Drug Products, U.S. Food and Drug Administration (FDA) Publication

2. DEFINITIONS

- a. For the purpose of the this Request for Proposal (RFP) only, the following information will provide clarification, in addition to modern English, Code of Federal Regulations, or industry standard definitions:

After Receipt of Order (ARO): The time after the Contractor receives the order from the ordering agency by purchase order.

Authorized Distributor: An approved supply chain provider through which a pharmaceutical manufacturer has agreed to sell and distribute its products.

Backorder: An item on a current purchase order which was not delivered within Contract terms.

Biennium: the State's two year financial period, beginning on July 1st of each odd number year and ending on June 30th two years later.

Bill of Lading (BOL): The legal document issued by the carrier detailing the items of the shipment, which must accompany the shipped goods and gives title of that shipment to specified parties.

Case: Shipping container containing a standard quantity of packages of the product. The standard quantity is typically also the minimum order quantity, e.g., a cardboard box/case of 24 bottles of aspirin.

Comparable Customer: Customer who has similar purchasing levels and generic product mix as noted in this RFP.

* Cooperative Purchasing Program: The Cooperative Purchasing Program administered by DAS, pursuant to Section 125.04(B) of the Ohio Revised Code, Cooperative Purchasing Act.

Contractor: The Offeror who is awarded a contract as a result of this RFP.

Contract Items: The items on the Formulary which are included in the Contract. The Contract Items may change as items are added or deleted from the formulary and may also be added or deleted from the Contract at the sole discretion of the Ohio Department of Administrative Services (DAS), e.g., to meet set-aside targets or item no longer competitively priced.

Contract Price: The negotiated price of an item between the Contractor and the State. The current price in effect for an item on the State's Formulary.

Customer: The ordering agency issuing the purchase order to the Contractor and/or the agency which contractually receives goods or services from the Contractor.

* Denotes change

Date of Payment: The date on the face of a state warrant or state agency check which is issued as payment on an invoice. A state agency has made prompt payment if the date of payment is before or no later than the required payment date.

DAS: The Ohio Department of Administrative Services

Discount: A deduction from the usual cost of product.

DMH: The Ohio Department of Mental Health

DOH: The Ohio Department of Health

DRC: The Ohio Department of Rehabilitation and Correction

DYS: The Ohio Department of Youth Services

Extended Contract Price: The Contract Price multiplied by the estimated annual usage of an item.

FDA: The U.S. Food and Drug Administration, of the U.S. Department of Health & Human Services (FDA)

Fill Rate: A measurement of the contractor's inventory effectiveness of meeting the customer's demands. Calculated on contractor's filling of purchase order by due date.

Formulary: The listing of pharmaceuticals and medications purchased by the State, which were recommended and approved by the Interdepartmental Pharmacy and Therapeutics (IP&T) Committee.

Generic Code Number (GCN): A number used to identify generic formulation of a drug.

Hash Total: A numerical control used to validate the accuracy of a submitted figure.

Late delivery: An item which was not delivered by the delivery due date on the purchase order.

Lead time: The number of days from receipt of purchase order by contractor until product is received by customer.

Long term backorder: That condition of product unavailability beyond normal lead time, requiring the contractor to notify customer of product unavailability in writing.

Lot: A quantity of drugs which share the same National Drug Code (NDC) number and lot numbers, and are assumed to be from the same production event.

Market Competitive Price: The best price in the market without compromising quality, safety or delivery reliability.

Material Safety Data Sheet (MSDS): Document to provide workers and emergency personnel with procedures for handling or working with a substance in a safe manner.

Merchantable: Suitable for purchase or sale.

Minority Business Enterprise (MBE): Businesses currently certified in the State of Ohio's minority business set-aside program (see Web address: <http://das.ohio.gov/Divisions/EqualOpportunity.aspx>).

National Drug Code (NDC): a unique 10-digit, 3-segment numeric identifier assigned to each medication.

Net Acquisition Price: The price paid by the State after all additional discounts have been applied to the Contract Price.

Ordering Agency: An approved governmental entity which issues a purchase order to the Contractor. Only authorized agencies, as specified, may issue purchase orders to the Contractor under the contract.

Offeror: Person or company that submits an offer in response to this RFP.

Package: The unit quantity of the product as intended, with any required labeling, e.g., bottle, kit, 10-dose vial.

Pallet: A portable platform on which goods can be moved, stacked, and stored, especially with the aid of a forklift. Current pallet size is 40 x 48.

Pedigree: The audit trail that follows a drug from the time it is manufactured through the distribution system to a pharmacy.

Price Index: Price benchmark used to compare the State's Contract Price relative to other Comparable Customers.

Price Submission Report: A list of items in the RFP in which the Offeror shall enter the offered price for each item. The Offeror shall submit the completed Price Submission Report as part of its Proposal. The list of items are taken from the Formulary.

Primary Ordering System: The software package and information system provided by the Contractor which allows the Ordering Agency to place orders for products, view product information, availability, alternate and substitute items, and various supply chain information.

Proposal: The Offeror's submitted, valid offer in response to this RFP.

Proper Invoice: A document that matches the contract and purchase order. Any difference in the product description, contract price, delivery terms, etc. as appearing on the purchase order and the vendor's invoice will be cause to reject the invoice and delay payment to the vendor. Product must have been received and free of defects, errors, discrepancies, and other improprieties. Invoices must be mailed under separate cover and cannot be included with the shipment.

Purchase Order (PO): Legal contract document produced by the ordering agency which includes, at minimum, the date the PO was created, purchase order number, contract number, contractor name, ordering agency, delivery address, delivery due date, item description, NDC number, quantity, and contract price.

Required Payment Date: Thirty days after the State receives a proper invoice for the amount due if a specific payment date or time of payment is not established by such a written agreement.

Service Level: The product fulfillment performance measurement of the Contractor.

Service Level Penalty: The financial penalty for non-compliance with the agreed service level requirements.

State: The State of Ohio; State of Ohio agencies.

Total Contract Price: The sum of all Extended Contract Prices.

Tote: The container that non-case packed quantities are provided by the contractor to the customer. Current size is 21 1/2" x 15" x 10".

b. Key to abbreviations in the Item Reference Number and/or Formulary (see below):

A = Ampule	L = 50	T = 30
C = 100	M = 1000	U or UD = Unit Dose 30
DISP = Disposable	N = 90	V = Vial
D = 500	P = Pint, Plastic, Punch Card	Pkg = Package
G = Gallon	S = 60 or Syringe	Unk = Unknown
H = 120	SR = Sustained Release	
K = 300	SYR = Syringe	

3. REQUIREMENTS - PRODUCT

For products supplies to OPSC, the Offeror affirms that the following product requirements will be adhered to:

- a. All types of pharmaceuticals and chemicals, as listed herein, shall be suitable for human medicinal use.
- b. Products shall adhere to the most updated regulations under the Federal Food, Drug, and Cosmetic Act, embodied in "Drugs: Current Good Manufacturing Practice in manufacture, processing, packaging, or holding"; and Part 210 and 211, Title 21 Code of Federal Regulations, Food and Drugs.
- c. The State of Ohio reserves the right to reject any or all products manufactured by a company which the FDA has found to have significant manufacturing and record-keeping irregularities.

- d. All products received shall be packaged and labeled in accordance with the best industry practices and shall meet all state and federal regulations for such products including all labeling and imprint requirements of oral solid dosage forms as outlined under section 3715.64 of the Ohio Pure Food, Drug and Cosmetic Law. This includes the tamper resistant packaging requirements for over-the-counter drug products and the manufacturer name and address being printed on the label of all legend (prescription) drugs. For items requested in Unit Dose packaging, EACH unit dose MUST be labeled with the product name, lot number and expiration date. Method of packing products for shipment/delivery shall meet the standards of the industry. Random packing or intermixing of multiple products and/or multiple lots within the same shipping tote are not the industry standards. Shipment of multiple lots and loose packaging of drug product may result in a "Complaint to Vendor" being issued.
- e. Hospital Unit Dose Labeling indicates that packaging must have Hospital, not Retail, Individual Labeling where each dose is labeled with Product Name, Lot Number and Expiration Date.
- f. Product Expiration Date: All products must be of current manufacture. The expiration period, if any, shall exceed one (1) year unless prior approval is obtained from the State. The State will not accept any drug product that is not labeled with an expiration date unless the product in question is specifically exempted by Federal statute 21 CFR 211.137 (g) and is not commercially available. In the absence of a labeled expiration date the State requires the manufacture date for each product and lot shipped as well as its shelf life. This information shall be submitted with both the packing slip and on the invoice. Vitamin products classified as dietary supplements (which are thereby subject to food, not drug, requirements and exempt from labeling the expiration date) are not acceptable.
- g. Vitamin and/or Mineral Product Formulations: Any Offeror offering vitamin and/or mineral products containing more than one ingredient shall provide the formulation of the product on request.
- h. The State's preference on injectable items is vials rather than ampules. If Offeror has both available, the Offeror shall offer both.
- i. For oral contraceptives, Offeror will clearly state that the offer is per cycle or per box.
- j. If items are changed in the State's formulary, the State would expect to be able to order within a reasonable notification to the Contractor of such change.

4. REQUIREMENTS – SERVICE

Minimum service requirements:

- a. A large number of pharmaceuticals will be distributed by the State's inpatient and outpatient operations. These operations utilize automated dispensing equipment, which necessitates the lot number be identical (same lot, same expiration). The State frequently utilizes bulk pharmaceuticals for its repackaging operations, and the quantity of lot numbers affect productivity.
- b. The Contractor will supply MSDS sheets with each shipment of product when required by law.
- c. The acceptable delivery service level (on-time delivery rate) will be a minimum of ninety-eight percent (98%), or as determined by written mutual agreement between the Contractor and ordering agency. If an item is on backorder, Contractor will notify the ordering agency in writing within one business day ARO. Items not shipped in less than 10 days ARO are subject to penalty. If an item is on backorder or if Contractor notifies the State in writing that the order will not be delivered within the Contract terms and conditions, the State reserves the right to procure the item from another source until Contractor notifies the State it will resume the normal service level.
- d. Purchase orders may be cancelled or revised only by the ordering agency and will remain open until complete, e.g., a "fill or kill" ordering system would not be acceptable.
- e. The State will never pay more than what is contracted to pay for any particular product. The Price on the purchase order is the final price. No adjustments will be accepted after the purchase order is accepted by the Contractor. The State does not consider an order placed until contractor receives a written purchase order.
- f. The State requires that pallets be separated by purchase order numbers. When this requirement cannot be met, the Offeror should provide an alternative solution. Contractor shall provide a packing slip for each pallet of the shipment. If not palletized, a packing slip will be provided for each box. The packing slip will include the Contractor, date, BOL number, quantity, description, NDC number, and PO number.

- g. The Contractor will ship by case when possible.
- h. The Contractor will provide the individual product pedigree when requested by the State.
- i. The Contractor shall produce custom managerial reports such as pricing, sales, and others in a timely manner, upon request by the State. Such requests will be reasonable.
- j. The service level percentage will be calculated by dividing the total lines of products completely shipped by the number of lines ordered. Products received within 10 days of original order will be counted as a line filled. The following items will be excluded from the service level calculation:
 - 1. Manufacturer back orders.
 - 2. Items where historical demand is exceeded by 125% over the preceding two months.
 - 3. Other exceptions may be negotiated on award of contract.
- k. The service level requirement will commence ninety days following the later of the effective date or receipt of accurate usage data. The service level guaranty for agencies added to this Agreement after the effective date will commence sixty days following receipt of accurate usage data. This will allow the contractor to gain usage information and adjust inventory levels appropriately.
- l. Dedicated Customer Support Representative (CSR) – Due to the many detailed, logistical, reporting and pricing coordination requirements between the State and the Contractor, the State requests that the Contractor dedicate a highly capable employee to serve as a liaison between the parties and inquire, research and follow-up on issues developed by the State that requires the Contractor's attention. The CSR will regularly report (at least monthly) on open issues between the parties and coordinate the delivery of reports at the agreed upon time.

The State will provide:

- a. Projected usage for 3 or 6 months.
- b. Orders in case quantities, in most situations.
- c. Notification of additions or deletions to formulary.

Offeror will provide:

- a. Describe the process whereby the State obtains an item's NDC Number (if applicable), price, manufacturer, packaging, and any available potential substitutes. Additional ordering or delivery options would be desirable. The State will expect same NDC number for product.
- b. Describe its primary ordering process. Offeror will describe its back-up plan for ordering due to failure of the ordering process.
- c. Demonstrate how purchase orders are confirmed, accepted or rejected, pricing is verified, and how out of stock situations will be handled.
- d. Demonstrate how it handles price changes and what corresponding effects are expected with the primary ordering system, accounting, invoicing, etc. Offeror will describe how State will be notified of price changes.
- e. Describe its service level computation process including report deliverables, with frequency and formatting of reporting.
- f. Provide a detailed service level penalty calculation process. The calculations of such penalties must include minimum delivery requirements in the RFP (to include, but not limited to: shipping issues, invoicing issues, fill rate, fulfillment accuracy, etc.). If the minimum service levels are not obtained, the Contractor will provide suggested penalty payments, along with payment frequency and format.
- g. Describe its suggested operational excellence initiatives to achieve optimum contract performance. The State is looking to partner with the awarded Contractor to develop a best in class service relationship.
- h. Describe its manner of shipping orders. The State prefers one lot per NDC number, per shipment. When this is not possible, all like-NDC numbered items shall be packed together, but the individual lots will be further separated. Contractor will make every effort to minimize the number of lots shipped to the State, while fulfilling these requirements.
- i. Provide a copy of the Offeror's return policy in the RFP.

ATTACHMENT ELEVEN
WEB ADDRESSES, REFERENCED IN RFP

Price Submission Report and Additional Discount Recap: <http://procure.ohio.gov/PDF/CSP902613Data.xls>, which include:

- Excel Tab 1: Instructions
- Excel Tab 2: Additional Discounts Recap
- * Excel Tab 3: Price Submission Report, "Submission Sheet (Rev.1)", which includes State of Ohio OPSC Formulary.
- Excel Tab 4: Example

LDC101 Pharmaceutical Contract: <http://www.procure.ohio.gov/proc/viewContractsAwards.asp?contractID=13174>

MAC060 Pharmaceutical Contract: <http://www.procure.ohio.gov/proc/viewContractsAwards.asp?contractID=31342>

MAC105 Pharmaceutical Contract: <http://www.procure.ohio.gov/proc/viewContractsAwards.asp?contractID=13220>

GPC009 Pharmaceutical Contract: <http://www.procure.ohio.gov/proc/viewContractsAwards.asp?contractID=13540>

Office of Support Services: <http://mentalhealth.ohio.gov/what-we-do/provide/warehouse-and-pharmacy/index.shtml>

* Cooperative Purchasing Program information:

<http://das.ohio.gov/Divisions/GeneralServices/ProcurementServices/CooperativePurchasing.aspx>

* Denotes change