

STATE OF SOUTH DAKOTA

Department of Health
Pierre, SD 57501

Medication Shortage Jurisdictional Risk Assessment
PROPOSALS ARE DUE NO LATER THAN September 8, 2023

RFP #: 24-0901005-002 State POC: Whitney Lutkemeier EMAIL: Whitney.Lutkemeier@state.sd.us

READ CAREFULLY

FIRM NAME: _____ AUTHORIZED SIGNATURE: _____

ADDRESS: _____ TYPE OR PRINT NAME: _____

CITY/STATE: _____ TELEPHONE NO: _____

ZIP (9 DIGIT): _____ FAX NO: _____

E-MAIL: _____

PRIMARY CONTACT INFORMATION

CONTACT NAME: _____ TELEPHONE NO: _____

FAX NO: _____ E-MAIL: _____

1.0 GENERAL INFORMATION

1.1 PURPOSE AND BACKGROUND OF REQUEST FOR PROPOSAL (RFP)

Pharmaceutical drug shortages are not new, and they occur due to manufacturing and quality problems, delays, and discontinuations. However, these shortages are occurring more frequently and lasting longer. The number of shortages is now hitting a critical point for healthcare practitioners and pharmacists who are unable to provide the recommended medication or treatment to give patients necessary care. For more background details, please view the [Governor of South Dakota's Executive Order 2023-07](#) and the corresponding [press release](#) with a formal report documenting this critical issue.

The South Dakota Department of Health (SDDOH) is currently analyzing the state's medication shortage and is seeking a partner to complete an assessment of the vulnerability to the hazard of medication shortages in South Dakota and recommend best management practices to mitigate this risk.

The ideal assessment partner would have specific subject matter expertise in pharmaceutical supply chain, medication shortage history, and assessment of population health and other epidemiologic data.

1.2 ISSUING OFFICE AND RFP REFERENCE NUMBER

The SDDOH is the issuing office for this document and all subsequent addenda relating to it, on behalf of the State of South Dakota, Department of Health. The reference number for the transaction is RFP #24-0901005-002. This number must be referred to on all proposals, correspondence, and documentation relating to the RFP.

1.3 SCHEDULE OF ACTIVITIES (SUBJECT TO CHANGE)

RFP Publication	8/07/2023
Offeror Inquiries Due	8/15/2023
Responses to Offeror Questions	8/22/2023
Proposals Due	9/08/2023
Anticipated Award Decision	10/02/2023

1.4 SUBMITTING YOUR PROPOSAL

All proposals must be completed and received by September 8, 2023. Proposals should be sent via email to Whitney.Lutkemeier@state.sd.us. The email subject should include the appropriate RFP Number and Title.

No proposal shall be accepted from, or no contract or purchase order shall be awarded to any person, firm or corporation that is in arrears upon any obligations to the State of South Dakota, or that otherwise may be deemed irresponsible or unreliable by the State of South Dakota.

1.5 CERTIFICATION REGARDING DEBARMENT, SUSPENSION, INELIGIBILITY AND VOLUNTARY EXCLUSION – LOWER TIER COVERED TRANSACTIONS

By signing and submitting this proposal, the offeror certifies that neither it nor its principals is presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation, by any Federal department or agency, from transactions involving the use of Federal funds. Where the offeror is unable to certify to any of the statements in this certification, the bidder shall attach an explanation to their offer.

1.6 NON-DISCRIMINATION STATEMENT

The State of South Dakota requires that all contractors, vendors, and suppliers doing business with any State agency, department, or institution, provide a statement of non-discrimination. By signing and submitting their proposal, the offeror certifies they do not discriminate in their employment practices with regard to race, color, creed, religion, age, sex, ancestry, national origin or disability.

1.7 CERTIFICATION RELATING TO PROHIBITED ENTITY

For contractors, vendors, suppliers, or subcontractors who enter into a contract with the State of South Dakota by submitting a response to this solicitation or agreeing to contract with the State, the bidder or offeror certifies and agrees that the following information is correct:

The bidder or offeror, in preparing its response or offer or in considering proposals submitted from qualified, potential vendors, suppliers, and subcontractors, or in the solicitation, selection, or commercial treatment of any vendor, supplier, or subcontractor, is not an entity, regardless of its principal place of business, that is ultimately owned or controlled, directly or indirectly, by a foreign national, a foreign parent entity, or foreign government from China, Iran, North Korea, Russia, Cuba, or Venezuela, as defined by South Dakota Executive Order 2023-02. It is understood and agreed that, if this certification is false, such false certification will constitute grounds for the State to reject the bid or response submitted by the bidder or offeror on this project and terminate any contract awarded based on the bid or response. The successful bidder or offeror further agrees to provide immediate written notice to the contracting executive branch agency if during the term of the contract it no longer complies with this certification and agrees such noncompliance may be grounds for contract termination.

1.8 RESTRICTION OF BOYCOTT OF ISRAEL

For contractors, vendors, suppliers, or subcontractors with five (5) or more employees who enter into a contract with the State of South Dakota that involves the expenditure of one hundred thousand dollars (\$100,000) or more, by submitting a response to this solicitation or agreeing to contract with the State, the bidder or offeror certifies and agrees that the following information is correct:

The bidder or offeror, in preparing its response or offer or in considering proposals submitted from qualified, potential vendors, suppliers, and subcontractors, or in the solicitation, selection, or

commercial treatment of any vendor, supplier, or subcontractor, has not refused to transact business activities, has not terminated business activities, and has not taken other similar actions intended to limit its commercial relations, related to the subject matter of the bid or offer, with a person or entity on the basis of Israeli national origin, or residence or incorporation in Israel or its territories, with the specific intent to accomplish a boycott or divestment of Israel in a discriminatory manner. It is understood and agreed that, if this certification is false, such false certification will constitute grounds for the State to reject the bid or response submitted by the bidder or offeror on this project and terminate any contract awarded based on the bid or response. The successful bidder or offeror further agrees to provide immediate written notice to the contracting executive branch agency if during the term of the contract it no longer complies with this certification and agrees such noncompliance may be grounds for contract termination.

1.9 MODIFICATION OR WITHDRAWAL OF PROPOSALS

Proposals may be modified or withdrawn by the offeror prior to the established due date and time.

No oral, telephonic, telegraphic or facsimile responses or modifications to informal, formal bids, or Request for Proposals will be considered.

1.10 OFFEROR INQUIRIES

Offerors may email inquiries concerning this RFP to obtain clarification of requirements. Questions and inquiries must be emailed to Whitney Lutkemeier at Whitney.Lutkemeier@state.sd.us by August 15, 2023, with the subject line "RFP #24-0901005-002".

The SDDOH will respond to offeror's inquiries (if required) via e-mail by August 22, 2023. In addition, all inquiries and the State's response will be posted on the state's e-procurement system. Offerors may not rely on any other statements, either of a written or oral nature, that alter any specification or other term or condition of this RFP. Offerors will be notified in the same manner as indicated above regarding any modifications to this RFP.

1.11 PROPRIETARY INFORMATION

The proposal of the successful offeror(s) becomes public information. Proprietary information can be protected under limited circumstances such as client lists and non-public financial statements. An entire proposal may not be marked as proprietary. Offerors must clearly identify in the Executive Summary and mark in the body of the proposal any specific proprietary information they are requesting to be protected. The Executive Summary must contain specific justification explaining why the information is to be protected. Proposals may be reviewed and evaluated by any person at the discretion of the State. All materials submitted become the property of the State of South Dakota and may be returned only at the State's option.

1.12 LENGTH OF CONTRACT

Anticipated contract date is November 1, 2023 – November 30, 2024.

1.13 GOVERNING LAW

Venue for any and all legal action regarding or arising out of the transaction covered herein shall be solely in the State of South Dakota. The laws of South Dakota shall govern this transaction.

1.14 DISCUSSIONS WITH OFFERORS (ORAL PRESENTATION/NEGOTIATIONS)

An oral presentation by an offeror to clarify a proposal may be required at the sole discretion of the State. However, the State may award a contract based on the initial proposals received without discussion with the Offeror. If oral presentations are required, they will be scheduled after the submission of proposals. Oral presentations will be made at the offeror's expense.

This process is a Request for Proposal/Competitive Negotiation process. Each Proposal shall be evaluated, and each respondent shall be available for negotiation meetings at the State's request. The State reserves the right to negotiate on any and/or all components of every proposal submitted. From the time the proposals are submitted until the formal award of a contract, each proposal is considered a working document and as such, will be kept confidential. The negotiation discussions will also be held as confidential until such time as the award is completed.

2.0 STANDARD CONTRACT TERMS AND CONDITIONS

Any contract or agreement resulting from this RFP will include the State's standard terms and conditions as listed below, along with any additional terms and conditions as negotiated by the parties:

- 2.1** The Contractor will perform those services described in the Scope of Work, attached hereto as Section 3 of the RFP and by this reference incorporated herein.
- 2.2** The Contractor's services under this Agreement shall commence and end on mutually agreed upon dates, unless sooner terminated pursuant to the terms hereof.
- 2.3** The Contractor will not use State equipment, supplies or facilities. The Contractor will provide the State with its Employer Identification Number, Federal Tax Identification Number or Social Security Number upon execution of this Agreement.
- 2.4** The State will make payment for services upon satisfactory completion of the services. The State will not pay Contractor's expenses as a separate item. Payment will be made pursuant to itemized invoices submitted with a signed state voucher. Payment will be made consistent with SDCL ch. 5-26.
- 2.5** The Contractor agrees to indemnify and hold the State of South Dakota, its officers, agents and employees, harmless from and against any and all actions, suits, damages, liability or other proceedings that may arise as the result of performing services hereunder. This section does not require the Contractor to be responsible for or defend against claims or damages arising solely from errors or omissions of the State, its officers, agents or employees.
- 2.6** The Contractor, at all times during the term of this Agreement, shall obtain and maintain in force insurance coverage of the types and with the limits as follows:
 - A. Commercial General Liability Insurance:**

The Contractor shall maintain occurrence based commercial general liability insurance or equivalent form with a limit of not less than \$1,000,000.00 for each occurrence. If such insurance contains a general aggregate limit it shall apply separately to this Agreement or be no less than two times the occurrence limit.
 - B. Professional Liability Insurance or Miscellaneous Professional Liability Insurance:**

The Contractor agrees to procure and maintain professional liability insurance or miscellaneous professional liability insurance with a limit not less than \$1,000,000.00.
 - C. Business Automobile Liability Insurance:**

The Contractor shall maintain business automobile liability insurance or equivalent form with a limit of not less than \$1,000,000.00 for each accident. Such insurance shall include coverage for owned, hired and non-owned vehicles.
 - D. Worker's Compensation Insurance:**

The Contractor shall procure and maintain workers' compensation and employers' liability insurance as required by South Dakota law.

Before beginning work under this Agreement, Contractor shall furnish the State with properly executed Certificates of Insurance which shall clearly evidence all insurance required in this Agreement. In the event a substantial change in insurance, issuance of a new policy, cancellation or nonrenewal of the policy, the Contractor agrees to provide immediate notice to the State and provide a new certificate of insurance showing continuous coverage in the amounts required. Contractor shall furnish copies of insurance policies if requested by the State.

- 2.7** While performing services hereunder, the Contractor is an independent contractor and not an officer, agent, or employee of the State of South Dakota.
- 2.8** Contractor agrees to report to the State any event encountered in the course of performance of this Agreement which results in injury to the person or property of third parties, or which may otherwise subject Contractor or the State to liability. Contractor shall report any such event to the State immediately upon discovery.

Contractor's obligation under this section shall only be to report the occurrence of any event to the State and to make any other report provided for by their duties or applicable law. Contractor's obligation to report shall not require disclosure of any information subject to privilege or confidentiality under law (e.g., attorney-client communications). Reporting to the State under this section shall not excuse or satisfy any obligation of Contractor to report any event to law enforcement or other entities under the requirements of any applicable law.

- 2.9** This Agreement may be terminated by either party hereto upon thirty (30) days written notice. In the event the Contractor breaches any of the terms or conditions hereof, this Agreement may be terminated by the State at any time with or without notice. If termination for such a default is effected by the State, any payments due to Contractor at the time of termination may be adjusted to cover any additional costs to the State because of Contractor's default. Upon termination the State may take over the work and may award another party an agreement to complete the work under this Agreement. If after the State terminates for a default by Contractor it is determined that Contractor was not at fault, then the Contractor shall be paid for eligible services rendered and expenses incurred up to the date of termination.
- 2.10** This Agreement depends upon the continued availability of appropriated funds and expenditure authority from the Legislature for this purpose. If for any reason the Legislature fails to appropriate funds or grant expenditure authority, or funds become unavailable by operation of law or federal funds reductions, this Agreement will be terminated by the State. Termination for any of these reasons is not a default by the State nor does it give rise to a claim against the State.
- 2.11** This Agreement may not be assigned without the express prior written consent of the State. This Agreement may not be amended except in writing, which writing shall be expressly identified as a part hereof, and be signed by an authorized representative of each of the parties hereto.
- 2.12** This Agreement shall be governed by and construed in accordance with the laws of the State of South Dakota. Any lawsuit pertaining to or affecting this Agreement shall be venued in Circuit Court, Sixth Judicial Circuit, Hughes County, South Dakota.
- 2.13** The Contractor will comply with all federal, state and local laws, regulations, ordinances, guidelines, permits and requirements applicable to providing services pursuant to this Agreement, and will be solely responsible for obtaining current information on such requirements.
- 2.14** The Contractor may not use subcontractors to perform the services described herein without the express prior written consent of the State. The Contractor will include provisions in its subcontracts requiring its subcontractors to comply with the applicable provisions of this

Agreement, to indemnify the State, and to provide insurance coverage for the benefit of the State in a manner consistent with this Agreement. The Contractor will cause its subcontractors, agents, and employees to comply, with applicable federal, state and local laws, regulations, ordinances, guidelines, permits and requirements and will adopt such review and inspection procedures as are necessary to assure such compliance.

- 2.15** Contractor hereby acknowledges and agrees that all reports, plans, specifications, technical data, miscellaneous drawings, software system programs and documentation, procedures, or files, operating instructions and procedures, source code(s) and documentation, including those necessary to upgrade and maintain the software program, and all information contained therein provided to the State by the Contractor in connection with its performance of services under this Agreement shall belong to and is the property of the State and will not be used in any way by the Contractor without the written consent of the State. Papers, reports, forms, software programs, source code(s) and other material which are a part of the work under this Agreement will not be copyrighted without written approval of the State.
- 2.16** The Contractor certifies that neither Contractor nor its principals are presently debarred, suspended, proposed for debarment or suspension, or declared ineligible from participating in transactions by the federal government or any state or local government department or agency. Contractor further agrees that it will immediately notify the State if during the term of this Agreement Contractor or its principals become subject to debarment, suspension or ineligibility from participating in transactions by the federal government, or by any state or local government department or agency.
- 2.17** Any notice or other communication required under this Agreement shall be in writing and sent to Whitney.Lutkemeier@state.sd.us. Notices shall be given by and to Whitney Lutkemeier on behalf of the State, and by the appropriate individual indicated in the Agreement, on behalf of the Contractor, or such authorized designees as either party may from time to time designate in writing. Notices or communications to or between the parties shall be deemed to have been delivered when emailed to the appropriate individual.
- 2.18** In the event that any court of competent jurisdiction shall hold any provision of this Agreement unenforceable or invalid, such holding shall not invalidate or render unenforceable any other provision hereof.
- 2.19** All other prior discussions, communications and representations concerning the subject matter of this Agreement are superseded by the terms of this Agreement, and except as specifically provided herein, this Agreement constitutes the entire agreement with respect to the subject matter hereof.

3.0 SCOPE OF WORK

Pharmaceutical drug shortages are not new, and they occur due to manufacturing and quality problems, delays, and discontinuations. However, these shortages are occurring more frequently and lasting longer. The number of shortages is now hitting a critical point for healthcare practitioners and pharmacists who are unable to provide the recommended medication or treatment to give patients necessary care.

The mission of the South Dakota Department of Health's Office of Public Health Preparedness and Response is to develop and maintain the relationships, infrastructure, and expertise necessary to prepare for and respond to public health emergencies. The purpose of this request for proposal is to complete a comprehensive assessment of South Dakota's vulnerability to the hazard of medication shortages and recommend best management practices to mitigate this risk.

- **Summit Event**
 - Convene a summit with pharmacists and healthcare providers to fully assess the scope of drug shortages during the discovery and information gathering phase.
 - Engage key informants through on-site and virtual meetings to assist in the process of gathering insights into their experiences, perspectives, and recommendations.
- **Comprehensive Risk Assessment**
 - Utilize a jurisdictional risk assessment tool to complete an in-depth assessment of the state's vulnerability to medication shortages.
 - Develop a targeted vulnerability list of medications which are most at risk.
 - Develop an immediate and future-focused action plan to minimize disruptions to patient care caused by shortages.
- **Final Recommendations**
 - Provide a final report that includes the assessment findings, vulnerability list of medications, and mitigation recommendations.
 - Present the assessment findings and action plan to the SDDOH.

4.0 PROPOSAL REQUIREMENTS AND COMPANY QUALIFICATIONS

- 4.1** The offeror is cautioned that it is the offeror's sole responsibility to submit information related to the evaluation categories and that the State of South Dakota is under no obligation to solicit such information if it is not included with the proposal. The offeror's failure to submit such information may cause an adverse impact on the evaluation of the proposal.
- 4.2** **Offeror's Contacts:** Offerors and their agents (including subcontractors, employees, consultants, or anyone else acting on their behalf) must direct all of their questions or comments regarding the RFP, the evaluation, etc. to the buyer of record indicated on the first page of this RFP. Offerors and their agents may not contact any state employee other than the buyer of record regarding any of these matters during the solicitation and evaluation process. Inappropriate contacts are grounds for suspension and/or exclusion from specific procurements. Offerors and their agents who have questions regarding this matter should contact the buyer of record.
- 4.3** The offeror may be required to submit a copy of their most recent audited financial statements upon the State's request.
- 4.4** Provide the following information related to at least three previous and current service/contracts, performed by the offeror's organization, which are similar to the requirements of this RFP. Provide this information for any service/contract that has been terminated, expired or not renewed in the past three years.
 - a. Name, address and telephone number of client/contracting agency and a representative of that agency who may be contacted for verification of all information submitted;

- b. Dates of the service/contract; and
- c. A brief, written description of the specific prior services performed and requirements thereof.

5.0 PROPOSAL RESPONSE FORMAT

5.1 An electronic copy shall be submitted.

5.1.1 In addition, the offeror should provide their entire proposal, including all attachments, in Microsoft Word or PDF electronic format by email.

5.1.2 The proposal should be page numbered and should have an index and/or a table of contents referencing the appropriate page number.

5.2 All proposals must be organized and tabbed with labels for the following headings:

5.2.1 **RFP Form.** The State's Request for Proposal form completed and signed.

5.2.2 **Executive Summary.** A one-page executive summary must be included with the proposal. This summary should highlight the major features of the proposal. It must indicate any requirements that cannot be met by the offeror. The reader should be able to determine the essence of the proposal by reading the executive summary. Proprietary information requests should be identified in this section.

5.2.3 **Detailed Response.** This section should constitute the major portion of the proposal and must contain at least the following information:

5.2.3.1 A complete narrative of the offeror's assessment of the work to be performed, the offeror's ability and approach, and the resources necessary to fulfill the requirements. This should demonstrate the offeror's understanding of the desired overall performance expectations.

5.2.3.2 A specific point-by-point response, in the order listed, to each requirement in the RFP. The response should identify each requirement being addressed as enumerated in the RFP.

5.2.3.3 A clear description of any options or alternatives proposed.

5.2.4 **Cost Proposal.** Cost will be evaluated independently from the technical proposal. Offerors may submit multiple cost proposals. All costs related to the provision of the required services must be included in each cost proposal offered.

See section 7.0 for more information related to the cost proposal.

6.0 PROPOSAL EVALUATION AND AWARD PROCESS

6.1 After determining that a proposal satisfies the mandatory requirements stated in the Request for Proposal, the evaluator(s) shall use subjective judgment in conducting a comparative assessment of the proposal by considering each of the following criteria:

- 6.1.1 Specialized expertise, capabilities, and technical competence as demonstrated by the proposed approach and methodology to meet the project requirements;
- 6.1.2 Resources available to perform the work, including any specialized services, within the specified time limits for the project;
- 6.1.3 Record of past performance, including price and cost data from previous projects, quality of work, ability to meet schedules, cost control, and contract administration;
- 6.1.4 Availability to the project locale;
- 6.1.5 Familiarity with the project locale;
- 6.1.6 Proposed project management techniques; and
- 6.1.7 Ability and proven history in handling special project constraints.

6.2 Experience and reliability of the offeror's organization are considered subjectively in the evaluation process. Therefore, the offeror is advised to submit any information which documents successful and reliable experience in past performances, especially those performances related to the requirements of this RFP.

6.3 The qualifications of the personnel proposed by the offeror to perform the requirements of this RFP, whether from the offeror's organization or from a proposed subcontractor, will be subjectively evaluated. Therefore, the offeror should submit detailed information related to the experience and qualifications, including education and training, of proposed personnel.

6.4 The State reserves the right to reject any or all proposals, waive technicalities, and make award(s) as deemed to be in the best interest of the State of South Dakota.

6.5 Award: The requesting agency and the highest ranked offeror shall mutually discuss and refine the scope of services for the project and shall negotiate terms, including compensation and performance schedule.

- 6.5.1 If the agency and the highest ranked offeror are unable for any reason to negotiate a contract at a compensation level that is reasonable and fair to the agency, the agency shall, either orally or in writing, terminate negotiations with the contractor. The agency may then negotiate with the next highest ranked contractor.
- 6.5.2 The negotiation process may continue through successive offerors, according to agency ranking, until an agreement is reached or the agency terminates the contracting process.

7.0 COST PROPOSAL

Provide a detailed budget that includes all costs related to the provision of the required services.