Controlled Substance Data Clearinghouse

REQUEST FOR PROPOSAL

AmerisourceBergen Corporation, Cardinal Health, Inc., and McKesson Corporation
on behalf of
The Clearinghouse Advisory Panel

May 2, 2022

1. OVERVIEW

You are invited to submit a proposal to serve as the "Controlled Substance Data Clearinghouse." The Clearinghouse Advisory Panel, comprised of representatives of the Participating Distributors and the Settling States, anticipates issuing a firm, fixed price contract for a base period of five years and option periods of five consecutive years thereafter to the Offeror that meets or exceeds the requirements and provides the best value in accordance with the terms and conditions contained in this Request for Proposal ("RFP").

Instructions for the proper preparation of your proposal are set forth in this RFP. The Clearinghouse Advisory Panel will conduct its evaluation according to the criteria listed in Section 4. To facilitate proper evaluation of your proposal, please do not deviate from the instructions outlined in Section 5. The technical proposal should not exceed 30 pages. Offeror is responsible for carefully reviewing all sections of the RFP and providing all required information.

Section 2 defines key terms used throughout this RFP. Section 3 provides some background and an overview of the objectives for this project. Section 4 describes the desired qualifications and general selection criteria that will be used by the Clearinghouse Advisory Panel. Sections 5, 6, and 7 provide additional instructions and guidance that will establish the acceptable minimum requirements for the format and contents of proposals for the Clearinghouse Advisory Panel.

Special attention is directed to the requirements for technical and business proposals to be submitted in accordance with these instructions. The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of this RFP.

Please indicate to the Point of Contact that you intend to submit a proposal by May 16, 2022. All questions regarding the RFP should be submitted in writing to the Point of Contact by May 25, 2022. Along with written questions, Offerors may request a remote meeting with members of the Clearinghouse House Advisory Panel to discuss the submitted questions or seek additional clarification. Your proposal must be submitted to the Point of Contact no later than 5:00 PM, Eastern Time, on or before June 10, 2022. Late proposals will not be considered absent good cause shown.

The Point of Contact is:

Geoffrey E. Hobart
Covington & Burling LLP
One CityCenter
850 Tenth Street, NW
Washington, DC 20001-4956
Office: 202-662-5281
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2. DEFINITIONS

2.1 "*Controlled Substances*." Those substances designated under schedules II-V pursuant to the federal Controlled Substances Act and the laws and regulations of the Settling States that incorporate federal schedules II-V. For purposes of the requirements of this RFP, Gabapentin shall also be treated as a Controlled Substance.

2.2 "*Dispensing Data*" shall include unique patient IDs, patient zip codes, the dates prescriptions were dispensed, the NDC numbers of the drugs dispensed, the quantities of drugs dispensed, the day's supply of the drugs dispensed, the methods of payment for the drugs dispensed, the prescribers' names, the prescribers' NPI or DEA numbers, and the prescribers' zip codes or addresses, unless altered by the Clearinghouse Advisory Panel.

2.3 "*Highly Diverted Controlled Substances.*" Includes: (i) oxycodone; (ii) hydrocodone; (iii) hydromorphone; (iv) tramadol; (v) oxymorphone; (vi) morphine; (vii) methadone; (viii) carisoprodol; (ix) alprazolam; and (x) fentanyl. The Clearinghouse Advisory Panel may add Controlled Substances to the list of Highly Diverted Controlled Substances as needed based on information provided by the DEA and/or other sources related to drug diversion trends.

2.4 "*Participating Distributors*." AmerisourceBergen Corporation, Cardinal Health, Inc. and McKesson Corporation.

3. STATEMENT OF WORK

3.1 Background

As part of a recent settlement, the Participating Distributors and the State Attorneys General from 46 states, the District of Columbia and five territories (the "Settling States") agreed to establish a Controlled Substance Data Clearinghouse to facilitate collection, sharing, and analysis of sales of Controlled Substances and non-Controlled Substances and Dispensing Data across the industry.

3.2 Objectives

The primary objectives of the Clearinghouse are structured into two phases as described generally below:

Phase 1: Data Collection, Initial Analytics, and Reporting

1. Collect sales data on controlled and non-controlled prescription pharmaceuticals from Participating Distributors and Dispensing Data (to the extent possible and pending an operational plan to obtain Dispensing Data developed by the Clearinghouse Advisory Panel) on an ongoing, daily or similarly frequent basis and set up a platform for Participating Distributors and regulatory agencies of the Settling States to access the data (blinding the data as appropriate and where necessary to comply with privacy laws, including HIPAA).

a. In Phase 1, the primary data required to be collected and displayed will be:

   i. Participating Distributors' transaction data for Controlled Substances and non-Controlled Substances, specified at the NDC, date, quantity, distribution center and customer level;

   ii. Participating Distributors' information on retail or chain pharmacy customers that have been terminated and/or declined onboarding due to concerns regarding Controlled Substance dispensing; and

   iii. Dispensing Data, to the extent possible and pending an operational plan to obtain Dispensing Data developed by the Clearinghouse Advisory Panel.

   iv. The system(s) shall also be designed to receive data from sources in addition to the Participating Distributors, including pharmacies, non-participating distributors, the DEA, State Boards of Pharmacy, and other relevant sources, pursuant to standardized electronic transmission formats. See Appendix A for more information on specific data elements. The Offeror should be positioned to obtain access to such additional data, including industry-wide data sources, and work with the Clearinghouse Advisory Panel during Phase 1 to develop a plan for obtaining the additional data.

b. Data obtained from Participating Distributors shall be automatically generated by the existing order management data platforms (e.g., SAP). On days when no relevant data is produced (e.g., holidays on which no transactions may occur), "zero reports" shall be generated to affirm the absence of relevant data.

c. The data should be quality checked and standardized such that it can be aggregated across distributing entities, dispensing pharmacies, geographic region, etc.

d. Appropriate summaries and extracts of the data should be made available to Participating Distributors and authorities of the Settling States via the web (with no specialized software) and include the capability of being automatically transferred back to Participating Distributors/Settling State authorities at regular, frequent intervals as desired.

e. The platform should provide robust capabilities to allow searching and sorting the data and allow Participating Distributors to download the data into commonly used, non-proprietary formats (e.g., data formats that can be used by systems such as Power BI, R, or Tableau).

f. The platform shall be designed to protect personally identifiable information ("PII") and protected health information ("PHI") from disclosure and shall comply with HIPAA and any federal and state laws relating to the protection of PII and PHI. In addition, for data made available to Participating Distributors, the data should be blinded to protect commercially sensitive information.

g. The data and web platform should be maintained using the latest security platforms to prevent unauthorized access.

h. Section 6.1.4 below sets forth requirements for protecting PII, PHI, HIPAA from improper disclosure and other data security requirements.

2. Develop a flexible tool (with a user-friendly dashboard/interface available via web browser with no specialized software) that allows decision makers for Participating Distributors and Settling States to access data and analytics relevant to the evaluation of risk of diversion of a particular pharmacy, prescriber, geographic area, etc. The user should be able to easily run queries on specific pharmacies, prescribers, and geographic areas and download the underlying data, if required. The tool would need to support customizable dashboards that are accessible by individual state regulators and Participating Distributors' regulatory compliance teams.

   a. The interface of the tool is important as it should provide the users with the ability to drill down to the pharmacy or prescriber level and aggregate up to a particular geographic area. The tool should be reasonably flexible to the typical demands of regulators, Settling State authorities, and the compliance personnel at Participating Distributors. It should be simple and quick for users to access the analytics. Relevant definitions and methodology should be easily understood and explained within the tool.

   b. The tool should be a HIPAA-compliant portal containing reports that can be accessed by state authorities, the Participating Distributors, and any entities that subsequently join the Clearinghouse. The portal that will be made available to the Participating Distributors and any non-governmental entities that subsequently participate in the Clearinghouse will also blind commercially sensitive information.

   c. Work with the Clearinghouse Advisory Panel to identify relevant analytics and metrics for display in the tool. The Offeror shall prepare sample analytical reports in a sample geographic region for review with the Clearinghouse Advisory Panel. Such reports may also be shared with DEA to obtain additional feedback. At a minimum the analytics and reports in Phase 1 will include:

      i. To the extent possible and pending an operational plan developed to obtain Dispensing Data by the Clearinghouse Advisory Panel:

         1. Identification of pharmacies whose dispensing may indicate Red Flags consistent with those discussed in Appendix B as well as those additionally determined by the Offeror and the Clearinghouse Advisory Panel.

         2. Identification of pharmacies whose aggregate dispensing volumes for Highly Diverted Controlled Substances are disproportionately high relative to the population of the relevant geographic area.

3. Identification of pharmacies that disproportionately fill prescriptions for prescribers whose prescribing behavior suggests they may not be engaged in the legitimate practice of medicine (see 2.c.ii below).

ii. Identification of prescribers whose prescribing behavior suggests they may not be engaged in the legitimate practice of medicine. The metrics used to identify such prescribers will be determined by the Offeror, in conjunction with the Clearinghouse Advisory Panel, but will include:

1. Prescribers who routinely prescribe large volumes of Highly Diverted Controlled Substances relative to other prescribers with similar specialties, including health care professionals who prescribe a large number of prescriptions for high dosage amounts of Highly Diverted Controlled Substances;

2. Prescribers whose prescriptions for Highly Diverted Controlled Substances are routinely and disproportionately filled in a geographic area that is unusual based on the prescriber's location; and

3. Prescribers who routinely prescribe out-of-specialty or out-of-practice area without legitimate reason.

d. The Participating Distributors shall be permitted to use data obtained from the system(s) for anti-diversion purposes.

e. As this tool will integrate a tremendous amount of data and information from a range of sources, it will need simple, clear displays. However, it is also expected that the Offeror will be able to think through creative and novel ways to present these data, which historically have not previously been displayed together.

f. The tool should include geospatial mapping capabilities allowing for display of pharmacy locations as well as important geographic features (e.g., locations of hospitals, universities, clinics, city/county lines).

3. Assist Participating Distributors with their controlled substance reporting obligations at the state level.

a. Participating Distributors are required to submit certain information to the state authorities on a regular basis. The requirements vary by state. The Offeror should be able to work with the Participating Distributors, as requested, to develop the necessary reports and transmit the reports to the States.

b. Participating Distributors may at their discretion continue to handle reporting rather than have the Clearinghouse undertake the transmission.

Phase 2

The exact plan for Phase 2 will be determined within the first year of Phase 1, with the Offeror working with the Clearinghouse Advisory Panel to develop a Phase 2 Planning Report. However, as part of its proposal, Offeror should convey that it has the capability to take on the potential components of Phase 2 and provide a general overview of its capabilities and initial plan for this phase. Phase 2 will consist of two parts as described below

Phase 2A: Additional Data Collection and Analytics

Phase 2-A will focus on increasing data collection from additional Distributors, pharmacies and other data sources and developing enhanced analytics based on the experiences gained from Phase 1. Phase 2-A will also include recommendations for the development of uniform federal and state reporting.

1. The Offeror will continue the functions defined in Phase 1 and work to expand the scope of its data collection and enhance its analytics and reporting capabilities including the following:

    a. Integration of data from additional sources, including:

        i. Transaction data from other distributors, including manufacturers that distribute directly to retail pharmacies and pharmacies that self-warehouse; and

        ii. Where possible, other data, including, but not limited to, State Board of Medicine and Board of Pharmacy sanctions, and agreed-upon industry data.

    b. Development of additional metrics analyzing the data available from the additional data sources (other pharmacy and other dispenser data, sanction authorities, and third-party volume projections).

    c. Development of real-time or near real-time access to distribution data, Dispensing Data and other data sources.

    d. Refinement of methodologies for analyzing Dispensing Data to identify suspicious prescribers.

    e. Development of additional capabilities to provide States, the Participating Distributors and potentially the DEA customized reporting from the Clearinghouse upon reasonable request.

2. The Offeror will work with the Clearinghouse Advisory Panel to develop uniform reporting recommendations for potential implementation by state regulators in order to allow the Participating Distributors to satisfy their regulatory obligations in a uniform and consistent manner. This includes determining reporting requirements that:

    a. Streamline and simplify required reporting in such a way that benefits Participating Distributors, the States, as well as the DEA;

b. Develop uniform transactional and Suspicious Order reporting requirements; and

c. Provide for the submission of uniform Suspicious Order reports.

Phase 2B: Potential Assumption of CSMP functions

Phase 2-B will potentially involve the assumption of various real-time controlled substance monitoring activities, including identifying Suspicious Orders/Threshold Setting and order management. The Phase 2 Planning Report will address precise methodologies and tasks for assumption of these activities; however, in its Proposal Offeror should describe its capabilities and initial concepts for this phase. The goal will be to have Phase 2-B fully operational within two (2) years of the Clearinghouse Retention Date and no later than three (3) years of the Clearinghouse Retention Date. Phase 2-B is expected to include:

1. Engagement with stakeholders, including the DEA, to develop the system of identifying Suspicious Orders/Setting Thresholds;

2. Development of technology and rules to report suspicious orders, including identification of any state regulations that may need adjustment to allow for the Clearinghouse to report suspicious orders uniformly;

3. Development of models for the identification of Suspicious Orders and/or setting universal Thresholds in a manner consistent with the principles described in Appendix B, while ensuring that legitimate medical needs can reasonably be fulfilled. These models shall include active order management and order fulfillment protocols to ensure that orders are evaluated against the Suspicious Order tests and/or compared to relevant Thresholds by the Clearinghouse before shipment instructions are provided by the Clearinghouse to the Participating Distributors. The models shall also include the identification of Suspicious Orders when they are placed by Customers, which will be held before shipment or blocked based on instructions provided by the Clearinghouse to the Participating Distributors.

4. Development of criteria governing distribution to Customers that have placed one or more Orders that are identified by the model and/or exceed a Threshold;

5. Development of rules for allocating Orders placed by Customers that have more than one Distributor if one or more Orders are identified by the model and/or exceed a Threshold;

6. Development of a pilot project for a sample geographic region to perform data analysis to test the models for Threshold setting and the identification of Suspicious Orders.

   In addition, Phase 2 may also include expansion of the data collection and analytics to other types of pharmacy customers, including hospitals, veterinary clinics, substance abuse treatment facilities, nursing homes, etc. The Clearinghouse Advisory Panel and Offeror will determine together the appropriate time and approach for the expansion.

3.3 Schedule

Offeror shall propose a schedule for milestones within the project. Specific milestones are to be proposed by Offeror based on the specific recommended approach. To assist Offeror with specifying milestone dates, below are some key dates per the settlement agreement that must be met. Offerors are encouraged to submit proposals as soon as practicable in advance of the June 10, 2022 deadline. The Distributors reserve the right to provide notices and make relevant selections prior to the deadlines set forth below.

Milestone	**Deadline**
Notification of intent to submit proposal:	May 16, 2022
Deadline for submitting questions about RFP:	May 25, 2022
Proposal submission deadline:	June 10, 2022
Notification of selection for presentation phase:	June 24, 2022
Presentations completed by:	July 29, 2022
Notification of selected Offeror:	September 2, 2022
Retention of selected Offeror:	November 1, 2022
Phase 1 Go Live:	November 1, 2023
Phase 2 Planning Report deadline:	August 1, 2024
Phase 2-A Go Live (tentative):	February 3, 2025
Phase 2-B Go Live (tentative):	November 2, 2025
Notification of contract extension intention:	November 1, 2028

3.4 Other Information

The Offeror shall confirm in its proposal that it understands and can adhere to the following data use terms:

a. All data provided to the Clearinghouse shall be confidential.

- Information provided by distributors participating in the Clearinghouse may not be provided to any other entity or individual outside those expressly contemplated by the objectives above.

- The Clearinghouse may not provide to any distributor information specific to another distributor. Notwithstanding the prior sentence, the Clearinghouse may provide blinded data to a distributor reflecting total Orders (across all distributors) for a particular Customer, region, and/or state at the base code and NDC number level and all transactional data information.

- If the Clearinghouse receives a request for disclosure of any data, material or other information created or shared under the Clearinghouse, pursuant to a Third Party Request, the Clearinghouse shall notify the Participating Distributors and the Clearinghouse Advisory Panel of the Third Party Request and any confidential information to be disclosed so that the Participating Distributors may seek a protective order or otherwise challenge or object to the disclosure. The Clearinghouse shall provide the Participating Distributors

and the Clearinghouse Advisory Panel with at least ten (10) days' advance notice before complying with any Third Party Request for confidential information, except where state law requires a lesser period of advance notice.

b. Data integrity and security

- The Clearinghouse shall use best-in-class technology to preserve the integrity and security of the data.

- The Clearinghouse shall be responsible for executing necessary agreements (e.g., Business Associate Agreements) with entities providing patient sensitive data. The Clearinghouse shall also report any data breaches under HIPAA and state law that occur as a result of any of its data collection and reporting activities to the Settling States and other authorities as required by law. Clearinghouse or its vendor(s) must comply with all state and federal laws and regulations governing (1) the protection of personal information and protected health information, or (2) notifications relating to Data Security Events.

- The Participating Distributors and the Participating States shall not be liable for any breaches of any databases maintained by the Clearinghouse.

c. No person or entity shall sell (or obtain license fees for) data obtained by or from Clearinghouse to any third-parties.

4. QUALIFICATIONS AND SELECTION CRITERIA

All timely proposals received pursuant to the solicitation and compliant with proposal instructions will be fully evaluated. The Clearinghouse Advisory Panel will make award to the responsible Offeror whose proposal is the best value to the Participating Distributors and the States. Best value will be determined using a cost-technical tradeoff process. The Clearinghouse Advisory Panel will evaluate proposals based upon the qualifications listed below and the ability to meet the technical objectives described in Section [[3.2]] of the RFP. Prior to being evaluated in terms of the qualifications and technical objectives, the proposal must comply with instructions specified in Sections [[5 and 6]]. The Offeror's proposed price will be considered independently of the technical factors. All evaluation factors other than price, when combined, are significantly more important than price. As technical differences narrow among offerors, price will become more important. If there are no significant technical differences between offerors, price may be the determining factor for source selection. The Clearinghouse Advisory Panel may or may not award to the lowest priced Offeror or highest technically rated Offeror.

4.1 Qualifications

The Clearinghouse Advisory Panel believes the following expertise is critical to the success of the project. Offerors should include a detailed description, including past projects, of its qualifications to meet the capabilities listed below. If the Offeror does not have the precise qualifications for a specific criteria, please describe similar relevant experience.

- Technology infrastructure: Offeror should have the ability to securely and efficiently collect on a real-time basis and store extremely large amounts of sensitive data. Familiarity with different automated data collection methods and ability to store and secure sensitive information (including complying with HIPAA other privacy requirements) over a multi-year period using best in class security systems is required. Offeror should also have demonstrated ability to maintain a multi-user portal with minimal to no downtime and secure backup options to quickly rectify any outages that do occur.

- Data aggregation: Offeror should have extensive experience working with large databases, ideally including pharmaceutical order/transaction and Dispensing Data. Offeror should have experience aggregating data across multiple sources to create a consistent analytically ready database, including the ability to de-identify and/or blind certain sensitive information.

- Knowledge of health care: Offeror should demonstrate prior experience with and or expertise in processing and analysis of large health care databases including those with sensitive information.

- Knowledge of pharmaceutical supply chain: Offeror should demonstrate prior experience with and or expertise in the way in which pharmaceuticals are ordered, supplied, and paid for from point of manufacture to the ultimate patient.

- Experience with controlled substance diversion issues: Offeror should demonstrate extensive knowledge of controlled substance diversion issues and the medical uses of controlled substances. If Offeror has any pharmacists or medical professionals on staff, this should be noted.

- Programming and interface creation: Offeror should have prior experience building flexible, user-friendly web-based portals to allow stakeholders to access the data, ability to filter, sort, and display information at various levels (e.g., pharmacy, prescriber, geographic region). Screen shots of prior interfaces created by Offeror would be useful to include and Offeror should be prepared to walk through an example during the presentation phase of the selection process.

- Data analysis, statistics, and visual display of data: Offeror should have experience with analyzing large databases and displaying results in a user-friendly, intuitive format. Training in data science and/or mathematics/statistics is important. Prior experience analyzing sales and/or Dispensing Data to identify outliers or atypical patterns is ideal.

- Customer service: Offeror should describe its ability to provide customer service both in terms of technical support and questions on analytics to the Participating Distributors and States that are accessing the user interface.

- References: Offeror should include references for similar projects.

4.2 Independence

While performing services for the Clearinghouse, all vendors and consultants, and their staff working on the Clearinghouse, shall be independent (*i.e.*, not perform services of any kind, including as a consultant or an employee on behalf of any Participating Distributor outside of the ordinary business operations of the Clearinghouse). Independence may be achieved by implementing appropriate ethical walls with employees who are currently performing or who have previously performed work for a Participating Distributor within two years of the Clearinghouse Retention Date. Offeror must list all current and prior work (within the past 10 years) for any pharmaceutical manufacturer, distributor, or pharmacy that manufactures/distributes/dispenses controlled substances. In addition, Offeror must list any current and prior work (within the past 10 years) done for DEA, State AGs, or State regulatory boards governing controlled substances. Finally, Offeror should disclose any perceived or potential conflicts of interest and provide a plan of action to eliminate or mitigate the conflict of interest.

4.3 Selection process

The Clearinghouse Advisory Panel intends to award a single contract with a firm fixed price for Phase 1. Phase 2-A and 2-B will also be a firm fixed price, however, given the exact scope of those activities is not fully known, for purposes of the evaluation of the award, Offeror should provide an estimated range of potential cost along with an explanation of what factors determine the low and high end of the range.

Based on the information provided in the proposals, the Clearinghouse Advisory Panel intends to select up to four Offerors to make a presentation to the Clearinghouse Advisory Panel. The final selection will be based on the content of the proposal and the presentation. Proposals should be sufficiently detailed to evaluate the Offeror without need for the presentation.

The Clearinghouse Advisory Panel will evaluate cost/price for the "set up" period, each of the first three operating years, successive optional extension years, the estimated ranges for Phase 2, and overall based on price reasonableness.

5. INSTRUCTIONS TO OFFEROR

1. Based on the Statement of Work (SOW) at Section 3, and the additional detail throughout this RFP, the Offeror shall propose a total annual cost for each year of the anticipated contract including the Base Year and three successive years of operation, plus the range of costs for Phase 2-A and 2-B.

2. The Clearinghouse Advisory Panel will not pay any cost incurred in the preparation and submission of any proposals.

3. OFFER ACCEPTANCE PERIOD – The Offeror shall provide an acceptance period of not less than 150 calendar days over which the proposed price is good.

4. QUESTIONS / COMMUNICATIONS – All communications concerning the solicitation, including any of a technical nature, shall be made through the Point of Contact at

ghobart@cov.com and received on or before 5:00 PM (ET) May 25, 2025. All questions and answers will be provided to Offerors as an amendment to the solicitation prior to the proposal due date.

5. TIME, DATE, AND PLACE FOR SUBMISSION OF PROPOSAL - Proposal shall be in a Microsoft Office compatible format and delivered electronically by email to ghobart@cov.com on or before 5:00 PM (ET) June 10, 2022.

6. The proposal shall conform to provisions and clauses included in Sections 5 and 6 of this RFP. To aid its evaluation, the proposal shall be clearly and concisely written as to what it is the Offeror will do to satisfy the requirements of the Statement of Work in Section 3 as well as be neat, indexed, and logically assembled. All pages of each part shall be appropriately numbered and identified with the name of the Offeror, and the date.

7. The proposal shall not merely offer to perform work in accordance with the scope of the work. It shall outline the actual work proposed as specifically as practical. The Statement of Work reflects the objectives of the program, therefore merely stating or affirming that the Offeror will execute the performance requirements without sufficient elaboration will not be acceptable.

8. The proposal shall be typed, single spaced, with one inch margins, using Times New Roman font, 12 pitch type (or equivalent) and unreduced in size, to fit on 8 ½" by 11" paper and should not exceed 30 pages for the Technical Proposal. Title page and table of contents will not be counted in the page count limitation. The Business Proposal does not have a page limitation.

9. The Offeror shall submit one proposal divided into two parts. Evaluation of the Technical Proposal (see Section 6) will be accomplished separately from evaluation of the Business Proposal (see Section 7).

6. TECHNICAL PROPOSAL

A detailed work plan must be submitted indicating how each aspect of the statement of work is to be accomplished. Your technical approach should be in as much detail as you consider necessary to fully explain your proposed technical approach or method. The technical proposal should reflect a clear understanding of the nature of the work being undertaken. The technical proposal must include information on how the project is to be organized, staffed, and managed. Information should be provided which will demonstrate your understanding and management of important events or tasks.

6.1 Technical Discussion

The technical discussion included in the technical proposal should include a Statement of Work that responds to the items set forth below:

6.1.1 Background/Literature Review Specific to RFP Response

Provide any unique elements of the rationale for your plan, to include relevant literature that informs your approach. Review pertinent work already published which is relevant to this project and your proposed approach. This should support the scope of the project, as you perceive it.

6.1.2 Objectives

State the overall objectives and the specific accomplishments you hope to achieve. Indicate the rationale for your plan and relation to comparable work in progress elsewhere. Use as many subparagraphs, appropriately titled, as needed to clearly outline the general plan of work. Discuss sequencing of tasks and dependencies for completing tasks.

6.1.3 Methods

Describe in detail the technologies and methodologies you will use for the project, indicating your level of experience with each, areas of anticipated difficulties, and any pass-through expenses you anticipate, including data acquisition fees if Offeror proposes to purchase industry data sources. If you will be using any sub-contractors or third-party technology solutions, please describe these in detail.

6.1.4 Technology and Data Security

The proposal must include a description of the technology Offeror proposes to use to collect and store the data securely described in the Statement of Work, including any cybersecurity insurance policies. In addition, Offeror must describe the following:

- All data security certifications it has in place, including but not limited to SOC-II Type 2 certification or equivalent
- Access control policies (e.g., username/password combinations, requirements for changing passwords, lockout procedures)
- Employee remote access policies and procedures
- Network security, including use of firewalls, anti-virus appliances, IDPS, anti-SPAM/phishing appliances, and logs/traffic review.
- Vulnerability management, including information on how servers and PCs are patched and updated as well as any vulnerability and/or 3rd party penetration testing
- Physical security for facilities storing/accessing the data
- Backup procedures and policies

Finally, Offeror must include a description of how the proposed technology will meet HIPAA and other relevant privacy requirements and its procedures for de-identifying and securing the

data and appropriately blinding the data where necessary. In addition, the proposal should discuss the technology that will be used to create the analytical tool accessed by Participating Distributors and State regulatory agencies.

6.1.5 Additional Technical Proposal Information

The Offeror must submit an explanation of any additional technical information considered relevant in conjunction with the tasks to be performed in achieving the project objectives. Record and discuss specific factors not included elsewhere, which support your proposal.

6.2 Project Management Discussion

6.2.1 Schedule

Offeror shall propose important milestones for the set-up of the Clearinghouse and the functionality of the data collection, aggregation, and analytics described in the Phase 1 objectives as well as tentative milestones and dates for Phase 2. Refer to Section 3.3 for the set of rigid dates that must be incorporated into Offeror's proposal.

6.2.2 Qualifications and Personnel

The Offeror shall designate one person as the Executive Director of the Clearinghouse. The Executive Director shall manage day-to-day operations and report periodically to the Clearinghouse Advisory Panel. In its proposal, Offeror shall describe past experience of the Offeror and any proposed sub-contractors relating to the objectives of the Clearinghouse. These qualifications should cover the qualification areas described in Section 4.1 above. In addition, Offeror shall describe the experience and qualifications of personnel who will be assigned for direct work on this program. Information is required which will show the composition of the task or work group, its general qualifications, and recent experience with related projects or programs. The identity and qualifications of the Executive Director, Technical/Analytical Managers, and key technical personnel, as well as the approximate percentage of the total time each will be available for this program. Key personnel assigned to this study may include the following:

- Executive Director
- Project Manager(s)
- Technology Manager
- Analytics Manager
- Other Managers and Lead Analysts
- Primary Programmers

6.2.3 Additional Personnel

List names, titles, and proposed duties of additional personnel, if any, who will be required for full -time employment, or on a subcontract or consultant basis. If specific personnel for data analysts and programmers are not yet known, a description of the qualifications such personnel will possess is acceptable. The technical areas, character, and extent of subcontract or consultant activity should be indicated and the anticipated sources should be specified and qualified. For all proposed key personnel who are not currently members of the Offeror's staff, a letter of commitment or other evidence of availability is desired. A resume does not meet this requirement. Commitment letters for use of consultants and other personnel to be hired must include:

- The specific items or expertise they will provide
- Their availability to the project and the amount of time anticipated
- Willingness to act as a consultant
- How rights to technology and IP will be handled.

6.2.4 Resumes

Resumes for all key personnel are desired. Each must indicate educational background, recent experience, specific or technical accomplishments, and a listing of clients in the pharmaceutical supply chain (e.g., drug manufacturers, wholesalers/distributors, pharmacies, industry trade groups) that each has worked for in the past five years. Additionally, if any personnel has worked with or for State or Federal regulatory agencies in the past five years, please list such work.

7. BUSINESS PROPOSAL

7.1 Basic Cost/Price Information

The business proposal must contain sufficient information to allow the Clearinghouse Advisory Panel to perform a basic analysis of the proposed cost or price of the work. This information shall include the amounts of the basic elements of the proposed cost or price. These elements will include, as applicable, technology costs, direct labor, travel, materials, subcontracts, purchased equipment, shipping, indirect costs and rate, fee, and profit.

7.2 Cost and Pricing

7.2.1 General Instructions

Offeror must provide the following information on the first page of your pricing proposal:

1. Name, title, address, and signature of Executive Director (Executive Director must be authorized to sign on behalf of Offeror);

2. Name and telephone number of point of contact (if different from the Executive Director);

3. Name of contract administration office (if available);

4. Proposed cost; and

5. Date of submission.

As part of the specific information required, Offeror must submit, with the proposal, cost or pricing data. In addition, Offeror must submit with the proposal any information reasonably required to explain your estimating process, including cost element information listed below:

7.2.2 Cost Elements

Under the terms of the Distributors' Settlement Agreement, the Distributors are obligated to pay a total of $7.5 million per year for years one and two of the operation of the Clearinghouse and a total of $3 million per year for years three through ten ("Required Funding"). In the event that an Offeror believes the Required Funding is not sufficient for each element of a proposal, please identify which elements are covered by the Required Funding and which elements require additional funding (and which could be cut, if necessary).

All costs associated with this project must be entered into an Excel spreadsheet. The cost bid needs to be inclusive, clearly delineated, and itemized per key deliverable.

7.2.2.1 Materials and Services

Provide a consolidated priced summary of individual material quantities included in the various tasks, orders, or contract line items being proposed and the basis for pricing (vend or quotes, invoice prices, etc.).

7.2.2.2 Direct Labor, Fixed and Variable Costs

Provide a breakdown of labor hours, rates, and cost by appropriate category, and furnish bases for estimates. Break down fixed cost and variable cost (i.e., the amount may vary depending upon the number of users of the tool or other variable factors).

7.2.2.3 Pass through Costs

Indicate any pass-through costs and the estimated timeframe for the obligation. Pass-through costs should be listed without mark -up.

7.2.2.4 Indirect Costs

The Participating Distributors generally do not accept indirect costs (overhead, including but not limited to office space costs, administrative support, and other general costs). In the unlikely event that the Offeror is requesting indirect costs to be considered indicate the rates used and provide an appropriate explanation. Indicate how you have computed and applied your

indirect costs, including cost breakdowns. Show trends and budgetary data to provide a basis for evaluating the reasonableness of proposed rates.

7.2.2.5 Other Costs

List all other costs not otherwise included in the categories described above (e.g., travel, computer and consultant services) and provide basis for pricing.

7.2.2.6 Other Conditions

Standard payment terms are Net 90 days from date invoice is received by the Project Manager. All proposals should be submitted in accordance with that standard. The Clearinghouse Advisory Panel reserves the right to reject any proposal requiring indirect costs or that does not meet its standards for providing the information being requested in this bid document. As such, please indicate your understanding and agreement with the conditions set forth in this section 7.2.2.6.

8. APPENDIX A -- DATA ELEMENTS

As described above in Section 3.2, the primary data required to be collected in Phase 1 are:

1. Participating Distributor transaction data (including returns) for Controlled Substances and non-Controlled Substances, specified at the NDC, date, quantity, and customer level;

2. Participating Distributors' information on Customers that have been terminated and/or declined onboarding due to concerns regarding Controlled Substance dispensing; and

3. Pharmacy Dispensing Data, to the extent possible and pending an operational plan to obtain Pharmacy Dispensing Data developed by the Clearinghouse Advisory Panel.

Specific data elements that are anticipated to be required for these three types of data files are:

1. Participating Distributor transaction data for Controlled Substances and non-Controlled Substances:

   11-digit NDC Number, Item Description, Base Code (if Controlled Substance), DEA Schedule (if Controlled Substance), Date Ordered, Date Shipped, Date Received, DEA Registration Number for Distribution Center that shipped the Product, Transaction Type (e.g., purchase, return, omitted/blocked order), Quantity in Packages, Quantity in Units, Unit of Measurement, Customer[1] DEA Registration Number, Customer Account

[1] As in the Injunctive Relief terms, "Customer" should generally be understood to refer to an individual location to which products are shipped, as opposed to the parent corporate entity, for which "Parent" is used. For example, a Customer would be an individual location of a chain pharmacy, while a "Parent" would be the chain to which it belongs.

Number, Customer Name, Customer Address, Parent Account Number (if applicable), Parent Name (if applicable).

2. Participating Distributors' information on Customers that have been terminated and/or declined onboarding due to concerns regarding Controlled Substance dispensing:

   Customer DEA Number, Customer Account Number, Customer Name, Customer Address, Parent Account Number (if applicable), Parent Name (if applicable), Date of Action, Type of Action (i.e., termination or declined onboarding), Explanation (open-text field)

3. Dispensing Data, to the extent possible and pending an operational plan to obtain Dispensing Data developed by the Clearinghouse Advisory Panel. If Offeror intends to license Dispensing Data from a data vendor, this should be described in the proposal with information on the coverage gaps of such licensed data and the cost to obtain such data.

   Pharmacy Name, Pharmacy DEA Number, Distributor Account Number, Pharmacy Address, Prescription Fill Date, 11-digit NDC Number, Item Description, Dosage Units Dispensed, Prescription Length (e.g., 30, 60, 90, 120 days, etc.), Prescriber Name, Prescriber DEA Number, Prescriber NPI Number, Prescriber Address, Payment Method (Cash or Not Cash), Patient ZIP Code (or blinded patient identifier, if required by HIPAA).

Additional data sources to be collected in Phase 2 described in Section 3.2, such as those from "non-participating Distributors, the DEA, State Boards of Pharmacy, and other relevant sources," are likely to include at least the following, which Offerors should discuss the plan to incorporate in the proposals:

- Transaction data from non-participating Distributors;
- Dispensing Data from dispensers other than pharmacies;
- ARCOS and registrant data from the DEA;
- Relevant data (e.g., sanctions) from State Boards of Pharmacy;
- Licensure data from State Boards of Pharmacy;
- NFLIS data on drug cases, reports, and seizures;
- NCPDP industry data and pharmacy database;
- NPI national registry database;
- Provider data (e.g., LexisNexis provider, HMS data);
- First Databank or equivalent database, to provide descriptive details at the NDC-level

- Therapeutic category data linkable by NDC (e.g., AHFS, MDDB)

- FDA Drug Shortage data (to assist with assessment of back-ordered products that may affect order and shipment patterns); and

- Aggregate sales and/or prescription data from common industry sources (e.g., Wolters-Kluwer, Symphony, IQVIA).

These sources and the specific data elements involved are less clearly defined in the RFP at this stage and will be refined by the Offeror working with the Clearinghouse Advisory Panel, the Participating Distributor, and the State AG governance committee. The Offeror should include in its proposal preliminary ideas for incorporating these and other relevant data sources that may be anticipated for Phase 2.

9. APPENDIX B -- ANALYTICAL CONSIDERATIONS

As described in Section 3.2, the Clearinghouse's role in Phase 1 is expected to include "identification of pharmacies whose dispensing may indicate Red Flags consistent with those discussed in [this appendix] as well as those additionally determined by the Offeror and the Clearinghouse Advisory Panel."

The Red Flags listed in the Injunctive Relief Terms are provided below:

1. **Ordering ratio of Highly Diverted Controlled Substances to non-Controlled Substances:** Analyze the ratio of the order volume of all Highly Diverted Controlled Substances to the order volume of all non-Controlled Substances to identify Customers with significant rates of ordering Highly Diverted Controlled Substances.

2. **Ordering ratio of Highly Diverted Controlled Substance base codes or drug families to non-Controlled Substances:** Analyze the ratio of the order volume of each Highly Diverted Controlled Substance base code or drug family to the total order volume of all non-Controlled Substances to identify Customers with significant rates of ordering each Highly Diverted Controlled Substance base code or drug family.

3. **Excessive ordering growth of Controlled Substances:** Analyze significant increases in the ordering volume of Controlled Substances using criteria to identify customers that exhibit percentage growth of Controlled Substances substantially in excess of the percentage growth of non-Controlled Substances.

4. **Unusual formulation ordering:** Analyze ordering of Highly Diverted Controlled Substances to identify customers with significant ordering of high-risk formulations. High-risk formulations include, but are not limited to, 10mg hydrocodone, 8mg hydromorphone, 2mg alprazolam, single-ingredient buprenorphine (*i.e.*, buprenorphine without naloxone), and highly-abused formulations of oxycodone. On an annual basis (or as otherwise necessary), high-risk formulations of Highly Diverted Controlled Substances may be added, removed, or revised based on the Injunctive Relief Distributors' assessment and regulatory guidance.

5. **Out-of-area patients:** Analyze Pharmacy Customer Data or Dispensing Data to assess volume of prescriptions for Highly Diverted Controlled Substances for out-of-area patients (based on number of miles traveled between a patient's zip code and the pharmacy location, depending on the geographic area of interest) taking into consideration the percentage of out-of-area patients for non-Controlled Substances.

6. **Cash prescriptions:** Analyze Pharmacy Customer Data or Dispensing Data to assess percentage of cash payments for purchases of Controlled Substances taking into consideration the percentage of cash payments for purchases of non-Controlled Substances.

7. **Prescriber activity of Customers:** Analyze Pharmacy Customer Data or Dispensing Data to identify Customers that are dispensing Highly Diverted Controlled Substance prescriptions for Top Prescribers as follows:

    a. Top Prescribers representing a significant volume of dispensing where the prescriber's practice location is in excess of 50 miles from the pharmacy ("out-of-area"), relative to the percentage of out-of-area prescriptions for non-Controlled Substances.

    b. Top Prescribers representing prescriptions for the same Highly Diverted Controlled Substances in the same quantities and dosage forms indicative of pattern prescribing (e.g., a prescriber providing many patients with the same high-dose, high-quantity supply of 30mg oxycodone HCL prescription without attention to the varying medical needs of the prescriber's patient population).

    c. Top Prescribers where the top five (5) or fewer prescribers represent more than fifty percent (50%) of total prescriptions for Highly Diverted Controlled Substances during a specified period.

8. **Public regulatory actions against Customers:** Review information retrieved from companies that provide licensing and disciplinary history records (e.g., LexisNexis), and/or other public sources, including governmental entities, showing that the Customer, pharmacists working for that Customer, or the Customer's Top Prescribers have been subject, in the last five (5) years, to professional disciplinary sanctions regarding the dispensing or handling of Controlled Substances or law enforcement action related to Controlled Substances diversion. Continued licensing by a relevant state agency may be considered, but shall not be dispositive, in resolving the Red Flag. For Chain Customer locations, representations from each Chain Customer that it reviews its pharmacists' licensing statuses annually and for the regulatory actions described in this paragraph has either (i) taken appropriate employment action, or (ii) disclosed the regulatory action to the Injunctive Relief Distributor, may be considered in resolving the Red Flag.

9. **Customer termination data:** Review information from the Injunctive Relief Distributor's due diligence files and, when operable, from the Clearinghouse, subject to Section VIII.F, regarding Customers that have been terminated from ordering Controlled Substances by another distributor due to concerns regarding Controlled Substances.

In addition, the Offeror should provide a preliminary discussion of other types of potential metrics/analyses that may be useful to the Participating Distributors and Settling States in monitoring for Controlled Substance diversion, including other analyses that DEA and other regulators may be assessing.

As also discussed in Section 3.2, the Clearinghouse's role in Phase 2-B may include "Development of models for the identification of Suspicious Orders and/or setting universal Thresholds in a manner consistent with the principles described in [this appendix]." The Injunctive Relief Terms include a discussion of principles for setting Thresholds, which are provided below:

a. Injunctive Relief Distributors shall primarily use model-based thresholds. For certain circumstances, Injunctive Relief Distributors may apply a non-model threshold based on documented customer diligence and analysis.

b. Each Injunctive Relief Distributor shall include in its Annual Threshold Analysis and Assessment Report (as required by Section XVIII.F.3.c) to the Monitor summary statistics regarding the use of non-model thresholds and such information shall be considered by the Monitor as part of its Threshold Setting Process Review in the annual Audit Report.

c. For the purposes of establishing and maintaining Thresholds, each Injunctive Relief Distributor shall take into account the Controlled Substances diversion risk of each drug base code. The diversion risk of each base code should be defined and reassessed annually by the Injunctive Relief Distributor's CSMP Committee and reviewed by the Monitor.

d. Each Injunctive Relief Distributor shall establish Thresholds for new Customers prior to supplying those Customers with Controlled Substances and shall continue to have Thresholds in place at all times for each Customer to which it supplies Controlled Substances.

e. When ordering volume from other distributors becomes readily available from the Clearinghouse, an Injunctive Relief Distributor shall consider including such information as soon as reasonably practicable in establishing and maintaining Thresholds.

f. Each Injunctive Relief Distributor shall incorporate the following guiding principles in establishing and maintaining Customer Thresholds, except when inapplicable to non-model Thresholds:

    i. Thresholds shall take into account the number of non-Controlled Substance dosage units distributed to, dispensed and/or number of prescriptions dispensed by the Customer to assist with the determination of Customer size. As a general matter, smaller customers should have lower Thresholds than larger customers.

    ii. For the purposes of establishing and maintaining Thresholds, Injunctive Relief Distributors shall use statistical models that are appropriate to the underlying data.

iii. For the purposes of establishing and maintaining Thresholds, Injunctive Relief Distributors shall take into account a Customer's ordering and/or dispensing history for a specified period of time.

iv. For the purposes of establishing and maintaining Thresholds, Injunctive Relief Distributors shall take into account the ordering history of Customers within similar geographic regions, or, where appropriate for Chain Customers, ordering history within the chain.

v. If appropriate, Thresholds may take into account the characteristics of Customers with similar business models.

vi. A Customer's statement that it employs a particular business model must be verified, to the extent practicable, before that business model is taken into account in establishing and maintaining a Customer's Threshold.