

EXHIBIT P**Injunctive Relief****I. INTRODUCTION**

- A. Within ninety (90) days of the Effective Date unless otherwise set forth herein, each Injunctive Relief Distributor shall implement the injunctive relief terms set forth in Sections II through XIX (the “*Injunctive Relief Terms*”) in its Controlled Substance Monitoring Program (“*CSMP*”).
- B. The Effective Date of these Injunctive Relief Terms shall be defined by Section I.P of the Settlement Agreement, dated as of July 21, 2021, which incorporates these Injunctive Relief Terms as Exhibit P.

II. TERM AND SCOPE

- A. The duration of the Injunctive Relief Terms contained in Sections IV through XVI shall be ten (10) years from the Effective Date.
- B. McKesson Corporation, Cardinal Health, Inc., and AmerisourceBergen Corporation are referred to collectively throughout these Injunctive Relief Terms as the “*Injunctive Relief Distributors*” or individually as an “*Injunctive Relief Distributor*.” Each Injunctive Relief Distributor is bound by the terms herein.
- C. The requirements contained in Sections VIII through XV shall apply to the distribution of Controlled Substances to Customers by each Injunctive Relief Distributor’s Full-Line Wholesale Pharmaceutical Distribution Business, including by any entities acquired by the Injunctive Relief Distributors that are engaged in the Full-Line Wholesale Pharmaceutical Distribution Business. The prior sentence is not limited to activity physically performed at each Injunctive Relief Distributor’s distribution centers and includes activity covered by the prior sentence performed by each Injunctive Relief Distributor at any physical location, including at its corporate offices or at the site of a Customer with respect to Sections III through XV.

III. DEFINITIONS

- A. “*Audit Report*.” As defined in Section XVIII.H.3.
- B. “*Chain Customers*.” Chain retail pharmacies that have centralized corporate headquarters and have multiple specific retail pharmacy locations from which Controlled Substances are dispensed to individual patients.
- C. “*Chief Diversion Control Officer*.” As defined in Section IV.A.
- D. “Clearinghouse.” The system established by Section XVII.

- E. “*Clearinghouse Advisory Panel.*” As defined in Section XVII.B.4.
- F. “*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 the Injunctive Relief Terms, Gabapentin shall be treated as a Controlled Substance, except for purposes of Section XII for Customers located in States that do not regulate it as a controlled substance or similar designation (e.g., drug of concern).
- G. “*Corrective Action Plan.*” As defined in Section XIX.B.7.b.
- H. “*CSMP.*” As defined in Section I.A.
- I. “*CSMP Committee.*” As defined in Section VI.A.
- J. “*Customers.*” Refers collectively to current, or where applicable potential, Chain Customers and Independent Retail Pharmacy Customers. “Customers” do not include long-term care facilities, hospital pharmacies, and pharmacies that serve exclusively inpatient facilities.
- K. “*Data Security Event.*” Refers to any compromise, or threat that gives rise to a reasonable likelihood of compromise, by unauthorized access or inadvertent disclosure impacting the confidentiality, integrity, or availability of Dispensing Data.
- L. “*Dispensing Data.*” Includes, unless altered by the Clearinghouse Advisory Panel: (i) unique patient IDs; (ii) patient zip codes; (iii) the dates prescriptions were dispensed; (iv) the NDC numbers of the drugs dispensed; (v) the quantities of drugs dispensed; (vi) the day’s supply of the drugs dispensed; (vii) the methods of payment for the drugs dispensed; (viii) the prescribers’ names; (ix) the prescribers’ NPI or DEA numbers; and (x) the prescribers’ zip codes or addresses. The Clearinghouse will be solely responsible for collecting Dispensing Data.
- M. “*Draft Report.*” As defined in Section XVIII.H.1.
- N. “*Effective Date.*” As defined in Section I.B.
- O. “*Full-Line Wholesale Pharmaceutical Distribution Business.*” Activity engaged in by distribution centers with a primary business of supplying a wide range of branded, generic, over-the-counter and specialty pharmaceutical products to Customers.
- P. “*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 Injunctive Relief Distributors shall confer annually and review this list to determine whether changes are appropriate and shall 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. The Injunctive Relief Distributors shall notify the State Compliance Review Committee and the Monitor of any additions to the list of Highly Diverted Controlled Substances. Access to Controlled Substances predominately used for Medication-Assisted Treatment shall be considered when making such additions.

- Q. **“Independent Retail Pharmacy Customers.”** Retail pharmacy locations that do not have centralized corporate headquarters and dispense Controlled Substances to individual patients.
- R. **“Injunctive Relief Distributors.”** As defined in Section II.B.
- S. **“Injunctive Relief Terms.”** As defined in Section I.A.
- T. **“Monitor.”** As defined in Section XVIII.A.
- U. **“National Arbitration Panel.”** As defined by Section I.GG of the Settlement Agreement, dated as of July 21, 2021, which incorporates these Injunctive Relief Terms as Exhibit P.
- V. **“NDC.”** National Drug Code.
- W. **“non-Controlled Substance.”** Prescription medications that are not Controlled Substances.
- X. **“Notice of Potential Violation.”** As defined in Section XIX.B.2.
- Y. **“Order.”** A unique Customer request on a specific date for (i) a certain amount of a specific dosage form or strength of a Controlled Substance or (ii) multiple dosage forms and/or strengths of a Controlled Substance. For the purposes of this definition, each line item on a purchasing document or DEA Form 222 is a separate order, except that a group of line items either in the same drug family or DEA base code (based upon the structure of a Injunctive Relief Distributor’s CSMP) may be considered to be a single order.
- Z. **“Pharmacy Customer Data.”** Aggregated and/or non-aggregated data provided by the Customer for a 90-day period.
1. To the extent feasible based on the functionality of a Customer’s pharmacy management system, Pharmacy Customer Data shall contain (or, in the case of non-aggregated data, shall be sufficient to determine) the following:
 - a) A list of the total number of prescriptions and dosage units for each NDC for all Controlled Substances and non-Controlled Substances;

- b) A list of the top five prescribers of each Highly Diverted Controlled Substance by dosage volume and the top ten prescribers of all Highly Diverted Controlled Substances combined by dosage volume. For each prescriber, the data shall include the following information:
 - (1) Number of prescriptions and doses prescribed for each Highly Diverted Controlled Substance NDC;
 - (2) Number of prescriptions for each unique dosage amount (number of pills per prescription) for each Highly Diverted Controlled Substance NDC;
 - (3) Prescriber name, DEA registration number, and address; and
 - (4) Medical practice/specialties, if available;
 - c) Information on whether the method of payment was cash for (a) Controlled Substances, and (b) non-Controlled Substances; and
 - d) Information on top ten patient residential areas by five-digit ZIP code prefix for filled Highly Diverted Controlled Substances by dosage volume, including number of prescriptions and doses for each Highly Diverted Controlled Substance NDC.
2. Injunctive Relief Distributors are not required to obtain Pharmacy Customer Data for all Customers. Pharmacy Customer Data only needs to be obtained under circumstances required by the Injunctive Relief Terms and the applicable CSMP policies and procedures. Each Injunctive Relief Distributor's CSMP policies and procedures shall describe the appropriate circumstances under which and methods to be used to obtain and analyze Pharmacy Customer Data.
 3. Injunctive Relief Distributors shall only collect, use, disclose or retain Pharmacy Customer Data consistent with applicable federal and state privacy and consumer protections laws. Injunctive Relief Distributors shall not be required to collect, use, disclose or retain any data element that is prohibited by law or any element that would require notice to or consent from the party who is the subject of the data element, including, but not limited to, a third party (such as a prescriber) to permit collection, use, disclosure and/or retention of the data.
- AA. *"Potential Violation."* As defined in Section XIX.B.1.
- BB. *"Reporting Periods."* As defined in Section XVIII.C.1.

- CC. “*Settling State.*” As defined by Section I.OOO of the Settlement Agreement, dated as of July 21, 2021, which incorporates these Injunctive Relief Terms as Exhibit P.
- DD. “*State Compliance Review Committee.*” The initial State Compliance Review Committee members are representatives from the Attorneys General Offices of Connecticut, Florida, New York, North Carolina, Tennessee, and Texas. The membership of the State Compliance Review Committee may be amended at the discretion of the Settling States.
- EE. “*Suspicious Orders.*” As defined under federal law and regulation and the laws and regulations of the Settling States that incorporate the federal Controlled Substances Act. Suspicious Orders currently include, but are not limited to, orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.
- FF. “*Threshold.*” The total volume of a particular drug family, DEA base code, or a particular formulation of a Controlled Substance that an Injunctive Relief Distributor shall allow a Customer to purchase in any particular period. This term may be reassessed during Phase 2-B of the Clearinghouse.
- GG. “*Third Party Request.*” A request from an entity other than an Injunctive Relief Distributor, a Settling State, or the Monitor pursuant to a subpoena, court order, data practices act, freedom of information act, public information act, public records act, or similar law.
- HH. “*Top Prescriber.*” A prescriber who, for a Customer, is either (i) among the top five (5) prescribers of each Highly Diverted Controlled Substance or (ii) among the top ten (10) prescribers of Highly Diverted Controlled Substances combined, as determined from the most recent Pharmacy Customer Data for that Customer.

IV. CSMP PERSONNEL

- A. Each Injunctive Relief Distributor shall establish or maintain the position of Chief Diversion Control Officer, or other appropriately titled position, to oversee the Injunctive Relief Distributor’s CSMP. The Chief Diversion Control Officer shall have appropriate experience regarding compliance with the laws and regulations concerning Controlled Substances, in particular laws and regulations requiring effective controls against the potential diversion of Controlled Substances. The Chief Diversion Control Officer shall report directly to either the senior executive responsible for U.S. pharmaceutical distribution or the most senior legal officer at the Injunctive Relief Distributor.
- B. The Chief Diversion Control Officer shall be responsible for the approval of material revisions to the CSMP.
- C. The Chief Diversion Control Officer shall provide at least quarterly reports to the CSMP Committee regarding the Injunctive Relief Distributor’s operation of the

CSMP, including the implementation of any changes to the CSMP required by these Injunctive Relief Terms.

- D. An Injunctive Relief Distributor's CSMP functions, including, but not limited to, the onboarding and approval of new Customers for the sale of Controlled Substances, setting and adjusting Customer Thresholds for Controlled Substances, terminating or suspending Customers, and submitting Suspicious Orders and other reports to Settling States (or the Clearinghouse, when operational), but excluding support necessary to perform these functions, shall be conducted exclusively by the Injunctive Relief Distributor's CSMP personnel or qualified third-party consultants.
- E. Staffing levels of each Injunctive Relief Distributor's CSMP department shall be reviewed periodically, but at least on an annual basis, by the Injunctive Relief Distributor's CSMP Committee. This review shall include consideration of relevant developments in technology, law, and regulations to ensure the necessary resources are in place to carry out the program in an effective manner.
- F. Personnel in an Injunctive Relief Distributor's CSMP department shall not report to individuals in an Injunctive Relief Distributor's sales department, and sales personnel shall not be authorized to make decisions regarding the promotion, compensation, demotion, admonition, discipline, commendation, periodic performance reviews, hiring, or firing of CSMP personnel.
- G. The CSMP policies and procedures shall be published in a form and location readily accessible to all CSMP personnel at each Injunctive Relief Distributor.

V. **INDEPENDENCE**

- A. For each Injunctive Relief Distributor, sales personnel compensated with commissions shall not be compensated based on revenue or profitability targets or expectations for sales of Controlled Substances. However, each Injunctive Relief Distributor's personnel may, as applicable, be compensated (including incentive compensation) based on formulas that include total sales for all of the Injunctive Relief Distributor's products, including Controlled Substances. The compensation of sales personnel shall not include incentive compensation tied solely to sales of Controlled Substances.
- B. For any Injunctive Relief Distributor personnel who are compensated at least in part based on Customer sales, the Injunctive Relief Distributor shall ensure the compensation of such personnel is not decreased by a CSMP-related suspension or termination of a Customer or as a direct result of the reduction of sales of Controlled Substances to a Customer pursuant to the CSMP.
- C. The Injunctive Relief Distributors' sales personnel shall not be authorized to make decisions regarding the implementation of CSMP policies and procedures, the design of the CSMP, the setting or adjustment of Thresholds, or other actions taken pursuant to the CSMP, except sales personnel must provide information

regarding compliance issues to CSMP personnel promptly. The Injunctive Relief Distributors' sales personnel are prohibited from interfering with, obstructing, or otherwise exerting control over any CSMP department decision-making.

- D. Each Injunctive Relief Distributor shall review its compensation and non-retaliation policies and, if necessary, modify and implement changes to those policies to effectuate the goals of, and incentivize compliance with, the CSMP.
- E. Each Injunctive Relief Distributor shall maintain a telephone, email, and/or web-based "hotline" to permit employees and/or Customers to anonymously report suspected diversion of Controlled Substances or violations of the CSMP, Injunctive Relief Distributor company policy related to the distribution of Controlled Substances, or applicable law. Each Injunctive Relief Distributor shall share the hotline contact information with their employees and Customers. Each Injunctive Relief Distributor shall maintain all complaints made to the hotline, and document the determinations and bases for those determinations made in response to all complaints.

VI. OVERSIGHT

- A. To the extent not already established, each Injunctive Relief Distributor shall establish a committee that includes senior executives with responsibility for legal, compliance, distribution and finance to provide oversight over its CSMP (the "*CSMP Committee*"). The Chief Diversion Control Officer shall be a member of the CSMP Committee. The CSMP Committee shall not include any employee(s) or person(s) performing any sales functions on behalf of the Injunctive Relief Distributor; provided that service on the CSMP Committee by any senior executives listed in this paragraph whose responsibilities may include, but are not limited to, management of sales functions shall not constitute a breach of the Injunctive Relief Terms.
- B. Each Injunctive Relief Distributor's CSMP Committee shall have regular meetings during which the Chief Diversion Control Officer shall present to the CSMP Committee with respect to, and the CSMP Committee shall evaluate, among other things: (1) any material modifications and potential enhancements to the CSMP including, but not limited to, those relating to Customer due diligence and Suspicious Order monitoring and reporting; (2) any significant new national and regional diversion trends involving Controlled Substances; (3) the Injunctive Relief Distributor's adherence to the CSMP policies and procedures, the Injunctive Relief Terms, and applicable laws and regulations governing the distribution of Controlled Substances; and (4) any technology, staffing, or other resource needs for the CSMP. The CSMP Committee shall have access to all CSMP reports. The CSMP Committee will review and approve the specific metrics used to identify the Red Flags set forth in Section VIII.
- C. On a quarterly basis, each Injunctive Relief Distributor's CSMP Committee shall send a written report to the Injunctive Relief Distributor's Chief Executive, Chief

Financial, and Chief Legal Officer, as well as its Board of Directors, addressing: (1) the Injunctive Relief Distributor's substantial adherence to the CSMP policies and procedures, the Injunctive Relief Terms, and applicable laws and regulations governing the distribution of Controlled Substances; (2) recommendations as appropriate about the allocation of resources to ensure the proper functioning of the Injunctive Relief Distributor's CSMP; and (3) significant revisions to the CSMP. The Board of Directors or a committee thereof at each Injunctive Relief Distributor shall document in its minutes its review of the quarterly CSMP Committee reports.

- D. To the extent not already established, the Board of Directors of each Injunctive Relief Distributor shall establish its own compliance committee (the "*Board Compliance Committee*") to evaluate, at a minimum, and on a quarterly basis: (1) the CSMP Committee's written reports; (2) the Injunctive Relief Distributor's substantial adherence to the CSMP policies and procedures, the Injunctive Relief Terms, and applicable laws and regulations governing the distribution of Controlled Substances; (3) the Injunctive Relief Distributor's code of conduct and any whistleblower reporting policies, including those prescribed by Section V.E; and (4) any significant regulatory and/or government enforcement matters within the review period relating to the distribution of Controlled Substances. An Injunctive Relief Distributor meets this requirement if it established, prior to the Effective Date, multiple committees of its Board of Directors that together have responsibilities outlined in this paragraph.
- E. The Board Compliance Committee shall have the authority to: (1) require management of the Injunctive Relief Distributor to conduct audits on any CSMP or legal and regulatory concern pertaining to Controlled Substances distribution, and to update its full Board of Directors on those audits; (2) to commission studies, reviews, reports, or surveys to evaluate the Injunctive Relief Distributor's CSMP performance; (3) request meetings with the Injunctive Relief Distributor's management and CSMP staff; and (4) review the appointment, compensation, performance, and replacement of the Injunctive Relief Distributor's Chief Diversion Control Officer.

VII. MANDATORY TRAINING

- A. Each Injunctive Relief Distributor shall require all new CSMP personnel to attend trainings on its CSMP, its obligations under the Injunctive Relief Terms, and its duties with respect to maintaining effective controls against potential diversion of Controlled Substances and reporting Suspicious Orders pursuant to state and federal laws and regulations prior to conducting any compliance activities for the Injunctive Relief Distributor without supervision.
- B. Each Injunctive Relief Distributor shall provide annual trainings to CSMP personnel on its CSMP, its obligations under the Injunctive Relief Terms, and its duties to maintain effective controls against potential diversion of Controlled

Substances and report Suspicious Orders pursuant to state and federal laws and regulations.

- C. On an annual basis, each Injunctive Relief Distributor shall test its CSMP personnel on their knowledge regarding its CSMP, its obligations under the Injunctive Relief Terms, and its duties to maintain effective controls against potential diversion of Controlled Substances and to report Suspicious Orders pursuant to state and federal laws and regulations.
- D. Each Injunctive Relief Distributor shall train all third-party compliance consultants (defined as non-employees who are expected to devote fifty percent (50%) or more of their time to performing work related to the Injunctive Relief Distributor's CSMP, excluding information technology consultants not engaged in substantive functions related to an Injunctive Relief Distributor's CSMP) performing compliance functions for the Injunctive Relief Distributor in the same manner as the Injunctive Relief Distributor's CSMP personnel.
- E. At least every three (3) years in the case of existing employees, and within the first six months of hiring new employees, each Injunctive Relief Distributor shall require operations, sales, and senior executive employees to attend trainings on its CSMP, its obligations under the Injunctive Relief Terms, the hotline established in Section V.E, and its duties to maintain effective controls against potential diversion of Controlled Substances and report Suspicious Orders pursuant to state and federal laws and regulations.

VIII. RED FLAGS

- A. Within one hundred and twenty days (120) of the Effective Date, each Injunctive Relief Distributor shall, at a minimum, apply specific metrics to identify the potential Red Flags described in Section VIII.D with respect to Independent Retail Pharmacy Customers. For Chain Customers, the metrics used to identify the Red Flags described in Section VIII.D may be adjusted based on the specific business model and supplier relationships of the Chain Customer.
- B. Each Injunctive Relief Distributor shall evaluate and, if necessary, enhance or otherwise adjust the specific metrics it uses to identify Red Flags set forth in Section VIII.D.
- C. Each Injunctive Relief Distributor shall provide annually to the Monitor the specific metrics it uses to identify Red Flags as set forth in Section VIII.D. The Monitor shall review the metrics used to identify Red Flags as set forth in Section VIII.D to assess whether the metrics are reasonable. The Monitor may, at its discretion, suggest revisions to the metrics in the annual Audit Report as part of the Red Flags Review set forth in Section XVIII.F.3.f. Each Injunctive Relief Distributor may rely on its specific metrics to comply with the requirements of Section VIII unless and until the Monitor proposes a revised metric in connection with Section XVIII.H.

D. For purposes of the Injunctive Relief Terms, “*Red Flags*” are defined as follows:

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.
- E. For any Red Flag evaluation in Section VIII.D that may be performed using Pharmacy Customer Data or Dispensing Data, an Injunctive Relief Distributor will analyze the Red Flag using Pharmacy Customer Data, to the extent feasible based on the functionality of a Customer's pharmacy management system, until Dispensing Data is collected and analyzed by the Clearinghouse as described in Section XVII. Until Dispensing Data is collected and analyzed by the Clearinghouse, an Injunctive Relief Distributor may satisfy the Red Flag evaluations in Sections VIII.D.5 through VIII.D.7 by engaging in considerations of out-of-area patients, cash payments for prescriptions and Top Prescribers

without satisfying the specific requirements of Sections VIII.D.5 through VIII.D.7. In the event that the Clearinghouse is not collecting and analyzing Dispensing Data within two years of the Effective Date, the Injunctive Relief Distributors and the State Compliance Review Committee shall meet and confer to consider alternatives for the performance of the analysis required by Sections VIII.D.5 through VIII.D.7 using Pharmacy Customer Data.

- F. As provided for in Section XVII.C.4, the foregoing Red Flag evaluations may be performed by the Clearinghouse and reported to the relevant Injunctive Relief Distributors.
- G. The Injunctive Relief Distributors and the State Compliance Review Committee shall work in good faith to identify additional potential Red Flags that can be derived from the data analytics to be performed by the Clearinghouse.

IX. ONBOARDING

- A. For each Injunctive Relief Distributor, prior to initiating the sale of Controlled Substances to a potential Customer, a member of the Injunctive Relief Distributor's CSMP department (or a qualified third-party compliance consultant trained on the Injunctive Relief Distributor's CSMP) shall perform the following due diligence:
 - 1. Interview the pharmacist-in-charge, either over the telephone, via videoconference, or in person. The interview shall include questions regarding the manner in which the potential Customer maintains effective controls against the potential diversion of Controlled Substances.
 - 2. Obtain a "Pharmacy Questionnaire" completed by the owner and/or pharmacist-in-charge of the potential Customer. The Pharmacy Questionnaire shall require going-concern potential Customers to list their top ten (10) prescribers for Highly Diverted Controlled Substances combined, along with the prescriber's specialty, unless the Injunctive Relief Distributor is able to obtain this data otherwise. The Pharmacy Questionnaire shall also require disclosure of the identity of all other distributors that serve the potential Customer, and whether the potential Customer has been terminated or suspended from ordering Controlled Substances by another distributor and the reason for any termination or suspension. The Pharmacy Questionnaire shall request information that would allow the Injunctive Relief Distributor to identify Red Flags, including questions regarding the manner in which the potential Customer maintains effective controls against the potential diversion of Controlled Substances. A potential Customer's responses to the Pharmacy Questionnaire shall be verified, to the extent applicable and practicable, against external sources (for example, the Clearinghouse, once operational, and Automation of Reports and Consolidated Orders System ("ARCOS") data made available to the Injunctive Relief Distributor by the

DEA). The Pharmacy Questionnaire shall be maintained by the Injunctive Relief Distributor in a database accessible to its CSMP personnel.

3. Complete a written onboarding report to be maintained in a database accessible to the Injunctive Relief Distributor's CSMP personnel reflecting the findings of the interview and any site visit, the findings regarding the identification of and, if applicable, conclusion concerning any Red Flag associated with the pharmacy, as well as an analysis of the Pharmacy Questionnaire referenced in the preceding paragraph.
 4. For going-concern potential Customers, review Pharmacy Customer Data to assist with the identification of any Red Flags.
 5. Document whether the potential Customer or the pharmacist-in-charge has been subject to any professional disciplinary sanctions or law enforcement activity related to Controlled Substances dispensing, and, if so, the basis for that action. For Chain Customers, this provision shall apply to the potential specific pharmacies in question.
- B. For Chain Customers, each Injunctive Relief Distributor may obtain the information in Section IX.A from a corporate representative of the Chain Customer.
- C. In the event that an Injunctive Relief Distributor identifies one or more unresolved Red Flags or other information indicative of potential diversion of Controlled Substances through the onboarding process or otherwise, the Injunctive Relief Distributor shall refrain from selling Controlled Substances to the potential Customer pending additional due diligence. If following additional due diligence, the Injunctive Relief Distributor is unable to resolve the Red Flags or other information indicative of diversion, the Injunctive Relief Distributor shall not initiate the sale of Controlled Substances to the potential Customer and shall report the potential Customer consistent with Section XIV. If the Injunctive Relief Distributor determines that the potential Customer may be onboarded for the sale of Controlled Substances, the Injunctive Relief Distributor shall document the decision and the bases for its decision. Such a good faith determination, if documented, shall not serve, without more, as the basis of a future claim of non-compliance with the Injunctive Relief Terms. For Chain Customers, these provisions shall apply to the potential specific pharmacies in question.

X. ONGOING DUE DILIGENCE

- A. Each Injunctive Relief Distributor shall periodically review its procedures and systems for detecting patterns or trends in Customer order data or other information used to evaluate whether a Customer is maintaining effective controls against diversion.
- B. Each Injunctive Relief Distributor shall conduct periodic proactive compliance reviews of its Customers' performance in satisfying their corresponding

responsibilities to maintain effective controls against the diversion of Controlled Substances.

- C. Each Injunctive Relief Distributor shall review ARCOS data made available to it by the DEA and, once operational, by the Clearinghouse, to assist with Customer specific due diligence. For Chain Customers, this provision shall apply to the potential specific pharmacies in question.
- D. Each Injunctive Relief Distributor shall conduct due diligence as set forth in its CSMP policies and procedures in response to concerns of potential diversion of Controlled Substances at its Customers. For Chain Customers, these provisions shall apply to the specific pharmacies in question. The due diligence required by an Injunctive Relief Distributor's CSMP policies and procedures may depend on the information or events at issue. The information or events raising concerns of potential diversion of Controlled Substances at a Customer include but are not limited to:
 - 1. The discovery of one or more unresolved Red Flags;
 - 2. The receipt of information directly from law enforcement or regulators concerning potential diversion of Controlled Substances at or by a Customer;
 - 3. The receipt of information concerning the suspension or revocation of pharmacist's DEA registration or state license related to potential diversion of Controlled Substances;
 - 4. The receipt of reliable information through the hotline established in Section V.E concerning suspected diversion of Controlled Substances at the Customer;
 - 5. The receipt of reliable information from another distributor concerning suspected diversion of Controlled Substances at the Customer; or
 - 6. Receipt of other reliable information that the Customer is engaged in conduct indicative of diversion or is failing to adhere to its corresponding responsibility to prevent the diversion of Highly Diverted Controlled Substances.
- E. On an annual basis, each Injunctive Relief Distributor shall obtain updated pharmacy questionnaires from five hundred (500) Customers to include the following:
 - 1. The top 250 Customers by combined volume of Highly Diverted Controlled Substances purchased from the Injunctive Relief Distributor measured as of the end of the relevant calendar year; and

2. Additional Customers selected as a representative sample of various geographic regions, customer types (Independent Retail Pharmacy Customers and Chain Customers), and distribution centers. Each Injunctive Relief Distributor's Chief Diversion Control Officer shall develop risk-based criteria for the sample selection.

F. Scope of Review

1. For reviews triggered by Section X.D, an Injunctive Relief Distributor shall conduct due diligence and obtain updated Pharmacy Customer Data or equivalent, or more comprehensive data from the Clearinghouse if needed, as set forth in its CSMP policies and procedures.
2. For questionnaires collected pursuant to Section X.E, Injunctive Relief Distributors shall conduct a due diligence review consistent with the Injunctive Relief Distributors' CSMP policies and procedures. These annual diligence reviews shall be performed in addition to any of the diligence reviews performed under Section X.D, but may reasonably rely on reviews performed under Section X.D.
3. If the Injunctive Relief Distributor decides to terminate the Customer due to concerns regarding potential diversion of Controlled Substances, the Injunctive Relief Distributor shall promptly cease the sale of Controlled Substances to the Customer and report the Customer consistent with Section XIV. If the Injunctive Relief Distributor decides not to terminate the Customer, the Injunctive Relief Distributor shall document that determination and the basis therefor. Such a good faith determination, if documented, shall not, without more, serve as the basis of a future claim of non-compliance with the Injunctive Relief Terms.

XI. SITE VISITS

- A. Each Injunctive Relief Distributor shall conduct site visits, including unannounced site visits, where appropriate, of Customers, as necessary, as part of Customer due diligence.
- B. During site visits, an Injunctive Relief Distributor's CSMP personnel or qualified third-party compliance consultants shall interview the pharmacist-in-charge or other relevant Customer employees, if appropriate, about any potential Red Flags and the Customer's maintenance of effective controls against the potential diversion of Controlled Substances.
- C. An Injunctive Relief Distributor's CSMP personnel or qualified third-party compliance consultants who conduct site visits shall document the findings of any site visit.
- D. Site visit and all other compliance reports shall be maintained by each Injunctive Relief Distributor in a database accessible to all CSMP personnel.

XII. THRESHOLDS

- A. Each Injunctive Relief Distributor shall use Thresholds to identify potentially Suspicious Orders of Controlled Substances from Customers.
- B. Each Injunctive Relief Distributor's CSMP department shall be responsible for the oversight of the process for establishing and modifying Thresholds. The sales departments of the Injunctive Relief Distributors shall not have the authority to establish or adjust Thresholds for any Customer or participate in any decisions regarding establishment or adjustment of Thresholds.
- C. Injunctive Relief Distributors shall not provide Customers specific information about their Thresholds or how their Thresholds are calculated.
 - 1. Threshold Setting
 - 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:
- (1) 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.
 - (2) For the purposes of establishing and maintaining Thresholds, Injunctive Relief Distributors shall use statistical models that are appropriate to the underlying data.
 - (3) 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.
 - (4) 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.
 - (5) If appropriate, Thresholds may take into account the characteristics of Customers with similar business models.
 - (a) 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.

2. Threshold Auditing

- a) The Injunctive Relief Distributors shall review their respective Customer Thresholds at least on an annual basis and modify them where appropriate.
- b) Each Injunctive Relief Distributor's CSMP department shall annually evaluate its Threshold setting methodology and processes and its CSMP personnel's performance in adhering to those policies.

3. Threshold Changes

- a) An Injunctive Relief Distributor may increase or decrease a Customer Threshold as set forth in its CSMP policies and procedures, subject to Sections XII.C.3.b through XII.C.3.e.
- b) Prior to approving any Threshold change request by a Customer, each Injunctive Relief Distributor shall conduct due diligence to determine whether an increase to the Threshold is warranted. This due diligence shall include obtaining from the Customer the basis for the Threshold change request, obtaining and reviewing Dispensing Data and/or Pharmacy Customer Data for the previous three (3) months for due diligence purposes, and, as needed, conducting an on-site visit to the Customer. This Threshold change request diligence shall be conducted by the Injunctive Relief Distributor's CSMP personnel.
- c) No Injunctive Relief Distributor shall proactively contact a Customer to suggest that the Customer request an increase to any of its Thresholds, to inform the Customer that its Orders-to-date are approaching its Thresholds or to recommend to the Customer the amount of a requested Threshold increase. It shall not be a violation of this paragraph to provide Chain Customer headquarters reporting on one or more individual Chain Customer pharmacy location(s) to support the anti-diversion efforts of the Chain Customer's headquarters staff, and it shall not be a violation of this paragraph for the Injunctive Relief Distributor's CSMP personnel to contact Customers to seek to understand a Customer's ordering patterns.
- d) An Injunctive Relief Distributor's Chief Diversion Control Officer may approve criteria for potential adjustments to Customer Thresholds to account for circumstances where the Thresholds produced by the ordinary operation of the statistical models require modification. Such circumstances include adjustments to account for seasonal ordering of certain Controlled Substances that are based on documented diligence and analysis, adjustments made to permit ordering of certain Controlled Substances during a declared national or state emergency (e.g., COVID-19 pandemic), IT errors, and data anomalies causing results that are inconsistent with the design of the statistical models. 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 information regarding the use of this paragraph and such information shall be considered by the Monitor as part of its Threshold Setting Process Review in the annual Audit Report.
- e) Any decision to raise a Customer's Threshold in response to a request by a Customer to adjust its Threshold must be documented

in a writing and state the reason(s) for the change. The decision must be consistent with the Injunctive Relief Distributor's CSMP and documented appropriately.

XIII. SUSPICIOUS ORDER REPORTING AND NON-SHIPMENT

- A. Each Injunctive Relief Distributor shall report Suspicious Orders to the Settling States ("*Suspicious Order Reports*" or "*SORs*"), including those Settling States that do not currently require such SORs, at the election of the Settling State.
- B. For the SORs required by the Injunctive Relief Terms, each Injunctive Relief Distributor shall report Orders that exceed a Threshold for Controlled Substances set pursuant to the processes in Section XII that are blocked and not shipped.
- C. No Injunctive Relief Distributor shall ship any Order that it (i) reports pursuant to Sections XIII.A or XIII.B, or (ii) would have been required to report pursuant to Sections XIII.A or XIII.B had the Settling State elected to receive SORs.
- D. In reporting Suspicious Orders to the Settling States, the Injunctive Relief Distributors shall file SORs in a standardized electronic format that is uniform among the Settling States and contains the following information fields:
 - 1. Customer name;
 - 2. Customer address;
 - 3. DEA registration number;
 - 4. State pharmacy license number;
 - 5. Date of order;
 - 6. NDC number;
 - 7. Quantity;
 - 8. Explanation for why the order is suspicious (up to 250 characters): Details that are order-specific regarding why an order was flagged as a Suspicious Order, including specific criteria used by an Injunctive Relief Distributor's Threshold system (except phrases such as "order is of unusual size" without any additional detail are not acceptable); and
 - 9. Name and contact information for a knowledgeable designee within the Injunctive Relief Distributor's CSMP department to be a point of contact for the SORs.
- E. On a quarterly basis, each Injunctive Relief Distributor shall provide a summary report to the Settling States that elect to receive it that provides the following

information for the relevant quarter with respect to the top ten (10) Customers by volume for each Highly Diverted Controlled Substance base code that have placed a Suspicious Order for that base code, in that quarter (for Chain Customers, only individual pharmacies in the chain will be considered for evaluation as a top ten (10) Customer):

1. The number of SORs submitted for that Customer by base code;
 2. The Customer's order volume by base code for the quarter for all Highly Diverted Controlled Substances;
 3. The Customer's order frequency by base code for the quarter for all Highly Diverted Controlled Substances;
 4. For each Highly Diverted Controlled Substance base code, the ratio of the Customer's order volume for that base code to the volume of all pharmaceutical orders for the quarter; and
 5. The ratio of the Customer's order volume of all Controlled Substances to the volume of all pharmaceutical orders for the quarter.
- F. The Injunctive Relief Distributors shall only be required to file a single, uniform, electronic form of SOR with any Settling State that receives SORs pursuant to these Injunctive Relief Terms. A Settling State retains the authority pursuant to applicable state law or relevant state agency authority to request additional information about a particular SOR.
- G. It is the objective of the Settling States and the Injunctive Relief Distributors for the Injunctive Relief Distributors to provide SORs to Settling States that identify the same Suspicious Orders as reported to the DEA pursuant to the definition and requirements of the federal Controlled Substances Act and its regulations, although the fields of the SORs submitted to the Settling States as required by Section XIII may differ from the content required by the DEA. To the extent federal definitions and requirements materially change during the term of the Injunctive Relief Terms, the Injunctive Relief Distributors may be required to adjust the format and content of the SORs to meet these federal requirements. The Injunctive Relief Distributors and the State Compliance Review Committee will engage in good faith discussions regarding such adjustments.
- H. It shall not be a violation of the Injunctive Relief Terms if an Injunctive Relief Distributor ships a Suspicious Order or fails to submit or transmit a SOR if:
1. The shipment of the Suspicious Order or failed SOR transmission was due to a computer error (data entry mistakes, coding errors, computer logic issues, software malfunctions, and other computer errors or IT failures); and

2. The Injunctive Relief Distributor reports the error, including a description of measures that will be taken to prevent recurrence of the error, to any affected Settling State, the State Compliance Review Committee, and the Monitor within five (5) business days of its discovery.

XIV. TERMINATED CUSTOMERS

- A. Each Injunctive Relief Distributor shall report to the Clearinghouse, once operational, within five (5) business days (or as otherwise required by state statute or regulation), Customers it has terminated from eligibility to receive Controlled Substances or refused to onboard for the sale of Controlled Substances due to concerns regarding the Customer's ability to provide effective controls against the potential diversion of Controlled Substances following the Effective Date.
- B. The Injunctive Relief Distributors shall report to the relevant Settling State(s), within five (5) business days (or as otherwise required by state statute or regulation) Customers located in such Settling States that it has terminated from eligibility to receive Controlled Substances or refused to onboard for the sale of Controlled Substances due to concerns regarding the Customer's ability to provide effective controls against the potential diversion of Controlled Substances following the Effective Date. Such reports will be made in a uniform format. The Injunctive Relief Distributors and the State Compliance Review Committee shall use best efforts to agree on such uniform format for inclusion prior to the requirement taking effect.
- C. In determining whether a Customer should be terminated from eligibility to receive Controlled Substances, Injunctive Relief Distributors shall apply factors set out in their CSMP policies and procedures, which shall include the following conduct by a Customer:
 1. Has generated an excessive number of Suspicious Orders, which cannot otherwise be explained;
 2. Has routinely demonstrated unresolved Red Flag activity;
 3. Has continued to fill prescriptions for Highly Diverted Controlled Substances that raise Red Flags following an Injunctive Relief Distributor's warning or communication about such practices;
 4. Has failed to provide Pharmacy Customer Data or Dispensing Data in response to a request from an Injunctive Relief Distributor or otherwise refuses to cooperate with the Injunctive Relief Distributor's CSMP after providing the Customer with a reasonable amount of time to respond to the Injunctive Relief Distributor's requests;
 5. Has been found to have made material omissions or false statements on a Pharmacy Questionnaire (the requirements for the contents of a Pharmacy Questionnaire are described in Section IX); or

6. Has been the subject of discipline by a State Board of Pharmacy within the past three (3) years or has had its owner(s) or pharmacist-in-charge subject to license probation or termination within the past five (5) years by a State Board of Pharmacy for matters related to Controlled Substances dispensing or a federal or state felony conviction.
- D. Once the Clearinghouse has made Customer termination data available to each Injunctive Relief Distributor, each Injunctive Relief Distributor shall consider terminating Customers that have been terminated from eligibility to receive Controlled Substances by another distributor as a result of suspected diversion of Controlled Substances if the Customer is ordering only Controlled Substances from the Injunctive Relief Distributor. If the Injunctive Relief Distributor determines not to terminate Customers to which this paragraph applies, the Injunctive Relief Distributor shall document its decision-making. A good-faith decision to continue shipping Controlled Substances to Customers to which this paragraph applies, shall not serve, without more, as the basis of a future claim of non-compliance with the Injunctive Relief Terms.
 - E. For Chain Customers, the provisions in Section XIV.A-D shall apply to the specific pharmacies in question.

XV. EMERGENCIES

- A. In the circumstances of declared national or state emergencies in which the healthcare community relies on the Injunctive Relief Distributors for critical medicines, medical supplies, products, and services, the Injunctive Relief Distributors may be required to temporarily modify their respective CSMP processes to meet the critical needs of the supply chain. These modifications may conflict with the requirements of the Injunctive Relief Terms.
- B. In the case of a declared national or state emergency, the Injunctive Relief Distributors shall be required to give notice to the State Compliance Review Committee of any temporary material changes to their CSMP processes which may conflict with the requirements of the Injunctive Relief Terms and specify the sections of the Injunctive Relief Terms which will be affected by the temporary change.
- C. The Injunctive Relief Distributors shall document all temporary changes to their CSMP processes and appropriately document all customer-specific actions taken as a result of the declared national or state emergency.
- D. The Injunctive Relief Distributors shall provide notice to the State Compliance Review Committee at the conclusion of the declared national or state emergency, or sooner, stating that the temporary CSMP processes put into place have been suspended.
- E. Provided the Injunctive Relief Distributors comply with the provisions of Sections XV.A through XV.D, the Injunctive Relief Distributors will not face liability for

any deviations from the requirements of the Injunctive Relief Terms taken in good faith to meet the critical needs of the supply chain in response to the declared national or state emergency. Nothing herein shall limit Settling States from pursuing claims against the Injunctive Relief Distributors based on deviations from the requirements of the Injunctive Relief Terms not taken in good faith to meet the critical needs of the supply chain in response to a declared national or state emergency.

XVI. COMPLIANCE WITH LAWS AND RECORDKEEPING

- A. The Injunctive Relief Distributors acknowledge and agree that they must comply with applicable state and federal laws governing the distribution of Controlled Substances.
- B. Good faith compliance with the Injunctive Relief Terms creates a presumption that the Injunctive Relief Distributors are acting reasonably and in the public interest with respect to Settling States' existing laws requiring effective controls against diversion of Controlled Substances and with respect to the identification, reporting, and blocking of Suspicious Orders of Controlled Substances.
- C. The requirements of the Injunctive Relief Terms are in addition to, and not in lieu of, any other requirements of state or federal law applicable to Controlled Substances distribution. Except as provided in Section XVI.D, nothing in the Injunctive Relief Terms shall be construed as relieving Injunctive Relief Distributors of the obligation to comply with such laws, regulations, or rules. No provision of the Injunctive Relief Terms shall be deemed as permission for Injunctive Relief Distributors to engage in any acts or practices prohibited by such laws, regulations, or rules.
- D. In the event of a conflict between the requirements of the Injunctive Relief Terms and any other law, regulation, or requirement such that an Injunctive Relief Distributor cannot comply with the law without violating the Injunctive Relief Terms or being subject to adverse action, including fines and penalties, the Injunctive Relief Distributor shall document such conflicts and notify the State Compliance Review Committee and any affected Settling State the extent to which it will comply with the Injunctive Relief Terms in order to eliminate the conflict within thirty (30) days of the Injunctive Relief Distributor's discovery of the conflict. The Injunctive Relief Distributor shall comply with the Injunctive Relief Terms to the fullest extent possible without violating the law.
- E. In the event of a change or modification of federal or state law governing the distribution of Controlled Substances that creates an actual or potential conflict with the Injunctive Relief Terms, any Injunctive Relief Distributor, any affected Settling State, or the State Compliance Review Committee may request that the Injunctive Relief Distributors, State Compliance Review Committee, and any affected Settling State meet and confer regarding the law change. During the meet and confer, the Injunctive Relief Distributors, the State Compliance Review

Committee, and any affected Settling State will address whether the change or modification in federal or state law requires an amendment to the Injunctive Relief Terms. In the event the Injunctive Relief Distributors, the State Compliance Review Committee, and any affected Settling State cannot agree on a resolution, and the dispute relates to whether the generally applicable Injunctive Relief Terms herein should be changed, an Injunctive Relief Distributor, the State Compliance Review Committee, or any affected Settling State may submit the question to the National Arbitration Panel. If the dispute relates to whether a change in an individual State's law requires a modification of the Injunctive Relief Terms only with respect to that State, an Injunctive Relief Distributor, the State Compliance Review Committee, or any affected Settling State may seek resolution of the dispute pursuant to Section XIX. Maintenance of competition in the industry and the potential burden of inconsistent obligations by Injunctive Relief Distributors shall be a relevant consideration in such resolution.

- F. Recordkeeping: Each Injunctive Relief Distributor shall retain records it is required to create pursuant to its obligations hereunder in an electronic or otherwise readily accessible format. The Settling States shall have the right to review records provided to the Monitor pursuant to Section XVIII. Nothing in the Injunctive Relief Terms prohibits a Settling State from issuing a lawful subpoena for records pursuant to an applicable law.

XVII. CLEARINGHOUSE

- A. Creation of the Clearinghouse
1. The Clearinghouse functions shall be undertaken by a third-party vendor or vendors.
 2. The vendor(s) will be chosen through a process developed and jointly agreed upon by the Injunctive Relief Distributors and the State Compliance Review Committee.
 3. Consistent with the process developed by the Injunctive Relief Distributors and the State Compliance Review Committee, within two (2) months of the Effective Date, the Injunctive Relief Distributors shall issue a Request for Proposal to develop the systems and capabilities for a Clearinghouse to perform the services of a data aggregator.
 4. Within five (5) months of the Effective Date, the Clearinghouse Advisory Panel shall select one or more entities to develop the systems for the Clearinghouse and perform data aggregator services. The Clearinghouse Advisory Panel shall select a vendor or vendors that employ or retain personnel who have adequate expertise and experience related to the pharmaceutical industry, the distribution of Controlled Substances, and the applicable requirements of the Controlled Substances Act and the DEA's implementing regulations.

5. Within sixty (60) days of the selection of a vendor(s) to serve as the Clearinghouse, the Injunctive Relief Distributors shall negotiate and finalize a contract with the vendor(s). The date that the contract is signed by the Injunctive Relief Distributors and the vendor(s) shall be referred to as the “*Clearinghouse Retention Date*.”
6. The development of the Clearinghouse shall proceed on a phased approach as discussed in Sections XVII.C and XVII.D.

B. Governance and Staffing of the Clearinghouse

1. *Capabilities.* The selected vendor or vendors shall staff the Clearinghouse in a manner that ensures the development of robust data collection, analytics and reporting capabilities for the Settling States and Injunctive Relief Distributors. To the extent additional expertise is required for the engagement, the vendor(s) may retain the services of third-party consultants.
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 Injunctive Relief 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 an Injunctive Relief Distributor within two years of the Clearinghouse Retention Date.
3. *Liability.* The Injunctive Relief Distributors are entitled to rely upon information or data received from the Clearinghouse, whether in oral, written, or other form. No Injunctive Relief Distributor, and no individual serving on the Clearinghouse Advisory Panel, shall have any liability (whether direct or indirect, in contract or tort or otherwise) to any Party for or in connection with any action taken or not taken by the Clearinghouse. In addition, no Injunctive Relief Distributor, and no individual serving on the Clearinghouse Advisory Panel, shall have any liability (whether direct or indirect, in contract or tort or otherwise) to any Party for or in connection with any action taken or not taken by an Injunctive Relief Distributor based on incorrect, inaccurate, incomplete or otherwise erroneous information or data provided by the Clearinghouse, unless the information or data was incorrect, inaccurate, incomplete or otherwise erroneous because the Injunctive Relief Distributor itself provided incorrect, inaccurate, incomplete or otherwise erroneous data or information to the Clearinghouse. For any legal requirements that are assumed by the Clearinghouse during Phase 2-B pursuant to Section XVII.D.3, liability shall be addressed pursuant to Section XVII.D.3.c.

4. *Clearinghouse Advisory Panel.* The State Compliance Review Committee and Injunctive Relief Distributors shall create a Clearinghouse Advisory Panel no later than sixty (60) days after the Effective Date to oversee the Clearinghouse.
- a) The Clearinghouse Advisory Panel shall have an equal number of members chosen by the State Compliance Review Committee on the one hand, and the Injunctive Relief Distributors on the other. The size of the Clearinghouse Advisory Panel will be decided by the State Compliance Review Committee and the Injunctive Relief Distributors, and the State Compliance Review Committee and the Injunctive Relief Distributors may select as members third-party experts, but no more than one half of each side's representatives may be such third-party experts. At least one member chosen by the State Compliance Review Committee will be based on consultation with the National Association of State Controlled Substances Authorities.
 - b) During the first two years of the operation of the Clearinghouse, the Clearinghouse Advisory Panel shall meet (in-person or remotely) at least once per month. After the first two years of operation, the Clearinghouse Advisory Panel shall meet at least quarterly. The Monitor may attend Clearinghouse Advisory Panel meetings and may provide recommendations to the Clearinghouse Advisory Panel.
 - c) The Clearinghouse Advisory Panel shall establish a subcommittee to advise on issues related to privacy, the Health Insurance Portability and Accountability Act of 1996 ("*HIPAA*"), and data security and a subcommittee to advise on issues related to Dispensing Data. It may establish additional subcommittees. Subcommittees may include individuals who are not members of the Clearinghouse Advisory Panel. The Clearinghouse Advisory Panel may invite one or more prescribers, dispensers, and representatives from state Prescription Drug Monitoring Programs ("*PDMP*") to serve on the Dispensing Data subcommittee. Each Injunctive Relief Distributor shall have a representative on each subcommittee created by the Clearinghouse Advisory Panel.
 - d) The Clearinghouse Advisory Panel may delegate tasks assigned to it by the Injunctive Relief Terms to the Executive Director.
5. *Executive Director.* One employee of the vendor, or one representative from the vendor group in the event that there are multiple vendors, shall be an Executive Director who shall manage day-to-day operations and report periodically to the Clearinghouse Advisory Panel.

C. Phase 1 of the Clearinghouse: Data Collection, Initial Analytics and Reporting

1. System Development

- a) Within one (1) year of the Clearinghouse Retention Date, the Clearinghouse shall develop systems to receive and analyze data obtained from the Injunctive Relief Distributors pursuant to electronic transmission formats to be agreed upon by the Clearinghouse Advisory Panel.
- b) In developing such systems, the Clearinghouse shall ensure that:
 - (1) The systems provide robust reporting and analytic capabilities.
 - (2) Data obtained from Injunctive Relief Distributors shall be automatically pulled from the existing order management data platforms (e.g., SAP).
 - (3) The systems shall be designed to receive data from sources other than the Injunctive Relief Distributors, including pharmacies, non-Injunctive Relief Distributors, the DEA, State Boards of Pharmacy, and other relevant sources, pursuant to standardized electronic transmission formats.
 - (4) The systems 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.
 - (5) The Clearinghouse will establish a HIPAA-compliant database that can be accessed by state authorities, the Injunctive Relief Distributors, and any entities that subsequently participate in the Clearinghouse. The database that will be made available to the Injunctive Relief Distributors and any non-governmental entities that subsequently participate in the Clearinghouse will also blind commercially sensitive information.
 - (6) State authorities shall have access to the HIPAA-compliant database via web-based tools and no additional or specialized equipment or software shall be required. This access shall allow state authorities to query the HIPAA-compliant database without limitation.

- (7) The Injunctive Relief Distributors shall be permitted to use data obtained from the Clearinghouse for anti-diversion purposes, including the uses expressly contemplated by the Injunctive Relief Terms. The Injunctive Relief Distributors shall not sell (or obtain license fees for) data obtained from Clearinghouse to any third-parties. Nothing in the Injunctive Relief Terms shall prohibit an Injunctive Relief Distributor from using its own data, including data provided to the Injunctive Relief Distributor by third-parties other than the Clearinghouse, for any commercial purposes, including selling or licensing its data to third-parties.

2. Aggregation of Data

- a) It is the goal of the Settling States and the Injunctive Relief Distributors for the Clearinghouse to obtain comprehensive data from all distributors, pharmacies, and other relevant data sources to provide maximum permissible transparency into the distribution and dispensing of Controlled Substances. During Phase 1, the Clearinghouse Advisory Panel shall develop recommendations for ways to achieve this goal.
- b) In Phase 1, the Injunctive Relief Distributors shall provide and/or facilitate the collection of, and the Clearinghouse shall collect and maintain, the following:
 - (1) Injunctive Relief Distributor transaction data for Controlled Substances and non-Controlled Substances, specified at the NDC, date, quantity, and customer level.
 - (2) Injunctive Relief Distributor information on Customers that have been terminated and/or declined onboarding due to concerns regarding Controlled Substance dispensing following the Effective Date.
- c) The Clearinghouse shall make available to the Injunctive Relief Distributors, in a format to be determined by the Clearinghouse Advisory Panel, blinded data for their CSMP due diligence functions. The data will include all Controlled Substances and non-Controlled Substances and be refreshed on a regular basis. The Clearinghouse will also seek to provide non-identifying information regarding whether a single distributor is associated with multiple warehouses with unique DEA registrations (e.g., multiple distribution centers operated by a single distributor), in the data it makes available.

- d) During Phase 1, the Clearinghouse Advisory Panel (with input from its Dispensing Data subcommittee) will develop an operational plan to obtain Dispensing Data directly from pharmacies, unless the Clearinghouse Advisory Panel determines it is inadvisable to do so. The operational plan developed by the Clearinghouse Advisory Panel shall address compliance with HIPAA and shall include recommendations to facilitate the collection of Dispensing Data in compliance with HIPAA and relevant state privacy laws. To the extent possible, the Clearinghouse will begin collecting Dispensing Data during Phase 1.
- e) Nothing in the Injunctive Relief Terms shall require the Injunctive Relief Distributors to indemnify or otherwise be responsible to pharmacy customers for any claims resulting from the provision of Dispensing Data to the Clearinghouse, including, but not limited to, claims related to any data breaches occurring with the data transmitted to or maintained by the Clearinghouse.

3. State and Federal Reporting Requirements

- a) The Injunctive Relief Distributors shall comply with state and federal transactional and Suspicious Order reporting requirements related to Controlled Substances as follows:
 - (1) Until such time as the Clearinghouse is able to provide transactional and Suspicious Order regulatory reporting to the states on behalf of the Injunctive Relief Distributors, the Injunctive Relief Distributors shall continue to file all required reports under state law and those reports required by these Injunctive Relief Terms.
 - (2) Once the Clearinghouse is able to process and submit such reports, the Clearinghouse may process and submit those reports on behalf of each Injunctive Relief Distributor to the states. At all times during Phase 1, each Injunctive Relief Distributor shall remain responsible for the identification of Suspicious Orders and will remain liable for a failure to submit transactional data or Suspicious Order reports required under state law or these Injunctive Relief Terms.
 - (3) An Injunctive Relief Distributor may elect to fulfill its reporting obligations directly, rather than have the Clearinghouse assume the responsibility for the transmission of the various reports.

4. Additional Reports and Analytics

- a) In consultation with the Clearinghouse Advisory Panel, the Clearinghouse shall work to develop additional reports and analyses to assist the Settling States and the Injunctive Relief Distributors in addressing Controlled Substance diversion, including, but not limited to, identifying Red Flags consistent with Section VIII.
- b) The Clearinghouse will generate analyses and reports to be used by the Settling States and the Injunctive Relief Distributors based on format and content recommended by the Clearinghouse Advisory Panel. In order to refine the format and reach final recommendations, the Clearinghouse shall prepare sample analytical reports for a sample geographic region to review with the Clearinghouse Advisory Panel. The sample reports will also be shared with the DEA in an effort to receive additional feedback.
- c) After the content and format of the sample reports have been approved by the Clearinghouse Advisory Panel, the Clearinghouse will begin producing reports on a periodic basis.
- d) The Clearinghouse will develop capabilities to provide Settling States customized reports upon reasonable request to assist in their efforts to combat the diversion of Controlled Substances and for other public health and regulatory purposes.
- e) After the Clearinghouse has obtained sufficient Dispensing Data from Customers, the Clearinghouse shall commence providing standard reports to the Settling States and Injunctive Relief Distributors that will include summaries and analysis of Dispensing Data. The reports and analytics of Dispensing Data shall be developed in consultation with the Clearinghouse Advisory Panel (including its Dispensing Data subcommittee) and shall include, but not be limited to:
 - (1) Identification of Customers whose dispensing may indicate Red Flags consistent with Section VIII, as determined by the Clearinghouse from aggregate data; and
 - (2) Identification of Customers whose aggregate dispensing volumes for Highly Diverted Controlled Substances are disproportionately high relative to the population of the relevant geographic area.
- f) The Clearinghouse shall also prepare reports and analyses for the Settling States and Injunctive Relief Distributors identifying prescribers whose prescribing behavior suggests they may not be

engaged in the legitimate practice of medicine. Such reports and analysis shall be developed in consultation with the Clearinghouse Advisory Panel (including its Dispensing Data subcommittee) and shall seek to identify and evaluate:

- (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.
- g) Reports or analysis generated by the Clearinghouse may not be based on complete data due to a lack of participation by non-Injunctive Relief Distributors and pharmacies. As such, Injunctive Relief Distributors shall not be held responsible for actions or inactions related to reports and analysis prepared by the Clearinghouse which may be based on incomplete data due to a lack of participation by non-Injunctive Relief Distributors and pharmacies.

D. Phase 2 of the Clearinghouse: Additional Data Collection and Analytics and Assumption of CSMP Functions

Within one (1) year of Phase 1 of the Clearinghouse being operational, the Clearinghouse and the Clearinghouse Advisory Panel shall develop a detailed strategic and implementation plan for Phase 2 of the Clearinghouse (“*Phase 2 Planning Report*”). Phase 2 will consist of two parts. Phase 2-A will focus on increasing data collection from non-Injunctive Relief 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. Phase 2-B will involve the potential assumption of various CSMP activities, including Threshold setting and order management by the Clearinghouse. The Phase 2 Planning Report will address both Phase 2-A and Phase 2-B. After the completion of the Phase 2 Planning Report, individual Injunctive Relief Distributors, in their sole discretion, may elect not to proceed with Phase 2-B as provided by Section XVII.E. If one or more Injunctive Relief Distributors elect to proceed with Phase 2-B, 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.

1. Phase 2-A: Additional Data Collection and Analytics

- a) During Phase 2-A, the Clearinghouse 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:
- (1) Integration of data from additional sources, including:
 - (a) Transaction data from other distributors, including manufacturers that distribute directly to retail pharmacies and pharmacies that self-warehouse; and
 - (b) Where possible, state PDMP data and other data, including, but not limited to, State Board of Medicine and Board of Pharmacy sanctions, and agreed-upon industry data. If state PDMP data is effectively duplicative of Dispensing Data already obtained in Phase 1, it will not be necessary for the Clearinghouse to obtain state PDMP data.
 - (2) Development of additional metrics analyzing the data available from the additional data sources (PDMP, other pharmacy data, sanction authorities, and third-party volume projections).
 - (3) Development of real-time or near real-time access to distribution data, dispensing data and other data sources.
 - (4) Refinement of methodologies for analyzing Dispensing Data to identify suspicious prescribers.
 - (5) Development of additional capabilities to provide Settling States, the Injunctive Relief Distributors and potentially the DEA customized reporting from the Clearinghouse upon reasonable request.

2. Phase 2-A: Uniform Required Reporting

- a) The Clearinghouse and the Clearinghouse Advisory Panel shall develop uniform reporting recommendations for potential implementation by state regulators in order to allow the Injunctive Relief Distributors to satisfy their obligations under the Injunctive

Relief Terms and state and federal laws in a uniform and consistent manner.

- b) It is a goal of the Settling States and the Injunctive Relief Distributors to:
 - (1) Streamline and simplify required reporting which will benefit the Injunctive Relief Distributors and the Settling States, as well as the DEA;
 - (2) Develop uniform transactional and Suspicious Order reporting requirements; and
 - (3) Provide for the submission of uniform Suspicious Order reports.
3. Phase 2-B: Clearinghouse Assumption of CSMP Functions
- a) With respect to Phase 2-B, the Phase 2 Planning Report shall address:
 - (1) Engagement with stakeholders, including the DEA, to develop the system of Threshold setting and Suspicious Order reporting to potentially be provided by the Clearinghouse;
 - (2) Development of technology and rules, including any proposed changes to federal law or regulations;
 - (3) Development of models for the identification of Suspicious Orders and setting universal Thresholds in a manner consistent with Section XII. These models shall include active order management and order fulfillment protocols to ensure that orders are compared to relevant Thresholds by the Clearinghouse before shipment instructions are provided by the Clearinghouse to the Injunctive Relief 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 Injunctive Relief Distributors.
 - (4) Development of criteria governing distribution to Customers that have placed one or more Orders that exceed a Threshold;

- (5) Development of rules for allocating Orders placed by Customers that have more than one Distributor if one or more Orders 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.
- b) Following implementation of Phase 2-B, the Injunctive Relief Distributors participating in Phase 2-B and the State Compliance Review Committee shall meet and confer with respect to whether to expand the scope of the Clearinghouse to cover additional anti-diversion functions, such as the performance of due diligence.
 - c) CSMP functions that have been assumed by the Clearinghouse during Phase 2-B will no longer be performed by participating Injunctive Relief Distributors individually through their CSMPs. CSMP functions performed by the Clearinghouse will assist participating Injunctive Relief Distributors to satisfy the applicable legal obligations of those Injunctive Relief Distributors. The Clearinghouse's performance of CSMP functions will not relieve participating Injunctive Relief Distributors from their legal obligations unless (i) the Injunctive Relief Distributors and the State Compliance Review Committee jointly enter into a written agreement for the Clearinghouse to assume legal requirements during Phase 2-B; and (ii) all vendors and consultants working on the Clearinghouse agree in writing to assume such obligations. Nothing in this paragraph shall apply to any Injunctive Relief Distributor that does not participate in Phase 2-B pursuant to Section XVII.E.

E. Option to Opt Out of Phase 2-B

1. Each Injunctive Relief Distributor shall have the option, in its sole discretion, to elect not to participate in Phase 2-B at any point. In the event that an Injunctive Relief Distributor elects not to participate in Phase 2-B, that Injunctive Relief Distributor shall cease to have any obligation to fund future costs directly related to Phase 2-B of the Clearinghouse or to implement the Clearinghouse's determinations as to identification of Suspicious Orders and Suspicious Order reporting. If an Injunctive Relief Distributor elects not to participate in Phase 2-B, that Injunctive Relief Distributor shall remain responsible for the requirements specified for Phase 1 and Phase 2-A of the Clearinghouse and shall be responsible for contributing to the costs associated with Phase 1 and Phase 2-A.

2. In the event that an Injunctive Relief Distributor elects not to participate in Phase 2-B, the Clearinghouse Advisory Panel shall discuss and make recommendations for any necessary adjustments to the Phase 2-B capabilities described in Section XVII.D.3.

F. Funding

1. The establishment and ongoing operations of the Clearinghouse shall be funded by the Injunctive Relief Distributors for a period of ten (10) years commencing on the Clearinghouse Retention Date.
2. For each of the first two (2) years of the operation of the Clearinghouse, the Injunctive Relief Distributors will make total payments of \$7.5 million per year combined. For years three (3) through ten (10), the Injunctive Relief Distributors will make total payments of \$3 million per year combined. Additional costs associated with Phase 2-B shall be billed to the Injunctive Relief Distributors participating in Phase 2-B.
3. Payments by the Injunctive Relief Distributors for the Clearinghouse shall be allocated among the Injunctive Relief Distributors as set forth in Section IV.H of the Settlement Agreement, dated as of July 21, 2021, which incorporates these Injunctive Relief Terms as Exhibit P.
4. In the event that the cost of the Clearinghouse exceeds the amounts provided by the Injunctive Relief Distributors, the Injunctive Relief Distributors and State Compliance Review Committee shall meet-and-confer on alternatives, which may include:
 - a) Limiting the operations of the Clearinghouse consistent with a revised budget;
 - b) Seeking additional sources of funding for the Clearinghouse; and/or
 - c) Allocating, in a manner consistent with the allocation of payments between the Injunctive Relief Distributors as set forth in Section XVII.F.3, additional amounts that are the responsibility of the Injunctive Relief Distributors to be used for the operation of the Clearinghouse.
5. The Injunctive Relief Distributors and the State Compliance Review Committee agree to engage in good faith discussions regarding potential continued operation and funding of the Clearinghouse following the initial ten (10) year period of Clearinghouse operations.
6. The Injunctive Relief Distributors and the State Compliance Review Committee shall develop a means to obtain payments from other parties that may use or benefit from the Clearinghouse, including, but not limited

to, other settling defendants, non-Injunctive Relief Distributors, or other parties and the Clearinghouse Advisory Panel shall consider other funding sources for the Clearinghouse. This may include consideration of a user fee or other model by which non-Injunctive Relief Distributors that use the Clearinghouse will contribute to funding the Clearinghouse.

7. In the event that ten (10) or more Settling States reach agreements with any national retail chain pharmacies to resolve claims related to the distribution of Controlled Substances, the Settling States' Attorneys' General agree to make participation in the Clearinghouse, including providing data to the Clearinghouse and contribution to the cost of the operation of the Clearinghouse, a condition of any settlement. The Settling States' Attorneys' General agree to make best efforts to ensure that any other settling distributors and/or pharmacies participate in the Clearinghouse. To the extent that the Attorneys General are able to secure participation by additional distributors and/or pharmacies, it is anticipated that, to the extent practicable based on the financial and relative size of the settling distributor and/or pharmacy, those entities will contribute to the cost of the operation of the Clearinghouse. The Injunctive Relief Distributors' obligation to fund the Clearinghouse shall be partially reduced by contributions obtained from other distributors and/or pharmacies pursuant to a formula to be determined by the Clearinghouse Advisory Panel.

G. Confidentiality

1. All data provided to the Clearinghouse shall be confidential.
2. Information provided by distributors participating in the Clearinghouse may not be provided to any other entity or individual outside those expressly contemplated by the Injunctive Relief Terms.
3. 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. Such information may only be used by receiving distributors for purposes of identifying, minimizing, or otherwise addressing the risk of Controlled Substances diversion. No distributor or pharmacy, including the Injunctive Relief Distributors, shall attempt to obtain revenue from this information. Such information provided by the Clearinghouse shall be compliant with all applicable laws and regulations.
4. If the Clearinghouse receives a request for disclosure of any data, material or other information created or shared under the Injunctive Relief Terms, pursuant to a Third Party Request, the Clearinghouse shall notify the

Injunctive Relief Distributors and the Clearinghouse Advisory Panel of the Third Party Request and any confidential information to be disclosed so that the Injunctive Relief Distributors may seek a protective order or otherwise challenge or object to the disclosure. The Clearinghouse shall provide the Injunctive Relief 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.

H. Data Integrity

1. The Clearinghouse shall use best-in-class technology to preserve the integrity of the data.
2. The Clearinghouse shall 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.
3. The Injunctive Relief Distributors and the Settling States shall not be liable for any breaches of any databases maintained by the Clearinghouse. This does not excuse the Clearinghouse or its vendor(s) from compliance 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.

I. Credit for Investment in the Clearinghouse

1. The Injunctive Relief Distributors and the State Compliance Review Committee shall negotiate in good faith regarding a potential credit against Injunctive Relief Distributors' overall settlement obligations if costs exceed the amounts specified in Section XVII.F.

XVIII. MONITOR

A. Monitor Selection and Engagement

1. The Injunctive Relief Distributors shall engage a Monitor to perform the reviews described in Section XVIII.F. The Monitor shall employ or retain personnel who have appropriate qualifications related to the pharmaceutical industry and the laws governing the distribution of pharmaceuticals, the distribution of Controlled Substances, and the applicable requirements of federal and state law. The Monitor may also employ or retain personnel who have appropriate qualifications in the audit and review of sample documents in order to conduct the reviews described in Section XVIII.F. To the extent additional expertise is required for the engagement, the Monitor may retain the services of third-party consultants.

2. The Monitor must perform each review described in Section XVIII.F in a professionally independent and objective fashion, as defined in the most recent Government Auditing Standards issued by the United States Government Accountability Office. A Monitor shall not be engaged in active litigation involving one or more of the Injunctive Relief Distributors or Settling States or present a potential conflict of interest involving matters concerning an Injunctive Relief Distributor, except by agreement of the affected parties. If the Monitor is employed by an entity that performed work for any Injunctive Relief Distributor or any of the Settling States prior to the Effective Date, the Monitor will cause to be implemented appropriate ethical walls between the Monitor team and the employees of the firm who have previously performed work for an Injunctive Relief Distributor or any of the Settling States.
3. The process for selecting the Monitor shall be as follows:
 - a) Within sixty (60) calendar days of the Effective Date, the Injunctive Relief Distributors and the State Compliance Review Committee shall exchange pools of recommended candidates to serve as the Monitor. The pools shall each contain the names of three (3) individuals, groups of individuals, or firms.
 - b) After receiving the pools of Monitor candidates, the Injunctive Relief Distributors and the State Compliance Review Committee shall have the right to meet with the candidates and conduct appropriate interviews of the personnel who are expected to work on the project. The Injunctive Relief Distributors (individually or in combination) and the State Compliance Review Committee may veto any of the candidates, and must do so in writing within thirty (30) days of receiving the pool of candidates. If all three (3) candidates within a pool are rejected by either the Injunctive Relief Distributors or the State Compliance Review Committee, the party who rejected the three (3) candidates may direct the other party to provide up to three (3) additional qualified candidates within thirty (30) calendar days of receipt of said notice.
 - c) If the Injunctive Relief Distributors or the State Compliance Review Committee do not object to a proposed candidate, the Injunctive Relief Distributors or the State Compliance Review Committee shall so notify the other in writing within thirty (30) days of receiving the pool of candidates. If more than one candidate remains, the State Compliance Review Committee shall select the Monitor from the remaining candidates. Within thirty (30) calendar days of the selection of the Monitor, the Injunctive Relief Distributors shall retain the Monitor, and finalize all terms of engagement, supplying a copy of an engagement letter to the State Compliance Review Committee. The terms of engagement

shall include a process by which Injunctive Relief Distributors may challenge Monitor costs as excessive, duplicative or unnecessary, which process must be approved by the State Compliance Review Committee.

4. The Injunctive Relief Distributors shall be responsible for the Monitor's fees and costs directly related to its performance of the work specified by the Injunctive Relief Terms up to a limit of \$1,000,000 per year per Injunctive Relief Distributor (*i.e.*, a total of \$3,000,000 per year).
5. Prior to each year, the Monitor shall submit a combined annual budget to the Injunctive Relief Distributors and State Compliance Review Committee that shall not exceed a total of \$3,000,000. The Monitor shall submit quarterly reports to the Injunctive Relief Distributors and the State Compliance Review Committee tracking actual spend to the annual budget.
6. In the event that any of the Injunctive Relief Distributors or State Compliance Review Committee believe that the Monitor is not performing its duties and responsibilities under the Injunctive Relief Terms in a reasonably cost effective manner, an Injunctive Relief Distributor or the State Compliance Review Committee shall recommend in writing changes to the Monitor's practices to reduce cost. The Monitor, Injunctive Relief Distributors, and the State Compliance Review Committee shall meet and confer in good faith in response to such a recommendation.
7. In the event that the Injunctive Relief Distributor and the State Compliance Review Committee cannot agree on whether the recommended cost reductions are warranted, either the State Compliance Review Committee or the Injunctive Relief Distributors may submit the question to the National Arbitration Panel, who shall determine whether the Monitor is performing its duties and responsibilities under the Injunctive Relief Terms in a reasonably cost effective manner, and, if not, the necessary changes to the Monitor's practices to reduce cost.
8. If the National Arbitration Panel determines that the Monitor cannot complete the reviews described in Section XVIII.F within the combined annual budget of \$3,000,000, the National Arbitration Panel shall require the Monitor to provide the Injunctive Relief Distributors and the State Compliance Review Committee with a written report explaining why it is not possible to complete the reviews within budget and all steps the Monitor has taken to perform its duties and responsibilities under the Injunctive Relief Terms in a reasonably cost effective manner. After receiving the Monitor's report, the Injunctive Relief Distributors, and the State Compliance Review Committee shall meet and confer in good faith to determine whether an increase in the combined budget is appropriate. If the Injunctive Relief Distributors and the State Compliance Review

Committee cannot reach an agreement on the amount of the reasonable costs in excess of \$3,000,000 for the relevant year, the issue will be submitted to the National Arbitration Panel for resolution. The National Arbitration Panel may award additional costs up to total cap of \$5,000,000 for the relevant year (\$3,000,000 plus an additional \$2,000,000).

9. Unless the Injunctive Relief Distributors and the State Compliance Review Committee agree otherwise as part of the meet and confer process in the prior paragraph (such as by agreeing to limit the Monitor's duties and responsibilities for the remainder of the year), the amount above \$3,000,000 and up to the total cap of \$5,000,000 in a given year necessary for the Monitor to complete the reviews described in Section XVIII.F shall be divided evenly among the Injunctive Relief Distributors without reducing any other amounts that are the responsibility of the Injunctive Relief Distributors.

B. Early Termination of the Monitor

1. In the event any of the Injunctive Relief Distributors or State Compliance Review Committee believe that the Monitor is not performing its duties and responsibilities under the Injunctive Relief Terms in a reasonably professional, competent and independent manner, an Injunctive Relief Distributor or the State Compliance Review Committee shall recommend replacement of the Monitor in writing. The Injunctive Relief Distributors and the State Compliance Review Committee shall meet and confer in good faith in response to a recommendation to replace the Monitor. If the State Compliance Review Committee and the Injunctive Relief Distributors agree that the Monitor should be replaced, a replacement Monitor will be selected in the manner set forth in Section XVIII.A.3.
2. In the event the Injunctive Relief Distributor and the State Compliance Review Committee cannot agree on whether the Monitor should be replaced, either the State Compliance Review Committee or the Injunctive Relief Distributors may submit the question of the Monitor's dismissal to the National Arbitration Panel, and the Monitor shall only be dismissed if that panel finds that there is Good Cause for dismissal. Good Cause for dismissal shall mean (a) a material and substantial breach of the terms of the Monitor's obligations under the Injunctive Relief Terms; (b) any act of dishonesty, misappropriation, embezzlement, intentional fraud, or similar conduct by the Monitor; (c) any clear pattern of bias or prejudice in favor or against any party by the Monitor; (d) conduct by the Monitor that demonstrates unfitness to fulfill the functions of the Monitor reasonably and competently; or (e) conflicts of interest described in Section XVIII.A.2. If the panel finds that the Monitor should be dismissed, a replacement Monitor will be selected in the manner set forth in Section XVIII.A.3.

3. In addition, if the Monitor resigns for any reason, a replacement Monitor will be selected in the manner set forth in Section XVIII.A.3.

C. Term and Reporting Periods

1. The term of the Monitor will be five (5) years from the date the Monitor is appointed, divided into one-year periods for purposes of the reviews and reporting described in Section XVIII (“*Reporting Periods*”).

D. Monitor Access to Information

1. In connection with its reviews set forth in Section XVIII.F, the Monitor may request to interview employees with appropriate authority and responsibilities as necessary. In the event that an Injunctive Relief Distributor believes that the Monitor is requesting an unreasonable number of interviews or requesting interviews of employees who do not have relevant information to the reviews required by Section XVIII.F, the Injunctive Relief Distributor and State Compliance Review Committee shall meet and confer in good faith to resolve this issue.
2. The Chief Diversion Control Officer of each Injunctive Relief Distributor or a direct report of the Chief Diversion Control Officer shall serve as the primary point of contact for the Monitor to facilitate the Monitor’s access to documents, materials, or staff necessary to conduct the reviews specified in Section XVIII.F. The Monitor shall communicate any request for documents, materials, or access to staff to the Chief Diversion Control Officers or their designees.
3. If at any time the Monitor believes there is undue delay, resistance, interference, limitation, or denial of access to any records or to any employee or former employee deemed necessary by the Monitor to conduct the reviews specified in Section XVIII.F, the Monitor shall notify the Chief Diversion Control Officer of the Injunctive Relief Distributor and they shall meet and confer to resolve such issue. If the Monitor believes that the matter was not resolved, the Monitor shall immediately report the issue to the State Compliance Review Committee.
4. To the extent any of the documents requested by the Monitor contain material protected from disclosure by any legal privilege, including the attorney-client privilege or attorney work product protections, an Injunctive Relief Distributor may redact such material before providing the documents to the Monitor, but must provide the Monitor with a privilege log describing the redacted information and identifying the basis for redaction.
5. Notwithstanding any other information referenced and produced pursuant to Section XVIII, the Monitor shall have access to, and each Injunctive Relief Distributor’s Chief Diversion Control Officer shall produce to the

Monitor, any settlement agreements with government entities entered into after the Effective Date specifically concerning the requirements contained in the Injunctive Relief Terms and an Injunctive Relief Distributor's distribution of Controlled Substances (as opposed to distribution of pharmaceutical products in general).

E. Settling States' Access to Monitor

1. Other than in connection with the initiation of a Notice of Potential Violation set forth in Section XIX.B.2, should the Monitor believe it needs to initiate communication with the State Compliance Review Committee regarding an Injunctive Relief Distributor's compliance with the Injunctive Relief Terms, the Monitor's communications should include the Chief Diversion Control Officer or counsel of the affected Injunctive Relief Distributor, regardless of the form of communication.
2. The State Compliance Review Committee shall have access to any settlement agreements produced to the Monitor pursuant to Section XVIII.D.5.

F. Reviews to be Conducted by the Monitor

1. There shall be two (2) types of reviews to be conducted by the Monitor:
 - a) Customer-specific reviews, as set forth in Section XVIII.F.2; and
 - b) System reviews, as set forth in Section XVIII.F.3.
2. Customer-Specific Reviews
 - a) The following Customer-specific reviews will be conducted by the Monitor for each Injunctive Relief Distributor for each of the Reporting Periods:
 - (1) Threshold Change Request Review ("*TCR Review*");
 - (2) Onboarding New Customer Review ("*Onboarding Review*");
 - (3) Ongoing Due Diligence Review ("*Ongoing Diligence Review*");
 - (4) Customer Termination Review ("*Termination Review*"); and
 - (5) Orders that Exceed Thresholds but are Shipped Review ("*Exceeded Threshold Review*").

- b) Sample selection and audit periods for TCR Reviews, Onboarding Reviews, Ongoing Diligence Reviews, Termination Reviews, and Exceeded Threshold Reviews:
- (1) For each Reporting Period, the Monitor will review a representative sample of files for the performance of the TCR Reviews, Onboarding Reviews, and Ongoing Diligence Reviews. The Monitor shall select a sample representative of various geographic regions, customer types (Independent Retail Pharmacy Customers or Chain Customer), and distribution centers.
 - (2) The Monitor will meet and confer with each of the Injunctive Relief Distributors to determine the appropriate audit period within each Reporting Period from which the samples will be selected (e.g. samples will be selected from the first six (6) months of a reporting period to allow the Monitor time to perform its review during the remainder of the reporting period).
 - (3) Within thirty (30) calendar days following the close of the agreed-upon audit period, the Injunctive Relief Distributors (or the Clearinghouse once operational, if able to do so) will provide the Monitor with the following lists of relevant Customers for each type of review:
 - (a) A list of all Customers that requested at least one Threshold increase for a Highly Diverted Controlled Substance during the relevant audit period, including the number of such requests by each Customer;
 - (b) A list of all Customers that were onboarded during the relevant audit period and, during that period, ordered and received Highly Diverted Controlled Substances;
 - (c) A list of all Customers that were the subject of an Ongoing Diligence Review during the relevant audit period;
 - (d) A list of all Customers that, for reasons related to Controlled Substance regulatory compliance, were terminated during the relevant audit period; and
 - (e) A list of all Orders for Highly Diverted Controlled Substances where a decision was made to ship the Order even though the order exceeded the otherwise

applicable Threshold, with number of such shipped orders.

- (4) Within fifteen (15) calendar days of compiling this Customer information for sample selection, each Injunctive Relief Distributor shall propose a reasonable number of customer files for each review to the Monitor.
- (5) Within fifteen (15) calendar days of receiving the lists specified above from the Injunctive Relief Distributors, the Monitor shall choose representative files to be reviewed from these lists. Each list will include the Customers' zip code, geographic region, distribution center, and customer type (Independent Retail Pharmacy Customer or Chain Customer).

c) TCR Reviews

- (1) For each Reporting Period, the Monitor shall conduct a TCR Review for a sample review of Customers who requested at least one Threshold increase for Highly Diverted Controlled Substances for each Injunctive Relief Distributor. For the TCR Reviews, the Monitor shall review the information contained in the files of the sample Customers and determine whether the information reflects substantial compliance with the requirements of Section XII.C.3.

d) Onboarding Reviews

- (1) For each Reporting Period, the Monitor shall conduct an Onboarding Review of a sample of Customers that were onboarded during the applicable audit period and, during that period, ordered and received Highly Diverted Controlled Substances from the Injunctive Relief Distributor. For the Onboarding Reviews, the Monitor shall review the information contained in the files of the sample Customers and determine whether the information reflects substantial compliance with the requirements of Section IX.

e) Ongoing Diligence Reviews

- (1) For each Reporting Period, the Monitor shall conduct an Ongoing Diligence Review of a sample of Customers for each Injunctive Relief Distributor that was the subject of an Ongoing Diligence Review during the relevant audit period. For the Ongoing Diligence Reviews, the Monitor shall review the information contained in the files of the

sample of Customers and determine whether the information reflects substantial compliance with the requirements of Section X.

f) Termination Reviews

- (1) For each Reporting Period, the Monitor shall conduct a review of a sample of Customers that were terminated by each Injunctive Relief Distributor during the audit period. For the Termination Reviews, the Monitor shall review the information contained in the files of the sample of Customers and determine whether the information reflects substantial compliance with the requirements of Section XIV.

g) Exceeded Threshold Review

- (1) For each Reporting Period, the Monitor shall conduct a review of a sample of Orders for Highly Diverted Controlled Substances where a decision was made by the Injunctive Relief Distributor to ship the Order even though the Order exceeded the applicable Threshold. For the Exceeded Threshold Reviews, the Monitor shall review the information contained in the Customer files related to the Orders and determine whether the information reflects substantial compliance with the requirements of Section XIII.B.

3. Annual System Reviews:

- a) The following system reviews will be conducted by the Monitor for each Injunctive Relief Distributor for each of the Reporting Periods:
- (1) CSMP Review;
 - (2) Threshold Setting Process Review;
 - (3) Suspicious Orders and Suspicious Order Report Review;
 - (4) Compensation Review;
 - (5) Red Flag Review; and
 - (6) Review of CSMP Integration with Clearinghouse.
- b) CSMP Review

- (1) For each Reporting Period, the Monitor shall conduct a review of the following materials from each Injunctive Relief Distributor:
 - (a) Current CSMP policies and procedures;
 - (b) Organizational charts for the departments that are relevant to the CSMP organization;
 - (c) Logs and/or summaries of any reports received on the “hot line” required by Section V.E and the action or response of an Injunctive Relief Distributor to any such reports;
 - (d) Copies of the quarterly reports provided by the Chief Diversion Control Officer to the CSMP Committee as required by Section IV.C;
 - (e) Copies of the quarterly reports provided by the CSMP Committee to senior management and the Board of Directors as required by Section VI.C; and
 - (f) Copies of the materials used for the training required by Section VII and lists of the attendees of the training.

- c) Threshold Setting Process Review:
 - (1) For each Reporting Period, each Injunctive Relief Distributor or its outside consultants shall prepare a summary report describing how its Threshold-setting methodology for Independent Retail Pharmacy Customers and Chain Customers complies with Section XII (the “*Annual Threshold Analysis and Assessment Report*”).
 - (2) For each Reporting Period, the Monitor shall review the Annual Threshold Analysis and Assessment Report, determine whether the information reflects substantial compliance with the requirements of Section XII, and include any Observations and Recommendations, as defined in Section XVIII.G, in its annual Audit Report.

- d) Suspicious Orders and Suspicious Order Reporting Review:
 - (1) For each Reporting Period, each Injunctive Relief Distributors will provide the Monitor with a report containing summary metrics for the Suspicious Orders that were reported to the DEA and the Settling States (the

“*Suspicious Order Metrics Report*”). In the Suspicious Order Metrics Report, the Injunctive Relief Distributors will also provide summary metrics for Orders of Highly Diverted Controlled Substances that exceeded a Threshold but were still shipped.

- (2) For each Reporting Period, the Monitor shall review the Suspicious Order Metrics Report, determine whether the information reflects substantial compliance with the requirements of Section XIII, and include any Observations and Recommendations in its annual Audit Report.

e) Compensation Reviews:

- (1) For each Reporting Period, the Monitor will review compensation-related policy documents for each Injunctive Relief Distributor for sales personnel. The Monitor shall analyze those documents and determine whether the compensation policies of each Injunctive Relief Distributor comply with the requirements contained in Section V.

f) Red Flags Review:

- (1) For each Reporting Period, the Monitor shall review the Red Flags defined in Section VIII and their incorporation into each Injunctive Relief Distributor’s policies and procedures. The Monitor shall determine whether the information reflects substantial compliance with the requirements of Section VIII and include any Observations and Recommendations, as called for by Section VIII.C, about those definitions in its annual Audit Report.

g) Review of CSMP Integration with the Clearinghouse:

- (1) For each Reporting Period, each Injunctive Relief Distributor shall prepare a report summarizing the status of the Injunctive Relief Distributor’s CSMP integration with the operation of the Clearinghouse (“*Clearinghouse Integration Report*”). The Monitor shall review each Injunctive Relief Distributor’s Clearinghouse Integration Report, determine whether the information reflects substantial compliance with the requirements of Section XVII, and include any Observations and Recommendations in its annual Audit Report.

G. Observations and Recommendations:

1. If the Monitor notes any areas for potential improvement during the course of the reviews conducted pursuant to the Injunctive Relief Terms, the Monitor shall include any such recommendations in the Audit Report. Collectively, any such questions, concerns or recommendations will be referred to as “*Observations and Recommendations.*”

H. Audit Reports:

1. No later than one hundred and twenty (120) calendar days prior to the end of a Reporting Period and/or at any other time deemed reasonably necessary by the Monitor, the Monitor shall provide each Injunctive Relief Distributor with a draft report detailing any instances of substantial non-compliance with the applicable provisions of the Injunctive Relief Terms from the reviews in Section XVIII.F (the “*Draft Report*”). The Draft Report will also describe any Observations and Recommendations.
2. Within thirty (30) calendar days of its receipt of the Draft Report, the Injunctive Relief Distributor will provide comments and responses to the Draft Report. The Injunctive Relief Distributor will, among other things:
 - a) Respond to each instance of substantial non-compliance, including, where appropriate, describing any corrective action taken (or to be taken).
 - b) Respond to each Observation and Recommendation.
3. Within thirty (30) calendar days of its receipt of the Injunctive Relief Distributors’ responses to the Draft Report, the Monitor shall provide a final report (the “*Audit Report*”) to each Injunctive Relief Distributor and the State Compliance Review Committee. The Monitor shall provide the State Compliance Review Committee with a copy of an Injunctive Relief Distributor’s response to the Draft Report.
4. No action or lack of action by the Settling States regarding information received from the Monitor concerning an Injunctive Relief Distributor’s conduct shall be considered affirmation, acceptance, or ratification of that conduct by the Settling States.

I. Confidentiality:

1. Materials and information provided by the Injunctive Relief Distributors to the Monitor that are designated “*Confidential*” (and any parts, portions, or derivations thereof) (the “*Confidential Information*”) will be kept confidential and not be shown, disclosed, or distributed to any other party, including any other Injunctive Relief Distributor.
2. The Monitor will not use materials or information received from one Injunctive Relief Distributor, or information or analysis developed using

the Confidential Information of an Injunctive Relief Distributor, in its assessment of any other Injunctive Relief Distributor. Because each Injunctive Relief Distributor operates pursuant to its own unique policies and procedures intended to comply with legal and other requirements of the Injunctive Relief Terms, the Monitor shall apply the standards of each Injunctive Relief Distributor to its reviews without preference to the practices or standards applied by any other Injunctive Relief Distributor.

3. If any of the Settling States or the Monitor receive a request for disclosure of any material or information created or shared under the Injunctive Relief Terms, pursuant to a Third Party Request, the Settling State or the Monitor, respectively, shall notify the Injunctive Relief Distributors of the Third Party Request and the Confidential Information to be disclosed so that the Injunctive Relief Distributors may seek a protective order or otherwise challenge or object to the disclosure. The Settling State or the Monitor will provide the Injunctive Relief Distributors 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.
4. Nothing herein will be deemed to prevent any party from claiming any applicable exemption to the public information act, freedom of information act, public records act, or similar law.

XIX. ENFORCEMENT OF INJUNCTIVE RELIEF TERMS

A. State Compliance Review Committee:

1. Any Settling State may initiate a review of a Potential Violation consistent with the process set forth in Section XIX.
2. The State Compliance Review Committee shall assign the Monitor the responsibilities set forth in Sections XIX.B.3 through XIX.B.7, regarding review of a Potential Violation and an opportunity to cure, except with respect to matters requiring interpretation of the Injunctive Relief Terms subject to Section XIX.C.2. The objective of the Monitor shall be to facilitate a resolution among the parties, providing an opportunity to cure, as applicable, for the party against whom a Potential Violation has been alleged.
3. No less than six (6) months before the Monitor's term expires pursuant to Section XVIII, the State Compliance Review Committee and Injunctive Relief Distributors shall meet and confer in good faith to determine the parameters and processes for continued enforcement, consistent to the maximum extent possible with the provisions set forth in Section XIX, for the period after the Monitor's term has ended. Absent agreement between the State Compliance Review Committee and Injunctive Relief

Distributors, all provisions set forth in Section XIX involving the Monitor are excused after the Monitor's term has ended.

4. Should an Injunctive Relief Distributor allege in good faith that a Settling State or the Monitor has impaired the ability of the Injunctive Relief Distributor to meet the Injunctive Relief Terms, the Injunctive Relief Distributor may request the State Compliance Review Committee to mediate any dispute in an effort to avoid the time and expense of litigation regarding interpretation and enforcement of the Injunctive Relief Terms.

B. Process for Review of Potential Violations and Opportunity to Cure:

1. Definition of "Potential Violation": A Potential Violation occurs when an Injunctive Relief Distributor is alleged to not be in substantial compliance with (i) the Injunctive Relief Terms or (ii) a Corrective Action Plan adopted consistent with the process set forth in Section XIX.B.7.
2. Submission of Notice of Potential Violation. An allegation of a Potential Violation shall be submitted to the State Compliance Review Committee in writing by one or more Settling States ("*Notice of Potential Violation*" or "*Notice*") and shall include the following to the extent practicable:
 - a) Specification of the particular Injunctive Relief Term(s) and/or Corrective Action Plan(s) implicated by the Potential Violation;
 - b) Description of the Potential Violation with specificity;
 - c) The reasoning for and, if available, any documentation supporting the allegation that a Potential Violation has occurred, including whether the Potential Violation is a matter identified by the Monitor in an Audit Report; and
 - d) Description of the time-sensitivity of the Potential Violation, if relevant.
3. Assignment to Monitor. The State Compliance Review Committee shall review every Notice. If the State Compliance Review Committee reasonably believes that further review is warranted, the State Compliance Review Committee shall forward the Notice to the Monitor. The Monitor shall ensure that the Injunctive Relief Distributor that is the subject of the Notice receives a copy of the Notice and a proposed schedule consistent with the process set forth in Sections XIX.B.4 and XIX.B.5.
4. Response to Notice of Potential Violation. Within thirty (30) days of receipt of the Notice of Potential Violation, the Injunctive Relief Distributor that is the subject of the Notice shall provide a written response to the referring Settling State(s), the Monitor, and the State Compliance Review Committee. The response (a) shall set forth the

reasons the Injunctive Relief Distributor that is the subject of the Notice believes that it is in substantial compliance with the relevant Injunctive Relief Term(s) and/or Corrective Action Plan(s), and (b) as applicable, shall explain efforts undertaken to cure the Potential Violation and a schedule for completing the efforts to cure.

5. Conference for Parties re Notice of Potential Violation. The parties to the Notice shall meet or otherwise confer regarding the Potential Violation. The parties and the Monitor shall make themselves available for such a meeting (which may at any party's election be a virtual or technology-based meeting), provided, however, that the meeting is not required to take place sooner than fifteen (15) days after a written response to the Notice of Potential Violation.
6. Process for Previously-Submitted Notices of Potential Violation. At the request of the parties to a Notice, the Monitor shall determine whether the Notice implicates the same or similar issues as a previously submitted Notice or is a matter previously identified by the Monitor in an Audit Report involving the same party alleged to have engaged in a Potential Violation, and make an initial determination as to whether the issues needs to be addressed anew. The Monitor shall inform the Settling State and Injunctive Relief Distributor involved in the previous Notice or the subject of a matter previously identified by the Monitor in an Audit Report of its determination within five (5) business days of receipt of the Notice. The Settling State and Injunctive Relief Distributor shall have five (5) business days to object to the determination. If an objection is made, the Monitor shall respond to the objection within five (5) business days. If no objection is made, the party involved in the prior Notice may rely on the response to the previously submitted Notice or matter previously identified by the Monitor in an Audit Report and no further action shall be required.
7. Monitor Resolution of Potential Violation and Opportunity to Cure. Within thirty (30) days of the meeting pursuant to Section XIX.B.5, the Monitor, taking into consideration the submissions of the parties involved in the Notice and other information available to the Monitor, shall resolve the Notice as follows:
 - a) If the Monitor reasonably believes that a Potential Violation is not ongoing or has been substantially resolved as of thirty (30) days from the meeting pursuant to Section XIX.B.5, the Monitor shall provide written notice to the State Compliance Review Committee and the Settling State(s) and Injunctive Relief Distributor involved in the Notice.
 - b) If the Monitor reasonably believes that a Potential Violation is ongoing and has not been substantially resolved as of thirty (30) days from the meeting pursuant to Section XIX.B.5, the Monitor

shall provide written notice to the State Compliance Review Committee and the Settling State(s) and Injunctive Relief Distributor involved in the Notice and request that the Injunctive Relief Distributor prepare, within thirty (30) days of the receipt of such written notice, a Corrective Action Plan to remedy such Potential Violation, including a reasonable period for implementation of such plan. The Monitor may extend the period of time to submit a Corrective Action Plan up to ninety (90) days based on a reasonable request by the affected party.

- c) A Corrective Action Plan may address multiple Potential Violations, and an existing Corrective Action Plan may be amended to address additional Potential Violations.
- d) Within ten (10) business days of submission of a Corrective Action Plan regarding a Potential Violation, the Monitor shall confer with the State Compliance Review Committee and the Settling State(s) and Injunctive Relief Distributor involved in the Notice regarding the proposed Corrective Action Plan. The Monitor may recommend revisions in its discretion. The conference required by this paragraph may at any party's election be a virtual or technology-based meeting.
- e) Within thirty (30) days of the conference in Section XIX.B.7.d, the Monitor shall advise the State Compliance Review Committee and the Settling State(s) and Injunctive Relief Distributor involved in the Notice whether the Monitor has adopted the proposed Corrective Action Plan or whether the Monitor has adopted it after making modifications. The Monitor shall also set forth a reasonable period for implementation of any such plan that has been adopted. The Injunctive Relief Distributor that is subject to a Corrective Action Plan adopted by the Monitor must begin to comply with the Corrective Action Plan within five (5) business days of receiving notice of the Corrective Action Plan has been adopted, unless it seeks review by the State Compliance Review Committee pursuant to Section XIX.C.1.

C. Enforcement Responsibilities of State Compliance Review Committee:

1. The Settling State(s) or Injunctive Relief Distributor involved in a Notice may request the State Compliance Review Committee to review the resolution (including a resolution pursuant to Section XIX.B.7.a) and/or Corrective Action Plan adopted by the Monitor regarding that Notice. Any such request must be made within five (5) business days of a resolution or adoption of a Corrective Action Plan by the Monitor. The State Compliance Review Committee, taking into consideration the resolution by the Monitor, submissions of the Settling State(s) or Injunctive Relief

Distributor, and other information available to the Committee, shall within thirty (30) days of receipt of the request resolve the matter by written notice to the affected parties, which shall include the State Compliance Review Committee's reasoning in reaching its resolution. The State Compliance Review Committee may agree, disagree, or modify any resolution or Corrective Action Plan that it reviews. An Injunctive Relief Distributor that is subject to a Corrective Action Plan that is affirmed or affirmed as amended by the State Compliance Review Committee must within five (5) business days begin to comply with the Corrective Action Plan.

2. The State Compliance Review Committee shall review any issues raised by a Notice regarding the interpretation of the Injunctive Relief Terms at the request of the Settling State(s), Injunctive Relief Distributor involved in a Notice, or the Monitor. Such a request may be made at any time after the Notice's submission, and the request will not extend the timelines set forth in Sections XIX.B and XIX.C.1. The State Compliance Review Committee shall notify the Monitor, Settling State(s) and Injunctive Relief Distributor involved in the Notice of its determination. Settling States and Injunctive Relief Distributors do not waive their rights to challenge the interpretation of the Injunctive Relief Terms by the State Compliance Review Committee in any subsequent proceeding pursuant to Section XIX.E.2.
3. The State Compliance Review Committee may, independent of a Notice of Potential Violation, review requests by a Monitor, Settling State, or Injunctive Relief Distributor regarding the interpretation of the Injunctive Relief Terms. The State Compliance Review Committee shall notify the Monitor and requesting party of its interpretation, including the State Compliance Review Committee's reasoning in reaching its conclusion. Settling States and Injunctive Relief Distributors do not waive their rights to challenge the interpretation of the Injunctive Relief Terms by the State Compliance Review Committee in any subsequent proceeding pursuant to Section XIX.E.2.
4. The State Compliance Review Committee shall make available to all Settling States and Injunctive Relief Distributors any interpretation it issues pursuant to Sections XIX.C.2 and XIX.C.3.

D. Composition of State Compliance Review Committee:

1. A Settling State on the State Compliance Review Committee that is in active litigation with one or more of the Injunctive Relief Distributors, or in another potential conflict of interest involving compliance with Controlled Substances laws and regulations, may not serve on the State Compliance Review Committee for matters involving the affected Injunctive Relief Distributor, and the remaining Settling States on the

State Compliance Review Committee shall within five (5) business days select an alternate Settling State as a replacement.

2. If the affected state on the State Compliance Review Committee disputes that it has a disqualifying active litigation or other conflict of interest, the determination of whether that state has a conflict disqualifying it from serving on the State Compliance Review Committee shall be made by the remaining states on the State Compliance Review Committee.

E. Enforcement Actions:

1. Any written notice or resolution by the State Compliance Review Committee regarding the matters set forth in Sections XIX.B and XIX.C shall provide the State Compliance Review Committee's assessment of the matter but will not be an official opinion of any individual Settling State.
2. Following the issuance of a written notice or resolution of the State Compliance Review Committee pursuant to Section XIX.C, a Settling State or Injunctive Relief Distributor may take whatever action it deems necessary related to the written notice or resolution issued by the State Compliance Review Committee, provided that the Settling State or Injunctive Relief Distributor is either (a) the Settling State that sought review by the State Compliance Review Committee, or (b) the Injunctive Relief Distributor that is the subject of the Potential Violation at issue. Such action may include but is not limited to bringing an action to enforce the settlement agreement, filing a new original action, or, the parties to a Notice attempting to negotiate a Corrective Action Plan directly with each other.
3. The Settling States agree that prior to taking any court or administrative action, other than an action that is necessary to address an immediate threat to the health, safety, or welfare of the citizens of the Settling State, or that a public emergency requiring immediate action exists, it will follow the process outlined in Sections XIX.B and XIX.C.
4. A Settling State or Injunctive Relief Distributor must bring a court or administrative action within six (6) months of any resolution of the State Compliance Review Committee, unless the alleged violation is also an independent violation of state or federal law, or an action that a Settling State concludes is necessary to address an immediate threat to the health, safety, or welfare of the citizens of the State, or that a public emergency requiring immediate action exists, in which cases, the applicable statute of limitations (if any) for sovereign actions shall apply.