

Compliance Addendum

1. RDC shall maintain and implement a Controlled Substance Monitoring Program (“CSMP”) that is designed to identify and report suspicious orders and maintain effective controls against the diversion of controlled substances. The CSMP shall meet the requirements set forth in this Compliance Addendum. The CSMP shall apply to all DEA-registered RDC distribution centers.

2. The effective date of the Compliance Addendum shall be the date upon which the Stipulation and Order of Settlement and Dismissal is approved by the Court. The obligations contained in this Compliance Addendum shall remain in full force and effect for a period of three years from the Effective Date, unless otherwise specified herein.

3. RDC acknowledges and agrees that the obligations undertaken in this Compliance Addendum do not fulfill the totality of RDC’s obligations to maintain effective controls against the diversion of controlled substances or to detect and report to DEA suspicious orders of controlled substances pursuant to the Controlled Substances Act, 21 U.S.C. §§ 801 *et seq.* (“the CSA”), and applicable regulations promulgated by DEA.

4. Definitions. The below terms shall be defined as follows for purposes of this Compliance Addendum:

a. The term “threshold” means the total monthly volume of a controlled substance as defined under the CSA, or a particular category of controlled substances, that RDC allows a pharmacy customer to purchase in any particular calendar month before triggering the investigation and approval process set forth in Paragraph 5(b) below.

b. The term “highly diverted controlled substances” means the controlled substances that RDC designates as being subject to the most restrictive thresholds and/or

supplemental due diligence because such substances have a higher risk of diversion compared to other controlled substances. RDC's list of highly diverted controlled substances currently includes, and shall continue to include, the following: (i) oxycodone; (ii) hydrocodone; (iii) hydromorphone; (iv) methadone; (v) morphine; (vi) carisoprodol; (vii) alprazolam; (viii) tramadol; (ix) oxymorphone; (x) fentanyl; (xi) amphetamine; and (xii) buprenorphine. RDC shall add other controlled substances to the list of highly diverted controlled substances as needed based on information obtained from DEA and other sources related to drug diversion trends.

c. The term "order" means a unique pharmacy customer request on a specific date for a certain amount of a specific dosage form or strength of a controlled substance in one given instance, regardless of other requests made concurrently with that given request. For the purposes of this definition, each line item on an invoice or DEA Form 222 is a separate order.

d. The term "dispensing activity data" means the following information regarding the controlled substances dispensed by a pharmacy during a specific period: (a) the prescription number; (b) the patient's zip code; (c) the drug's name, strength, dosage form, and National Drug Code ("NDC") number; (d) the quantity of the drug dispensed and the days supply; (e) the date the drug was dispensed; (f) the prescriber's name and DEA number; (g) the method of payment; and (h) the total number of prescriptions dispensed, broken down by controlled and non-controlled substances.

5. Within 90 days of the Effective Date, RDC shall implement improved CSMP procedures and systems to review all orders of controlled substances and to detect and report suspicious orders to DEA.

a. RDC shall review and enhance its methodology for calculating and establishing appropriate thresholds designed to detect potentially suspicious orders from pharmacy customers. These thresholds shall be based not only on the customer's historical dispensing activity data, but also on the ordering patterns of comparable pharmacy customers. RDC shall set more restrictive thresholds for orders of highly diverted controlled substances. RDC shall establish appropriate initial thresholds for new customers prior to supplying them with any controlled substances. RDC compliance personnel shall be exclusively responsible for establishing and modifying initial thresholds, and may consult with other RDC personnel to gather information relevant to such determinations.

b. RDC shall not fulfill any order that exceeds the customer's threshold without conducting a thorough and diligent investigation to determine whether the order is suspicious and must be reported to DEA. This investigation shall include, but not be limited to, contacting the customer to obtain an explanation for the increase in ordering and obtaining and reviewing a report from the customer reflecting its most recent dispensing activity data. RDC compliance personnel trained in detecting suspicious orders shall conduct this investigation and shall create documentation sufficiently specific to show the basis for their determination as to whether the order is suspicious and must be reported to DEA. Any decision that an order is not suspicious and need not be reported to DEA must be approved in writing by RDC's Chief Compliance Officer, Director of Compliance, or Assistant Director of Compliance. In addition, RDC will notify the Independent Monitor in writing of any decision that results in fulfilling an order that exceeds a customer's threshold.

c. RDC shall review and enhance its procedures and systems for evaluating and approving customer requests for increased thresholds ("Threshold Change Requests"). Prior

to approving a Threshold Change Request, RDC shall conduct a thorough and diligent investigation to determine whether the increased threshold is warranted. This investigation shall include, but not be limited to, contacting the customer to obtain the basis for the Threshold Change Request, obtaining and reviewing a report from the customer reflecting its most recent dispensing activity data, and conducting an on-site visit to the pharmacy if the pharmacy has not been subject to a site visit within the prior six months. RDC compliance personnel shall conduct this investigation and shall create documentation sufficiently specific to show the basis for their determination as to whether the Threshold Change Request should be approved. RDC shall not temporarily increase thresholds in order to circumvent the requirement to conduct Threshold Change Request investigations. Any increase in a customer's thresholds must be approved in writing by RDC's Chief Compliance Officer, Director of Compliance, or Assistant Director of Compliance. In addition, RDC will notify the Independent Monitor in writing of any decision that results in the approval of a customer's Threshold Change Request.

d. RDC shall review and enhance its procedures and systems for detecting patterns or trends in customer orders and dispensing activity that indicate a pharmacy may be dispensing controlled substances for other than a legitimate medical purpose ("Red Flags"). In the event that RDC identifies a Red Flag for a pharmacy customer, RDC shall conduct a thorough and diligent investigation to determine whether any orders or customer Red Flags should be reported to DEA. Red Flags include, but are not limited to:

- (i) A high percentage of the pharmacy's controlled substance sales are paid for in cash.
- (ii) The pharmacy fills prescriptions for many patients who live far from the pharmacy.

(iii) The pharmacy frequently fills prescriptions for higher quantities than the accepted medical standards.

(iv) A high percentage of the pharmacy's overall dispensing consists of controlled substances.

(v) A disproportionate percentage of the pharmacy's controlled substance sales are for highly diverted controlled substances.

(vi) The pharmacy fills prescriptions written by prescribers acting outside their practice or specialty.

(vii) The pharmacy fills prescriptions for prescribers who have been subject to discipline or a law enforcement action.

(viii) The pharmacy dispenses the same quantity of highly diverted controlled substances to most patients.

(ix) Additional red flags identified by DEA to RDC in writing or otherwise published by DEA.

Upon identification of one or more Red Flags, RDC shall suspend and not resume distribution of controlled substances to the customer unless it reasonably concludes, based on specific and articulable facts, that there is a legitimate explanation for the identified Red Flag(s). RDC compliance personnel trained in detecting suspicious orders shall conduct this investigation and shall create documentation sufficiently specific to show the basis for their determination, including its decision, if any, not to suspend distribution of controlled substances.

e. RDC shall electronically submit all suspicious orders to DEA Headquarters. DEA agrees to provide RDC with instructions and procedures for electronically submitting suspicious orders. RDC shall submit the suspicious order reports in the format as

defined by DEA pursuant to reporting requirements to the centralized database as defined in the SUPPORT Act, § 3292, or as otherwise designated by DEA. RDC shall also submit all suspicious order reports to the DEA Field Division, and these reports shall specify the basis for reporting the order. RDC shall transmit suspicious order reports, if any, to DEA Headquarters and the DEA Field Division within two business days of discovery. RDC shall not fulfill any order deemed to be suspicious.

6. Within 90 days of the Effective Date of this Stipulation, RDC shall implement improved CSMP procedures and systems for conducting due diligence reviews of pharmacy customers to prevent the diversion of controlled substances.

a. RDC shall review and enhance its customer on-boarding procedures and systems to better assess whether prospective customers dispense controlled substances for only legitimate medical purposes. RDC shall, to the extent possible, verify any information that is self-reported by the prospective customer and relied upon to make this assessment. Prior to initiating the sale of controlled substances to a pharmacy, RDC compliance personnel, or a qualified third party consultant acting on behalf of RDC, shall engage in at least the following due diligence: (i) conduct an on-site visit to the pharmacy and interview the pharmacist-in-charge; (ii) complete a report reflecting the findings based on this visit and interview and noting any areas of concern; (iii) review recent dispensing activity data for the pharmacy to identify any Red Flags; (iv) determine whether the pharmacy or the pharmacist-in-charge has been subject to any disciplinary action, and, if so, the basis for the disciplinary action; and (v) conduct a diligent inquiry to determine whether another distributor has previously suspended the pharmacy's ability to purchase controlled substances, and, if so, the reason. In the event that RDC identifies a Red Flag that does not have a legitimate explanation or RDC's due diligence reveals any other

credible information suggesting that the pharmacy may be engaging in diversion, RDC shall not sell controlled substances to the pharmacy and shall report its findings and the results of its due diligence review to the DEA Field Division within two business days.

b. RDC shall review and enhance its procedures and systems for conducting meaningful due diligence of existing customers that purchase controlled substances to better assess whether existing customers dispense controlled substances for only legitimate medical purposes. RDC compliance personnel, or a qualified third party consultant acting on behalf of RDC, must engage in at least the following due diligence for each controlled substance customer: (i) conduct on-site visits and interviews of the pharmacist-in-charge, which shall be done at least once a year for RDC's 100 largest customers of highly diverted controlled substances, as measured by total volume of sales of highly diverted controlled substances during the prior year, and at least once every three years for all other controlled substances customers; (ii) complete a report reflecting their findings based on the visit and interview and noting any areas of concern; (iii) at least three times each calendar year for RDC's 100 largest customers of highly diverted controlled substances, as measured by total volume of sales of highly diverted controlled substances during the prior year, and at least two times each calendar year for all other controlled substances customers, obtain and review the pharmacy's dispensing activity data for the prior three months to identify any Red Flags; (iv) obtain updated completed questionnaires from the pharmacy on an annual basis; and (v) conduct all necessary additional due diligence in response to any information or events raising concerns of potential diversion activities (*e.g.*, the receipt of reliable information from law enforcement about possible diversion, the receipt of information regarding the suspension or revocation of a DEA registration or state license). . Upon identification of any credible information suggesting that an existing customer may be

engaging in diversion, including the presence of one or more Red Flags, RDC shall report its findings and the results of its due diligence review to the DEA Field Division within two business days. In addition, upon identification of such evidence suggesting diversion, including the presence of one or more Red Flags, RDC shall suspend and not resume distribution of controlled substances to the customer unless it reasonably concludes, based on specific and articulable facts, that no such diversion is occurring, including that there is a legitimate explanation for the evidence suggesting diversion and the identified Red Flag(s). RDC compliance personnel trained in detecting suspicious orders shall conduct this investigation and shall create documentation sufficiently specific to show the basis for their determination, including its decision, if any, not to suspend distribution of controlled substances.

c. All steps taken with respect to the due diligence review of prospective or existing customers shall be documented in the customer's file.

7. RDC shall ensure that all policies and procedures relating to its CSMP are included in an updated version of its compliance manual ("CSMP Manual").

8. RDC shall submit periodic reports to DEA Headquarters, the United States Attorney's Office for the Southern District of New York (the "SDNY"), and the Independent Monitor. RDC shall submit its first report within 90 days of the Effective Date. After making its first report, RDC shall thereafter make a report every 180 days (a "Reporting Period"). The reports shall be submitted on or before the last day of each Reporting Period. Each report shall include the following:

a. A list of all RDC compliance personnel, as well as any third-party consultants used by RDC to perform compliance functions.

- b. RDC's list of highly diverted controlled substances as of the end of the Reporting Period.
 - c. A list of RDC's 20 largest customers of highly diverted controlled substances, as measured by total volume of sales of highly diverted controlled substances during the Reporting Period, and a breakdown of the sales of highly diverted controlled substances to each of these customers during the Reporting Period.
 - d. A description of the methodology used during the Reporting Period to calculate and establish thresholds for new and existing RDC pharmacy customers, as well as any changes that were made to the methodology since the prior Reporting Period.
 - e. The total number of suspicious orders reported to DEA during the Reporting Period.
 - f. A copy of any version of the CSMP Manual that was in effect during the Reporting Period, which shall include, among other things, a description of the manner in which RDC identified and reported suspicious orders to DEA during the Reporting Period and a description of the procedures and systems in place during the Reporting Period to conduct due diligence reviews of new and existing pharmacy customers.
9. RDC agrees that DEA personnel may enter its registered locations at any time during regular business hours, without prior notice, to verify compliance with this Compliance Addendum. RDC will permit entry of DEA personnel without an Administrative Inspection Warrant. RDC personnel shall sign a Notice of Inspection when requested to do so by DEA personnel during regular business hours.

10. RDC shall maintain customer due diligence files and all other records sufficient to document compliance with this Compliance Addendum during the period from the Effective Date through six months after the last Reporting Period.

11. RDC may notify the Independent Compliance Monitor of any material provision set forth in this Compliance Addendum that it believes is unduly burdensome, inconsistent with applicable law or regulation, excessively expensive, or otherwise inadvisable, as well as the basis for such conclusion. Such notification shall be sent to the Monitor and the Office, and must include a written proposal of an alternative approach, policy, procedure or system that RDC believes will achieve the same objective or purpose as the challenged provision. The Office shall in its sole discretion, determine whether to accept RDC's proposed revision, to maintain the existing provision, or to adopt a different alternative.