

## **COMPLIANCE ADDENDUM**

### **I. PREAMBLE**

McKesson Corporation ("McKesson") and the Drug Enforcement Administration ("DEA") hereby enter into this Compliance Addendum ("Addendum") to the Memorandum of Agreement ("MOA") between McKesson and DEA.

McKesson recognizes that the implementing regulations (21 C.F.R. Part 1300 et seq.) of the Controlled Substances Act ("CSA") (21 U.S.C. §§ 801, et seq.) require it to "design and operate a system to disclose to the registrant suspicious orders of controlled substances" and to report those orders to DEA, including "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency," 21 C.F.R. § 1301.74(b), and to "maintain[] . . . effective controls against diversion," 21 U.S.C. § 823(b)(1). Prior to the Effective Date (defined in Section II.A below), McKesson established and implemented a U.S. Pharmaceutical Controlled Substances Monitoring Program ("CSMP") that McKesson believes is designed to detect and report suspicious orders and to maintain effective controls against diversion of controlled substances, as required under the CSA and the implementing regulations. McKesson believes that the obligations set forth in this Addendum serve to promote compliance with the requirements contained in its CSMP and the requirements of the CSA and the implementing regulations.

DEA does not endorse or approve of any specific system or approach implemented by DEA registrants to satisfy their obligations under 21 C.F.R. § 1301.74(b) or 21 U.S.C. § 823(b)(1). DEA has taken no action during the negotiation of this Addendum, and is taking no action by entering into this Addendum that can be interpreted to be directly or indirectly endorsing or approving the system that McKesson is currently utilizing to meet its obligations under the CSA and the implementing regulations. Going forward, DEA's actions in fulfilling the oversight of McKesson under this Addendum, including the receipt of information from McKesson or the Independent Review Organization ("IRO") provided for in Section IV and/or its participation in meetings with McKesson representatives or the IRO, shall not be construed or interpreted to be directly or indirectly endorsing or approving the system that McKesson is utilizing to meet its obligations under the CSA and the implementing regulations.

DEA expects McKesson, like all distributor registrants, to employ a controlled substance monitoring program that is effective at all times in meeting the requirements of the CSA and the implementing regulations. If McKesson's system proves to be ineffective in meeting these requirements, it will not be a valid defense in any legal action for McKesson to claim that it was employing a system that was known to or disclosed to DEA.

## **II. TERM, SCOPE AND DEFINITIONS**

### **A. Term and Scope**

The "Effective Date" of this Addendum shall be the date on which the final signatory of the MOA executes the MOA. The term of this Addendum shall be five (5) years from the Effective Date, unless otherwise specified herein. Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a "Reporting Period."

Except as otherwise stated herein, this Addendum shall apply to sales of controlled substances to independent retail pharmacy customers ("customers" or "independent retail pharmacy customers") by: (i) all McKesson U.S. Pharmaceutical distribution centers that currently hold a DEA Certificate of Registration, as identified in Appendix A and (ii) any McKesson U.S. Pharmaceutical distribution center that may obtain a DEA Certificate of Registration during the term of this Addendum.

This Addendum provides specific compliance and audit obligations to be undertaken by McKesson U.S. Pharmaceutical. McKesson understands that policies and procedures, such as a Code of Conduct, are central components to an effective controlled substance monitoring program, and further, that maintenance and oversight of policies to address DEA requirements create a culture of compliance in support of those requirements. To the extent that any compliance obligations set forth in this Addendum have not been implemented as of the Effective Date, McKesson shall include descriptions of the status of the implementation of those obligations in the reports to be submitted to DEA and DOJ (collectively "the government"), as specified in Section VIII herein.

### **B. Definitions**

This Addendum shall be governed by the following definitions:

#### **1. Threshold**

The term "threshold" refers to the mechanism by which McKesson's CSMP monitors orders for controlled substances on a monthly basis. Customers eligible to purchase controlled substances have a monthly volume-based threshold assigned to each controlled substance base code purchased by the customer. The monthly threshold caps the total amount of doses that a customer may purchase for a controlled substance base code in any particular calendar month.

#### **2. Highly Diverted Controlled Substances**

The term "Highly Diverted Controlled Substances" refers to controlled substances that McKesson has designated as subject to the most restrictive thresholds and/or supplemental diligence because they have a higher risk of diversion compared to other controlled substances. During the term of this Addendum, McKesson shall have a

designated list of Highly Diverted Controlled Substances. As of the Effective Date, McKesson has listed the following drugs on the Highly Diverted Controlled Substances List: 1) oxycodone, 2) hydrocodone, 3) hydromorphone, 4) methadone, 5) morphine, 6) carisoprodol, 7) alprazolam, 8) tramadol, and 9) oxymorphone.

### 3. Order

The term "Order" means a unique 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 that is entered into McKesson's electronic order processing and fulfillment system for delivery by McKesson or its contracted couriers. For the purposes of this definition, each line item on an invoice or DEA Form 222 is a separate Order.<sup>1</sup>

### 4. Omit

The term "omit" or "omitted" refers to McKesson's practice of blocking and not filling a customer's Order for a specific controlled substance base code that exceeds the customer's threshold.

## III. COMPLIANCE OBLIGATIONS

### A. U.S. Pharmaceutical Compliance Program

As set forth in the Preamble, prior to the Effective Date, McKesson established and implemented its CSMP that McKesson believes is designed to detect and report suspicious orders and to maintain effective controls against diversion of controlled substances. This Addendum addresses certain elements of McKesson's CSMP.

Prior to the Effective Date, McKesson provided DEA with information about its CSMP, including a copy of the current CSMP Operating Manual for independent retail pharmacy customers ("CSMP Operating Manual"). The information that McKesson provided to DEA included details about the methodology and procedures to be used to establish monthly thresholds and about McKesson's suspicious order identification and reporting procedures. As set forth in the Preamble, DEA's review of the CSMP and any other actions taken during the negotiations of this Addendum do not constitute DEA's direct or indirect approval or endorsement of the CSMP.

McKesson acknowledges that the CSMP it employs must be and remain effective in identifying and reporting suspicious orders, as required by the CSA and the implementing regulations. Prior to the Effective Date, McKesson implemented a system

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<sup>1</sup> The term "order" is not defined in the CSA or the implementing regulations. McKesson agrees that the definition of Order set forth above is appropriate for use in this Addendum only and that any litigation arising out of an alleged breach of this Addendum will be governed by this definition. McKesson expressly reserves the right to challenge the use of this definition in any future administrative or court proceeding brought by DEA or the Department of Justice under the CSA or the implementing regulations.

for detecting suspicious orders that utilized monthly thresholds. After the Effective Date, McKesson intends to continue to utilize monthly thresholds to detect suspicious orders and report such orders to DEA. In addition, after the Effective Date, McKesson intends to implement enhanced methodologies to establish monthly thresholds which will take into account customer specific data and benchmark data for customers of similar sizes in specified geographic regions.

As provided in the CSMP Operating Manual, omitted Orders are reported to DEA pursuant to 21 C.F.R. § 1301.74(b) in the manner described above. No omitted Orders will subsequently be shipped to customers.

After the Effective Date, McKesson intends to utilize other metrics and tools to monitor customers who order controlled substances. McKesson may also conduct additional due diligence based on certain events (e.g., receipt of reliable information from law enforcement about diversion or receipt of information regarding the suspension or revocation of a DEA registration or state license, etc.) (referred to herein as "Event Triggered Due Diligence"). Depending on the results of the Event Triggered Due Diligence, McKesson may suspend a customer's ability to purchase controlled substances or terminate the customer in question.

#### B. Organization

During the term of this Addendum, McKesson shall maintain a U.S. Pharmaceutical Regulatory Affairs & Compliance Department.

##### 1. U.S. Pharmaceutical Regulatory Affairs & Compliance Department

###### a. Senior Vice President, U.S. Pharmaceutical Regulatory Affairs & Compliance

The CSMP shall be administered by employees within McKesson's U.S. Pharmaceutical Regulatory Affairs & Compliance Department and supervised by the Senior Vice President, U.S. Pharmaceutical Regulatory Affairs & Compliance ("Senior VP").

The Senior VP shall report directly to the President of U.S. Pharmaceutical. The Senior VP shall have primary responsibility for overseeing the development and implementation of CSMP policies, procedures, and practices, which are designed to promote compliance with the requirements set forth in this Addendum, the CSA, and the implementing regulations. The Senior VP shall also be responsible for overseeing the operation of McKesson's CSMP as it is implemented. The Senior VP shall also be responsible for the reporting obligations set forth in Section VIII of this Addendum.



b. Regulatory Affairs Department

As of the Effective Date, McKesson has appointed individuals to the following positions:

- i Senior VP;
- ii Senior Director, Regulatory Affairs CSMP, East Region;
- iii Senior Director, Regulatory Affairs CSMP, West Region;
- iv Senior Director, Regulatory Affairs CSMP, Retail National Accounts;
- v Senior Director, Regulatory Affairs CSMP, Statistics and Analytics;
- vi Directors of Regulatory Affairs CSMP;
- vii Regulatory Affairs Managers CSMP; and
- viii Regulatory Affairs Administrative Support CSMP.

During the term of this Addendum, McKesson may create new positions in addition to those listed above. Collectively, the positions listed above, as well as any new positions that are created during the term of this Addendum, are referred to as the "Regulatory Affairs Department."

c. Independent Contractors

The Regulatory Affairs Department may also retain qualified non-employees, independent contractors, or outside firms to perform work for or on behalf of the Regulatory Affairs Department. All such outside personnel who are expected to devote 50% or more of their time to performing work for or on behalf of the Regulatory Affairs Department during the applicable Reporting Period are referred to in this Addendum as "Regulatory Affairs Third-Party Personnel."

The Senior VP shall take reasonable steps to inform all Regulatory Affairs Third-Party Personnel about their specific responsibilities with respect to the CSMP and this Addendum, including their obligations to notify any member of the CSMP Regulatory Operating Committee, their McKesson client contact, and/or members of McKesson's legal department about any known or suspected violations of the CSMP, the CSA, and the implementing regulations.

## 2. CSMP Regulatory Operating Committee

Prior to the Effective Date, McKesson established a CSMP Regulatory Operating Committee ("ROC") comprised of the Senior VP, Senior Directors within the Regulatory Affairs Department, as well as a representative from McKesson's legal department. The ROC currently includes: the Senior VP; the Senior Director, Regulatory Affairs, East Region; the Senior Director, Regulatory Affairs, West Region; the Senior Director, Regulatory Affairs, Retail National Accounts; the Senior Director, Regulatory Affairs, Statistics and Analytics; and Counsel to the Regulatory Affairs Department. The ROC shall oversee the effectiveness of the CSMP including making and/or reviewing program based decisions, (e.g., customer due diligence, controlled substance thresholds and customer terminations), development, implementation and execution of CSMP enhancements, and supporting technology and work needs of the Regulatory Affairs Department.

## 3. U.S. Pharmaceutical Controlled Substance Compliance Program National Governance Committee

Prior to the Effective Date, McKesson established the U.S. Pharmaceutical Controlled Substance Compliance Program National Governance Committee ("National Governance Committee") with oversight responsibility of U.S. Pharmaceutical's compliance with the CSA and DEA regulations regarding controlled substances. This committee is chaired by the President of U.S. Pharmaceutical and is comprised of executives of U.S. Pharmaceutical including the Senior VP, Senior Vice Presidents for Distribution Operations, Chief Operating Officer, Retail National Accounts, Chief Financial Officer and Human Resources as well as representatives from McKesson legal and Internal Audit Departments. The National Governance Committee shall provide high-level oversight of U.S. Pharmaceutical's controlled substance compliance program, including training and education, compliance with the CSA and the implementing regulations, and the CSMP.

### C. Compensation and Independence

#### 1. Independence of Regulatory Affairs Department

McKesson agrees that members of the Regulatory Affairs Department and Regulatory Affairs Third-Party Personnel will not report to the U.S. Pharmaceutical Chief Operating Officer, the Senior Vice President of Retail National Accounts, or any employee in their direct chain of command or department (these collective organizations referred to as "McKesson Sales Department").

McKesson agrees that the McKesson Sales Department shall have no authority to make decisions regarding the promotion, compensation, demotion, admonition, discipline, commendation, periodic performance reviews, hiring, or firing of members of the Regulatory Affairs Department and Regulatory Affairs Third-Party Personnel. However, nothing in this Addendum shall be construed to prevent the McKesson Sales Department from reporting noncompliance with the CSA, the implementing regulations,

McKesson's Code of Conduct or other policies, the CSMP Operating Manual, or this Addendum by members of the Regulatory Affairs Department or Regulatory Affairs Third-Party Personnel. Similarly, McKesson agrees that employment decisions (e.g., promotions, demotions, admonitions, disciplinary decisions, periodic performance reviews, hiring or firing) regarding members of the Regulatory Affairs Department and Regulatory Affairs Third-Party Personnel shall not be based in part or whole on levels of sales of controlled substances (e.g., the McKesson Sales Department shall not recommend an adverse employment decision for a member of the Regulatory Affairs Department due to declining sales of controlled substances).

Nothing in this Addendum shall prevent McKesson from taking into account levels of controlled substances sales in making determinations regarding the overall structure and composition of the Regulatory Affairs Department, including headcount, individual skill requirements and workload management. In addition, nothing in this Addendum shall prevent the Senior VP from soliciting input from the McKesson Sales Department about the general performance of Regulatory Affairs Department or Regulatory Affairs Third-Party Personnel (e.g., quality of training, timeliness in the performance of daily tasks, communication skills, work ethic and other general employment criteria not directly based on levels of controlled substances sales).

## 2. Compensation

McKesson agrees the compensation for Regulatory Affairs Department and Regulatory Affairs Third-Party Personnel shall not be based on revenue or profitability targets or expectations for sales of controlled substances, either in isolation from or in comparison to sales of non-controlled substances (e.g., members of the Regulatory Affairs Department shall not be paid individual commissions based on level of controlled substances sales in a particular geography). Members of the Regulatory Affairs Department and Regulatory Affairs Third-Party Personnel (as applicable) shall be entitled to participate in generally available incentive compensation programs involving grants of McKesson stock and stock options, the Management Incentive Plan ("MIP"), Long-term Incentive Plan ("LTIP") and other equivalent programs that may be introduced in the future during the term of this Addendum. Formulas for those compensation programs and for setting base salaries include company-wide or business unit financial performance, which includes total sales for all McKesson products, including controlled substances.

### D. Written Standards

#### 1. McKesson's Code of Conduct

Prior to the Effective Date, McKesson implemented the McKesson Code of Conduct which is applicable to all McKesson U.S. Pharmaceutical employees ("Code of Conduct"). The Code of Conduct, among other obligations, requires the following: employees must conduct business with integrity, report violations of law, regulations or Company policy related to McKesson's business, and cooperate with any investigations of potential violations of laws related to McKesson's business or corporate policy.

Employees are expected to comply with the Code of Conduct on an ongoing basis. McKesson shall maintain its Code of Conduct on its website throughout the term of this Addendum.

The Compliance, Regulatory & Ethics Department shall periodically review the Code of Conduct to determine if revisions are appropriate and shall facilitate any necessary revisions based on such review. A revised Code of Conduct shall be posted on McKesson's website no later than thirty (30) calendar days after any revisions are finalized.

## 2. Policies and Procedures

Prior to the Effective Date, McKesson finalized and provided copies of the CSMP Operating Manual to all Regulatory Affairs Department personnel.

The CSMP Operating Manual addresses procedures and policies related to the detection and reporting of suspicious orders of controlled substances and maintaining effective controls against diversion. The CSMP Operating Manual addresses the following: (i) monthly threshold management for certain controlled substance drug families; (ii) customer due diligence for new and existing customers, including identification of potential "red flags" for controlled substance diversion; (iii) customer onboarding processes and procedures; and (iv) identification and submission to DEA of suspicious order reports. The CSMP Operating Manual shall be updated as necessary (including any updates based on guidance from the National Governance Committee). McKesson shall provide all members of the Regulatory Affairs Department with updates to the CSMP Operating Manual within thirty (30) calendar days after any substantive revisions are finalized.

McKesson agrees that the CSMP policies and procedures, however amended during the term of this Addendum, shall not authorize: (i) final threshold determinations to be made by any member of the McKesson Sales Department; or (ii) improper continuous temporary threshold increases in order to circumvent the threshold review investigation and due diligence process.

### E. Training and Awareness

#### 1. Regulatory Affairs Department

Within thirty (30) calendar days of the Effective Date, McKesson will provide all members of the Regulatory Affairs Department and Regulatory Affairs Third-Party Personnel with a copy of this Addendum. In addition, within thirty (30) calendar days of the Effective Date, McKesson shall provide all members of the Regulatory Affairs Department and Regulatory Affairs Third-Party Personnel with direction about their individual responsibilities concerning meeting the requirements and obligations contained in this Addendum. This direction shall be provided by an appropriate supervisor in the Regulatory Affairs Department.

For all individuals who become employees of the Regulatory Affairs Department, including Regulatory Affairs Third-Party Personnel, after the Effective Date ("new Regulatory Affairs employees"), McKesson shall provide the training described below within sixty (60) calendar days of the commencement of employment. McKesson shall provide training to all new Regulatory Affairs employees on the following subjects: (i) relevant portions of the CSMP Operating Manual; (ii) relevant provisions of the CSA and the implementing regulations; (iii) relevant obligations contained in the MOA; and (iv) relevant obligations set forth in this Addendum. In addition, within sixty (60) calendar days of the commencement of employment of a new Regulatory Affairs employee, McKesson shall provide that employee with direction about their individual responsibilities concerning meeting the requirements and obligations contained in the CSA, the implementing regulations and this Addendum. This direction shall be provided by an appropriate supervisor in the Regulatory Affairs Department.

## 2. Training Certification

After the completion of any training required by this Addendum, each member of the Regulatory Affairs Department shall certify that they have received the applicable training. McKesson shall maintain copies of the training certifications ("Training Certificates") within the Regulatory Affairs Department or the compliance department until the expiration of the term of this Addendum. McKesson agrees that, upon written request by DEA, it will provide DEA with copies of the Training Certifications within ten (10) calendar days of the receipt of the written request. McKesson also agrees that, upon written request by DEA, it will provide DEA with a list of other U.S. Pharmaceutical positions (by title and region) who were required to attend CSMP training within a specified Reporting Period within ten (10) calendar days of receipt of the written request. McKesson agrees that it will provide DEA with copies of Training Certificates and training lists without requiring a Notice of Inspection, an administrative subpoena, or other process.

### F. Non-Retaliation Policies

Prior to the Effective Date, McKesson issued various policies prohibiting retaliation against employees who report violations of company policy or the law committed by other employees (collectively "non-retaliation policies"). During the term of this Addendum, McKesson shall maintain non-retaliation policies that prohibit retaliation against an employee who reports in good faith a violation of the CSMP, the CSA, or the implementing regulations, as well as employees who cooperate in good faith with DEA investigations.

### G. Ethics Hotline

Prior to the Effective Date, McKesson established an ethics hotline known as the "Integrity Line" in order to permit employees to report violations of company policy or the law anonymously. The Integrity Line is administered by an independent third-party vendor under the supervision of McKesson's Compliance, Regulatory and Ethics



Department. McKesson agrees to maintain an ethics hotline during the term of this Addendum.

#### H. CSMP Record-Keeping

The CSMP Operating Manual sets forth various requirements concerning the documentation that is required to be completed and maintained for different functions performed by the Regulatory Affairs Department. More specifically, the CSMP Operating Manual requires the Regulatory Affairs Department to complete certain documents when (i) onboarding new customers, (ii) evaluating and approving customer requests for increased thresholds (a "threshold change request" or "TCR"), and (iii) performing Event Triggered Due Diligence (collectively "due diligence documents"). The Regulatory Affairs Department shall complete due diligence documents, in substance, within the time frames specified in the CSMP Operating Manual.

McKesson shall maintain electronic and/or hard copy customer files for due diligence documents created after the Effective Date ("customer files"). The Regulatory Affairs Department shall store due diligence documents created after the Effective Date in the manner specified in the CSMP Operating Manual.

#### I. Thresholds

The CSMP Operating Manual sets forth procedures for establishing and adjusting thresholds by the Regulatory Affairs Department. The Regulatory Affairs Department establishes initial thresholds after the completion of the customer onboarding process. As set forth in the CSMP Operating Manual, the Regulatory Affairs Department may adjust a threshold based on periodic threshold review or after the review and evaluation of a TCR for a customer.

After the Effective Date, McKesson intends to implement an updated methodology for calculating and establishing customer thresholds. McKesson expects to implement this updated methodology during the First Reporting Period and will provide notice to DEA in accordance with Section VIII of this Addendum. The implementation of this new methodology will be done in an automated fashion and will be the primary mechanism for identifying Orders to be reported to DEA pursuant to 21 C.F.R. § 1301.74(b). To the extent that this new methodology resets existing thresholds or thresholds are changed as a result of programmatic threshold adjustments (*i.e.*, threshold adjustments initiated by the Regulatory Affairs Department that are approved in advance by the ROC), those threshold changes will be made in an automated fashion and will not be separately documented in due diligence documents for maintenance in individual customer files. Similarly, if thresholds are adjusted in the future based on the application of an updated methodology through the automated process, those adjustments will not be separately documented in due diligence documents and maintained in customer files.

As set forth in the CSMP Operating Manual, McKesson shall maintain appropriate documentation for audit purposes for automated threshold adjustments and

programmatic threshold adjustments. McKesson anticipates that its computer systems will have the ability to generate reports that list automated and programmatic threshold adjustments.

With the exception of the automated or programmatic processes described above, individual customer thresholds may only be increased through the TCR process or the process for establishing due diligence based thresholds. Threshold increases that are approved by the Regulatory Affairs Department in accordance with these processes shall be documented in the manner specified in the CSMP Operating Manual and those documents shall be maintained in the customer due diligence files.

J. Suspicious Order Reporting

1. Suspicious Order Reports

McKesson currently transmits Orders that are omitted to DEA at the end of each business day via submissions to DEA Headquarters through DEA's website. Such submissions are McKesson's suspicious orders reports pursuant to 21 C.F.R. § 1301.74(b). McKesson submits the suspicious order reports in the same format as ARCOS data. McKesson agrees to continue to submit suspicious order reports to DEA, pursuant to 21 C.F.R. § 1301.74(b), in this manner during the term of this Addendum.

2. No Shipment of Suspicious Orders

Omitted Orders shall be blocked and not shipped (*i.e.*, omitted Orders are "killed" in the McKesson order processing and fulfillment computer system). In the past, McKesson's order processing and fulfillment system has experienced data entry mistakes, coding errors, software malfunctions, and other computer errors or IT failures (these types of errors or failures are referred to herein as "computer errors"). During the term of this Addendum, computer errors that result in the shipment of Orders that should have been omitted and blocked shall not be a breach of any provision in this Addendum and shall not be the subject of penalties under Section IX. Should McKesson experience any such computer errors after the Effective Date, McKesson will report the event to DEA within three (3) business days of discovery. McKesson shall include in its report a description of the scope of the computer error and an estimate of time necessary to correct the error. Once the computer error is corrected, McKesson will notify DEA of the correction and, to the extent feasible, will provide DEA a list of the customers that received affected orders (*i.e.*, orders that would have been omitted but for the event).

K. Highly Diverted Controlled Substances

The CSMP Operating Manual sets forth the procedures to be followed by the Regulatory Affairs Department concerning eligibility to purchase Highly Diverted Controlled Substances by new and existing customers. In addition, the CSMP Operating Manual sets forth procedures for the establishment of initial thresholds for Highly Diverted Controlled Substances and procedures for evaluating and approving

increases in thresholds for those substances. The CSMP Operating Manual also sets forth the documentation that is required to be completed by the Regulatory Affairs Department for threshold determinations for Highly Diverted Controlled Substances and for onboarding new customers who wish to purchase Highly Diverted Controlled Substances (excluding pilot programs that test and evaluate methodology changes for a limited period of time for a limited number of distribution centers, "Pilot Programs").

McKesson agrees that, during the term of this Addendum, it will maintain a system that requires the establishment and maintenance of thresholds for Highly Diverted Controlled Substances for those customers who are eligible to purchase Highly Diverted Controlled Substances.

#### **IV. COMPLIANCE REVIEWS**

##### **A. IRO Selection and Engagement**

McKesson shall engage an IRO that employs or retains personnel who have adequate expertise and experience related to the pharmaceutical industry, the distribution of controlled substances, and the applicable requirements of the CSA and DEA's implementing regulations. To be qualified, the IRO shall also employ or retain personnel who have expertise in the audit and review of sample documents in order to conduct the reviews described below. To the extent that additional expertise is required for the engagement, the IRO may retain the services of third-party consultants. The IRO must perform each review described below in a professionally independent and objective fashion, as defined in the most recent Government Auditing Standards issued by the United States Government Accountability Office. For firms that performed work for McKesson prior to the term of the Addendum and/or may be expected to perform work during the term of the Addendum, independence may be achieved by implementing appropriate ethical walls between the IRO team and the employees who have previously performed work for McKesson.

The process for selecting the IRO shall be as follows.

1. Within sixty (60) calendar days of the Effective Date, McKesson shall provide to the government, in writing, a list of three (3) qualified candidates to serve as the IRO.
2. If the government, in its sole discretion, determines that one or more of the proposed candidates does not meet the criteria set forth above, the government may direct McKesson to provide up to two (2) additional qualified IRO candidates by notifying McKesson in writing within ten (10) business days of receiving McKesson's original submission. In this event, McKesson must provide the government with additional qualified candidates within thirty (30) calendar days of receipt of the government's notice.

3. Within thirty (30) calendar days of receiving the final list of qualified IRO candidates from McKesson, the government shall select and notify McKesson in writing of its selection of the IRO from among the qualified IRO candidates submitted.
4. Within thirty (30) calendar days of receiving written notice of the selection of the IRO, McKesson shall retain the IRO and finalize all terms of engagement, supplying a copy of an engagement letter to the government. McKesson shall bear all costs for the IRO under the Addendum.

B. Restrictions on Future Employment of IRO

McKesson U.S. Pharmaceutical agrees that, absent written permission from DEA, it shall not solicit members of the IRO team who performed work on any of the reviews conducted pursuant to the terms of this Addendum as employees for a period of twelve (12) months following the termination of the IRO's duties, as set forth herein. Following the termination of the IRO's duties under the Addendum, McKesson U.S. Pharmaceutical may retain members of the IRO team to perform consulting or other services. For the purposes of this paragraph, the term "solicit" excludes recruitment or hiring activities with respect to individuals who independently respond to publicly posted job opportunities, including but not limited to, opportunities posted on-line, described in print advertisements or offered at job fairs.

C. Early Termination of the IRO

In the event the IRO does not perform its duties and responsibilities under the terms of this Addendum in a reasonably professional and competent manner, McKesson may make a written request to the government to terminate the services of the IRO before the end of the term of the Addendum. The government retains sole discretion to grant any such request. In the event that a request for early termination of the IRO is granted, the selection of a substitute IRO shall be done in the manner set forth in Section IV.A above.

D. Review Schedule

The following reviews will be conducted in accordance with the schedule set forth below: 1.) Threshold Change Request Review ("TCR Review"); 2.) Onboarding New Customer Review ("Onboarding Review"); 3.) Event Triggered Due Diligence Review ("Due Diligence Review"); and 4.) Incentive Compensation Review ("Compensation Review"). Collectively, the four reviews will be referred to as the "Compliance Reviews."

#### First Reporting Period

1. TCR Review
2. Onboarding Review
3. Compensation Review

#### Second Reporting Period

1. TCR Review
2. Onboarding Review
3. Due Diligence Review

#### Third Reporting Period

1. TCR Review;
2. Onboarding Review
3. Compensation Review

#### Fourth Reporting Period

1. TCR Review
2. Onboarding Review
3. Due Diligence Review

#### Fifth Reporting Period

1. TCR Review
2. Onboarding Review
3. Compensation Review

The IRO shall conduct the reviews specified above for the first three reporting periods. The government may, in its sole discretion, permit McKesson to utilize its internal audit department ("Internal Audit Department") to conduct the reviews in this Section and Section V for the Fourth and/or Fifth Reporting Periods. Within thirty (30) days of the receipt of the Annual Report for the Third Reporting Period and, if applicable, within thirty (30) days of the receipt of the Annual Report for the Fourth Reporting Period, the government shall notify McKesson in writing of its decision whether or not to permit McKesson to utilize its Internal Audit Department to conduct the reviews for the applicable reporting period. In the event that the government does not



permit McKesson to utilize its Internal Audit Department to conduct the reviews for the subsequent reporting periods, the government shall provide the reasons for its decision in its written notification.

E. Sample Selection and Audit Periods

1. Audit Periods

The table below sets forth the applicable audit periods for the Compliance Reviews and the Annual Threshold System Analysis and Assessment required by Section V.B.

<b><u>FIRST REPORTING PERIOD</u></b>	<b><u>FIRST AUDIT PERIOD</u></b>
TCR Review	February 1, 2017 to July 31, 2017
Onboarding Review	February 1, 2017 to July 31, 2017
Compensation Review	February 1, 2017 to July 31, 2017
Threshold System Analysis	February 1, 2017 to July 31, 2017
<b><u>SECOND REPORTING PERIOD</u></b>	<b><u>SECOND AUDIT PERIOD</u></b>
TCR Review	August 1, 2017 to July 31, 2018
Onboarding Review	August 1, 2017 to July 31, 2018
Due Diligence Review	August 1, 2017 to July 31, 2018
Threshold System Analysis	August 1, 2017 to July 31, 2018
<b><u>THIRD REPORTING PERIOD</u></b>	<b><u>THIRD AUDIT PERIOD</u></b>
TCR Review	August 1, 2018 to July 31, 2019
Onboarding Review	August 1, 2018 to July 31, 2019
Compensation Review	August 1, 2018 to July 31, 2019
Threshold System Analysis	August 1, 2018 to July 31, 2019
<b><u>FOURTH REPORTING PERIOD</u></b>	<b><u>FOURTH AUDIT PERIOD</u></b>
TCR Review	August 1, 2019 to July 31, 2020
Onboarding Review	August 1, 2019 to July 31, 2020
Due Diligence Review	August 1, 2019 to July 31, 2020
Threshold System Analysis	August 1, 2019 to July 31, 2020
<b><u>FIFTH REPORTING PERIOD</u></b>	<b><u>FIFTH AUDIT PERIOD</u></b>
TCR Review	August 1, 2020 to July 31, 2021
Onboarding Review	August 1, 2020 to July 31, 2021
Compensation Review	August 1, 2020 to July 31, 2021
Threshold System Analysis	August 1, 2020 to July 31, 2021

2. TCR Reviews

During each audit period, the IRO or, if permitted by the government, McKesson's Internal Audit Department shall conduct an audit of McKesson customers who requested and were granted one or more threshold increases for Highly Diverted Controlled Substances. The sample customers for each TCR Review will be selected as follows:

Within ten (10) calendar days following the close of the relevant audit period, McKesson will provide DEA with a list of all McKesson distribution centers that had more than twenty-five (25) independent retail pharmacy customers who requested, received, and had threshold increases for Highly Diverted Controlled Substances approved by the Regulatory Affairs Department during the audit period. Within fifteen (15) calendar days of receipt of this list, DEA shall select five (5) distribution centers for the purposes of the selection of customers for the TCR Reviews. If DEA does not notify McKesson of its distribution center selections within fifteen (15) calendar days after receiving the list, McKesson may select the five (5) subject distribution centers, and notify DEA that it has done so.

Within fifteen (15) calendar days of the selection of the five (5) subject distribution centers (either by DEA or McKesson), McKesson will provide DEA with lists of customers who requested, received, and had threshold increases for Highly Diverted Controlled Substances approved by the Regulatory Affairs Department during the applicable Audit Period. Within fifteen (15) calendar days of receiving the customer lists from McKesson, DEA, in consultation with the IRO when applicable, will select up to fifty (50) customers for review from the provided lists. If DEA does not notify McKesson of its selections within fifteen (15) calendar days after receiving the customer lists, McKesson will select the fifty (50) customers for review, and will notify DEA that it has done so. The selected customers for the TCR Reviews, along with the customers selected for the Onboarding Reviews and the Due Diligence Reviews (as described below) are referred to as "Sample Customers" for the various reviews.

### 3. Onboarding Reviews

In accordance with the schedule set forth above, the IRO or McKesson's Internal Audit Department, if permitted by the government, shall conduct an Onboarding Review of fifty (50) Sample Customers. The Sample Customers for each Onboarding Review will be selected as follows:

Within ten (10) calendar days following the close of the relevant audit period, McKesson will provide DEA with a list of new independent retail customers that were onboarded during the applicable audit period.

Within fifteen (15) calendar days of receiving the customer lists from McKesson, DEA, in consultation with the IRO when applicable, will select up to fifty (50) customers for review from the provided lists. If DEA does not notify McKesson of its selections within fifteen (15) calendar days after receiving the customer lists, McKesson will select the fifty (50) customers for review, and notify DEA that it has done so.

### 4. Due Diligence Reviews

In accordance with the schedule set forth above, the IRO or McKesson's Internal Audit Department, if permitted by the government, shall conduct a Due Diligence Review of twenty (20) Sample Customers. The Sample Customers for each Due Diligence Review will be selected as follows:

Within ten (10) calendar days following the close of the relevant audit period, McKesson will provide DEA with a list of independent retail customers that were the subject of Event Triggered Due Diligence during the applicable audit period.

Within fifteen (15) calendar days of receiving the customer lists from McKesson, DEA, in consultation with the IRO when applicable, will select up to twenty (20) customers for review from the provided lists. If DEA does not notify McKesson of its selections within fifteen (15) calendar days after receiving the customer lists, McKesson will select the twenty (20) customers for review, and notify DEA that it has done so.

**F. Scope of TCR, Onboarding and Due Diligence Reviews**

After identification of the Sample Customers (either by DEA or McKesson), the IRO or McKesson's Internal Audit Department, if permitted by the government, will have sixty (60) calendar days to analyze the Sample Customers' files. For each type of review (TCR Review, Onboarding Review and Due Diligence Review), the IRO or McKesson's Internal Audit Department will compare the documents contained in each Sample Customer file to the documentation standards contained in the CSMP Operating Manual to determine whether the file contains the documentation required under the terms of the CSMP Operating Manual for the subject activity. If any Sample Customer file contains more than one TCR or Event Triggered Due Diligence, the IRO or McKesson's Internal Audit Department will review the documentation for the most recent TCR request or Event Triggered Due Diligence.

For the purposes of determining deficiencies under Section IX.A subject to penalties under Section IX.C, only deficiencies involving the absence of or incomplete documentation required by the CSMP Operating Manual shall be subject to money penalties.

**G. Compensation Reviews**

For the Compensation Reviews, the IRO or McKesson's Internal Audit Department, if permitted by the government, will review the compensation related documents for all members of the Regulatory Affairs Department and analyze the compensation received by those individuals for the period under audit. For each member of the Regulatory Affairs Department, the IRO or McKesson's Internal Audit Department will review the relevant compensation plan documents and analyze how the compensation for each member of the McKesson Regulatory Department was determined under the relevant McKesson programs.

**V. ANNUAL ASSESSMENT ANALYSIS AND REVIEW**

**A. Observations and Recommendations**

To the extent that the compliance reviews conducted by the IRO or McKesson's Internal Audit Department identify questions or concerns about particular decisions made by the Regulatory Affairs Department related to one or more sample files under

review, the IRO or McKesson's Internal Audit Department may conduct interviews of the members of the Regulatory Affairs Department who were involved in the decisions at issue. A member of McKesson's legal team will be permitted to be present for any such interviews. The IRO or McKesson's Internal Audit Department may also request the opportunity to review e-mails and other documents that are directly related to the decisions at issue. McKesson's legal department will be responsible for responding to any such requests. To the extent that any of the requested documents are protected from disclosure by any applicable privileges, the legal department will inform the IRO in writing and provide a general description of the document and the privilege being asserted. If the IRO and the Internal Audit Department continue to have questions or concerns about particular decisions made by the Regulatory Affairs Department after conducting interviews and/or reviewing relevant documents, the IRO or the Internal Audit Department will include a description of the question or concern in the audit report, as provided in Section VI.

In addition, if the IRO or McKesson's Internal Audit Department notes any areas for potential improvement during the course of the compliance reviews, the IRO or McKesson's Internal Audit Department shall include any such recommendations in the audit report, as provided in Section VI. Collectively, any such questions, concerns or recommendations will be referred to as "Observations and Recommendations." Observations and Recommendations shall be treated as advisory only and shall not be treated as deficiencies for the purposes of Section IX.

#### B. Annual Threshold System Analysis and Assessment

For each Reporting Period, McKesson or its outside consultant shall prepare a report setting forth the metrics described below for the thresholds utilized by McKesson for independent retail pharmacy customers as part of its enhanced threshold calculation model. The metrics described below shall be calculated by McKesson or its outside consultant based on data from the audit periods specified in the table set forth in Section V.E.1. The report summarizing the metrics listed below shall be referred to as the "Annual Threshold Analysis and Assessment Report." McKesson or its outside consultant shall provide the Annual Threshold Analysis and Assessment Report to the IRO or McKesson's Internal Audit Department no later than sixty (60) days from the end of the applicable Reporting Period.

The Annual Threshold Analysis and Assessment Report shall contain the following:

1. Table listing the threshold calculation model settings at the beginning and the end of the Threshold Review Period for the following:
  - a. Base code risk group assignments;
  - b. Statistical parameters used for each risk group;
  - c. Permitted minimum dosage amounts by base code; and

- d. Customer counts underlying the statistical calculations by geographic region.
- 2. Table showing frequency distribution of threshold types (defined as a percentage of total thresholds) at the beginning and the end of the Threshold Review Period for the following:
  - a. Percentage of customer base codes assigned i) a model generated binding ("model binding") threshold, ii) a model generated non-binding threshold, and iii) a non-model threshold;
  - b. Within those assigned model binding thresholds, percentage receiving each type (i.e., benchmark, same customer, minimum, rare drug national benchmark); and
  - c. Within those assigned non-model thresholds, percentage receiving each type.
- 3. Tables illustrating statistical analysis of gap between threshold and purchasing level at the beginning and end of the Threshold Review Period for the following:
  - a. Distribution of dosage unit gap between threshold and actual purchasing (data points: median, 25th percentile and 75th percentile); and
  - b. Distribution of changes in size of gap over time (e.g., average gap in the first month of the Threshold Review Period compared to the average gap in the last month of the Threshold Review Period).
- 4. Table illustrating the overall change in threshold levels during the Threshold Review Period by showing the distribution of threshold change direction (i.e., compare percentage increasing, decreasing and staying the same).

During the First Reporting Period, the analysis for items 2 through 4 above will be limited to those independent retail pharmacy customers for whom the enhanced threshold calculation model was fully implemented on or before the first full month of the reporting period.

## **VI. AUDIT REPORTS**

### **A. Annual Assessment Meeting and Review**

Within fourteen (14) days of completing all of the designated reviews for a particular Reporting Period, the IRO or McKesson's Internal Audit Department shall meet with the Senior VP, the Senior Director, Regulatory Affairs CSMP, East Region, the Senior Director, Regulatory Affairs CSMP, West Region, and members of



McKesson's legal department. McKesson may also invite its outside consultant to this meeting. During this meeting, the IRO or McKesson's Internal Audit Department shall review the preliminary results of the relevant compliance reviews and discuss any Observations and Recommendations based on those reviews. The IRO or McKesson's Internal Audit Department shall also review the information contained in the Annual Threshold Analysis and Assessment Report during this meeting. In addition, the IRO or McKesson's Internal Audit Department will also review any potential weaknesses in the CSMP and discuss ways in which to address those weaknesses. The IRO or McKesson's Internal Audit Department will include a detailed summary of the substance of this meeting in its draft audit report for the relevant Reporting Period. The IRO or McKesson's Internal Audit Department shall provide its draft audit report to McKesson on or before the end of the relevant Reporting Period.

B. TCR, Onboarding and Due Diligence Reviews

The IRO or McKesson's Internal Audit Department shall prepare a draft audit report that details the preliminary results of the compliance reviews specified for a particular Reporting Period. To the extent a review reveals deficiencies in the documentation required by the CSMP Operating Manual, the IRO or McKesson's Internal Audit Department will describe those deficiencies in detail in the draft report and describe any actions necessary to correct the deficiencies.

The IRO or McKesson's Internal Audit Department shall provide its draft audit report to the Regulatory Affairs Department for a response. Within thirty (30) calendar days of its receipt of the draft report, the Regulatory Affairs Department will respond to each finding of a deficiency, including, where appropriate, describing any corrective action taken (or to be taken) as a result of the findings made by the IRO or McKesson's Internal Audit Department, providing contemporaneous alternative documentation supporting a relevant decision, as allowed by the CSMP Operating Manual (e.g., an e-mail approval describing the justification for a decision), or providing additional context explaining the deficiency and why it occurred. The Regulatory Affairs Department may not correct a deficiency by providing *post hoc* justifications for relevant decisions or approvals in the absence of contemporaneous alternative documentation.

For TCR Reviews, Onboarding Reviews and Due Diligence Reviews, the final audit report shall set forth the following: i.) the original findings of the IRO or McKesson's Internal Audit Department; ii.) the Regulatory Affairs Department's responses to those findings; and iii.) the conclusion of the IRO or McKesson's Internal Audit Department as to whether its original deficiency findings, if any, have been adequately addressed by the responses of the Regulatory Affairs Department. In the event that the Regulatory Affairs Department did not address and resolve any findings of deficiencies, the IRO or McKesson's Internal Audit Department will separately list customers for whom there were the unresolved deficiencies in the required documentation. The IRO or McKesson's Internal Audit Department shall complete its final audit report within thirty (30) calendar days of its receipt of the responses of the Regulatory Affairs Department.

McKesson shall provide a copy of the final audit report to the government within five (5) business days of receipt from the IRO or McKesson's Internal Audit Department. McKesson shall also include a copy of the final audit report with its Annual Reports. Nothing in this Addendum shall be interpreted as obligating the IRO or McKesson's Internal Audit Department to submit any additional documentation (e.g., work papers created by the IRO or McKesson's Internal Audit Department during the audits) to DEA.

### C. Compensation Reviews

No later than three (3) months before the end of the applicable Reporting Period, the IRO or McKesson's Internal Audit Department shall complete its review of the compensation received by the Regulatory Affairs Department and Regulatory Affairs Third-Party Personnel and determine whether the compensation received was consistent with the limitations set forth in Section III.C.2. In the event that the IRO or McKesson's Internal Audit Department concludes that the compensation received by the members of the Regulatory Affairs Department or Regulatory Affairs Third-Party Personnel was consistent with the limitations contained in Section III.C.2, the IRO or McKesson's Internal Audit Department shall include a certification to that effect in its final audit report.

In the event that the IRO or McKesson's Internal Audit Department initially determines that the compensation received by a member of the Regulatory Affairs Department or Regulatory Affairs Third-Party Personnel was inconsistent with the limitations contained in Section III.C.2 of this Addendum, the IRO or McKesson's Internal Audit Department shall meet with U.S. Pharmaceutical's SVP, Human Resources Department ("Human Resources SVP") to review this initial determination. This meeting shall take place within fourteen (14) days of the completion of the Compensation Review.

If the Human Resources SVP agrees with the initial determination made by the IRO or McKesson's Internal Audit Department or if the IRO or McKesson's Internal Audit Department and the Human Resources Department disagree after consultation, the IRO or McKesson's Internal Audit Department will generally describe the compensation that, in its professional judgment, violated the terms of this Addendum and provide the number of individuals who received improper compensation in its draft audit report. Within thirty (30) days of receiving the draft audit report, McKesson shall provide a response to the findings contained in the draft audit report, including a description of any corrective action to be taken as a result of the findings. In the final audit report, the IRO or McKesson's Internal Audit Department shall state its conclusion as to whether McKesson has adequately addressed its findings. In the event that McKesson is unable to demonstrate that the compensation received by the Regulatory Affairs Department was consistent with the requirements of Section III.C.2, the IRO or McKesson's Internal Audit Department shall state the number of individuals who received improper compensation and state the total value of the improper compensation that was paid in the final audit report.

If the IRO or McKesson's Internal Audit Department changes its initial determination after meeting with the Human Resources SVP, the IRO or McKesson's Internal Audit Department will report its initial determination and its revised determination in the final audit report in sufficient detail so that the government can evaluate the basis for both determinations (without identifying any individuals by name).

D. Observations and Recommendations

The IRO or McKesson's Internal Audit Department shall provide detailed descriptions of any Observations and Recommendations in the draft audit report. Within thirty (30) days of receiving the draft audit report, McKesson shall provide responses to each Observation and Recommendation. The final audit report shall include a listing of the Observations and Recommendations made by the IRO or McKesson's Internal Audit Department and McKesson's responses.

E. Annual Threshold Analysis and Assessment Report

The IRO or McKesson's Internal Audit Department shall include comments on the metrics contained in the Annual Threshold Analysis and Assessment Report in the draft audit report. Within thirty (30) days of receiving the draft audit report, McKesson, or its outside consultant, shall provide a response to any comments. The final audit report shall attach the Annual Threshold Analysis and Assessment Report and shall include any comments by the IRO or McKesson's Internal Audit Department and McKesson's responses.

**VII. MEETINGS**

A. Briefings on Drug Diversion Trends

DEA and McKesson agree that during the term of this Addendum DEA may, at its discretion, brief the IRO and McKesson on trends and developments in the diversion of controlled substances. DEA may provide up to four (4) such briefings in any Reporting Period. Said briefings may be carried out through live trainings, video conferences, telephone conferences and/or the dissemination of written materials.

B. Periodic Presentations and Meetings

Within thirty (30) days of the government's receipt of the final audit report from McKesson, the IRO or McKesson's Internal Audit Department shall make an oral presentation of the report to the DEA and DOJ contacts identified in Section X.D. McKesson shall participate in this presentation.

DEA and McKesson agree that the parties, including representatives from DOJ, and the IRO, shall meet at least once during each Reporting Period at a mutually agreeable date and location to discuss the IRO's responsibilities and activities required by this Addendum. If the parties and the IRO cannot agree on a date and location for any such presentation or meeting, then DEA shall select the date and location.

McKesson shall send representatives, who are familiar with the IRO's responsibilities and activities and have authority to make binding decisions on behalf of McKesson, to each such meeting.

C. Implementation and Annual Meetings

No later than sixty (60) calendar days after the government's receipt of the Implementation Report and no later than sixty (60) calendar days after receipt of each Annual Report (unless the parties mutually agree), McKesson and appropriate personnel from the government shall meet in person at a location to be determined by the government to review the information contained in the Implementation Report and Annual Reports, review any Observations and Recommendations made by the IRO or McKesson's Internal Audit Department and discuss other issues related to the prevention of diversion of controlled substances. McKesson's General Counsel and the Senior VP shall participate in these meetings. As stated in the Preamble, DEA's participation in these meetings and any statements made by DEA during the meetings shall not be construed as an endorsement or approval by DEA that McKesson's current or future programs satisfy McKesson's obligations under the CSA and the implementing regulations.

**VIII. REPORTING**

A. Notification Requirements

1. CSMP Operating Manual

If McKesson implements a material change to the CSMP Operating Manual for independent retail pharmacy customers during the term of this Addendum, McKesson will notify DEA in writing within thirty (30) calendar days of the implementation of such a change. For the purposes of this notification requirement, material changes to the CSMP Operating Manual are:

- a. Changes in the manner in which suspicious orders are identified and reported to DEA;
- b. Changes in the methodology by which monthly thresholds are calculated (Pilot Programs are exempt from this notification requirement);
- c. Changes in the process by which TCRs are evaluated and approved;
- d. Changes in the criteria by which customers may be eligible for temporary threshold increases; and
- e. Changes in the process by which new customers are onboarded.

McKesson understands that the material changes listed above could affect the original intent of the parties with respect to the terms and conditions contained in this Addendum. DEA shall have the right, within sixty (60) calendar days of its receipt of a notice of a material change to the CSMP Operating Manual, as provided by this subsection, to require McKesson to meet with representatives of DEA for the purpose of negotiating an amendment to the Addendum to the extent necessary to ensure the continued application and intent of the Addendum as applied to McKesson's revised CSMP Operating Manual.

## 2. List of Highly Diverted Controlled Substances

McKesson and DEA recognize that drugs may need to be added or removed from the list of Highly Diverted Controlled Substances depending on the evaluation of drug diversion trends. McKesson shall make reasonable efforts to stay informed about drug diversion trends in order to continue to identify appropriate drugs for inclusion on the Highly Diverted Controlled Substances list and to potentially remove drugs that are no longer appropriate for inclusion on the list.

McKesson agrees to notify DEA in writing of any changes to the list of Highly Diverted Controlled Substances within thirty (30) calendar days of making a change to the list. DEA shall have the right, within sixty (60) calendar days of receipt of such notice, to request a meeting with McKesson to discuss McKesson's changes to the list.

During the term of this Addendum, DEA may provide McKesson with written notification of drugs it proposes to be added to, or removed from, the Highly Diverted Controlled Substances list. McKesson agrees to review DEA's proposal in good faith, and to notify DEA of McKesson's determination within thirty (30) calendar days of receipt of DEA's written notification. If McKesson agrees with DEA's proposal, McKesson will modify its Highly Diverted Controlled Substances list and provide DEA with written notice of the effective date of the modification. After making a modification suggested by DEA, McKesson reserves the right to make future modifications to the Highly Diverted Controlled Substances list (e.g., deleting a drug that DEA had previously requested be added) and provide DEA with written notice of that modification, as set forth above.

## 3. Regulatory Affairs Department

McKesson shall report to DEA, in writing, any changes in the identity or material changes in the job description for the following positions in the Regulatory Affairs Department within thirty (30) calendar days of the effective date of any such change:

- a. Senior VP;
- b. Senior Directors CSMP; and
- c. Directors of Regulatory Affairs CSMP.



In addition, McKesson shall report to DEA in writing, any permanent reduction in the number of full time employees in the Regulatory Affairs Department within thirty (30) calendar days of any such reduction becoming effective. DEA shall have the right, within sixty (60) calendar days of receipt of any notice required by this subsection, to request a meeting with McKesson to discuss such changes.

#### 4. Compliance Committees

McKesson shall report to DEA, in writing, any changes in the membership of the ROC or the National Governance Committee (by position or title) within thirty (30) calendar days of the date of any such change becoming effective. DEA shall have the right, within sixty (60) calendar days of receipt of any notice required by this subsection, to request a meeting with McKesson to discuss such changes.

#### B. Implementation Report

No later than one hundred and twenty (120) calendar days from the Effective Date (unless otherwise agreed to in writing by the parties), McKesson shall submit an Implementation Report to the government containing the information set forth below.

##### 1. Regulatory Affairs Department

- a. Copies of current organizational charts for the Regulatory Affairs Department;
- b. A description of the position of Senior VP, the scope of responsibilities involved with that position and the authority included with that position;
- c. A description of each position within the Regulatory Affairs Department, the name of the current occupant, the scope of responsibility involved with the position, and the authority included with the position; and

For Regulatory Affairs Third-Party Personnel, McKesson will provide the name of each individual, the name of the outside firm that employs that individual (if applicable) and a description of the work performed by that individual on behalf of the Regulatory Affairs Department. For the purposes of this reporting requirement, it will be permissible for McKesson to identify the outside firm, identify the individuals from that firm who performed work for the Regulatory Affairs Department and describe generally the work performed by the outside firm.

## 2. Compliance Committees

- a. A list of the titles of the members of the of the CSMP Regulatory Operating Committee; and

A list of the titles of the members of the National Governance Committee.

## 3. Code of Conduct and Policies and Procedures

- a. A copy of the current version of the Code of Conduct; and
- b. A copy of the current version of the CSMP Operating Manual.

If any of the substantive provisions of the CSMP Operating Manual or Code of Conduct have changed since the Effective Date, McKesson shall include a description of those changes in the Implementation Report.

## 4. Distribution Centers

A list of any McKesson U.S. Pharmaceutical distribution centers that hold a DEA certificate of registration as of the date of the report that are not listed on Appendix A. If there have been no changes to the list of distribution centers in Appendix A, McKesson shall state in the Implementation Report that there has been no change.

## 5. Thresholds

A description of the enhanced methodology to be used by McKesson to set and calculate thresholds for independent retail customers. McKesson shall include a detailed description of the enhanced methodologies in the Implementation Report and provide a description of the implementation plan for those new methodologies.

## 6. Suspicious Order Reports

A summary of the manner in which suspicious orders are identified and reported to DEA as of the date of the report.

## 7. Highly Diverted Controlled Substances

A copy of the list of Highly Diverted Controlled Substances in effect as of the date of the Implementation Report.

C. Annual Reports

No later than ninety (90) calendar days following the first anniversary of the Effective Date (unless otherwise agreed to by the parties), McKesson shall submit its first Annual Report to the government. Thereafter, in order to set an established schedule, McKesson will notify the government of an annual due date for the remaining Annual Reports required by this Section.

Each Annual Report shall contain the following information:

1. Regulatory Affairs Department

- a. Copies of current organizational charts for the Regulatory Affairs Department;
- b. A description of the position of Senior VP, the scope of responsibilities involved with that position and the authority included with that position. To the extent that the job description and/or responsibilities of the Senior VP have changed since the previous report to the government, McKesson shall describe the change in the Annual Report;
- c. A description of each position within the Regulatory Affairs Department, the name of the current occupant, the scope of responsibility involved with the position, and the authority included with the position. To the extent that there have been changes in the organizational structure of the Regulatory Affairs Department since the previous report to the government, McKesson shall describe the change in the Annual Report; and
- d. For Regulatory Affairs Third-Party Personnel, McKesson will provide the name of each individual, the name of the outside firm that employs that individual (if applicable) and a general description of the work performed by that individual on behalf of the Regulatory Affairs Department. For the purposes of this reporting requirement, it will be permissible for McKesson to identify the outside firm, identify the individuals from that firm who performed work for the Regulatory Affairs Department and describe generally the work performed by the outside firm.

2. Compliance Committees

- a. A list of the members of the CSMP Regulatory Operating Committee (by title or position); and

- b. A list of the members of the National Governance Committee (by title or position).

To the extent that the membership of the CSMP Regulatory Operating Committee or National Governance Committee has changed (by titles or positions) since the previous report or notification to DEA, McKesson shall describe any changes in the Annual Report.

### 3. Code of Conduct and Policies and Procedures

- a. A copy of the current version of the Code of Conduct;
- b. A copy of the current version of the CSMP Operating Manual; and
- c. A copy of the CSMP operating manual applicable to Retail National Accounts.

To the extent that the Code of Conduct or CSMP Operating Manual have substantively changed since the previous report or notification to DEA, McKesson shall describe the changes in the Annual Report.

### 4. Distribution Centers

A list of any McKesson U.S. Pharmaceutical distribution centers that hold a DEA certificate of registration as of the date of the report that are not listed on Appendix A. If there have been no changes to the list of distribution centers in Appendix A, McKesson shall state in the Annual Report that there has been no change.

### 5. Thresholds

A description of the methodology used by McKesson as of the date of the report to set and calculate thresholds for independent retail customers. To the extent that McKesson changed its threshold methodologies after the date the previous report or notification to DEA, McKesson shall include a detailed description of the change. If the methodology used by McKesson to set and adjust thresholds has not changed since the previous report to DEA, McKesson shall state that there has been no change in methodology.

A description of McKesson's ability to run threshold change reports that reflect automated and programmatic threshold adjustments that have been implemented during the Reporting Period. DEA shall have the right to make a written request to McKesson for a sample threshold change report to verify the description provided by McKesson. McKesson shall respond to any such written request within fourteen (14) calendar days.

#### 6. Suspicious Order Reports

A detailed description of the manner in which suspicious orders are identified and reported to DEA as of the date of the Annual Report. To the extent that McKesson changed its procedures for identifying and reporting suspicious orders after the previous report to DEA, McKesson shall include a detailed description of the change in the Annual Report.

#### 7. Highly Diverted Controlled Substances

A copy of the list of Highly Diverted Controlled Substances in effect as of the date of the Annual Report.

#### 8. Training

In the Annual Report, McKesson shall describe the CSMP training that was performed during the Reporting Period. This description shall include a summary of the topics covered during each training session, the length of each training session, and the number of people who attended each training session. Copies of the training materials used during each session during a Reporting Period and the names of attendees shall be made available to DEA upon written request.

#### 9. Audit Reports

McKesson shall include copies of the final audit reports required in Section VI in the Annual Report.

All annual reports and all final Audit Reports produced by the IRO, or McKesson's Internal Audit Department, shall be provided to each member of the Audit Committee of McKesson's Board of Directors.

#### D. Designation of Information

McKesson shall clearly identify any portions of this Addendum and the submissions it makes to DEA or DOJ pursuant to this Addendum (including the Interim Report, Annual Reports and Audit Reports) that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, or otherwise potentially exempt from disclosure under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552. McKesson shall also be afforded the opportunity to identify any portions of submissions made by the IRO to the government that McKesson believes are trade secrets, or information that is commercial or financial and privileged or confidential, otherwise exempt from disclosure under FOIA. All such information may be exempt from disclosure under the FOIA and any other state or federal law or regulation protecting such information from public disclosure and, upon receipt of a request to release such, DEA agrees to provide McKesson reasonable opportunity to respond to any such requests.



E. Requests for Extensions of Time

McKesson may request an extension of any deadline contained in this Addendum by submitting a written request to DEA and provide good cause for the requested extension. With the exception of the three (3) business day deadline for reporting computer errors, McKesson shall submit any request for an extension of time at least fourteen (14) calendar days prior to the applicable deadline. DEA shall not unreasonably withhold its consent to a request for an extension. In the event that DEA fails to respond in writing to a written request for an extension within seven (7) calendar days, McKesson's request for an extension will be deemed granted.

**IX. BREACH AND DEFAULT PROVISIONS**

As the exclusive contractual remedy for the breach of any provision contained in this Addendum, McKesson and DEA agree that the failure to comply with the obligations set forth below in Section IX.A may lead to the imposition of monetary penalties, subject to the notice and opportunity to cure and dispute resolution procedures contained in this Section. DEA's ability to seek contractual remedies does not preclude it from seeking administrative remedies under the CSA and the implementing regulations.

These penalties are not intended to supplant or waive any other remedy available to DEA under the CSA and the implementing regulations and do not waive any civil penalties available to the United States under 21 U.S.C. § 842(c) for future misconduct. Monetary penalties shall be paid in the same manner as the United States' Settlement Agreement and Release, Section V. In the event that disputes arise under this Addendum concerning the application of monetary penalties, DEA may seek to recover monetary penalties for breach of this Addendum in any federal court of competent jurisdiction.

In addition, DEA, in its sole discretion, may elect to reduce or waive any penalties imposed pursuant to this Addendum if the relevant violation is timely reported to DEA. Where McKesson has affirmatively reported the violation or deficiency, DEA shall favorably consider that fact. In the event that DEA elects to exercise its discretion and reduce or waive any penalties, DEA shall notify McKesson in writing of its decision. The decision by DEA to waive enforcement of any such provision does not constitute any waiver as to any other remedy under the CSA or the implementing regulations.

A. Obligations Subject to the Potential Imposition of Monetary Penalties

1. Organizational and Policy Requirements:

Other than for violations that DEA has waived or McKesson has cured, McKesson's failure to do any of the following shall result in the imposition of monetary penalties:

- a. Maintain the position of Senior VP as required by Section III.B.1.a;

- b. Maintain a CSMP Regulatory Operating Committee as required by Section III.B.2;
  - c. Maintain a National Governance Committee as required by Section III.B.3;
  - d. Maintain a Code of Conduct as required by Section III.D.1;
  - e. Maintain a CSMP Operating Manual as required by Section III.D.2;
  - f. Maintain an ethics hotline as required by Section III.G; or
  - g. Maintain non-retaliation policies as required by Section III.F.
2. Failure to Submit Timely Notifications or Reports
- a. Other than for violations that DEA has waived or McKesson has cured, McKesson's failure to submit any notification or report required by the deadlines contained in Section VIII (as modified by any extension of time requested by McKesson and approved by DEA) shall be deemed a violation of this Subsection.
  - b. Other than for violations that DEA has waived or McKesson has cured, each instance where McKesson fails to include material information in a report required by Section VIII, as described in this Addendum, shall be deemed a violation of this Subsection.
3. Audit Report Findings Subject to the Potential Imposition of Monetary Penalties
- a. To the extent that IRO or McKesson's Internal Audit Department lists findings of deficiencies (other than those addressed and resolved as permitted by Section VI.B) in any of its final audit reports for TCR Reviews, Onboarding Reviews, Due Diligence Reviews and Compensation Reviews, those unresolved deficiencies, unless waived or cured, shall result in the imposition of monetary penalties for each deficient customer file or for each member of the Regulatory Affairs Department who received improper compensation. Any Observations and Recommendations made by the IRO or McKesson's Internal Audit Department shall not be subject to the imposition of monetary penalties.
4. Highly Diverted Controlled Substances

McKesson's shipment of any Order after the Effective Date in the following circumstances shall, unless waived, result in the imposition of monetary penalties for each Order shipped:

- a. Where McKesson ships an omitted Order of a Highly Diverted Controlled Substance to an independent retail customer;
- b. Where McKesson ships an Order for a Highly Diverted Controlled Substance to an independent retail customer who does not have a documented threshold for such Highly Diverted Controlled Substance;
- c. Where McKesson ships an Order for a Highly Diverted Controlled Substance to a new independent retail customer without documenting the approval for the initial threshold for such Highly Diverted Controlled Substance if that threshold is different from the default threshold, the threshold based on a programmatic adjustment or the threshold calculated by McKesson's automated system for such Highly Diverted Controlled Substance;
- d. Where McKesson ships an Order for a Highly Diverted Controlled Substance to an existing independent retail customer after having raised the Threshold for that Highly Diverted Controlled Substances within the same Month without documenting the approval for the changed threshold, if that changed threshold is different from the initial default threshold, the threshold based on a programmatic adjustment or the threshold calculated by McKesson's automated system for such Highly Diverted Controlled Substance; or
- e. Where McKesson ships an Order for a Highly Diverted Controlled Substance to an independent retail customer that exceeds the threshold that exists at the time of the Order for such Highly Diverted Controlled Substance without an increase in the threshold that is supported by appropriate Regulatory Affairs Department approval.

Computer errors shall not be the subject of penalties under this Section. DEA reserves the right to seek penalties for unaddressed or recurring computer errors (*i.e.*, the identical computer failure occurring on a regular basis without correction). To seek penalties for unaddressed or recurring computer errors, DEA must follow the notice and opportunity to cure provisions set forth below.

For Orders shipped in violation of Section IX.A.4.c and IX.A.4.d, only those orders shipped in the same month of the non-compliant threshold change or threshold setting shall be considered violations for purposes of imposing monetary penalties under this Addendum.

## B. Notice and Opportunity to Cure

### 1. Demand Letter

Upon a finding made by DEA during the term of this Addendum that McKesson failed to comply with any of the obligations listed in Section IX.A, DEA, Office of Diversion Control, shall promptly notify McKesson in writing of (a) the specific obligations that DEA alleges that McKesson failed to follow, and (b) DEA's intention to seek the imposition of monetary penalties. This notification shall be referred to as a "Demand Letter." DEA must act promptly once it has knowledge of the alleged violation and include sufficient detail of its allegations in a Demand Letter to permit McKesson to investigate and respond to those allegations.

### 2. Response to Demand Letter

Within ten (10) calendar days after the receipt of a Demand Letter, McKesson shall respond in writing to DEA and either (a) state that it has cured or will cure within a specified amount of time the failure to comply with the obligations in question and describe the proposed cure in sufficient detail to permit DEA to evaluate the cure or proposed cure; (b) state that McKesson disputes that it has breached an obligation contained in Section IX.A, or (c) set forth an offer to pay DEA monetary penalties in accordance with the schedule below. If McKesson cures the failure to comply, no stipulated penalties shall be due. For failures that cannot be cured (e.g., improper compensation paid to employee that is not feasibly retrievable, Orders shipped in violation of Section IX.A.4.a-e without contemporaneous alternative documentation), McKesson must either pay the specified monetary penalty within ten (10) calendar days (in accordance with instructions contained in the Demand Letter) or inform DEA in writing within ten (10) calendar days that it disputes that it has breached an obligation contained in Section IX.A. McKesson may cure a failure to comply with certain obligations by providing contemporaneous alternative documentation (i.e., an e-mail approval describing the justification for a decision) and completing the missing documentation required by the CSMP Operating Manual. The Regulatory Affairs Department may not cure a failure to comply by providing post hoc justifications for relevant decisions or approvals in the absence of contemporaneous alternative documentation or by providing prospective remedial measures. Computer errors shall not be deemed failures that cannot be cured under this Section.

### 3. Enforcement

If McKesson believes that there is no deficiency or that it has cured an alleged deficiency noted by DEA, but DEA disagrees, DEA shall have the right to initiate an action to recover monetary penalties for breach of this Addendum in any federal court of competent jurisdiction. Where a response purports to cure a violation and the court finds that McKesson's actions did not cure the violation, any applicable per diem penalties for the violation shall be calculated from the date of the receipt of the Demand Letter by McKesson. Once DEA has knowledge of the violation, it must act expeditiously to issue a Demand Letter.

C. Schedule of Penalties

Subject to the notice and opportunity to cure and dispute resolution procedures set forth above, McKesson and DEA agree to the following schedule of penalties:

1. A monetary penalty of \$1,000 for each day that an uncured violation of Section IX.A.1 persists.
2. A monetary penalty of \$5,000 for each day that an uncured violation of Section IX.A.2.a persists.
3. A monetary penalty of \$1,000 for each uncured violation of Section IX.A.2.b.
4. A Stipulated Penalty of \$10,000 for each customer file reflecting an uncured violation of Section IX.A.3.
5. A Stipulated Penalty of \$25,000, or three (3) times the value of the total improper compensation, as identified by the audit report, whichever is greater, for each employee of the Regulatory Affairs Department who was found to have received improper compensation by the IRO or McKesson's Internal Audit Department.
6. A Stipulated Penalty of three (3) times the total amount of money charged for each Order, as defined in Section II.B.3, and shipped in violation of Section IX.A.4.

For the purposes of the penalties provided in Section IX.C.1-3, the penalties may begin to accrue on the day on which McKesson receives a Demand Letter.

X. MISCELLANEOUS

A. Record Retention

McKesson shall maintain customer due diligence files relating to compliance with the terms of this Addendum from the Effective Date up through and including one year from the date that the final Annual Report is submitted to the government.

B. Other Remedies

DEA is not waiving, and is expressly reserving its right to pursue, any other remedy it may have under the CSA and the implementing regulations, including issuing an Order to Show Cause seeking the revocation of McKesson's DEA registrations, for any breach of this Addendum or for failure to comply with the CSA and the implementing regulations. McKesson expressly reserves the right to dispute that any such alleged breach of this Addendum occurred or that any such alleged breach warrants revocation or suspension. In addition, nothing in this Addendum should be



construed as a waiver of any of McKesson's Due Process rights in any future administrative or court proceeding.

C. Beneficiaries

The obligations and commitments contained in the MOA and this Addendum are intended for the benefit of McKesson and DEA only and do not confer any rights or impose any obligations or commitments to any third party.

D. Notifications and Submission of Reports

Unless otherwise stated in writing after the Effective Date, notifications and reports required by this Addendum shall be submitted to the following points of contact for DEA or DOJ:

- Drug Enforcement Administration, Diversion Control Division, 8701 Morrisette Drive, Springfield, Virginia 22152;
- Drug Enforcement Administration, Office of Chief Counsel, Diversion and Regulatory Litigation Section, 8701 Morrisette Drive, Springfield, Virginia 22152;
- U.S. Department of Justice, Criminal Division, Narcotic and Dangerous Drug Section, 145 N St. NE (2 Constitution Square), 2<sup>nd</sup> Floor, East Wing, Washington, D.C. 20530.

DEA, Diversion Control Division, shall have the sole responsibility for requesting additional information as provided in various places in this Addendum, making sample selections for the various compliance reviews (Section IV), requesting meetings with McKesson (e.g., Section VIII.A.1), granting extensions of time (Section VIII.E), and waiving penalties (Section IX).

McKesson shall also provide copies of the Implementation Report required by Section VIII.B and the Annual Reports required by Section VIII.C to the following DEA Field Divisions:

- Drug Enforcement Administration, Denver Field Division, Office of Diversion, 12154 East Easter Boulevard, Centennial, Colorado 80112;
- Drug Enforcement Administration, Detroit Field Division, Office of Diversion, 431 Howard Street, Detroit, Michigan 48226; and
- Drug Enforcement Administration, Miami Field Division, Office of Diversion, 2100 North Commerce Parkway, Weston, Florida 33326.

Notifications required by this Addendum shall be submitted to the following points of contact for McKesson:

- Senior Vice President, U.S. Pharmaceutical, Regulatory Affairs and Compliance  
McKesson Corporation  
One Post Street, 36th Floor  
San Francisco, CA 94104
- Vice President, U.S. Pharmaceutical, Regulatory Affairs & Compliance  
McKesson Corporation  
6535 State Highway 161  
Irving, TX 75039-2402
- Assistant General Counsel, U.S. Pharmaceutical  
McKesson Corporation  
One Post Street, 36th Floor  
San Francisco, CA 94104

All notifications and reports required by this Addendum may be transmitted by e-mail, with a confirmation copy mailed by overnight or first class mail. Within thirty (30) days of the Effective Date, the parties will exchange e-mail addresses for the relevant points of contact.

E. Amendments to the Addendum

This Addendum, together with the MOA, constitute the complete agreement between the DEA and McKesson and may not be amended except by written consent of the DEA and McKesson.

F. Termination of this Addendum

This Addendum, and all the representations, obligations, requirements and remedies shall terminate sixty (60) days from the date on which the government receives McKesson's final Annual Report under Section VIII.C.