AGREEMENT

This Agreement ("Agreement") is entered into by and between the United States of America, acting through its United States Attorney for the Eastern District of Pennsylvania on behalf of the Drug Enforcement Administration (collectively, the "United States"), Express Scripts, Inc. and Express Scripts Pharmacy Services, Inc. (collectively herein, "ESI"), through their authorized representatives. The Parties agree as follows:

1. ESI is a pharmacy benefit manager that maintains facilities, including mail order facilities, for filling and/or processing drug prescriptions in Bensalem, PA, St. Louis, MO, Tempe, AZ, Harrisburg, PA, Albuquerque, NM, Mason, OH, Fort Worth, TX and Troy, NY.

2. The United States contends that it has certain claims against ESI arising under the Comprehensive Drug Abuse Prevention and Control Act, commonly known as the Controlled Substances Act, Title 21 United States Code Sections 801 et seq. (21 U.S.C. §§ 801 et seq.), for the following conduct occurring between 2002 and 2009 (hereinafter the conduct described in this paragraph, including subparagraphs a and b below, will be referred to as the "Covered Conduct"):

   a. From 2002 through 2006, instances of inventory discrepancies, thefts of controlled substances by ESI employees, in-transit losses not reported to the DEA, and other diversions and/or losses of controlled substances at ESI's Bensalem, PA, Harrisburg, PA, Tempe, AZ, and Albuquerque, NM mail order facilities;

   b. From 2004 through 2009, ESI site DEA numbers and certain invalid DEA numbers (hereinafter "Non-prescriber DEA Numbers") were utilized by ESI employees in ESI's computerized prescription processing system in order to process certain controlled substances prescriptions at all of its mail order facilities.
3. ESI represents that it has taken and will continue to take numerous steps both to improve the physical security over controlled substances at its mail order facilities and to improve the systems ESI uses for tracking inventory, including discontinuing the use of non-prescriber DEA numbers for any controlled substances prescriptions prescribed by persons who are required to be registered with the Drug Enforcement Administration.

4. ESI has approved and adopted the Controlled Substance Security Compliance Plan ("CSSCP") and has incorporated into the CSSCP suggestions provided by representatives of the United States. The CSSCP is intended as a model plan for secure controlled substance dispensing operations and prescription processing that meets or exceeds the requirements of the Controlled Substances Act and its implementing regulations. This Agreement and the CSSCP are intended to enhance the requirements imposed on ESI by the Controlled Substances Act, and its implementing regulations, and in no way are meant to reduce or waive these requirements. The CSSCP provides standards for secure controlled substances dispensing operations, standards for prescription processing operations, as well as security protections for the physical security of the dispensing facility.

ESI will implement the CSSCP at the following facilities: dispensing pharmacies located in St. Louis, Missouri (North Park), and Tempe, Arizona, and front end pharmacies located in Harrisburg, Pennsylvania, Mason, Ohio, Albuquerque, New Mexico, Fort Worth, Texas, Troy, New York, Tempe, Arizona, St. Louis, Missouri, and Bensalem, Pennsylvania (Street Road). Any material failure to maintain the standards set forth in the CSSCP will constitute a breach of this Agreement and will permit the United States to avail itself of any of the remedies described in this Agreement.
A copy of the CSSCP is attached hereto as exhibit A. The parties will cooperate to produce a redacted version of the CSSCP that will be available publicly that addresses ESI's concerns with security and proprietary information.

5. ESI self-reported to law enforcement authorities the instances of diversion of controlled substances described in paragraph 2.a, and ESI has cooperated and continues to cooperate with local law enforcement authorities and prosecutors in pursuing cases of employee diversion.

6. ESI has cooperated and continues to cooperate with the investigation into the Covered Conduct by the United States.

7. Without any admission of fault by ESI and in the interest of avoiding the delay, uncertainty and cost of litigation, both parties wish to reach a full and final settlement with respect to the Covered Conduct described above.

8. ESI shall pay to the United States the sum of $2,750,000 ("Settlement Payment"). The Settlement Payment is immediately due and owing as of the date the last signature is executed hereon and shall be paid no later than three (3) business days thereafter to the United States by electronic funds transfer to the United States Attorney's Office for the Eastern District of Pennsylvania, 615 Chestnut Street, Suite 1250, Philadelphia, PA 19106-4476.

9. In consideration of ESI's full and timely performance of all obligations set forth in this Agreement, including the CSSCP, and subject to the exceptions described in paragraphs 10 and 16 below (concerning bankruptcy proceedings commenced within 91 days of the effective date of this Agreement), the United States agrees to release ESI and its directors, officers, and employees (except any employee who has been previously charged with criminal conduct relating to his/her employment at ESI), from all claims, that the United States has or may have
under the Controlled Substances Act, 21 U.S.C. §§ 801-971, and related regulations for the Covered Conduct described in paragraph 2 above.

10. Notwithstanding any term of this Agreement, specifically reserved and excluded from the scope and terms of this Agreement as to any entity or person (including ESI) are any and all of the following:
   a. Any civil, criminal or administrative claims arising under Title 26, U.S. Code (Internal Revenue Code);
   b. Any criminal liability;
   c. Except as explicitly stated in this Agreement, any administrative liability, including mandatory exclusion or debarment from any and all Federal programs;
   d. Any future violations of the Controlled Substances Act and any failure by ESI to satisfy the obligations as are created by this Agreement and/or the CSSCP.

11. ESI agrees, on behalf of itself and its parents, subsidiaries, and affiliates, to release the United States, its agencies, employees, servants, and agents (including but not limited to the United States Drug Enforcement Administration) from any claims (including attorney’s fees, costs and expenses of every kind and however denominated) which ESI has asserted, could have asserted, or may assert in the future against the United States, its agencies, employees, servants and agents, related to the events and occurrences described in paragraph 2 above, and the United States’ investigation and prosecution thereof.

12. ESI agrees that all provisions of this Agreement and the CSSCP (except for Section 18.1 and Section 34 of the CSSCP) will be implemented within six months of the signing of this Agreement. ESI will advise the government of the date upon which both this Agreement and the CSSCP will be deemed implemented. The Agreement and the CSSCP and will be in
effect for, and will expire after, two (2) years from the date of the implementation. The implementation schedules for Sections 18.1 and 34 are as set forth in those sections of the CSSCP. Provided, however, that any provisions of the Agreement and CSSCP necessary for the certifications and enforcement of sections 18.1 and 34 of the CSSCP will be in effect until the expiration of the effective periods of 18.1 and 34. This Agreement does not reduce ESI’s obligation to remain in compliance with the Controlled Substances Act.

a. Section 18.1 of the CSSCP will be in effect for, and will expire after, one (1) year from the date of notification to the United States that Section 18.1 of the CSSCP was fully implemented, or two (2) years from the implementation of this Agreement, whichever is later.

b. Section 34 of the CSSCP will be in effect for, and will expire after, one (1) year from the date of notification to the United States that Section 34 of the CSSCP was fully implemented, or two (2) years from the implementation of this Agreement, whichever is later.

13. ESI agrees not to modify this Agreement or the CSSCP without the consent of the United States during the term of this Agreement. Should ESI wish to modify the provisions of this Agreement or the CSSCP for any reason, it agrees to notify the United States at the address listed in paragraph 21 below no later than 30 days before the date of ESI wishes to implement the modifications. The United States will have 30 calendar days from the receipt of such notice to approve or disapprove said modifications; provided, however, that if ESI wishes to modify the provisions of this Agreement or the CSSCP to meet an operational, technological, regulatory, or financial need, the United States agrees not to unreasonably withhold approval of modifications that ESI recommends after exercising its business judgment. The United States recognizes that if, after ESI merges with Medco Health Solutions, Inc. ("Medco"), ESI chooses to utilize
Medco’s prescription processing IT system, ESI may have a legitimate need to request modification of this Agreement or the CSSCP.

14. One month following the implementation of this Agreement and the CSSCP and again one month prior to the expiration of this Agreement, ESI will furnish certifications of material compliance with this Agreement and the CSSCP. ESI will furnish additional certifications, using the language below with appropriate substitutions, for Sections 18.1 and 34 of the CSSCP, one month after notification to the United States of the full implementation of each of those sections, and one month prior to expiration, for each.

a. The Vice President and General Manager of Pharmacy Operations shall sign a certification that states: “I have reviewed the Settlement Agreement and the CSSCP and made reasonable inquiry of appropriate ESI employees and contractors regarding ESI’s material compliance with its obligations under the Agreement and the CSSCP. To the best of my knowledge, except as described herein, ESI is in material compliance with the obligations of the Agreement and the CSSCP. I understand that this certification is being provided to and is being relied upon by the United States.” If the Vice President and General Manager of Pharmacy Operations is aware of any material non-compliance with the obligations of the CSSCP, he or she shall report with specificity such non-compliance in the certification.

b. The Vice President and Chief Compliance Officer shall sign a certification that states: “I have reviewed the Settlement Agreement, the CSSCP and the audit reports generated as a result of the Agreement and CSSCP including any corrective action taken based on any observed material non-compliance with the Agreement or the CSSCP. I have made reasonable inquiry regarding these matters of appropriate ESI employees and contractors. To the best of my knowledge, except as otherwise described herein, the compliance department performed the
audits required by the CSSCP, including appropriate follow-up regarding any observed material non-compliance with the CSSCP. I understand that this certification is being provided to and is being relied upon by the United States.” If the Vice President and Chief Compliance Officer is aware of any material failure to perform such audits and follow up, he or she shall report with specificity such non-compliance in the certification.

c. At the request of the government, the certifying officers will meet with the representatives of the government to explain the certifications.

15. This Agreement will be binding on any successor entity that succeeds to the interests of ESI, including, in particular, any entity created as a result of the merger with Medco.

16. If, within 91 days of the effective date of this Agreement, ESI commences, or a third party commences, any case, proceeding, or other action under any law relating to bankruptcy, insolvency, reorganization, or relief of debtors, (a) seeking to have any order for relief of ESI’s debts, or seeking to adjudicate ESI as bankrupt or insolvent; or (b) seeking appointment of a receiver, trustee, custodian, or other similar official for ESI or for all or any substantial part of ESI’s assets, ESI agrees as follows:

a. ESI’s obligations under this Agreement may not be avoided pursuant to 11 U.S.C. §§ 547 or 548, and ESI will not argue or otherwise take the position in any such case, proceeding, or action that: (i) ESI’s obligations under this Agreement may be avoided under 11 U.S.C. §§ 547 or 548; (ii) ESI was insolvent at the time this Agreement was entered into, or became insolvent as a result of the payment made to the United States hereunder; or (iii) the mutual promises, covenants, and obligations set forth in this Agreement do not constitute a contemporaneous exchange for new value given to ESI;
b. If ESI's obligations under this Agreement are avoided for any reason, including, but not limited to, through the exercise of a trustee's avoidance powers under the Bankruptcy Code, the United States, at its sole option, may rescind the releases in this Agreement, and bring any civil and/or administrative claim, action, or proceeding against ESI for the claims that would otherwise be covered by the release provided in Paragraph 9 above. ESI agrees that (i) any such claims, actions, or proceedings brought by the United States are not subject to an "automatic stay" pursuant to 11 U.S.C. § 362(a) as a result of the action, case, or proceeding described in the first clause of this Paragraph 16, and that ESI will not argue or otherwise contend that the United States' claims, actions, or proceedings are subject to an automatic stay; (ii) that ESI will not plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any such civil or administrative claims, actions, or proceeding which are brought by the United States after notification to ESI that the releases herein have been rescinded pursuant to this Paragraph 16; and (iii) the United States has a valid claim against ESI in the amount of at least $2,750,000, and the United States may pursue its claim in any case, action, or proceeding brought against any or all of the individuals and/or the entity collectively referred to herein as ESI;

c. ESI acknowledges that agreements in this Paragraph are provided in exchange for valuable consideration provided in this Agreement.

17. This Agreement shall not be construed as an admission of liability, or wrongdoing on the part of ESI.

18. If, in the judgment of the United States, ESI is determined to have violated the terms and conditions of this Agreement (including material violations of the CSSCP), the U.S. Attorney’s Office may seek injunctive enforcement of these provisions in the United States
District Court for the Eastern District of Pennsylvania during the effective periods of this Agreement. Prior to the commencement of any injunctive litigation, the U.S. Attorney's Office shall provide notice of the violation as described in paragraph 21 below and provide a cure period of no less than sixty (60) days.

19. All agreements between ESI and the United States to toll any applicable statute of limitations, repose, or other limitations period, executed prior to the effective date of this Agreement shall be and are hereby terminated as of the effective date of this Agreement.

20. Each party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement. ESI shall bear the costs of compliance with this Agreement, including the CSSCP.

21. Notices: Any notice required under this Agreement shall be satisfied by providing in writing delivered by any postal method requiring a receipt or express delivery unless either party has revised or updated the contact information provided below. Notice shall be effective upon receipt by the party in question.

To ESI:

Julia Brncic  
Vice President and Associate General Counsel  
Express Scripts, Inc.  
One Express Way  
St. Louis, Mo 63121  
Mail Stop HQ2E03

Peter L. Welsh  
Ropes & Gray LLP  
Prudential Tower  
800 Boylston Street  
Boston, MA 02199-3600
To the United States:

Thomas F. Johnson, Esquire
Assistant United States Attorney
United States Attorney’s Office
615 Chestnut Street
Philadelphia, PA 19106

22. This Agreement in all respects has been voluntarily and knowingly executed by the parties on advice and with approval of their respective counsel.

23. Each party acknowledges that it has participated in the drafting and preparation of this Agreement. Each party further agrees that no inference should be drawn against or in favor of any party based on such drafting and preparation.

24. This Agreement shall be construed and enforced under and in accordance with the laws of the United States. Should any judicial action be required to enforce or interpret this Agreement, or to resolve any dispute hereunder, the parties acknowledge that jurisdiction and venue for such action shall lie solely in the United States District Court for the Eastern District of Pennsylvania.

25. This Agreement may be executed in counterparts, each of which shall be considered an original, but such counterparts together shall constitute one and the same Agreement.

26. This Agreement is effective on the date of signature of the last signatory to this Agreement. The exhibit attached hereto is part of the Agreement and the obligations which the exhibit sets out are binding to the same extent as if they were part of the Agreement itself;

27. Each party who signs this Agreement in a representative capacity warrants that he or she is duly authorized to do so.
28. This Agreement, including the exhibit, constitutes the full and complete agreement between the parties, with respect to the matters covered herein, and no modification hereof shall be effective unless in writing and signed by the party against which it is sought to be enforced.

FOR THE UNITED STATES OF AMERICA:

[Signatures and dates]

ZANE DAVID MEMER
United States Attorney

MARGARET L. HUTCHINSON
Chief, Civil Division

Marilyn May
Assistant United States Attorney

THOMAS F. JOHNSON
Assistant United States Attorney
FOR EXPRESS SCRIPTS, INC.:  

Keith J. Ebling  

5.14.12  
Date  

Executive Vice President and  
General Counsel
CONTROlLED SUBSTANCE SECURITY COMPLIANCE PLAN FOR EXPRESS SCRIPTS ("ESl") MAIL ORDER PHARMACIES (5-10-12)

1. Introduction

1.1. ESI's dispensing pharmacies carry millions of dosage units of controlled substance in inventory and dispense thousands of prescriptions containing controlled substances every day. ESI's non-dispensing (front-end) facilities process thousands of prescriptions daily including those for controlled substances. ESI is required to comply with the Controlled Substances Act and is expected to take reasonable measures to minimize opportunities for diversion of controlled substances. This plan is in furtherance of that objective. The plan seeks to create a sustainable compliance infrastructure and describe compliance strategies for meeting the most common controlled substance security challenges. Some of these compliance strategies go above and beyond the minimum requirements of the Controlled Substances Act. The compliance plan is not intended to waive or diminish each pharmacy's obligations pursuant to the Controlled Substances Act.

1.2. Terminology

The term "pharmacy" within this document refers to any single ESI mail service facility where controlled substance prescriptions are processed and/or dispensed. Dispensing pharmacies actually have controlled substances in stock on the premises, fill prescriptions, and ship them to patients. Non-dispensing (front-end) pharmacies input prescriptions into the ESI data system, but do not have controlled substances on the premises. Certain requirements in this document, such as the use of proper prescriber identifiers, apply to both types of pharmacies; others, such as controlled substance security, apply only to dispensing pharmacies. As of the date of this document, ESI has two dispensing pharmacies located in St. Louis, Missouri (North Park) and Tempe, Arizona. ESI presently has eight front end pharmacies located in Harrisburg, Pennsylvania, Mason, Ohio, Albuquerque, New Mexico, Fort Worth, Texas, Troy, New York, Tempe, Arizona, St. Louis, Missouri and Bensalem, Pennsylvania (Street Road).

The term "secure holding area" refers to a location within the dispensing pharmacy with increased security where controlled substances may be initially stored when they are first received at the facility from vendors. It is also where expired, damaged or otherwise unusable controlled substances are stored in locked cabinets awaiting shipment back to suppliers as returns or to be picked up by reverse distributors for destruction. The secure holding area requires badge access to enter.

The term "controlled substances room" refers to an area within the dispensing pharmacy with the highest level of security where prescriptions for controlled substances are filled and stocks of controlled substances are stored.

The term "supplying registrant" refers to a company registered with the DEA that supplies controlled substances to ESI.
The term "reverse distributor" refers to a company registered with the DEA that collects unusable controlled substances from ESI to be destroyed.

The term "inventory" as used in this plan has two meanings: a) the electronic records maintained by ESI for all of its stock of controlled substances; and b) the process of manual counting of controlled substances on a periodic basis to determine whether there is a shortage or an overage.

The term "controlled substances area" refers to the secure holding area, the controlled substances room, and/or the C-II cage.

The term "Doctor Call" refers to a location in a pharmacy where technicians and pharmacists contact physicians to address problems with prescriptions.

The term "adjudicate," when used in reference to ESI's data entry process for controlled substance prescriptions, refers to the electronic submission of prescription claim information by a providing pharmacy to the patient's prescription benefit plan (or the pharmacy benefit manager or third party administrator designated by the prescription benefit plan).

The term "non-prescriber DEA number" refers to the association of a DEA number with a practitioner to whom that DEA number has not been assigned.

2. Physical Security Infrastructure for Dispensing Pharmacies

2.1. The objectives of ESI's dispensing pharmacy physical security plan shall be to: (1) move controlled substance inventory to a secure controlled substances area promptly upon receipt; (2) accurately record every controlled substance received; (3) prevent diversions of controlled substance inventory while in the pharmacy's possession; (4) accurately record all dispensing of controlled substances and transfers of controlled substances to other registrants; and (5) precisely reconcile controlled substance inventory at regular intervals. To this end, the ESI dispensing pharmacy shall provide:
3. Controlled Substance Security Leaders

3.1. Each pharmacy, whether dispensing or non-dispensing, shall have a pharmacist in charge ("PIC") who is responsible for compliance with all state and federal regulations at that facility and seeing that safe, lawful and ethical pharmacy practice is carried out at that facility.

Each dispensing pharmacy shall designate at least one controlled substance security pharmacist ("CSSP") whose full time responsibility is the implementation and monitoring of the pharmacy's controlled substance security compliance plan. The CSSP(s) shall report directly to the PIC. If the CSSP(s) is/are absent for any reason, certain pharmacists who work in the controlled substances room or C-II cage are designated as alternate CSSP(s) and receive training to perform those functions.

The term "designated receivers" (DR) refers to a member of the receiving department at a dispensing pharmacy who has been trained and qualified to move controlled substances into the secure controlled substances holding area, look up purchase orders that may contain controlled substances and to assist the CSSP to count and enter new controlled substances into electronic inventory.

4. Background Checks
4.2. The director of investigations shall be responsible for seeing that these re-checks are completed. The re-checks shall consist of checks against the federal database, watch and debarment lists and criminal history checks.

4.3 All employees are required to affirmatively disclose any change in their circumstances that may impact their security status, such as criminal charges.

4.4. Subject to applicable local, state, and federal law, if the background check or annual re-check reveals a pending criminal charge or a criminal history involving drugs, violence, dishonesty, or theft which has been adjudicated, and where the end of the punishment occurred within the last seven years, ESI shall not employ the individual in any capacity including as a contractor, or in the case of a current employee, ESI shall remove employees from access to controlled substances or terminate them.

4.5. The ESI internal audit department audits twice a year to see if the initial background checks were completed and if the re-checks were performed. The internal audit department shall report the results of these audits to the pharmacy compliance officer.

5. Inventory Limit for dispensing pharmacies

5.1. The PIC shall limit the pharmacy's inventory of controlled substances, as inventories and reconciliations are easier to perform, and diversions are easier to detect, if the inventory is moderated. The PIC (or in the absence of the PIC, the CSSP) may authorize exceptions to this rule and must document the basis for such an exception, such as low volume products, inconsistent availability/unavailability of a product, acquisition of new business, etc. The PIC (or CSSP) shall document any departure from the rule and the pharmacy shall return to a when the circumstances justifying an increased supply cease to exist.

5.1.1 Exception category: Manufacturers/sponsors of patient assistance programs for controlled substance drug products that provide their products to ESI in minimum quantity deliveries. ESI will attempt in good faith to limit the supply of these products, but the Government recognizes that products in this category will not be subject to the general rule stated above.
7. Limited Access to Controlled Substance Areas

7.1. The PIC shall be responsible for limiting access to areas of the pharmacy where controlled substances are stored, handled, or dispensed. A badge-based access control system shall be employed. Only employees who regularly work in each controlled substances area, and their supervisors, are allowed access. Non-pharmacists shall not be granted independent access to any controlled substance areas. Each entrance to the controlled substance area shall have a posted notice listing the persons who are allowed access. The notice shall be prepared by the PIC with the assistance of the CSSP and shall be updated monthly. This review shall ensure that only those who need access have access.

7.2. The PIC or CSSP may allow temporary access for one day to controlled substance areas to personnel that do not have badge access, for legitimate business reasons such as periodic inventory. Temporary access data (name, date, times of entrance and exit, reason for access, name of person authorizing access) must be documented by the controlled substances room security guard.

7.3 Persons needing temporary access to the controlled substances room shall first obtain the PIC’s or CSSP’s approval. They shall report to the security guard with their supervisors. The supervisor shall confirm that the person in question has a legitimate reason to enter the controlled substances room. One of the controlled substances room pharmacists shall also confirm that access is permitted. Any non-badge holder who needs access to the controlled substances room for more than one day shall apply for a badge.

8. Security Guard for Controlled Substance Processing Area

8.1. The pharmacy shall have a security guard monitor each entrance to the controlled
substances room. The guard shall require all persons exiting the controlled substances room area to turn their pockets inside out and to raise the bottom of their trousers to expose their socks. The guard shall inspect any item carried from the controlled substances room. The only circumstance under which totes or packages containing pharmaceuticals can be removed from the controlled substances room is where the CSSP is moving controlled substances that have become unusable, or pharmaceuticals that are not controlled substances that are part of a cancelled order and must be restocked. Only the PIC or CSSP may transport pharmaceuticals out of the controlled substances room. The guard shall document the entrance and exit of all persons who lack badge access, and confirm PIC or CSSP and controlled substances room pharmacist approval prior to allowing such access.

9. Other Physical Security Measures for Controlled Substance Areas

9.1. ESI shall use an automated access control system to restrict access to and provide for automated audit trails for persons using badges to access the controlled substance area.

The security department shall inspect, test and maintain the access control system on a regular basis.

9.2. In addition to restricting physical access by constructed physical barriers, self closing and self latching doors, ESI shall construct the controlled substances areas in such a way to facilitate general observation of area operations by the CSSP, PIC, management, and security personnel.

9.3. Security personnel shall observe the controlled substance areas at all times by video from a central location in the facility.

ESI shall retain recorded video for at least 30 days. The security department shall inspect, test and maintain the CCTV system regularly, including a review of the adequacy of camera coverage every month or whenever the layout or designated work-flow of
the controlled substance areas in the pharmacy changes; whichever is the more frequent.

9.4. ESI shall employ an alarm system to protect the secure controlled substance areas from unauthorized access/intrusion, burglary and robbery. The alarm system shall provide for both local monitoring by security and/or pharmacy personnel and remote monitoring via an UL-listed central alarm station. Security personnel and/or the alarm central station shall monitor the alarm system, but the alarm system shall be controlled by the PIC or CSSP.

ESI shall retain the alarm history for at least one year. The security department shall inspect, test and maintain the alarm system on a regular basis.

10. Physical Receipt of Controlled Substances in Receiving Area

10.1. ESI shall physically receive controlled substances from a supplying registrant with the following precautions: (1) a security guard shall be present in the receiving area anytime a door is open to the outside loading dock; (2) DRs shall have a means for determining whether a package contains a controlled substance, which means does not require that the package be opened; (3) upon recognizing that a package contains a controlled substance, the DR shall move the unopened package to the secure controlled substances area which shall be protected by badge access; (4) if a package, which contains controlled substances, is erroneously opened outside of a secure controlled substances area, the DR and his/her supervisor shall immediately validate the quantity of controlled substances in the package, move the opened package into a secure controlled substances area, and notify the CSSP of the event and the results of the quantity validation; and (5) the CSSP shall document the event and notify the PIC. The controlled substances area shall require either a badge or a badge and a key to enter.

11. Electronic Receipt of Controlled Substances

11.1. ESI shall maintain an electronic inventory of all controlled substances. The receipt of controlled substance inventory shall be documented in the electronic inventory.

The CSSP shall also write the quantity of each item received and the date of receipt on the paper invoice provided by the supplying registrant, or the blue copy of DEA form 222 (for schedule II items). Schedule II controlled substances that were ordered by CSOS shall be documented as received within the approved CSOS automated software. The CSSP shall make
sure that the paper record of receipt, usually an invoice, contains all required data elements. If any of the foregoing information is missing, the CSSP must investigate and locate all of the required data elements. The CSSP shall maintain all paperwork regarding controlled substances in locked filing cabinets restricted to controlled substances paperwork.

11.2. For those facilities that do not have a secure holding area, the DR shall transport the packages to the controlled substances room where he shall be met by the CSSP and the two of them shall immediately enter the newly received product into the electronic inventory system as described in the preceding section.

11.3. If the supplying registrant makes any error, e.g., sends an incorrect product, sends incorrect quantity, etc., the CSSP and DR shall still electronically receive, and document receipt of, all controlled substances actually received. The CSSP and DR shall each perform a physical count until they both agree on the actual quantity received. The CSSP must document the actual quantity received for all products. The CSSP shall manually write the drug name, strength, dosage form, package size, and number of commercial containers received on DEA form 222 for every un-ordered Schedule II product, or document receipt within the approved CSOS automated software. It is not necessary that the quantity ordered and quantity received match on the blue copy of DEA form 222 or within CSOS. Under no circumstances shall the pharmacies execute an additional DEA form 222 to "cover" for the error of a supplying registrant. The CSSP, in conjunction with the PIC, shall decide whether to retain or return the incorrect product or quantity.

11.4. If a controlled substance is unusable upon receipt for any reason, e.g., damaged, short dated, etc., the CSSP and DR shall still physically count, electronically receive, and document receipt of the controlled substance. After electronic receipt, the CSSP and DR shall place the unusable controlled substances into locked file cabinets in the secured holding area. The CSSP shall arrange for it to be shipped back to the supplier or given to the reverse distributor to be destroyed.

11.5. The PIC or CSSP shall immediately notify the supplying registrant of any shortage between the quantity shipped and the quantity received. If the supplying registrant maintains that it correctly documented the quantity shipped, 21 C.F.R. 1301.74 (c) shall be followed. ESI shall provide the supplier with any information it has relevant to the discrepancy.

11.6. For each receipt,
12. Adjustments to Controlled Substance Inventory

12.1. The purchasing department of the pharmacy shall limit the personnel that have the ability to change the "on hand" physical quantity for any controlled substance in the electronic inventory system. The CSSP shall daily review all manual adjustments to controlled substance inventory to ensure that all were appropriate and had the requisite written approval. If a dispute arises between the purchasing department and the PIC or CSSP as to whether such a change should occur, it shall be resolved by the legal department.

13. Monthly Inventory of Controlled Substances

13.1. The PIC at each pharmacy shall supervise an exact physical count of all controlled substances on hand at least twelve times during each calendar year, approximately every 30 days. All dispensing shall be stopped while the physical inventory is taken and the objective shall be to have all dispensed prescriptions recorded in the electronic inventory system. Any prescriptions in process (“in pan”) before the inventory begins will be included in the inventory count.

The count shall be taken by controlled substance room employees with assistance from other employees, as needed. Contractors shall not be used for physical counts.

13.2. At least once every two years the pharmacy shall designate a monthly inventory as its biennial inventory in compliance with 21 C.F.R. § 1304.11.

13.3. Each facility shall report its monthly inventories to the compliance department and the PIC shall be required to explain any discrepancies that are found. Every quarter there shall be a meeting between the PIC and the compliance department to review inventories and decide whether any shortages exceed ESI’s thresholds and if there is a need to make a report to the DEA pursuant to DEA regulations.

14. Monthly Reconciliation of Controlled Substances

14.1. The PIC or the CSSP shall supervise monthly reconciliations of all controlled substances in tandem with the monthly inventory. Every month, after the physical count is completed, the results of that count shall be compared to the electronic inventory for each controlled substance drug product by NDC number. ESI shall perform a separate reconciliation for each subtotalled inventory category.
14.2. The reconciler shall compute the following for each controlled substance product for each inventory category: number of dosage units the pharmacy should have according to the electronic inventory, number of dosage units the pharmacy actually has on hand according to the physical count, and the difference or variance between them. A variance is defined as a discrepancy between what ESI has and what ESI is supposed to have. The reconciler shall then compute the rate of the variance for that drug by dividing the variance by the total number of dosage units the pharmacy handled during the month. It is important to keep the sign (+ or -) so the reconciliation records shall accurately reflect an overage or a shortage for each drug. Variances shall be calculated drug by drug, strength by strength.

14.3. The CSSP shall create a monthly reconciliation report for the PIC with a separate tab for each inventory category and a separate row for each controlled substance drug product. There shall also be separate tabs for Schedule II and Schedule III-V for each inventory category. The report shall contain all the data used for the reconciliation. The report shall include the results of any research which explains the reason for an apparent variance, e.g., receiving error, etc. If the PIC or CSSP discovers diversion or theft of controlled substances, the DEA shall be notified as set forth in 21 C.F.R. § 1301.76(b).

14.4 In the course of the annual audit of each dispensing pharmacy, the compliance department shall choose at random two monthly inventory and reconciliation reports for each facility to determine whether the reports are accurate and in compliance with this plan.

15. Quarterly Reconciliation of Controlled Substances and Loss Reporting.

15.1. The PIC or the CSSP shall supervise quarterly reconciliations of all controlled substances. Quarterly reconciliations shall be conducted in the same manner as monthly reconciliations, except that the beginning inventory is the beginning inventory for the earliest of the three monthly inventories, and the ending inventory is the ending inventory for the latest of the three monthly inventories. The other data elements may be obtained manually by adding the totals from the three monthly inventory reconciliations.

15.2. Significant quarterly losses, theft, and diversion of controlled substances shall be reported as set forth in 21 C.F.R. § 1301.76(b).

15.3. In the course of the annual audit of each dispensing pharmacy, the compliance department shall choose at random one quarterly reconciliation report for each facility to determine whether the reports are accurate, the loss reporting obligations have been followed and the reconciliation is in compliance with this plan.

16. Data Entry of Controlled Substance Prescriptions at Dispensing and Front-End Pharmacies
16.1. Where the Controlled Substances Act requires the prescriber of a controlled substance prescription to be registered with the DEA, at each step of the verification process all ESI employees shall record and utilize the prescriber’s own DEA registration number, and shall not associate any other registrant's DEA number, any ESI pharmacy site DEA number or any non-prescriber DEA number with such controlled substance prescriptions. Any pharmacist or other ESI employee who violates this provision shall have this counted as an error and be subject to discipline by the company.

16.2. Data entry for controlled substance prescriptions shall occur in the following manner.

16.3. ESI shall prevent and block known non-prescriber DEA numbers from being associated with controlled substance prescriptions as described in Section 16.1. ESI shall prevent and block its site DEA numbers from being associated with any controlled substance prescriptions.

16.4. ESI shall not use pharmacy site DEA numbers for military prescribers of controlled substances. A military prescriber of controlled substances must comply with 21 C.F.R. 1301.23 and provide either a DEA number or a service identification number. ESI shall not fill a controlled substance prescription unless one of these two numbers is provided by a military prescriber. ESI has been provided with a contact at DEA Headquarters Registration Section who shall be contacted within one month in the event a military prescriber of a controlled substance
does not have a DEA number. When Section 34 is fully implemented, the reporting obligation described in Section 34.6 shall replace the reporting obligation in the preceding sentence.

16.5. The ESI compliance department shall audit the effectiveness of the blocks against pharmacy site and known non-prescriber DEA numbers from being associated with controlled substance prescriptions. This audit shall consist, at least, of a semi-annual generation of reports of all blocked DEA numbers associated with controlled substance prescriptions. The compliance department shall also audit the effectiveness of the NTIS mismatch program by confirming that the retrospective reviews of NTIS mismatch resolutions are taking place and that appropriate action is taken in the event of an improper resolution.

17. Prescription Blank Security

17.1. The pharmacy shall not use paper prescription blanks for pharmacist transcribed telephoned prescriptions. Instead, the pharmacy shall provide a secure, electronic means of prescription transcription, which is only accessible by pharmacists who are assigned by the PIC to receive telephoned prescriptions from prescribers.

17.2. The compliance department shall determine that this policy is being complied with in its audit of each facility.

18. Drug Utilization Review/Corresponding Responsibility for Controlled Substance Prescriptions

18.1. The pharmacy shall designate all pharmacists that handle controlled substances as controlled substance verification pharmacists and provide corresponding training about the pharmacy's responsibility for dispensing controlled substance prescriptions. Controlled substance verification pharmacists may verify data entry of non-controlled substance prescriptions as needed; however no pharmacist may verify data entry of or review any controlled substance prescription unless he or she has been properly designated as a controlled substance verification pharmacist and has received this training.

18.1.1. ESI will implement Section 18.1 within 1 year of the date of the implementation of the CSSCP. ESI will use reasonable efforts to fully implement Section 18.1 within three years of the date of the implementation of the CSSCP and will notify the United States of the date Section 18.1 is fully implemented.

18.2. After review of the prescription order, and any other pertinent information, the pharmacist must exercise his/her professional judgment as to whether the prescription was written for a legitimate medical purpose and should be dispensed, as required by 21 C.F.R. § 1306.04(a). The reviewing pharmacist may contact the prescriber for additional information regarding the patient's condition and the need for controlled substances. The
reviewing pharmacist may be the verification pharmacist or another pharmacist who has received training in controlled substances dispensing.

18.3. The verification pharmacist shall consider, at least, the following factors in assessing the authenticity of the prescription:

18.3.1. Prescriber’s handwriting appears too legible;
18.3.2. Directions written in full, with no abbreviations;
18.3.3. Different types of handwriting are used;
18.3.4. A date on prescription is not within a reasonable time;
18.3.5 DEA number is invalid;

These factors are based on ESI’s past experience and the DEA Pharmacist’s Manual.

19. Preparation of Controlled Substance Prescriptions

19.3. This section is not intended to prevent the CSSP from removing unusable product from the controlled substances room to the secure holding area.

20. Special Standards for Handling Schedule II Controlled Substances

20.1. Only pharmacists may shelve, pick, label, dispense, or inspect schedule II prescriptions. Where state law allows, a pharmacy technician may prepare a Schedule II prescription, but if a technician counts the prescription first, the inspection pharmacist shall perform a second count.
20.2. The pharmacy shall keep a perpetual inventory of Schedule II pharmaceuticals. A pharmacist shall update the perpetual inventory immediately upon inspection of each Schedule II prescription. Schedule II prescriptions shall be sent to shipping as a group, once or twice a day. Before the Schedule II prescriptions are sent to shipping, all dispensing of Schedule II prescriptions ceases and there is a manual inventory count for all drug products that have been dispensed since the last count. If there is even a single pill missing, the filled prescriptions shall be reopened and recounted until the discrepancy can be explained. If the pharmacy ships multiple times per day, it shall be necessary to reconcile the Schedule II inventory more than once daily. No Schedule II prescription may leave the controlled substances room (or C-II cage) for shipping until the reconciliation has occurred.

21. Handling of Dropped Controlled Substances

21.1. The cage reduction spreadsheet records product removed from the controlled substances room that cannot be dispensed because it is damaged, expired, recalled or otherwise unusable.

22. Handling of Recalled Controlled Substance Pharmaceuticals

22.1. Recalls are made voluntarily by manufacturers at the request of the Food and Drug Administration. ESI typically learns of recalls from the manufacturers, wholesalers or the FDA. The transfer shall be documented on a cage reduction spreadsheet and on a perpetual inventory for recalled controlled substance pharmaceuticals by the CSSP.

There shall be a separate perpetual inventory for Schedule II and Schedule III-V recalled pharmaceuticals that shall be accounted for in the monthly inventory by actual physical count. ESI shall then follow the instructions of the manufacturer who has recalled the product as to whether it should be returned to the manufacturer or given to a reverse distributor.

23. Handling of Damaged or Expired Controlled Substance Pharmaceuticals

23.1. Any ESI employee who observes damaged or expired controlled substance pharmaceuticals shall bring them to the attention of the CSSP. There shall be a separate perpetual inventory for Schedule II and
Schedule III-V damaged or expired pharmaceuticals that shall be accounted for in monthly inventory by actual physical count.

24. Handling of Dispensed Controlled Substance Pharmaceuticals Returned to the Pharmacy

24.1. [Blank]

25. Destruction of Controlled Substances

25.1. At least once per month, and preferably just before the monthly inventory, the CSSP shall transfer all controlled substances awaiting destruction to a reverse distributor duly registered with DEA. The transfer shall be documented on DEA form 222 (schedule II) or with the data elements set forth in section 11.1 (schedule III-V). The CSSP is responsible for maintaining records for all such transfers. The CSSP shall maintain a separate transfer record for each discrete inventory area within the controlled substance holding area, i.e., damaged or expired pharmaceuticals, patient returns, etc. The CSSP shall reconcile the perpetual inventories for all controlled substances with the controlled substances actually transferred to the returns vendor. All unresolved discrepancies shall be immediately reported to DEA by the CSSP on DEA form 106 as lost in-house. The pharmacy shall not apply any significance threshold before making this loss report.

26. Controlled Substance Record keeping

26.1. The CSSP is responsible for the pharmacy’s record keeping compliance, including DEA form 222 and other records of receipt, records of transfer of controlled substance pharmaceuticals to other registrants, original prescriptions, power of attorney forms, biennial inventory, DEA form 106s, the pharmacy's DEA certificate of registration, cage reduction spreadsheet and the daily statements by dispensing pharmacists attesting to the accuracy of the refill information entered into the automated data processing system. These records are all open to inspection by the DEA.

26.2. The daily statement by the dispensing pharmacist attesting to the accuracy of refill information is a certification required by the Controlled Substances Act that every dispensing pharmacist must make on a daily basis. The pharmacist must attest that the electronic records regarding refills are accurate.

27. Reporting Obligations

27.1. The CSSP is responsible for the pharmacy’s compliance with reporting obligations to DEA. In addition to reporting significant quarterly losses, the CSSP shall also report any theft or diversion of controlled substances and any controlled substances lost in transit, without regard to the pharmacy’s threshold standard for determining whether a loss of controlled substances is
significant. Significant quarterly losses, theft, and diversion of controlled substances shall be reported as set forth in 21 C.F.R. § 1301.76(b).

28. Trash Handling within the Controlled Substance Room

28.1. Each controlled substance dispensing station within the controlled substance room or C-II cage shall have two trash receptacles. One receptacle shall be for commercial containers without lids. The other receptacle shall be for paper and lids. **New trash bags shall be used at the beginning of each workday. Empty boxes must be completely broken down prior to removal from the controlled substances room or C-II cage areas. All trash, broken down boxes, and empty vendor totes must be inspected by a controlled substances room pharmacist immediately prior to removal from any secure controlled substance area.** Only one cart or bin of trash may be removed from any secure controlled substance area at one time. The cart or bin shall be escorted by a controlled substances room pharmacist and one other controlled substances room employee or security guard to a trash compactor, and the trash shall be compacted in the presence of the two escorts.

29. Prescriptions Lost-in-Transit

29.1. Patients sometimes report that prescription orders containing controlled substances have not arrived when expected. The pharmacy shall designate a period of time after which replacement authorization from the physician shall be sought, e.g., 12 days after shipment. Once this time has elapsed, the pharmacy shall contact the prescriber and request authorization to replace the missing order and obtain a new prescription if necessary. The calling pharmacist shall inform the prescriber of any previous controlled substance replacement requests by the same patient so the prescriber can consider this history in deciding whether to authorize the replacement. The pharmacist shall also inform the prescriber of the possibility that the missing order may eventually be delivered to the patient.

29.2. If ESI learns from the patient that the missing order was delivered to the patient after the replacement has been dispensed, pharmacy personnel shall inform the prescriber's office, and the pharmacy shall consider both prescriptions when computing the next available refill date for the controlled substance.

29.3. If a patient reports that an order is missing and ESI has not been advised within 30 days of date of shipment that it has been delivered to the patient, ESI shall call the patient to confirm that the product has still not arrived. The CSSP shall then report the controlled substances to DEA as lost-in-transit on DEA form 106 without delay.

29.4. If a patient reports that a package containing a controlled substance was received with signs of tampering and controlled substance dosage units are missing, the CSSP shall immediately report the missing controlled substance(s) to DEA as lost in transit on DEA form 106.
29.5. If a patient reports a shortage for a controlled substance prescription, but the patient reports that the package did not appear to be tampered with, the pharmacy shall check the inventory records of the product in question. If the inventory and any other available data, e.g., the weight of the package shipped to the patient, indicate that the pharmacy dispensed the correct quantity, the CSSP shall report the missing controlled substance(s) to DEA as lost in transit on DEA form 106 without delay. If the investigation determines that ESI made an error and dispensed less than the proper amount, it shall dispense the additional product to the patient, subject to applicable state and federal law.

29.6. ESI shall include in its investigation a review of any available video surveillance of the filling of the prescription in question. If ESI concludes that an ESI employee has diverted a controlled substance, ESI shall terminate the employee and the DEA and all appropriate law enforcement authorities shall be notified immediately.

29.7. The ESI compliance department shall audit the lost in transit records. The compliance department shall randomly select, on an annual basis, 2% of the files of those drugs reported as having been lost-in-transit. These files shall be examined to verify that the proper procedures were followed including patient and prescriber communication, DEA notification and record-keeping, and that the company made appropriate responses to information it was given.

30. Drug Testing Program

30.1. The pharmacy shall conduct pre-employment, reasonable suspicion and random testing for all employees in accordance with local, state, and federal law and based upon their position in the Company. All employees may be required to take a drug or alcohol test due to a work-related post accident or injury. Employees located in pharmacies shall be subject to random testing if local, state, and federal law allows random testing for the positions identified.

30.3. Reasonable Suspicion Testing

30.3.1. An employee must submit to a drug and alcohol test if, in the opinion of the human resources department and pharmacy operations leadership, there is reasonable suspicion that the employee is using an illegal drug or impaired due to the use of alcohol. Reasonable suspicion may include, but is not limited to, the following:
30.3.1.1. Abnormal, unusual, or suspicious behavior or appearance that suggests the employee may be impaired;

30.3.1.2. Direct observation of drug or alcohol use;

30.3.2. If an employee is tested under this section, the employee shall be suspended from work, with pay, until the results of the applicable test are available.

30.3.3. Depending upon the test results, an individual may be subject to disciplinary action up to and including termination of employment and/or may be required to complete treatment.

30.4. Work Related Post Injury or Accident Testing

30.4.1. The pharmacy may require a drug and alcohol test for any employee who is involved in any workplace accident resulting in injury to the employee or any other person requiring medical attention, or resulting in significant property damage or loss of productive working time.

30.5. Random Testing

30.5.1. In a pre-established system of random selection, the pharmacy may require any employee who works in the pharmacy to submit to drug testing in accordance with applicable local, state, and federal laws.

30.5.2. A randomly selected employee shall be required to submit to drug testing, in accordance with applicable local, state, and federal laws, in the same workday in which they are notified. Failure to submit to drug test once notified shall be considered a failed drug test.

30.5.3. Methods of selection for random testing shall ensure that no employee shall be unlawfully discriminated against. Depending upon the test results, an individual may be subject to disciplinary action up to and including termination of employment and/or may be required to complete treatment.

30.6 The ESI compliance department shall audit the drug testing program as follows. The compliance department shall randomly select, on a monthly or annual basis, 2% of the new hire and random drug tests performed that month (or year). The goal of the audit is to verify that the tests were done and that the company made appropriate responses to the results of the tests.

31. Compliance Oversight

31.1. The pharmacy shall be subject to oversight by a compliance department that is independent of the pharmacy’s operational chain of command. Oversight shall include periodic on-site controlled substance security audits by compliance personnel. These audits shall assess the pharmacy’s implementation of this compliance plan as well as its compliance with the Controlled Substances Act.
31.2. Once a year compliance personnel shall visit each dispensing pharmacy and conduct a controlled substances audit pursuant to the audit template previously provided to the United States. The auditor shall review all records regarding ordering, receipt and inventory of controlled substances. The auditor shall also review physical security of the controlled substance areas to see that all security precautions are being carried out. The auditor shall evaluate the PIC and CSSP to see that they are properly following the CSA. The audit shall result in a report that is shared with operating personnel, the chief compliance officer and ESI’s General Counsel.

31.3. ESI’s oversight program shall also include a legal advice forum where a controlled substance expert renders legal advice to pharmacy operations personnel, and review of monthly controlled substance reconciliations from each dispensing pharmacy by compliance personnel. Finally, a compliance hotline shall be available for anonymous reporting of diversion or a breach of controlled substance security. Compliance personnel shall investigate and resolve all hotline reports.

32. Self-Audits

32.1. Once per quarter the PIC or CSSP at each pharmacy shall conduct an audit of the pharmacy’s implementation of this compliance plan and its compliance with the Controlled Substances Act. The PIC or CSSP shall employ the same audit template and the same auditing standards used by compliance personnel in their on-site audits. The results of all self-audits shall be reported to compliance personnel.

33. Training

33.1 ESI shall establish a training program for pharmacy technicians who are part of the data entry process with regard to controlled substance prescriptions. Such training shall include instruction on the Controlled Substances Act, the consequences for ESI of violations of the CSA and the terms of this plan and the accompanying agreement. ESI shall also establish appropriate training programs for other employees who have physical access to or exercise control over controlled substances. This training shall include instruction on provisions of the Controlled Substances Act and this plan that relate to the employee’s job responsibilities.

34. Prescriber Identifier Functionality for Prescriptions

ESI will implement the below functionality, or functionality substantially similar to the below, within 1 year of the date of implementation of the CSSCP

ESI will use reasonable efforts to fully implement the below functionality, or functionality substantially similar to the below, within three years of the date of implementation of the CSSCP and will notify the United States of the date such functionality is fully implemented.

34.1. Currently, every prescriber in the ESI computer system must have a completed DEA number field associated with that prescriber, and this DEA number is adjudicated every time an ESI pharmacy fills or refills a prescription. ESI will remove the requirement that every
prescriber in its system have a completed DEA number field. Subject to the requirements of section 34.7 regarding controlled substances, ESI will impose a new requirement that every prescriber in its system have an NPI number.

34.2. Prescriber identifier priority. Each time ESI fills or refills a prescription, a prescriber identifier (and other data relating to ESI’s claim for providing pharmacy services) is adjudicated. Currently, the system always adjudicates a DEA number as the prescriber identifier. In the new system, subject to the requirements of section 34.7 regarding controlled substances, the prescriber identifier will be selected in the following priority: (1) prescriber’s NPI; (2) prescriber’s DEA; and, if the prescriber does not have either a DEA or NPI: (3) pharmacy’s site NPI.

34.3. One time identifier cleanup. ESI is aware of certain non-prescriber DEA numbers in its prescriber files. ESI will delete all known non-prescriber DEA numbers from all prescriber files. For any prescribers lacking an NPI number in ESI’s system, ESI will also attempt to locate a valid NPI within a database of NPI numbers compiled by an outside vendor (the “NPI authority file”) at the time of the cleanup, using the full name and zip code of the prescriber. If an NPI number is not found, the pharmacy’s site NPI will be entered automatically into that prescriber’s NPI number field.

34.4. Ongoing identifier cleanup. For any prescribers lacking an NPI number in ESI’s system, ESI will make ongoing efforts to obtain the prescribers’ NPI. One effort will be a monthly search in the NPI authority file using the prescriber’s full name and zip code, as described in subsection 34.3.

34.5. Physician outreach. Another effort to obtain an NPI number for a prescriber lacking such a number will be an outreach directly to such prescribers. It will work as follows. Each prescriber’s file in the system will contain a field called “ID Status” that indicates the need for an outreach to obtain the prescriber’s NPI number. All prescribers who have pharmacy site NPI numbers will be set to an ID status of “O” meaning that an outreach to discover NPI is needed. Once an outreach is made, ID status will be set to “C”, which will prevent additional outreaches. If the physician fails to respond, ID status will be reset to “O”. Once a valid NPI is obtained, ID status will be changed to “V”. If the physician refuses to provide NPI and requests that we cease our requests for NPI, ID status will be changed to “N”.

34.6. Military prescribers. For controlled substance prescriptions, pursuant to 21 C.F.R. § 1301.23, ESI will require service identification number and branch of service before a military prescriber is exempted from the requirement to have a DEA number before ESI fills a controlled substance prescription. This exemption is only available for the prescribing of controlled substances in the course of official duties. Military prescribers lacking a DEA and NPI number will use a pharmacy’s site NPI number for adjudication. ESI will notify the Registration Unit, Office of Diversion Control, DEA Headquarters, on a quarterly basis of any military prescribers who lack either a DEA or NPI number.

For non-controlled substance prescriptions, ESI will follow 34.2 above.

34.7. Controlled Substance Prescriptions. ESI will always require a valid DEA number for
controlled substance prescriptions. (The only exception is military prescribers for whom ESI has service identification number and branch of service on file.) Each time a controlled substance prescription is adjudicated, the prescriber’s DEA number is subject to the NTIS check described in section 16.2 of the Controlled Substance Security Compliance Plan.

34.8. Report to USAO. After each monthly NPI cleanup, ESI will send the United States Attorney’s Office a report of all prescribers associated with a pharmacy’s site NPI number.