



**ENFORCEMENT AND COMPOUNDING COMMITTEE  
MEETING MATERIALS  
MARCH 27, 2014**

**I. PUBLIC COMMENT FOR ITEMS NOT ON THE AGENDA/AGENDA ITEMS FOR FUTURE MEETINGS**

Note: The committee may not discuss or take action on any matter raised during this public comment section that is not included on this agenda, except to decide whether to place the matter on the agenda of a future meeting. [Government Code Sections 11125, 11125.7(a)]

**II. ENFORCEMENT MATTERS**

**a. FOR DISCUSSION: Update on Implementation of AB 1136 (Levine) Chapter 304, Statutes of 2013 Regarding Warning Labels on Prescription Container Labels**

**Attachment 1**

Background

Existing law requires a pharmacist to inform a patient orally or in writing of the harmful effects of a drug (1.) if the drug poses a substantial risk to the person consuming the drug when taken in combination with alcohol, or if the drug may impair a person's ability to drive a motor vehicle, whichever is applicable, and (2.) the drug is determined by the Board of Pharmacy to be a drug or drug type for which the warning shall be given.

Assembly Bill 1136 (Levine), signed by the Governor on September 9, 2013, amends existing law to require a pharmacist on or after July 1, 2014, to include a written label on a prescription drug container indicating that the drug may impair a person's ability to operate a vehicle or vessel, if in the pharmacist's professional judgment, the drug may impair a person's ability to operate a vehicle or vessel. The required label may be printed on an auxiliary label that is affixed to the prescription container.

Section 1744 provides the specific classes of drugs which trigger a pharmacist's verbal or written notice to patients where a patient's ability to operate a vehicle may be impaired. Section 1744 is also provided in **Attachment 1**.

At the January Board Meeting, Mr. Santiago commented that existing statute already makes the allowance for a pharmacist's professional judgment to decide if a drug could impair a patient's ability to operate a vehicle or vessel so the regulation does not need to say "including but not limited to".

Mr. Santiago further stated that 1744 needed to be amended only if the board wanted to change the list of classes of drugs for which an oral or written warning must be communicated to the patient pursuant to Business and Professions Code section 4074.

The board had no specific action directed as a result of this discussion. Nevertheless, there will be a newsletter article noting the changes made to Business and Professions Code Section 4074 by AB 1136, advising that pharmacists who have a professional opinion that a drug may impair a person's ability to operate a vehicle or vessel must provide a warning label to the prescription container.

**b. FOR DISCUSSION AND POSSIBLE ACTION: Requests from UCLA Health System, Ronald Reagan UCLA Medical Center, for a Waiver as Permitted by California Business and Professions Code Section 4118 Pertaining to Licensure as a Centralized Hospital Packaging Pharmacy, California Business and Professions Code Section 4128 et seq.**

**Attachment 2**

Background

In 2012 the California Society of Health System Pharmacists and the California Hospital Association sponsored legislation to establish a centralized hospital packaging license which would allow a hospital chain under common ownership to consolidate packaging operations into a single location in a specialized pharmacy to prepare single dose medications that are bar coded. The specific provisions were contained in AB 377 (Solorio, Chapter 687, Statutes of 2012). Included in the provisions of this measure was the requirement that the unit dose medications filled by the centralized hospital packaging license be barcoded to be readable at the inpatient's bedside and specifies the information that must be retrievable when the barcode is read.

The board supported this measure and actively advocated for its passage because of the significant positive impact the use of barcoding would have on the reduction of medication errors that occur in hospitals. Specifically, the board's letter to the Governor included the following:

“...Bar coding is important for patient safety. Before a medication is administered to a patient, by scanning the bar code on a medication, a patient's chart and a patient's wristband – the right medication, in the right dose will be ensured at the patient's bedside. This provides an important step forward to improve patient safety and decrease the rate of medication errors and potential adverse drug events...”

In January 2014, the Enforcement Committee discussed an identical request from Sharp Healthcare and Scripps Health. At that meeting, both hospitals requested that the board

approve their waiver requests to forego the specific labeling of elements in section 4128.4 that require the bar code to contain:

- (a) The date the medication was prepared
- (b) The components used in the drug product
- (c) The lot number or control number
- (d) The expiration date
- (e) The National Drug Code Directory number
- (f) The name of the centralized hospital packaging pharmacy

These items appear on the label but not in the bar code because the technology does not possess the capability.

Following a discussion at the January board meeting, the board voted to approve a five-year waiver for Sharp Healthcare and Scripps Health, so long as the information specified in section 4128.4 is provided on the prescription label, and the bar code on the container can still identify the name of the drug, the strength, and can be read against a bar code on the patient's wrist and patient medication record to ensure it is the right medication for that patient.

Similarly, Ronald Reagan UCLA Medical Center's current computerized physician order entry (CPOE) system is not configured to do a bar code read of the elements in section 4128.4, but it can read the NDC number on the container with a reader to ensure the container is read at the patient's bedside to ensure it is right medication for the patient.

**Attachment 2** contains a copy of UCLA's waiver request, the board's support letter on AB 377, the waiver provisions provided in Business and Professions Code section 4118, and the specific items that must be contained in the bar code by section 4128.4.

**c. FOR DISCUSSION AND POSSIBLE ACTION: Opportunity to Provide Written Comments to the Federal Drug Enforcement Administration on the Possible Rescheduling of Hydrocodone Combination Products From Schedule III to Schedule II, 21 CFR Part 1308 [Federal Register Docket No. DEA-389]**

**Attachment 3**

Background

Hydrocodone combination products are pharmaceuticals containing specified doses of hydrocodone in combination with other drugs in specified amounts. These products are approved for the marketing for the treatment of pain and for cough suppression.

The Drug Enforcement Administration (DEA) recently published a notice of proposed rulemaking (NPR) to reschedule hydrocodone combination products from Schedule III to Schedule II of the federal Controlled Substances Act. This proposed action is based on a rescheduling recommendation from the Assistant Secretary of Health of the Department of

Health and Human Services and an evaluation of all other relevant data by the DEA. Written comments on the NPR are due on or before April 28, 2014.

**Attachment 3** includes a copy of the article from the Federal Register / Vol. 79, No. 39 / Thursday, February 27, 2014 / Proposed Rules

Hydrocodone is a frequently prescribed drug for pain. Get a tooth removed and you may be prescribed hydrocodone. Injure your leg or undergo minor (or even major) surgery and you may be prescribed hydrocodone. Often the quantities prescribed for a patient greatly exceed the amount needed by a patient, so patients may have hydrocodone stored in their medicine cabinets. Hydrocodone is also a widely abused prescription medication, and a frequently diverted drug from pharmacies. Depending on the strength and local availability, a pill may be worth \$2-\$10 each.

Hydrocodone is the predominant controlled drug prescribed in California. During the joint DEA/Board of Pharmacy Prescription Drug Abuse presentations for which pharmacists may earn 6 units of CE, hydrocodone is a frequent discussion point.

In recent years, hydrocodone has been identified as a stepping stone drug, where individuals start with hydrocodone, like the feeling, take more and more of the widely available drug as they become habituated, and then move to stronger drugs like hydromorphone and then to oxycodone. And then when it becomes too expensive to obtain and purchase these drugs, leads individuals to heroin.

California is the nation's largest consumer of hydrocodone. From CURES, the following number of medications have been dispensed in 2012-2013:

### **In California**

April 2012-April 2013

- All Hydrocodone: 1,441,550,660
- All Morphine-Dilaudid-Hydromorphone: 148,979,816
- All Oxy: 269,751,340
- All Alprazolam: 206,204,094
- All Lorazepam: 171,045,455
- All Zolpedem Tartrate-Ambien: 147,642,379

The question before the DEA and this Federal Register docket is whether hydrocodone should be rescheduled to federal Schedule II. If so, this drug will not be able to be refilled or prescribed orally. Instead, each time another fill of hydrocodone is needed, a new prescription will be required, much like that which occurs for oxycodone or Dilaudid.

d. **FOR DISCUSSION: Opportunity to Submit Comments on the Standards for the Interoperable Exchange of Information for the Tracing of Human, Finished, Prescription Drugs, in Paper or Electronic Format; Establishment of a Public Docket, Federal Register, Food and Drug Administration [Docket No. FDA-2014-N-0200]**

**Attachment 4**

Background:

The Food and Drug Administration (FDA) is establishing a public docket to receive information and comments on standards for the interoperable exchange of information associated with transactions involving prescription drugs to comply with the new requirements in the Drug Supply Chain Security Act (DSCSA). Written comments are due by April 21, 2014.

This is one of the early steps undertaken by the FDA to develop a national system to secure the pharmaceutical supply. This was a frequent inquiry to the board when the board was working to implement California's e-pedigree system; however, the board declined to specify such a system.

**Attachment 4** includes a copy of the notice from the Federal Register / Vol. 79, No. 34 / Thursday, February 20, 2014 / Notices

e. **FOR INFORMATION: Development of an Alternative Process for Pharmacists to Become Registered to Access CURES**

Last year, SB 809 (DeSaulnier) was enacted to enhance and rev up the CURES prescription drug monitoring program.

Part of the discussion associated with the bill's progression through the Legislature was the growing concern about the need for pharmacists and prescribers to access CURES before dispensing or prescribing controlled drugs. To access CURES to see the history of controlled drugs dispensed to a single patient over the last year, a prescriber or pharmacist must have been preapproved by the CA Department of Justice. However, an abysmally low number of prescribers and dispensers have applied for and been granted access to CURES.

Provisions enacted in SB 809 require all prescribers and pharmacists to be registered with the DOJ to access CURES by January 1, 2016. However, the new computer system and funding for staffing for the DOJ to operate the CURES system will not be available until perhaps July 2015. Meanwhile, the Department of Consumer Affairs' agencies are transferring to a new computer system of their own that will create new systems for license issuance and renewal. Only the first one-third of DCA's boards have converted to the new BreZE system. It may be late 2014 before phase II converts (this board is part of this group).

As such, it looks likely that few if any DCA boards will be able to comply with the January 1, 2016 CURES registration deadline for licensees.

The current process for CURES registration is frustrating and laborious. Individuals must start an email contact with the DOJ, then fill out an application they download, and then copy various documents (driver's license, professional license) and have the whole package notarized and then mailed to the DOJ. Lacking staff, the DOJ is taking months to process this material.

Board staff have discussed with the DOJ a process whereby the board could authenticate the identity of a pharmacist and aid the DOJ in getting this individual registered. Details are still being worked out, but a general process has been drafted. We hope to have a trial available by the board meeting in April, perhaps whereby those attending the meeting could be "processed" by the board's staff and then routed to DOJ for access to CURES.

**f. FOR DISCUSSION AND POSSIBLE ACTION: Losses of Controlled Drugs Reported in California**

**Attachment 5**

A pharmacy or a wholesaler must report any loss of controlled substances to the board within 14 days. A separate requirement also mandates these entities to notify the DEA of significant losses of controlled drugs (a loss is reported on a form DEA 106).

Recently, the board's staff compiled some statistics regarding drug losses reported to the board in order to respond to press inquiries. The staggering results will be shared during the board meeting.

**Attachment 5 includes** a copy of an article by the LA Times regarding drug losses at several CVS Pharmacies in northern California. Data regarding the drug losses reported to the board over the last few years will be shared with the committee during the meeting.

**g. FOR INFORMATION: Presentation on "What We Find When We (the Board of Pharmacy) Inspect Pharmacies"**

**Attachment 6**

The board's executive officer continues to be asked to speak about pharmaceutical supply chain issues that have been discovered by the board. At this meeting, a short PowerPoint presentation will be given by the executive officer regarding what the board finds when inspecting pharmacies or reading the industry's journals.

As an example of what is being found and prosecuted by regulators and law enforcement is provided in **Attachment 6**, which is an article from *Drug Topics*, "Michigan Pharmacy Employees Indicated in \$60 Million Fraud".

**h. FOR INFORMATION: Demonstration by Omnicell Regarding Technology Currently in Use for Pharmacies Providing Automated Drug Delivery Systems in Health Care Facilities Licensed Under Health and Safety Code section 1250 (c), (d) or (k)**

**Attachment 7**

During this meeting Rich Hooper, System Sales Director Non-Acute Care, Omnicell and Omnicare, will provide a demonstration on restocking procedures of their automated dispensing cabinet (ADC) as it is used in long term care for emergency/first dose medication.

Omnicell plans to demonstrate the stocking procedures by the personnel allowed to stock the automated e-kit when delivered to the facility in the current approved manner. Omnicell is requesting an acknowledgment from the committee that their system satisfies the intent in Health and Safety Code section 1261.6.

**Attachment 7** includes the procedures for restocking provided by Omnicell, and as statutory authority, Health and Safety Code section 1261.6 which authorizes the use of automated dispensing systems in certain facilities (those licensed under California Health and Safety Code section 1250 (c), (d) and (k) which is also provided).

**III. COMPOUNDING MATTERS**

**a. FOR DISCUSSION AND POSSIBLE ACTION: General Discussion on the Board's Proposed Compounding Regulations**

At the October 2013 Board Meeting, the board moved to initial notice of proposed changes in the California's compounding regulations (located in 16 California Code of Regulations Sections 1735 et seq. and 1751 et seq). The 45-day comment period ran from November 29, 2013 – January 13, 2014. A regulation hearing was held on January 16, 2014, to provide the public with an opportunity to provide comments in another forum.

During the notice period, the board received many written and oral comments. Board staff sorted all written and oral comments received by section number, to facilitate review all of related comments by section. This compilation document was available at the January 2014 board meeting and online. At the January 2014, the board made a motion to allow the sterile compounding workgroup to work through the comments received and submit a second version of the proposed text based on comments.

After reviewing and considering the written and oral comments received, board staff recommends the following for discussion and possible action:

1. Withdraw the current rulemaking file originally noticed November 29, 2013.
2. Provide general guidance to the sterile compounding workgroup to develop updated language based on substantive comments received by the board and notice the revised language as a new rulemaking.

**b. FOR INFORMATION: Update on Compounding Provisions Enacted by HR 3204, The Federal Drug Quality and Security Act and the Recent Meeting Between the FDA and the States' Boards of Pharmacy**

**Attachment 8**

Background

Included as part of the federal Drug Quality and Security Act (HR 3204) are provisions that establish provisions for federal regulation and oversight of large scale drug compounding by "outsourcing facilities." The federal law sets forth voluntary requirements for licensure and enforcement of these entities.

At this meeting

During the meeting counsel will provide a high-level overview of the sterile compounding requirements of this new law for informational purposes only. It is important to note that California's law is more restrictive than the federal law in several areas.

California will continue to require any pharmacy that is compounding sterile products for California residents or practitioners to possess licensure with our board and comply with CA requirements.

**Attachment 7** includes the relevant compounding sections of HR 3204.

**c. FOR DISCUSSION: Data Collected on Violations Found During Compounding Inspections in California**

Very recently, the FDA convened a meeting of all states to discuss their activities with respect to compounding, and principally sterile compounding within their jurisdictions. The board's executive officer was asked to provide an overview of California's inspections and outcomes. She will provide this presentation to the committee.

**d. FOR INFORMATION: Update on the National Shortage of IV Solutions**

**Attachment 8**

**Attachment 8** includes a copy of the update provided by the California Hospital Association on the continuing shortage of essential IV solutions.

#### IV. **MEETING DATES FOR 2014**

Meeting dates for the remainder of 2014 have been scheduled for:

- June 26, 2014
- September 30, 2014
- December 17, 2014

# **Attachment 1**

## Assembly Bill No. 1136

### CHAPTER 304

An act to amend Section 4074 of the Business and Professions Code, relating to pharmacy.

[Approved by Governor September 9, 2013. Filed with  
Secretary of State September 9, 2013.]

#### LEGISLATIVE COUNSEL'S DIGEST

AB 1136, Levine. Pharmacists: drug disclosures.

The Pharmacy Law provides for the licensure and regulation of pharmacists by the California State Board of Pharmacy. Existing law requires a pharmacist to inform a patient orally or in writing of the harmful effects of a drug dispensed by prescription if a prescription drug poses a substantial risk to the person consuming the drug when taken in combination with alcohol or if the drug may impair a person's ability to drive a motor vehicle. This requirement applies when the board determines that the drug is a drug or drug type for which this warning shall be given. A violation of the Pharmacy Law is a crime.

This bill would additionally require, on and after July 1, 2014, a pharmacist to include a written label on the drug container indicating that the drug may impair a person's ability to operate a vehicle or vessel if the pharmacist, in exercising his or her professional judgment, determines that the drug may impair a person's ability to operate a vehicle or vessel, as specified. Because a violation of this requirement would be a crime, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

*The people of the State of California do enact as follows:*

SECTION 1. Section 4074 of the Business and Professions Code is amended to read:

4074. (a) A pharmacist shall inform a patient orally or in writing of the harmful effects of a drug dispensed by prescription if both of the following apply:

(1) The drug poses substantial risk to the person consuming the drug when taken in combination with alcohol or the drug may impair a person's ability to drive a motor vehicle, whichever is applicable.

(2) The drug is determined by the board pursuant to subdivision (c) to be a drug or drug type for which this warning shall be given.

(b) In addition to the requirement described in subdivision (a), on and after July 1, 2014, if a pharmacist exercising his or her professional judgment determines that a drug may impair a person's ability to operate a vehicle or vessel, the pharmacist shall include a written label on the drug container indicating that the drug may impair a person's ability to operate a vehicle or vessel. The label required by this subdivision may be printed on an auxiliary label that is affixed to the prescription container.

(c) The board may by regulation require additional information or labeling.

(d) This section shall not apply to a drug furnished to a patient in conjunction with treatment or emergency services provided in a health facility or, except as provided in subdivision (e), to a drug furnished to a patient pursuant to subdivision (a) of Section 4056.

(e) A health facility shall establish and implement a written policy to ensure that each patient shall receive information regarding each drug given at the time of discharge and each drug given pursuant to subdivision (a) of Section 4056. This information shall include the use and storage of each drug, the precautions and relevant warnings, and the importance of compliance with directions. This information shall be given by a pharmacist or registered nurse, unless already provided by a patient's prescriber, and the written policy shall be developed in collaboration with a physician, a pharmacist, and a registered nurse. The written policy shall be approved by the medical staff. Nothing in this subdivision or any other law shall be construed to require that only a pharmacist provide this consultation.

SEC. 2. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

**CCR 1744**

**1744. Drug Warnings.**

Pursuant to Business and Professions Code Section 4074, a pharmacist shall inform the patient or his or her representative of the harmful effects of certain drugs dispensed by prescription.

(a) The following classes of drugs may impair a person's ability to drive a motor vehicle or operate machinery when taken alone or in combination with alcohol:

- (1) Muscle relaxants.
- (2) Analgesics with central nervous system depressant effects.
- (3) Antipsychotic drugs including phenothiazines.
- (4) Antidepressants.
- (5) Antihistamines, motion sickness agents, antipruritics, anti-nauseants, anticonvulsants and antihypertensive agents with central nervous system depressant effects.
- (6) All Schedule II, III, IV and V depressant or narcotic controlled substances as set forth in Health and Safety Code at Section 11055 et seq. prescribed in doses which could have an adverse effect on a person's ability to operate a motor vehicle.
- (7) Anticholinergic agents and other drugs which may impair vision.

(b) The following are examples of drugs which may have harmful effects when taken in combination with alcohol. These may or may not affect a person's ability to operate a motor vehicle.

- (1) Disulfiram and other drugs (e.g. chlorpropamide, metronidazole) which may cause a disulfiram-like reaction.
- (2) Mono amine oxidase inhibitors.
- (3) Nitrates.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4022, 4055 and 4074, Business and Professions Code.

# **Attachment 2**

# **Waiver Request**

RECEIVED BY CALL  
BOARD OF PHARMACIA  
2014 JAN 15 AM 11:29

California State Board of Pharmacy  
1625 N. Market Blvd, N219  
Sacramento, CA 95834

January 14, 2014

RE: Centralized Packaging Pharmacy Request for Waiver

Dear Ms. Herold,

Ronald Reagan UCLA Medical Center applied for a Centralized Packaging Pharmacy License in August of 2013 (attached). The regulations state the required information that must be included in a barcode for medications labeled in a Centralized Packaging Pharmacy. We respectfully request a waiver from the requirements of Article 7.6 Section 4128.4 of the Business and Professions Code. According to Section 4128.4, the barcode shall have the following information:

- (a) The date the medication was prepared.
- (b) The components used in the drug product.
- (c) The lot number or control number.
- (d) The expiration date.
- (e) The National Drug Code Directory number.
- (f) The name of the centralized hospital packaging pharmacy.

With our current computerized physician order entry (CPOE) system, nurses scan the barcode on the medication prior to administration as part of the medication safety validation (right patient, right drug, right dose, right route and right time). The barcode on the label must contain the NDC number that matches the NDC number in the system for the patient's medication order to ensure that the correct medication is being administered. The system is only configured to recognize NDC numbers; if we were to add the addition information required by Article 7.6 Section 4128.4, the barcode would not be recognized by the CPOE system, and the medication safety check would fail. In compliance with the Article 7.6 Section 4128.4 requirements, all of the information is provided in text form on the medication label.

If you have any questions or required additional information, please feel free to contact Diane Zalba, Pharm.D., at (310)267-8500 or [dzalba@mednet.ucla.edu](mailto:dzalba@mednet.ucla.edu).

Sincerely,



Diane Zalba, Pharm.D.  
Chief Pharmacy Officer  
UCLA Health System

# **Support Letter**



**California State Board of Pharmacy**

1625 N. Market Blvd, N219, Sacramento, CA 95834

Phone: (916) 574-7900

Fax: (916) 574-8618

www.pharmacy.ca.gov

STATE AND CONSUMER SERVICES AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

September 13, 2012

The Honorable Edmund G. Brown Jr.  
Governor  
State of California  
State Capitol  
Sacramento, CA 95814

RE: Assembly Bill 377 (Solorio) - Enrolled

Dear Governor Brown:

The California State Board of Pharmacy respectfully requests your signature on **Assembly Bill 377** (Solorio). This bill would allow a hospital chain under common ownership to prepare consolidated packaging operations to prepare single dose medications that are bar coded. The unit medications would be delivered to any of multiple campuses of the general acute care hospitals under the same ownership for patient administration. Such operations would be done in a specialty pharmacy licensed and regulated by the board. The FDA has determined that a pharmacy performing such packaging is not “manufacturing.”

Currently a hospital may package such unit dose medication for administration to patients solely within the same hospital’s premises. Assembly Bill 377 would require a specialty license that would result in bar coding of all unit dose medications produced. Hospitals would still be required to maintain existing pharmacies to evaluate, prepare, compound and dispense medication ordered for patients that are not fulfilled by the centralized packaging pharmacy. Further, under AB 377, the new packaging pharmacies would be subject to annual inspections by this board before issuance or renewal of the specialty pharmacy permit.

The board strongly supports this consolidation of specific pharmacy operations to prepare unit dose medication for patients of the same hospital chain. This would facilitate the use of costly, specialized equipment that would affix bar codes to every dose of medication packaged. Bar coding is important for patient safety. Before a medication is administered to a patient, by scanning the bar code on a medication, a patient’s chart and a patient’s wristband – the right medication, in the right dose will be ensured at the patient’s bedside. This provides an important step forward to improve patient safety and decrease the rate of medication errors and potential adverse drug events.

Published examples of how bar coding would benefit patients include:

- Medication errors in hospitals are common, and dispensing errors made in the pharmacy contribute considerably to these errors. Overall, dispensing error rates are relatively low, but because of the high volume of medications dispensed, more than 100 undetected dispensing errors may occur in a busy hospital pharmacy every day.

Because only about one third of these dispensing errors are intercepted by nurses before medication administration, many errors reach hospitalized patients. Therefore, dispensing errors are an important target for patient safety interventions. Bar code technology has been touted as a promising strategy to prevent medication errors. (Poon, et al., 2006)

- Medications are the most frequent cause of adverse events. More than a million injuries and nearly 100,000 deaths are attributable to medical errors annually. (Maviglia, et al., 2009)

Under the regulation of the Board of Pharmacy, packaging pharmacies would repackage three principal forms of medication: pill or other solid dosage forms, compounded medication and injectable compounded medication. Existing law allows pharmacies to compound medication for administration to patients either pursuant to a prescription or in advance of a prescription, based on normal usage or needs. Further, California law allows pharmacies to compound for future furnishing for their use or for use by physicians.

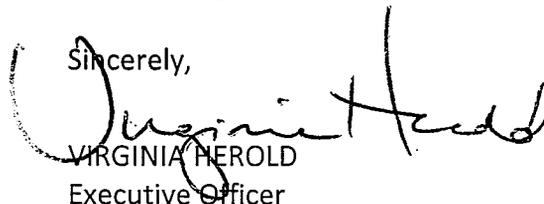
Compounding in such a manner is the practice of pharmacy – not manufacturing. Pursuant to the Compliance Policy Guide Section 460.100, the US FDA provides, in part, the following:

*“We interpret Section 510 of the Federal Food, Drug, and Cosmetic Act as not requiring registration by the hospital pharmacy that compounds medication for inpatient dispensing, outpatient dispensing (sale or free), mailing to a patient within the State or out of the State, or for transferral to another unit of the same hospital (within the State or in another State) for dispensing by that unit of the hospital.”*

In 2010, Board of Pharmacy regulations took effect to ensure the safety of medication compounded for administration or injection pursuant to a patient-specific prescription or in advance of receipt of a prescription. These are encompassing regulations that require efficacy assays, staff training, specialized equipment, specific processes and detailed recordkeeping to ensure the quality of medication compounded by pharmacies. These regulations and the pharmacy self-assessments that pharmacies that compound must complete periodically ensure the public safety.

Permitting hospital pharmacies under common ownership to repackage into unit doses if they bar code the medication will aid hospitals in improving patient safety. Annual inspections by the board will ensure these pharmacies are following all requirements. The Board of Pharmacy supports this measure and respectfully requests that you sign Assembly Bill 377.

Sincerely,



VIRGINIA HEROLD  
Executive Officer

cc: Assembly Member Solorio

**B&PC 4118**

**4118. Waiving of Minimum Requirements by Board**

(a) When, in the opinion of the board, a high standard of patient safety, consistent with good patient care, can be provided by the licensure of a pharmacy that does not meet all of the requirements for licensure as a pharmacy, the board may waive any licensing requirements.

(b) When, in the opinion of the board, a high standard of patient safety, consistent with good patient care, can be provided by the licensure of a hospital pharmacy, as defined by subdivision (a) of Section 4029, that does not meet all of the requirements for licensure as a hospital pharmacy, the board may waive any licensing requirements. However, when a waiver of any requirements is granted by the board, the pharmaceutical services to be rendered by this pharmacy shall be limited to patients registered for treatment in the hospital, whether or not they are actually staying in the hospital, or to emergency cases under treatment in the hospital.

**B&PC 4128.4**

**BUSINESS AND PROFESSIONS CODE - BPC**

**DIVISION 2. HEALING ARTS [500 - 4999.129]** ( *Division 2 enacted by Stats. 1937, Ch. 399.* )

**CHAPTER 9. Pharmacy [4000 - 4426]** ( *Chapter 9 repealed and added by Stats. 1996, Ch. 890, Sec. 3.* )

**ARTICLE 7.6. Centralized Hospital Packaging Pharmacies [4128 - 4128.7]** ( *Article 7.6 added by Stats. 2012, Ch. 687, Sec. 2.* )

<sup>4128.4</sup>. Any unit dose medication produced by a centralized hospital packaging pharmacy shall be barcoded to be readable at the inpatient's bedside. Upon reading the barcode, the following information shall be retrievable:

- (a) The date the medication was prepared.
- (b) The components used in the drug product.
- (c) The lot number or control number.
- (d) The expiration date.
- (e) The National Drug Code Directory number.
- (f) The name of the centralized hospital packaging pharmacy.

(*Added by Stats. 2012, Ch. 687, Sec. 2. Effective January 1, 2013.*)

# **Attachment 3**



Director, Office of Trade Agreements Negotiations and Compliance  
 Director, Office of Accounting  
 Director, Office of Policy  
*Global Markets*  
 Assistant Secretary of Global Markets and Director General for the US&FCS  
 Deputy Director General  
 Principal Deputy Assistant Secretary  
 Executive Director, Advocacy Center  
 Director, Business Information and Technology Office  
 Director, Global Knowledge Center  
 Director, Office of Budget  
 Director, Office of Foreign Service Human Capital  
 Director, Office of Strategic Planning  
 Director, Office of Administrative Services  
 Executive Director, SelectUSA  
 Deputy Assistant Secretary for U.S. Field National U.S. Field Director  
 Deputy Assistant Secretary for Asia  
 Executive Director for Asia  
 Director, Office of the ASEAN and Pacific Basin  
 Director, Office of East Asia and APEC  
 Director, Office of South Asia  
 Deputy Assistant Secretary for China, Hong Kong, and Mongolia  
 Executive Director for China, Hong Kong, and Mongolia  
 Director, Office of China, Hong Kong, and Mongolia  
 Deputy Assistant Secretary for Western Hemispheres  
 Executive Director for Western Hemispheres  
 Director, Office of North and Central America  
 Director, Office of South America  
 Deputy Assistant Secretary for Europe, Middle East, and Africa  
 Executive Deputy Assistant Secretary for Europe, Middle East, and Africa  
 Executive Director for Europe and Eurasia  
 Director, Office of Europe Country Affairs  
 Director, Office of the European Union  
 Director, Office of Russia, Ukraine, and Eurasia  
 Executive Director for Africa and Middle East  
 Director, Office of the Middle East and North Africa  
 Director, Office of Sub-Saharan Africa  
*Industry and Analysis*  
 Assistant Secretary for Industry and Analysis  
 Deputy Assistant Secretary for Industry and Analysis  
 Trade Agreements Secretariat  
 Executive Director, Office of Trade Programs and Strategic Partnerships  
 Director, Trade Promotion Programs  
 Director, Strategic Partnerships  
 Director, Office of Advisory Committees and Industry Outreach  
 Director, Office of Planning, Coordination and Management  
 Deputy Assistant Secretary for Services  
 Director, Office of Financial and Insurance Industries  
 Director, Office of Digital Service Industries  
 Director, Office of Supply Chain, Professional and Business Services  
 Executive Director for National Travel and Tourism Office  
 Director, Office of Travel and Tourism Industries

Deputy Assistant Secretary for Trade Policy and Analysis  
 Director, Office of Standards and Investment Policy  
 Director, Office of Trade and Economic Analysis  
 Director, Office of Trade Negotiations and Analysis  
 Director, Office of Intellectual Property Rights  
 Deputy Assistant Secretary for Manufacturing  
 Director, Office of Energy and Environmental Industries  
 Director, Office of Transportation and Machinery  
 Director, Office of Health and Information Technologies  
 Deputy Assistant Secretary for Textiles, Consumer Goods, and Materials  
 Director, Office of Textiles and Apparel  
 Director, Office of Materials  
 Director, Office of Consumer Goods  
**Minority Business Development Agency**  
 Chief Counsel  
 Freedom of Information Officer  
**National Institute of Standards and Technology**  
 Director for Administration and Chief Financial Officer  
 Chief, Management and Organization Office  
 NIST Counsel  
**National Oceanic and Atmospheric Administration**  
 Under Secretary  
 Deputy Under Secretary for Operations  
 Chief, Resource and Operations Management  
 Director, Office of Communications and External Affairs  
 Director, Office of Marine and Aviation Operations  
 General Counsel  
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 Deputy Assistant Administrator for National Ocean Services  
 Assistant Administrator for National Marine Fisheries Service  
 Deputy Assistant Administrator for Regulatory Programs for National Marine Fisheries Service  
 Assistant Administrator for National Weather Services  
 Deputy Assistant Administrator for National Weather Services  
 Assistant Administrator for National Environmental Satellite, Data, and Information Service  
 Deputy Assistant Administrator for National Environmental Satellite, Data, and Information Service  
 Assistant Administrator for Oceanic and Atmospheric Research  
 Deputy Assistant Administrator for Programs & Administration (Oceanic and Atmospheric Research)  
 Assistant Administrator for Program, Planning and Integration  
 Chief Administrative Officer  
 Chief Financial Officer  
 Chief Information Officer  
 Director, Acquisition and Grants Office  
 Deputy Director, Acquisition and Grants Office

Head of Contracting Offices, Acquisition and Grants Office  
 Director, Workforce Management Office  
 Senior Advisor for International Affairs  
 Director, Office of Legislation & Intergovernmental Affairs  
 Freedom of Information Officer  
**National Technical Information Service**  
 Director  
 Deputy Director  
 Chief Financial Officer/Associate Director for Finance and Administration  
**National Telecommunications and Information Administration**  
 Deputy Assistant Secretary  
 Chief Counsel  
 Deputy Chief Counsel  
 [FR Doc. 2014-03633 Filed 2-26-14; 8:45 am]  
**BILLING CODE 3510-17-P**

**DEPARTMENT OF JUSTICE**

**Drug Enforcement Administration**

**21 CFR Part 1308**

[Docket No. DEA-389]

**Schedules of Controlled Substances: Rescheduling of Hydrocodone Combination Products From Schedule III to Schedule II**

**AGENCY:** Drug Enforcement Administration, Department of Justice.  
**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Drug Enforcement Administration (DEA) proposes to reschedule hydrocodone combination products from schedule III to schedule II of the Controlled Substances Act. This proposed action is based on a rescheduling recommendation from the Assistant Secretary for Health of the Department of Health and Human Services and an evaluation of all other relevant data by the DEA. If finalized, this action would impose the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule II controlled substances on persons who handle (manufacture, distribute, dispense, import, export, engage in research, conduct instructional activities, or possess) or propose to handle hydrocodone combination products.  
**DATES:** Interested persons may file written comments on this proposal pursuant to 21 CFR 1308.43(g). Electronic comments must be submitted, and written comments must be postmarked, on or before April 28, 2014. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after midnight Eastern Time on the last day of the comment period.

Interested persons, defined as those "adversely affected or aggrieved by any rule or proposed rule issuable pursuant to section 201 of the Act (21 U.S.C. 811)," 21 CFR 1300.01, may file a request for hearing or waiver of an opportunity for a hearing or to participate in a hearing pursuant to 21 CFR 1308.44 and in accordance with 21 CFR 1316.45, 1316.47, 1316.48 or 1316.49, as applicable. Requests for hearing, notices of appearance, and waivers of an opportunity for a hearing or to participate in a hearing must be received on or before March 31, 2014.

**ADDRESSES:** To ensure proper handling of comments, please reference "Docket No. DEA-389" on all electronic and written correspondence. The DEA encourages that all comments be submitted electronically through the Federal eRulemaking Portal which provides the ability to type short comments directly into the comment field on the Web page or attach a file for lengthier comments. Please go to [www.regulations.gov](http://www.regulations.gov) and follow the on-line instructions at that site for submitting comments. Paper comments that duplicate electronic submissions are not necessary. Should you, however, wish to submit written comments, in lieu of electronic comments, they should be sent via regular or express mail to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODW, 8701 Morrisette Drive, Springfield, Virginia 22152. All requests for a hearing and waivers of participation must be sent to: Drug Enforcement Administration, Attention: Hearing Clerk/LJ, 8701 Morrisette Drive, Springfield, Virginia 22152.

**FOR FURTHER INFORMATION CONTACT:** Ruth A. Carter, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152, Telephone: (202) 598-6812.  
**SUPPLEMENTARY INFORMATION:**

#### Posting of Public Comments

Please note that all comments received in response to this docket are considered part of the public record and will be made available for public inspection online at [www.regulations.gov](http://www.regulations.gov). Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

The Freedom of Information Act (FOIA) applies to all comments received. If you want to submit personal identifying information (such as your name, address, etc.) as part of your

comment, but do not want it to be made publicly available, you must include the phrase "PERSONAL IDENTIFYING INFORMATION" in the first paragraph of your comment. You must also place all of the personal identifying information you do not want made publicly available in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be made publicly available, you must include the phrase "CONFIDENTIAL BUSINESS INFORMATION" in the first paragraph of your comment. You must also prominently identify the confidential business information to be redacted within the comment. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be made publicly available. Comments containing personal identifying information or confidential business information identified as directed above will be made publicly available in redacted form.

An electronic copy of this document and supplemental information to this proposed rule are available at [www.regulations.gov](http://www.regulations.gov) for easy reference. If you wish to personally inspect the comments and materials received or the supporting documentation the DEA used in preparing the proposed action, these materials will be available for public inspection by appointment. To arrange a viewing, please see the "For Further Information Contact" paragraph above.

#### Request for Hearing, Notice of Appearance at Hearing, or Waiver of an Opportunity for a Hearing or To Participate in a Hearing

Pursuant to the provisions of the Controlled Substances Act (CSA), 21 U.S.C. 811(a), this action is a formal rulemaking "on the record after opportunity for a hearing." Such proceedings are conducted pursuant to the provisions of the Administrative Procedure Act (APA), 5 U.S.C. 551-559. 21 CFR 1308.41-1308.45; 21 CFR Part 1316 subpart D. In accordance with 21 CFR 1308.44(a)-(c), requests for a hearing, notices of appearance, and waivers of an opportunity for a hearing or to participate in a hearing may be submitted only by interested persons, defined as those "adversely affected or aggrieved by any rule or proposed rule issuable pursuant to section 201 of the Act (21 U.S.C. 811)." 21 CFR 1300.01. Requests for hearing and notices of appearance must conform to the requirements of 21 CFR 1308.44(a) or

(b), and 1316.47 or 1316.48 as applicable, and include a statement of the interest of the person in the proceeding and the objections or issues, if any, concerning which the person desires to be heard. Any waiver must conform to the requirements of 21 CFR 1308.44(c) and 1316.49, including a written statement regarding the interested person's position on the matters of fact and law involved in any hearing.

Please note that pursuant to 21 U.S.C. 811(a)(1), the purpose and subject matter of a hearing held in relation to this rulemaking is restricted to: "(A) find[ing] that such drug or other substance has a potential for abuse, and (B) mak[ing] with respect to such drug or other substance the findings prescribed by subsection (b) of section 812 of [title 21] for the schedule in which such drug is to be placed \* \* \*." Requests for a hearing, notices of appearance at a hearing, and waivers of an opportunity for a hearing or to participate in a hearing must be submitted to the DEA using the address information provided above.

#### Legal Authority

The DEA implements and enforces titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended. Titles II and III are referred to as the "Controlled Substances Act" and the "Controlled Substances Import and Export Act," respectively, and are collectively referred to as the "Controlled Substances Act" or the "CSA" for the purpose of this action. 21 U.S.C. 801-971. The DEA publishes the implementing regulations for these statutes in title 21 of the Code of Federal Regulations (CFR), parts 1300 to 1321. The CSA and its implementing regulations are designed to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while providing for the legitimate medical, scientific, research, and industrial needs of the United States. Controlled substances have the potential for abuse and dependence and are controlled to protect the public health and safety.

Under the CSA, controlled substances are classified into one of five schedules based upon their potential for abuse, their currently accepted medical use, and the degree of dependence the substance may cause. 21 U.S.C. 812. The initial schedules of controlled substances established by Congress are found at 21 U.S.C. 812(c), and the current list of all scheduled substances is published at 21 CFR Part 1308. 21 U.S.C. 812(a).

Pursuant to 21 U.S.C. 811(a)(1), the Attorney General may, by rule, "add to such a schedule or transfer between such schedules any drug or other substance if he (A) finds that such drug or other substance has a potential for abuse, and (B) makes with respect to such drug or other substance the findings prescribed by [21 U.S.C. 812(b)] for the schedule in which such drug is to be placed \* \* \*." Pursuant to 28 CFR 0.100(b), the Attorney General has delegated this scheduling authority to the Administrator of the DEA.

The CSA provides that the scheduling of any drug or other substance may be initiated by the Attorney General (1) on his own motion; (2) at the request of the Secretary of the Department of Health and Human Services (HHS); or (3) on the petition of any interested party. 21 U.S.C. 811(a). This proposed action was initiated by a petition to reschedule hydrocodone combination products (HCPs)<sup>1</sup> from schedule III to schedule II of the CSA, and is supported by, *inter alia*, a recommendation from the Assistant Secretary for Health of the HHS.<sup>2</sup> If finalized, this action would impose the regulatory controls and administrative, civil, and criminal sanctions of schedule II controlled substances on any person who handles, or proposes to handle, HCPs.

### Background

Hydrocodone was listed in schedule II of the CSA upon the enactment of the CSA in 1971. Public Law 91-513, 84 Stat. 1236, sec. 202(c), schedule II, paragraph (a), clause (1) (codified at 21 U.S.C. 812(c)); initially codified at 21 CFR 308.12(b)(1)(x) (36 FR 7776, April 24, 1971) (currently codified at 21 CFR 1308.12(b)(1)(vi)). At that time, HCPs in specified doses (containing no greater than 15 milligrams (mg) hydrocodone per dosage unit or not more than 300 mg hydrocodone per 100 milliliters) were listed in schedule III of the CSA when formulated with specified amounts of an isoquinoline alkaloid of opium or one or more therapeutically active nonnarcotic ingredients. Public Law 91-513, 84 Stat.

<sup>1</sup> Hydrocodone combination products (HCPs) are pharmaceuticals containing specified doses of hydrocodone in combination with other drugs in specified amounts. These products are approved for marketing for the treatment of pain and for cough suppression.

<sup>2</sup> As set forth in a memorandum of understanding entered into by the HHS, the Food and Drug Administration (FDA), and the National Institute on Drug Abuse (NIDA), the FDA acts as the lead agency within the HHS in carrying out the Secretary's scheduling responsibilities under the CSA, with the concurrence of the NIDA. 50 FR 9518, Mar. 8, 1985. The Secretary of the HHS has delegated to the Assistant Secretary for Health of the HHS the authority to make domestic drug scheduling recommendations.

1236, sec. 202(c), schedule III, paragraph (d), clauses (3) and (4) (codified at 21 U.S.C. 812(c)); initially codified at 21 CFR 308.13(e)(3) and (4) (36 FR 7776, April 24, 1971) (currently codified at 21 CFR 1308.13(e)(1)(iii) and (iv)). Any other products that contain single-entity hydrocodone or combinations of hydrocodone and other substances outside the range of specified doses are listed in schedule II of the CSA.<sup>3</sup>

### Proposed Determination To Transfer HCPs to Schedule II

Pursuant to 21 U.S.C. 811(a), proceedings to add a drug or substance to those controlled under the CSA, or to transfer a drug between schedules, may be initiated on the petition of any interested party. In response to a petition the DEA had received requesting that HCPs be controlled in schedule II of the CSA, in 2004 the DEA submitted a request to the HHS to provide the DEA with a scientific and medical evaluation of available information and a scheduling recommendation for HCPs, pursuant to 21 U.S.C. 811(b) and (c). In 2008 the HHS provided to the DEA its recommendation that HCPs remain controlled in schedule III of the CSA. In response, in 2009, the DEA requested that the HHS re-evaluate their data and provide another scientific and medical evaluation and scheduling recommendation based on additional data and analysis.

On July 9, 2012, President Obama signed the Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144) (FDASIA). Section 1139 of the FDASIA<sup>4</sup> directed

<sup>3</sup> In the United States there are currently no approved, marketed, products containing hydrocodone in combination with other active ingredients that fall outside schedule III of the CSA. Further, until recently, there were no approved hydrocodone single-entity schedule II products. In Oct. 2013, the FDA approved Zohydro™ ER, a single-entity, extended release schedule II product. The sponsor of this product in a press release dated Oct. 25, 2013, stated that Zohydro™ ER will be launched in approximately four months. Accordingly, all of the historical data regarding hydrocodone from different national and regional databases that support this proposal should refer to HCPs only, regardless of whether the database utilizes the term "hydrocodone" or "hydrocodone combination products."

<sup>4</sup> FDASIA, SEC1139. SCHEDULING OF HYDROCODONE. (a) IN GENERAL.—Not later than 60 days after the date of enactment of this Act, if practicable, the Secretary of Health and Human Services (referred to in this section as the "Secretary") shall hold a public meeting to solicit advice and recommendations to assist in conducting a scientific and medical evaluation in connection with a scheduling recommendation to the Drug Enforcement Administration regarding drug products containing hydrocodone, combined with other analgesics or as an antitussive. (b)

the Food and Drug Administration (FDA) to hold a public meeting to "solicit advice and recommendations" pertaining to the scientific and medical evaluation in connection with its scheduling recommendation to the DEA regarding drug products containing hydrocodone, combined with other analgesics or as an antitussive. Additionally the Secretary was required to solicit stakeholder input "regarding the health benefits and risks, including the potential for abuse" of hydrocodone combination products and the impact of up-scheduling of these products.

Accordingly, on January 24–25, 2013, the FDA held a public Advisory Committee meeting at which the DEA made a presentation. The Advisory Committee included members with scientific and medical expertise in the subject of opioid abuse, and a patient representative. Members included representatives from National Institute on Drug Abuse (NIDA) and the Centers for Disease Control (CDC). There was also an opportunity for the public to provide comment. The Advisory Committee voted 19 to 10 in favor of recommending that hydrocodone combination products be placed into schedule II. According to the FDA, 768 comments were submitted by patients, patient groups, advocacy groups, and professional societies to the FDA.

Upon evaluating the scientific and medical evidence, along with the above considerations (e.g., recommendation of the Advisory Committee, the public comments, consideration of the health benefits and risks, and information about the impact of rescheduling) mandated by the FDASIA, the HHS on December 16, 2013, submitted to the Administrator of the DEA its scientific and medical evaluation (henceforth called HHS review) entitled, "Basis for the Recommendation to Place Hydrocodone Combination Products in Schedule II of the Controlled Substances Act." Pursuant to 21 U.S.C. 811(b), this document contained an eight-factor analysis of the abuse potential of HCPs, along with the HHS's recommendation to control HCPs under schedule II of the CSA.

The HHS stated that the comments received during the open public hearing, to the docket, and the discussion of the Advisory Committee

STAKEHOLDER INPUT.—In conducting the evaluation under subsection (a), the Secretary shall solicit input from a variety of stakeholders including patients, health care providers, harm prevention experts, the National Institute on Drug Abuse, the Centers for Disease Control and Prevention, and the Drug Enforcement Administration regarding the health benefits and risks, including the potential for abuse and the impact of up-scheduling of these products.

members of the FDA Advisory Committee meeting provided support for its conclusion that individuals are taking HCPs in amounts sufficient to create a hazard to their health or to the safety of other individuals or to the community; that there is significant diversion of HCPs; and that individuals are taking HCPs on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such drugs. The HHS stated it has also given careful consideration to the fact that the members of the Advisory Committee voted 19 to 10 in favor of rescheduling HCPs from schedule III to schedule II under the CSA. The HHS considered the increasing trends, the public comments, the recommendation of the Advisory Committee, the health benefits and risks, and the information available about the impact of rescheduling, and concluded that HCPs have high potential for abuse.

#### Summary of Eight Factor Analyses

The DEA has reviewed the scientific and medical evaluation and scheduling recommendation provided by the HHS, and all other relevant data, and completed its own eight-factor review document pursuant to 21 U.S.C. 811(c). Included below is a brief summary of each factor as considered by the DEA in its proposed rescheduling action. Both the DEA and HHS analyses are available in their entirety in the public docket for this proposed rule (Docket No. DEA-389) at [www.regulations.gov](http://www.regulations.gov) under "Supporting and Related Material." Full analysis of, and citations to, information referenced in this summary may also be found in the supporting material.

##### 1. The Drug's Actual or Relative Potential for Abuse

The term "abuse" is not defined in the CSA. However, the legislative history of the CSA provides the following criteria to determine whether a particular drug or substance has a potential for abuse:<sup>5</sup>

(a) Individuals are taking the drug or other substance in amounts sufficient to create a hazard to their health or to the safety of other individuals or to the community; or

(b) There is a significant diversion of the drug or other substance from legitimate drug channels; or

(c) Individuals are taking the drug or other substance on their own initiative rather than on the basis of medical

advice from a practitioner licensed by law to administer such drugs; or

(d) The drug is so related in its action to a drug or other substance already listed as having a potential for abuse to make it likely that it will have the same potential for abuse as such substance, thus making it reasonable to assume that there may be significant diversions from legitimate channels, significant use contrary to or without medical advice, or that it has a substantial capability of creating hazards to the health of the user or to the safety of the community.

The DEA considered the HHS's evaluation and all other relevant data, including data related to the above mentioned criteria, and finds that:

(a) *Individuals are using HCPs in amounts sufficient to create a hazard to their health, to the safety of other individuals, or to the community.*

The HHS states that there are increasing trends in the adverse effects from abuse of HCPs, including emergency department (ED) visits, admissions to addiction treatment centers, and deaths in selected States. In 2011, HCPs were listed in 3,376 admissions for drug treatment as the primary drug of abuse and in 6,601 admissions listing HCPs in addition to other drugs in the Treatment Episode Data Set (TEDS).<sup>6</sup> HCPs are prescribed in an unprecedented manner and their total prescriptions exceed prescriptions for any other opioid analgesic; this characteristic drives their abuse potential and sets them apart from other opioid analgesics in terms of abuse risks.

Drug Abuse Warning Network (DAWN)<sup>7</sup> data indicate that abuse of HCPs, similar to oxycodone products<sup>8</sup> (schedule II), has been associated with large numbers of admissions to the ED.

<sup>5</sup> "TEDS is a program coordinated and managed by the SAMHSA. This database includes information on treatment admissions that are routinely collected by states to monitor their individual substance abuse treatment systems. Thus, TEDS includes data primarily from treatment facilities that receive public funds. TEDS includes information on demographic variables including age, gender, race and ethnicity. TEDS also reports on the top three drugs of abuse at the time of admission. TEDS does not include all drugs that may have been abused prior to admission. States and jurisdictions can choose whether or not to report the detailed listing.

<sup>7</sup> The Drug Abuse Warning Network (DAWN) is a national representative public health surveillance system that continuously monitors drug-related visits to hospital EDs. The DAWN data are used to monitor trends in drug misuse and abuse in the United States. DAWN captures both ED visits that are directly caused by drugs and those in which drugs are a contributing factor but not the direct cause of the ED visit.

<sup>8</sup> Unless otherwise specified, for purposes of this document "oxycodone products" refers to both its single-entity and its combination products. All oxycodone products are schedule II controlled substances.

For example, in 2011 the total number of ED visits related to nonmedical use of HCPs and oxycodone products were 82,479 and 151,218, respectively.<sup>9</sup> The American Association of Poison Control Centers' National Poison Data System<sup>10</sup> (NPDS; formerly known as Toxic Exposure Surveillance System or TESS) reported that HCPs were involved in 30,792 and 29,391 annual toxic exposures in 2011 and 2012, respectively. The corresponding data for oxycodone products was 19,423 and 18,495. The majority of exposures for both drug products were for intentional reasons.<sup>11</sup>

The HHS mentions that nationwide estimates of overdose deaths due to HCPs cannot be quantified, but the available data for a limited number of States suggest that HCPs contribute to a substantial number of overdose deaths each year. According to the HHS, DAWN medical examiner (ME) data for five States from 2004 through 2010 reported an increase of 63% and 133% in deaths related to HCPs and oxycodone products, respectively. According to the Florida Department of Law Enforcement (FDLE),<sup>12</sup> HCPs have

<sup>9</sup> In DAWN, nonmedical use of pharmaceuticals includes taking more than the prescribed dose of a prescription pharmaceutical or more than the recommended dose of an over-the-counter pharmaceutical or supplement; taking a pharmaceutical prescribed for another individual; deliberate poisoning with a pharmaceutical by another person; and documented misuse or abuse of a prescription drug, an over-the-counter pharmaceutical, or a dietary supplement.

<sup>10</sup> The American Association of Poison Control Centers (AAPCC) maintains the national database of information logged by the United States' 57 Poison Control Centers (PCCs). Case records in this database are from self-reported calls: they reflect only information provided when the public or healthcare professionals report an actual or potential exposure to a substance (e.g., an ingestion, inhalation, or topical exposure, etc.), or request information/educational materials. Exposures do not necessarily represent a poisoning or overdose. The AAPCC is not able to completely verify the accuracy of every report made to member centers. Additional exposures may go unreported to PCCs and data referenced from the AAPCC should not be construed to represent the complete incidence of national exposures to any substance(s).

<sup>11</sup> According to the AAPCC's NPDS database, "intentional reasons" include suspected suicide, misuse, abuse, and intentional unknown.

<sup>12</sup> The Florida Department of Law Enforcement Medical Examiners Commission publishes an Annual Medical Examiners Report, the Annual and Interim Drugs in Deceased Persons Report. In order for a death to be considered "drug-related" at least one drug identified must be in the decedent; each identified drug is a drug occurrence. The State's medical examiners were asked to distinguish between whether the drugs were the "cause" of death or merely "present" in the body at the time of death. A drug is only indicated as the cause of death when, after examining all evidence and the autopsy and toxicology results, the medical examiner determines the drug played a causal role in the death. It is not uncommon for a decedent to have multiple drugs listed as a cause of death.

<sup>5</sup> Comprehensive Drug Abuse Prevention and Control Act of 1970, H.R. Rep. No 91-1444, 91st Cong., Sess. 1 (1970) reprinted in U.S.C.A.N. 4566, 4601.

been associated with large numbers of deaths in Florida. For example, in 2012, HCPs were associated with 777 deaths, while oxycodone products were associated with 1,426.

As summarized below, a review of drug abuse indicators for HCPs over the past several years further indicates that these products, similar to oxycodone products, are among the most widely diverted and abused drugs in the country and have high potential for abuse.

(b) *There is a significant diversion of HCPs from legitimate drug channels.*

According to forensic laboratory data as reported by the National Forensic Laboratory System<sup>13, 14</sup> (NFLIS) and the System to Retrieve Information from Drug Evidence<sup>15</sup> (STRIDE), HCPs, similar to oxycodone products, are among the top 10 most frequently encountered drugs. From 2002 through 2010, total cases (from both NFLIS and STRIDE) for both HCPs and oxycodone products gradually increased with some decline in 2011 and 2012. From 2002 through 2008, annual total cases involving HCPs (range: 9,106 in 2002 to 33,611 in 2008) consistently exceeded those for oxycodone products (range: 7,993 in 2002 to 28,343 in 2008). In 2009, total cases for HCPs (37,894) were similar to that for oxycodone products (37,680). From 2010 through 2012, total cases for oxycodone products (47,238 in 2010 and 41,915 in 2012) exceeded those for HCPs (39,261 in 2010 and 34,832 in 2012). The DEA has documented a large number of diversion and trafficking cases involving HCPs. DEA investigations conducted from 2005 through 2007 determined that HCPs were diverted from rogue Internet pharmacies.

Although a medical examiner may determine a drug is present or detected in the decedent, the drug may not have played a causal role in the death. A decedent may have multiple drugs listed as present.

<sup>13</sup> The NFLIS is a program of the DEA, Office of Diversion Control. NFLIS systematically collects drug identification results and associated information from drug cases submitted to and analyzed by State and local forensic laboratories. NFLIS represents an important resource in monitoring illicit drug abuse and trafficking, including the diversion of legally manufactured pharmaceuticals into illegal markets. NFLIS is a comprehensive information system that includes data from forensic laboratories that handle approximately 90% of an estimated 1.0 million distinct annual State and local drug analysis cases. NFLIS includes drug chemistry results from completed analyses only.

<sup>14</sup> While NFLIS data is not direct evidence of abuse, it can lead to an inference that a drug has been diverted and abused. See 76 FR 77330, 77332, Dec. 12, 2011.

<sup>15</sup> STRIDE is a database of drug exhibits sent to DEA laboratories for analysis. Exhibits from the database are from the DEA, other federal agencies, and local law enforcement agencies.

(c) *Individuals are using HCPs on their own initiative rather than on the basis of medical advice.*

According to the data from the National Survey on Drug Use and Health<sup>16</sup> (NSDUH), the lifetime (i.e., ever used) users of HCPs for nonmedical purposes exceeded those for oxycodone products in the United States. For example, in 2004, over 17.7 million Americans age 12 years or older reported lifetime nonmedical use of HCPs as compared to over 11.9 million reported for oxycodone products. In 2012, the corresponding data for HCPs and oxycodone products were over 25.6 and 16 million, respectively. The NSDUH also reported large increases from 2004 through 2012 in the number of individuals using HCPs and oxycodone products for nonmedical purposes.

The past year initiates (i.e., the first use of a substance within the 12 months prior to the interview date) of HCPs exceeded those of oxycodone products from 2002 through 2005. Past year initiates for HCPs were over 1.3, 1.4, 1.3 and 1.3 million in 2002, 2003, 2004 and 2005, respectively. The corresponding data for oxycodone products were over 0.47, 0.5, 0.6 and 0.45 million.

According to a report by the NSDUH, the combined data from 2002 through 2005 indicate that 57.7% of persons who first used pain relievers nonmedically in the past year used HCPs while 21.7% used oxycodone products. The NSDUH data from 2002 through 2006 also indicate that the lifetime users of HCPs have a higher propensity than that of lifetime users of oxycodone immediate release products (single-entity and combination products combined) to have used for nonmedical purposes any pain relievers in the past year.

According to the Monitoring the Future<sup>17</sup> (MTF) survey, from 2002 through 2011 the annual prevalence of

<sup>16</sup> The National Survey on Drug Use and Health, formerly known as the National Household Survey on Drug Abuse (NHSDA), is conducted annually by the Department of Health and Human Service's Substance Abuse and Mental Health Services Administration (SAMHSA). It is the primary source of estimates of the prevalence and incidence of nonmedical use of pharmaceutical drugs, illicit drugs, alcohol, and tobacco use in the United States. The survey is based on a nationally representative sample of the civilian, non-institutionalized population 12 years of age and older. The NSDUH provides yearly national and state level estimates of drug abuse, and includes prevalence estimates by lifetime (i.e., ever used), past year, and past year abuse or dependence.

<sup>17</sup> Monitoring the Future (MTF) is a national survey conducted by the Institute for Social Research at the University of Michigan under a grant from the NIDA that tracks drug use trends among American adolescents among the 8th, 10th, and 12th grades.

nonmedical use of Vicodin®, an HCP, ranged from about 8% to 10.5% among high school seniors (12th graders) and exceeded that of OxyContin® (4% to 5.5%), an oxycodone extended release product. In 2012, the annual prevalence rate for nonmedical use of OxyContin® was 1.6%, 3.0%, and 4.3% among 8th, 10th and 12th graders, respectively. The corresponding rates for Vicodin® were 1.3%, 4.4% and 7.5%. According to the MTF, the annual prevalence of nonmedical use of Vicodin® in college students and young adults was 3.8% and 6.3% in 2012. The corresponding data for OxyContin® were 1.2% and 2.3%. The aforementioned data from drug abuse surveys (NSDUH and MTF) collectively indicate high prevalence of abuse of HCPs among Americans including students thereby indicating their high abuse potential.

(d) *HCPs are so related in their action to a drug or other substance already listed as having a potential for abuse to make it likely that they will have the same potential for abuse as such substance, thus making it reasonable to assume that there may be significant diversion from legitimate channels, significant use contrary to or without medical advice, or that they have a substantial capability of creating hazards to the health of the user or to the safety of the community.*

Hydrocodone possesses abuse liability effects substantially similar to morphine (schedule II) in both animals and humans. Hydrocodone, similar to morphine, is a  $\mu$  opioid receptor agonist and shares pharmacological properties with morphine. Hydrocodone substitutes for morphine in animals trained to discriminate the presence and absence of morphine. Hydrocodone, similar to morphine, is self-administered by animals. Hydrocodone substitutes for morphine in opioid-dependent subjects. Clinical abuse liability studies have also demonstrated that HCPs (Hycodan® or hydrocodone in combination with acetaminophen) are similar to morphine with respect to physiological effects, subjective effects, and drug "liking" scores.

Hydrocodone/acetaminophen and oxycodone/acetaminophen combination products at equi-miopic doses, in general, produce similar profiles of psychopharmacological effects. These two opioid products produced prototypic opiate-like effects and psychomotor impairment of similar magnitudes.

Collectively these data demonstrate that HCPs have a high potential for abuse similar to other schedule II opioid analgesic drugs such as morphine and oxycodone products.

## 2. Scientific Evidence of the Drug's Pharmacological Effects, if Known

The HHS states that hydrocodone's pharmacological effects are similar to other  $\mu$  opioid receptor agonists. It is effective as an antitussive agent and as an analgesic drug. Opioid analgesics have an important role in the management of pain. HCPs contain other nonnarcotic active ingredients such as acetaminophen, nonsteroidal anti-inflammatory drugs (NSAIDs) (aspirin and ibuprofen), chlorpheniramine or homatropine methylbromide. The mechanism of analgesic and antitussive effects of HCPs are different from those of nonnarcotic active ingredients present in HCPs. Acetaminophen and NSAIDs are less effective against severe pain, but have a recognized role in a variety of pain settings.

HCPs, similar to other opioid analgesics such as oxycodone products, are associated with a substantial number of overdose, suicide, abuse, and dependence reports. Overdose of HCPs, similar to other opioid analgesics, can lead to respiratory depression and death. Common adverse effects of NSAIDs include gastrointestinal, cardiovascular, renal and renovascular adverse events, and hepatic injury. Acetaminophen has low incidence of gastrointestinal side effects and is a common household analgesic available over the counter. Overdoses of acetaminophen can cause severe hepatic damage and death. Opioid/acetaminophen combination products are linked to numerous liver injuries.

## 3. The State of Current Scientific Knowledge Regarding the Drug or Other Substance

The HHS provided additional scientific information with focus on chemical and toxicological properties of hydrocodone and nonnarcotic components of HCPs. Hydrocodone is a semisynthetic opioid. The bitartrate salt form of hydrocodone is the main active component in all currently marketed HCPs. Nonnarcotic drugs present as co-ingredients are acetaminophen, aspirin, ibuprofen, chlorpheniramine or homatropine methylbromide. Hydrocodone and nonnarcotic drugs present in HCPs have potential to produce adverse effects.

## 4. Its History and Current Pattern of Abuse

Soon after introduction for clinical use, there were reports of hydrocodone abuse and addiction. By the 1950s, it was established that hydrocodone has an abuse liability similar to that of

morphine. Data regarding the pharmacological effects of hydrocodone and its high potential for abuse were available prior to the enactment of the CSA and the placement of hydrocodone in schedule II reflects that knowledge base. In the United States, popularity of hydrocodone as a drug of abuse increased in the 1990s coinciding with its increased use as an analgesic. Currently HCPs are widely diverted and abused throughout the United States as demonstrated in national and regional drug-abuse-related databases. HCPs and oxycodone products (schedule II) are the two most common opioid analgesic products encountered by law enforcement.

Data from DEA field offices indicate that HCPs are diverted and are among the most sought after licit drugs in every geographic region of the country. DEA case investigations document numerous methods of diversion of HCPs. These methods involve drug theft, doctor shopping, fraudulent oral (call-in) prescriptions, fraudulent prescriptions, diversion by registrants, and various other drug trafficking schemes. HCPs are abused by individuals of diverse ages from adolescents to older populations. According to the NSDUH, in 2012, of the 37 million people in the United States who used pain relievers nonmedically in their lifetime, over 25.6 million (representing 9.9% of the United States population age 12 years or older) reported lifetime nonmedical use of HCPs. The MTF surveys indicate that from 2002 through 2012, 8.1% to 10.5% of high school seniors used Vicodin<sup>®</sup>, an HCP, for nonmedical purposes. In 2012, the annual prevalence of nonmedical use of Vicodin<sup>®</sup> in college students and young adults was 3.8% and 6.3%, respectively.

Several published epidemiological studies indicate that HCPs are widely abused. For example, a published epidemiological study reviewed prescription opioid abuse data collected by drug abuse experts (representatives of the nation's methadone programs, treatment centers, impaired health care professional programs, NIDA grantees and high-prescribing physicians) and found that HCPs are one of the most commonly abused prescription opioid drugs. Rates of abuse, expressed as cases per 100,000 population, were the highest for hydrocodone and extended release oxycodone products, while the rest of the opioid analgesics, including immediate release oxycodone products, had lower rates. Another published epidemiological study also indicates that the rate of intentional exposure (abuse, intentional misuse, suicide or intentional unknown) was highest for

HCPs at 3.75 per 100,000 population followed by oxycodone products at 1.81 per 100,000. HCPs were involved in 55% of all of the intentional exposure cases, whereas oxycodone products were involved in 27%. In addition, published data on toxic exposure calls received by Texas poison centers from 1998 through 2009 showed that toxic exposure calls related to ingestion of the combination of HCPs, carisoprodol and alprazolam (commonly referred under street names such as "Holy Trinity," "Houston Cocktail," or "Trio") have increased from 2000 through 2007 with some decline in 2009.

## 5. The Scope, Duration, and Significance of Abuse

The HHS mentions that abuse of HCPs is considerable and is associated with considerable negative public health impact. The extent of nonmedical use of HCPs by adolescents is higher than for oxycodone products. These data are of significant concern as this may reflect particular risk for younger individuals. The HHS also states that because of the large number of prescriptions, large amounts of HCPs are potentially available for illicit use. Large numbers of adversely affected individuals and the severity of the adverse effects related to abuse of HCPs suggest that individuals are taking these products in amounts sufficient to create a hazard to their health and to the safety of other individuals and the community. Abuse of HCPs is associated with progressively increasing trends in serious adverse effects, including ED visits, admissions for abuse treatment, and in mortality data in selected States. The HHS cites the widespread prescriptions for HCPs as one of the reasons for these adverse outcomes. According to the HHS, data suggests that HCPs have high potential for abuse.

The DEA notes that initial reports of abuse of HCPs in the U.S. were published in the 1960s. Since the 1990s, the diversion and abuse of HCPs has escalated in the country. By the late 1990s, there were large increases in the diversion and abuse of HCPs. HCPs, similar to oxycodone products, are widely diverted and abused pharmaceutical opioid analgesics. HCPs are associated with significant illicit activity and abuse. Federal, State and local forensic laboratory data rank HCPs as one of the two most frequently encountered opioid pharmaceuticals in submissions to the laboratories. For example, in 2012, there were over 34,000 exhibits for HCPs (NFLIS). All DEA field divisions across the U.S. have reported that HCPs are among the most sought after pharmaceuticals.

In 2012, according to the poison control centers data (NPDS), there were over 29,390 toxic exposures involving HCPs. In 2002, there were over 25,000 DAWN ED visits associated with HCPs and it was ranked sixth among all controlled substances. According to DAWN, the nonmedical use related ED visits for HCPs were 86,258; 95,972; and 82,480 in 2002, 2009, 2010, and 2011, respectively. A number of data sources indicate that abuse of HCPs is associated with a large number of deaths.

According to NSDUH, there were large numbers of lifetime and past year initiates of HCPs for nonmedical purposes and these numbers exceeded those of oxycodone. According to the MTF, about 8% to 10% of high school seniors reported nonmedical use of Vicodin<sup>®</sup>, an HCP, in recent years.

DEA case investigations document numerous methods of diversion of HCPs. These methods involve drug theft, doctor shopping, fraudulent oral (call-in) prescriptions, fraudulent prescriptions, diversion by registrants, and various other drug trafficking schemes.

#### 6. What, if Any, Risk There Is to the Public Health

Despite the medical value of HCPs as antitussive and analgesic drugs, the misuse and abuse of these products present numerous risks to the public health. Many of the risk factors associated with these products are common risks shared with other  $\mu$  opioid receptor agonists. These include the risks of developing tolerance, dependence and addiction, and the attendant problems associated with these risks including death. According to the CDC, from 1999 to 2010, the number of drug poisoning deaths<sup>18</sup> involving any opioid analgesic (e.g., oxycodone, methadone, or hydrocodone) markedly increased (over four-fold), from 4,030 to 16,651, and accounted for 43% of the 38,329 drug poisoning deaths and 39% of the 42,917 total poisoning deaths<sup>19</sup> in 2010. In 1999, opioid analgesics were involved in 24% of the 16,849 drug poisoning deaths and 20% of the 19,741 total poisoning deaths.

The HHS reviewed the HCPs related adverse events that were reported to the

FDA Adverse Events Reporting System (FAERS)<sup>20</sup> from 1969 through 2012 and compared them to those associated with oxycodone products. The most common adverse events reported for HCPs included terms such as *complete suicide, intentional overdose, drug abuse, drug dependence, and drug abuser*.<sup>21</sup> The HHS found that both HCPs and oxycodone products are associated with substantial numbers of reports of overdose, suicide, abuse, and dependence reports. Both products have large numbers of adverse events reported that reflect abuse, misuse and injury due to inappropriate use. HCPs had fewer such reports than oxycodone products.

According to the DAWN, ED mentions associated with HCPs and oxycodone products are the highest among all opioid analgesics suggesting that both HCPs and oxycodone products have a great adverse risk to the public health. According to the HHS, DAWN ME data for five States from 2004 through 2010 reported an increase of 63% and 133% in deaths related to HCPs and oxycodone products, respectively. According to the FDLE, HCPs have been associated with large numbers of deaths in Florida in recent years. According to the NPDS annual reports, since 2002, annual figures for toxic exposures (within the category of opioid analgesic drugs) were the largest for HCPs, followed by oxycodone products (see summary of Factor 1 above). From 2006 through 2012, NPDS reported a total of 84,798 single substance exposures related to HCPs resulting in 195 deaths. The corresponding data for oxycodone products is 57,219 exposures and 173 deaths.

<sup>20</sup> FAERS is a computerized information database designed to support FDA's surveillance program for the post-marketing safety of all drug and therapeutic biologic products. FDA receives adverse drug reaction reports from manufacturers as required by regulation. Health care professionals and consumers voluntarily submit reports through the MedWatch program. All reported adverse terms are coded according to standardized international terminology, MedDRA (the Medical Dictionary for Regulatory Activities). These numbers are crude reports and may include duplicates. These reports were not individually reported to determine the association between the drug and the adverse event reported and may contain concomitant use of other medications.

<sup>21</sup> The top 20 most frequently reported adverse event terms associated with all hydrocodone reports (a report may contain more than one adverse event) received from 1969 to 2012 in the FAERS, in decreasing frequency, were: Completed suicide, overdose, cardio-respiratory arrest, toxicity to various agents, cardiac arrest, respiratory arrest, drug ineffective, intentional overdose, nausea, intentional drug misuse, vomiting, death, drug abuse, accidental overdose, pain, dizziness, medication error, drug dependence, headache, and drug abuser.

#### 7. Its Psychic or Physiological Dependence Liability

According to the HHS, data from animal and human studies indicate the dependence potential of hydrocodone. The severe dependence potential is reflected by the number of individuals admitted to addiction treatment centers citing HCPs as their substance of abuse. The HHS also states that the treatment admissions linked to abuse of HCPs are increasing. The HHS concluded that abuse of HCPs may lead to severe psychological or physical dependence.

The DEA notes that as evident from the NSDUH data from 2002 through 2006, the propensity of the lifetime users of HCPs to develop substance use disorders on any pain relievers is higher than that of lifetime users of any pain relievers, as well as lifetime users of oxycodone products other than OxyContin<sup>®</sup> (i.e., oxycodone immediate release single-entity products and immediate release combination products). The FAERS data (from 1969 through August 28, 2008) indicate that the abuse and dependence reports associated with HCPs expressed as a percentage of all its adverse events (13.3%) were similar (both in magnitude and temporal distribution) to that for oxycodone products other than OxyContin<sup>®</sup> (13.6%).

The DEA also notes that according to several published epidemiological surveys and retrospective review of medical records of addiction treatment populations, HCPs are among the most abused opioid pharmaceuticals in prescription opioid dependent individuals in the country and are frequently mentioned as the primary drug of abuse in these subjects.

The above data collectively indicate that HCPs, similar to oxycodone products, have high potential to cause severe psychological or physiological dependence.

#### 8. Whether the Substance Is an Immediate Precursor of a Substance Already Controlled Under the CSA

HCPs are not immediate precursors of a substance already controlled under the CSA, as defined in 21 U.S.C. 811(e).

#### Conclusion

Based on consideration of the scientific and medical evaluation and accompanying recommendation of the HHS, and based on the DEA's consideration of its own eight-factor analysis, the DEA finds that these facts and all other relevant data constitute substantial evidence of high potential for abuse of HCPs. As such, the DEA hereby proposes to transfer HCPs from

<sup>18</sup> Drug poisoning deaths include unintentional and intentional poisoning deaths resulting from overdoses of a drug, being given the wrong drug, using the drug in error, or using a drug inadvertently.

<sup>19</sup> Total poisoning deaths include those resulting from drugs, and those associated with solid or liquid biologics, gases or vapors, or other substances. Poisoning deaths are from all manners, including unintentional, suicide, homicide, and undetermined intent.

schedule III to schedule II under the CSA.

#### Proposed Determination of Appropriate Schedule

The CSA outlines the findings required to transfer a drug or other substance between schedules (I, II, III, IV, or V) of the CSA. 21 U.S.C. 811(a); 21 U.S.C. 812(b). After consideration of the analysis and rescheduling recommendation of the Assistant Secretary for Health of the HHS and review of available data, the Administrator of the DEA, pursuant to 21 U.S.C. 811(a) and 21 U.S.C. 812(b)(2), finds that:

1. HCPs have a high potential for abuse similar to that of schedule II substances;
2. HCPs have a currently accepted medical use in treatment in the United States. According to the HHS, several pharmaceutical products containing hydrocodone in combination with acetaminophen, aspirin, NSAIDs, and homatropine are approved by FDA for use as analgesics for pain relief and for the symptomatic relief of cough and upper respiratory symptoms associated with allergies and colds; and
3. Abuse of HCPs may lead to severe psychological or physical dependence similar to that of schedule II substances.

Based on these findings, the Administrator of the DEA concludes that HCPs warrant control in schedule II of the CSA. 21 U.S.C. 812(b)(2).

#### Requirements for Handling HCPs

If this rule is finalized as proposed, persons who handle HCPs would be subject to the CSA's schedule II regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, dispensing, importing, exporting, research, and conduct of instructional activities, including the following:

**Registration.** Any person who handles (manufactures, distributes, dispenses, imports, exports, engages in research, or conducts instructional activities with) HCPs, or who desires to handle HCPs, would be required to be registered with the DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, 958, and in accordance with 21 CFR parts 1301 and 1312.

**Security.** HCPs would be subject to schedule II security requirements and would need to be handled and stored pursuant to 21 U.S.C. 821, 823, 871(b) and in accordance with 21 CFR 1301.71–1301.93.

**Labeling and Packaging.** All labels and labeling for commercial containers of HCPs would need to comply with 21

U.S.C. 825, 958(e), and be in accordance with 21 CFR part 1302.

**Quotas.** A quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303 would be required in order to manufacture HCPs.

**Inventory.** Any person who becomes registered with the DEA after the effective date of the final rule would be required to take an initial inventory of all stocks of controlled substances (including HCPs) on hand on the date the registrant first engages in the handling of controlled substances, pursuant to 21 U.S.C. 827, 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11(a) and (b).

After the initial inventory, every DEA registrant would be required to take a new inventory of all stocks of controlled substances on hand every two years, pursuant to 21 U.S.C. 827, 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

**Records.** Every DEA registrant would be required to maintain records with respect to HCPs pursuant to 21 U.S.C. 827, 958, and in accordance with 21 CFR parts 1304, 1307, and 1312.

**Reports.** Every DEA registrant would be required to submit reports regarding HCPs to the Automation of Reports and Consolidated Order System (ARCOS) pursuant to 21 U.S.C. 827 and in accordance with 21 CFR 1304.33.

**Orders for HCPs.** Every DEA registrant who distributes HCPs would be required to comply with order form requirements, pursuant to 21 U.S.C. 828, and in accordance with 21 CFR part 1305.

**Prescriptions.** All prescriptions for HCPs would need to comply with 21 U.S.C. 829, and would be required to be issued in accordance with 21 CFR part 1306, and part 1311 subpart C.

**Importation and Exportation.** All importation and exportation of HCPs would need to be in compliance with 21 U.S.C. 952, 953, 957, 958, and in accordance with 21 CFR part 1312.

**Liability.** Any activity involving HCPs not authorized by, or in violation of, the CSA, would be unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

#### Regulatory Analyses

##### *Executive Orders 12866 and 13563*

In accordance with 21 U.S.C. 811(a), this proposed scheduling action is subject to formal rulemaking procedures performed "on the record after opportunity for a hearing," which are conducted pursuant to the provisions of 5 U.S.C. 556 and 557. The CSA sets forth the procedures and criteria for scheduling a drug or other substance.

Such actions are exempt from review by the Office of Management and Budget (OMB) pursuant to Section 3(d)(1) of Executive Order 12866 and the principles reaffirmed in Executive Order 13563.

##### *Executive Order 12988*

This proposed regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 Civil Justice Reform to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

##### *Executive Order 13132*

This proposed rulemaking does not have federalism implications warranting the application of Executive Order 13132. The proposed rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government.

##### *Executive Order 13175*

This proposed rule does not have tribal implications warranting the application of Executive Order 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

##### *Regulatory Flexibility Act*

The Administrator, in accordance with the Regulatory Flexibility Act (5 U.S.C. 601–612) (RFA), has reviewed this proposed rule, and by approving it, certifies that it will not have a significant economic impact on a substantial number of small entities. The purpose of this proposed rule is to place HCPs into schedule II of the CSA. No less restrictive measures (i.e., non-control or control in a lower schedule) would enable the DEA to meet its statutory obligation under the CSA.

HCPs are widely prescribed drugs for the treatment of pain and cough suppression. Handlers of HCPs primarily include manufacturers, distributors, exporters, pharmacies, practitioners, mid-level practitioners, and hospitals/clinics.<sup>22</sup> It is possible

<sup>22</sup> For purposes of performing regulatory analysis, the DEA uses the definition of a "practitioner" as a physician, veterinarian, or other individual licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he/she practices, to dispense a controlled substance in the

that other registrants, such as importers, researchers, analytical labs, teaching institutions, etc., also handle HCPs. However, based on its understanding of its registrant population, the DEA assumes for purposes of this analysis that for all business activities other than manufacturers, distributors, exporters, pharmacies, practitioners, mid-level practitioners, and hospitals/clinics, that the volume of HCPs handled is nominal, and therefore *de minimis* to the economic impact determination of this proposed rescheduling action.

Because HCPs are so widely prescribed, for the purposes of this analysis, the DEA conservatively assumes all distributors, exporters, pharmacies, practitioners, mid-level practitioners, and hospitals/clinics currently registered with the DEA to handle schedule III controlled substances are also handlers of HCPs. The DEA estimated the number of manufacturers and exporters handling HCPs directly from DEA records. In total, the DEA estimates that nearly 1.5 million controlled substance registrations, representing approximately 376,189 entities, would be affected by this rule.

The DEA does not collect data on company size of its registrants. The DEA used DEA records and multiple subscription-based and public data sources to relate the number of registrations to the number of entities and the number of entities that are small entities. The DEA estimates that of the 376,189 entities that would be affected by this rule, 366,351 are "small entities" in accordance with the RFA and Small Business Administration size standards. 5 U.S.C. 601(6); 15 U.S.C. 632.<sup>23</sup>

The DEA examined the registration, security (including storage), labeling and packaging, quota, inventory, recordkeeping and reporting, ordering, prescribing, importing, exporting, and disposal requirements for the 366,351 small entities estimated to be affected by the proposed rule. The DEA estimates that only the physical security requirements will have material economic impact and such impacts will be limited to manufacturers, exporters, and distributors. Many manufacturers and exporters are likely to have sufficient space in their existing vaults to accommodate HCPs. However, the DEA understands that some manufacturers, exporters, and

course of professional practice, but does not include a pharmacist, pharmacy, or hospital (or other person other than an individual).

<sup>23</sup> The estimated break-down is as follows: 50 manufacturers, 4 exporters, 683 distributors, 50,774 pharmacies, and 314,840 practitioners/mid-level practitioners/hospitals/clinics.

distributors will need to build new vaults or expand existing vaults to store HCPs in compliance with schedule II controlled substance physical security requirements. Due to the uniqueness of each business, the DEA made assumptions based on research and institutional knowledge of its registrant community to quantify the costs associated with physical security requirements for manufacturers, exporters and distributors.

The DEA estimates there will be significant economic impact on 1 (2.0%) of the affected 50 small business manufacturers, and 54 (7.9%) of the affected 683 small business distributors. The DEA estimates no significant impact on the remaining affected 4 small business exporters, 50,774 small business pharmacies, or 314,840 small business practitioners/mid-level practitioners/hospitals/clinics. In summary, 55 of the 366,351 (0.015%) affected small entities are estimated to experience significant impact, (i.e., incur costs greater than 1% of annual revenue) if the proposed rule were finalized. The percentage of small entities with significant economic impact is below the 30% threshold for all registrant business activities. The DEA's assessment of economic impact by size category indicates that the proposed rule will not have a significant effect on a substantial number of these small entities.

The DEA's assessment of economic impact by size category indicates that the proposed rule to reschedule HCPs as schedule II controlled substances will not have a significant economic impact on a substantial number of small entities. The DEA will consider written comments regarding the DEA's economic analysis of the impact of such rescheduling, including this certification, and requests that commenters describe the specific nature of any impact on small entities and provide empirical data to illustrate the extent of such impact.

#### *Unfunded Mandates Reform Act of 1995*

On the basis of information contained in the "Regulatory Flexibility Act" section above, the DEA has determined and certifies pursuant to the Unfunded Mandates Reform Act (UMRA) of 1995 (2 U.S.C. 1501 *et seq.*), that this action would not result in any Federal mandate that may result "in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted for inflation) in any one year \* \* \*." Therefore, neither a Small Government Agency Plan nor any other

action is required under provisions of the UMRA of 1995.

#### *Paperwork Reduction Act of 1995*

This action does not impose a new collection of information requirement under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3521). This action would not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

#### **List of Subjects in 21 CFR Part 1308**

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, 21 CFR part 1308 is proposed to be amended to read as follows:

#### **PART 1308—SCHEDULES CONTROLLED SUBSTANCES**

■ 1. The authority citation for 21 CFR part 1308 continues to read as follows:

**Authority:** 21 U.S.C. 811, 812, 871(b) unless otherwise noted.

#### **§ 1308.13 [Amended]**

■ 2. Amend § 1308.13 by removing paragraphs (e)(1)(iii) and (iv) and redesignating paragraphs (e)(1)(v) through (viii) as (e)(1)(iii) through (v), respectively.

Dated: February 21, 2014.

Michele M. Leonhart,  
Administrator.

[FR Doc. 2014-04333 Filed 2-26-14; 8:45 am]

BILLING CODE 4410-09-P

#### **DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT**

#### **24 CFR Parts 50 and 58**

[Docket No. FR-5616-P-01]

RIN 2506-AC34

#### **Environmental Compliance Recordkeeping Requirements**

**AGENCY:** Office of Secretary, HUD.

**ACTION:** Proposed rule.

**SUMMARY:** This proposed rule would revise the regulations governing the format used for conducting the required environmental reviews for HUD program and policy actions. HUD's current regulations require that HUD staff document part 50 environmental review compliance using form HUD-

# **Attachment 4**

§ 581 (Part 24)  
 defn of DXX  
 9745

shown to be safe for use under the conditions that formed the basis upon which the applications were approved.

In the August 14, 2001, notice, FDA provided the NDA and ANDA holders an opportunity to request a hearing to show why approval of the NDAs or ANDAs should not be withdrawn. One company, KV Pharmaceutical, requested a hearing by letter dated September 13, 2001, but that request was subsequently withdrawn by letter dated October 15, 2001. No other party requested a hearing on this matter following publication of the notice in the **Federal Register**. As stated above, all products listed in the notice were subsequently discontinued.

Subsequent to the August 14, 2001, notice, one of the ANDAs listed in that notice was withdrawn. In a notice published in the **Federal Register** of February 20, 2002 (67 FR 7702), FDA withdrew approval of ANDA 71-099 for BROMATAPP Extended-Release Tablets after the application holder informed FDA that the product was no longer being marketed and requested withdrawal.

In a letter to FDA dated February 25, 2013, Pfizer requested on behalf of its subsidiaries, Wyeth Pharmaceuticals, Inc. and A.H. Robins, that FDA withdraw approval of NDA 11-694 for DIMETANE-DC under § 314.150(d), noting that the product has been discontinued and is no longer marketed. In that letter, Pfizer and its named subsidiaries waived any opportunity for a hearing provided under the August 14, 2001, notice. In a response letter of March 28, 2013, the Agency acknowledged A.H. Robins' agreement to permit FDA to withdraw approval of DIMETANE-DC under § 314.150(d) and to waive its opportunity for a hearing.

For the reasons discussed in the August 14, 2001 notice, the Director, under section 505(e)(2) of the FD&C Act and under authority delegated to her by the Commissioner, finds that new evidence of clinical experience, not contained in the applications listed in table 1 and not available at the time the applications were approved, shows that phenylpropanolamine is not shown to be safe for use under the conditions of use that formed the basis upon which the applications were approved (21 U.S.C. 355(e)(2)). Therefore, approval of the NDAs listed in table 1 is hereby withdrawn. Furthermore, the Director finds that the ANDAs listed in table 1 refer to the drugs that are the subject of the NDAs listed above. Therefore, as required under section 505(j)(6) of the FD&C Act, approval of the ANDAs listed in table 1 is also withdrawn.

Under 21 CFR 314.161 and 314.162(a)(1), FDA will remove the

products containing phenylpropanolamine named in table 1 from the list of drug products with effective approvals published in FDA's "Approved Drug Products With Therapeutic Equivalence Evaluations." FDA will not approve or accept ANDAs that refer to these drug products.

Dated: February 14, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014-03596 Filed 2-19-14; 8:45 am]

BILLING CODE 4160-01-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2014-N-0200]

**Standards for the Interoperable Exchange of Information for Tracing of Human, Finished, Prescription Drugs, in Paper or Electronic Format; Establishment of a Public Docket**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; establishment of docket; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) is establishing a public docket to receive information and comments on standards for the interoperable exchange of information associated with transactions involving human prescription drugs in a finished dosage form (prescription drugs) to comply with new requirements in the Drug Supply Chain Security Act (DSCSA). We are seeking information from drug manufacturers, repackagers, wholesale distributors, dispensers (primarily pharmacies) and other drug supply chain stakeholders and interested parties, including standards organizations, State and Federal Agencies, and solution providers. In particular, stakeholders and other interested parties are requested to comment about the interoperable exchange of transaction information, transaction history, and transaction statements, in paper or electronic format, for each transfer of product in which a change of ownership occurs. This action is related to FDA's implementation of the DSCSA.

**DATES:** Submit either electronic or written comments by April 21, 2014.

**ADDRESSES:** Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm.

1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:**

Connie T. Jung, Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20933, 301-796-3130.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

On November 27, 2013, the DSCSA (Title II, Pub. L. 113-54) was signed into law. The DSCSA outlines critical steps to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed within the United States. Section 202 of the DSCSA, which adds section 582 to the Federal Food, Drug, and Cosmetic Act (FD&C Act), directs the Secretary of Health and Human Services (the Secretary) to establish standards for the interoperable exchange of transaction information, transaction history, and transaction statements, in paper or electronic format, in consultation with other appropriate Federal officials, manufacturers, repackagers, wholesale drug distributors, dispensers, and other pharmaceutical distribution supply chain stakeholders.

FDA has been engaged in efforts to improve the security of the drug supply chain for many years to protect U.S. patients from unsafe, ineffective, and poor quality drugs. Since the formation of the first FDA Counterfeit Drug Task Force in 2003, FDA has strongly advocated for a multilayered approach to securing the supply chain and protecting consumers from the threats posed by counterfeit and diverted drugs. The ability to track and trace finished prescription drugs plays a significant role in providing transparency and accountability in the drug supply chain. Under section 505D of the FD&C Act (21 U.S.C. 355e), FDA has been evaluating existing and emerging standards, system attributes and needs, and adoption of track and trace and authentication systems and technology. The system that will be established under DSCSA will enhance FDA's ability to help protect U.S. consumers from exposure to drugs that may be counterfeit, stolen, contaminated, or otherwise harmful by improving detection and removal of potentially dangerous drugs from the drug supply chain.

FDA is announcing the establishment of a public docket to provide an opportunity for interested persons to

share information, current practices, research, and ideas on the feasibility of establishing standardized documentation to be used by members of the pharmaceutical distribution supply chain to convey the transaction information, transaction history, and transaction statement to the subsequent purchaser of a product and to facilitate the exchange of lot level data.

## II. Definitions

The following definitions for transaction information, transaction history, and transaction statement as defined under the DSCSA are provided to assist stakeholders in developing comments or responses. In addition, FDA is interested in learning about practices, processes, and systems that supply chain stakeholders currently use to exchange information, such as product information, information related to the sale or change of ownership of prescription drugs, or communications about drugs in distribution. For other definitions, please refer to section 202 of DSCSA.

Under DSCSA, "transaction information" means (A) The proprietary or established name or names of the product; (B) the strength and dosage form of the product; (C) the National Drug Code number of the product; (D) the container size; (E) the number of containers; (F) the lot number of the product; (G) the date of the transaction; (H) the date of shipment, if more than 24 hours after the date of transaction; (I) the business name and address of the person from whom ownership is being transferred; and (J) the business name and address of the person to whom ownership is being transferred. "Transaction history" means a statement in paper or electronic form, including the transaction information for each prior transaction going back to the manufacturer of the product. "Transaction statement" is a statement, in paper or electronic form, that the entity transferring ownership in a transaction—(A) is authorized as required under the DSCSA; (B) received the product from a person that is authorized as required under the DSCSA; (C) received transaction information and a transaction statement from the prior owner of the product, as required under section 582 [of the DSCSA]; (D) did not knowingly ship a suspect or illegitimate product; (E) had systems and processes in place to comply with verification requirements under section 582 [of the DSCSA]; (F) did not knowingly provide false transaction information; and (G) did not knowingly alter the transaction history.

## III. Request for Comments and Information

FDA is requesting comments and supporting information on the following: (1) Current practices and ideas that may be used for the interoperable exchange of transaction information, transaction history, and transaction statements, in paper or electronic format, for each transfer of product in which a change of ownership occurs (i.e., transaction); (2) the feasibility of establishing standardized documentation to be used by members of the pharmaceutical distribution supply chain to convey the transaction information, transaction history, and transaction statement to the subsequent purchaser of a product and to facilitate the exchange of lot level data; and (3) current practices and ideas that may be used for the exchange of information between members of the pharmaceutical distribution supply chain and FDA to provide, receive, and terminate notifications, respond to requests for verification of product, and respond to requests for information from FDA or other appropriate Federal or State officials in the event of a recall or for the purpose of investigating a suspect or illegitimate product.

To facilitate this discussion, FDA has included several questions in the following paragraphs. These questions, which are not meant to be exhaustive, are provided to stimulate public comments that will help FDA establish initial standards for the interoperable exchange of information for tracing of prescription drugs in paper or electronic format. The public is encouraged to address these and/or other related issues.

*Questions related to (1) current practices and suggestions for the interoperable exchange of transaction information, transaction history, and transaction statements and (2) the feasibility of establishing standardized documentation to be used by members of the pharmaceutical distribution supply chain to convey the transaction information, transaction history, and transaction statement to the subsequent purchaser of prescription drugs and to facilitate the exchange of lot level data:*

1. What types of information about transactions do you exchange? What practices, processes, or systems, either paper-based or electronic, do supply chain stakeholders use to exchange this information? Are the practices, processes, or systems based on a standard? Are they interoperable with other systems that supply chain stakeholders may be using?

2. What practices, processes or systems, either paper-based or electronic, do supply chain stakeholders use to exchange information related to prior transactions? Are the practices, processes, or systems based on a standard? Are they interoperable with other systems that supply chain stakeholders may be using?

3. Do the practices, processes, or systems that supply chain stakeholders use to exchange transaction information or transaction histories include or have the ability to include lot level data?

4. If you are currently using paper means to exchange transaction information or history, when do you plan to move to an electronic format?

5. Are there challenges to adopting and using a system, in paper or electronic format, for the interoperable exchange of transaction information or history? How can these challenges be addressed?

6. Are there practices, processes, or systems that supply chain stakeholders can use now to exchange the information in the transaction statement required by the DSCSA?

7. Are there challenges to providing the transaction statement to supply chain stakeholders in either paper or electronic form? How can these challenges be addressed?

8. Are there standards or current practices that you would recommend for FDA to consider as a model for providing any or all of the transaction information, transaction history, or transaction statement to other supply chain stakeholders?

9. Are there other technologies, systems, or solutions available now that would enable the interoperable exchange of transaction information, transaction history, or transaction statements?

*Questions related to (3) current practices and suggestions for the exchange of information between supply chain stakeholders or with FDA to provide, receive, and terminate notifications, respond to requests for verification of suspect product, and respond to requests for information from FDA or other appropriate Federal or State officials in the event of a recall or for the purpose of investigating a suspect or illegitimate product:*

10. Are there current practices, processes, or systems that could be used to exchange information between supply chain stakeholders and FDA with respect to providing, receiving, and terminating a notification that an illegitimate product is found in distribution? Are these practices, processes, or systems effective? If not, please provide recommendations to

improve these practices, processes, or systems.

11. Are there current practices, processes, or systems that could be used to exchange information between supply chain stakeholders or with FDA to respond to requests to verify the lot number, expiration date, and other indices of identity assigned to a product by the manufacturer or repackager (i.e., requests for verification of suspect product)? Are these practices, processes, or systems effective? If not, please provide recommendations to improve these practices, processes, or systems.

12. Are there current practices, processes, or systems that could be used for providing information in response to requests from FDA or other appropriate Federal or State officials in the event of a recall or for the purpose of investigating a suspect or illegitimate product? Are these practices, processes, or systems effective? If not, please provide recommendations to improve these practices, processes, or systems.

*Question related to capturing information that has not necessarily been addressed by the previous questions:*

13. Are there other considerations related to standards for the interoperable exchange of information for tracing of human, finished, prescription drugs that have not been addressed by the previous questions? Please provide any additional information that you think could be helpful for the Agency to consider as it implements these provisions of the DSCSA.

### III. Submission of Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Dated: February 13, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014-03592 Filed 2-19-14; 8:45 am]

BILLING CODE 4160-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Notice of Diabetes Mellitus Interagency Coordinating Committee Meeting

**SUMMARY:** The Diabetes Mellitus Interagency Coordinating Committee (DMICC) will hold a meeting on March 12, 2014 from 1:00 to 4:00 p.m. at the Natcher Conference Center (Building 45) Conference Room E1/E2, on the NIH Campus in Bethesda, MD. The topic for this meeting will be "Future Needs and Direction of Surveillance of Diabetes in Youth and Young Adults." The meeting is open to the public.

**DATES:** The meeting will be held on March 12, 2014 from 1:00 to 4:00 p.m. Individuals wanting to present oral comments must notify the contact person at least 10 days before the meeting date.

**ADDRESSES:** The meeting will be held at the Natcher Conference Center (Building 45) Conference Room E1/E2, on the NIH Campus in Bethesda, MD.

**FOR FURTHER INFORMATION CONTACT:** For further information concerning this meeting, see the DMICC Web site, [www.diabetescommittee.gov](http://www.diabetescommittee.gov), or contact Dr. B. Tibor Roberts, Executive Secretary of the Diabetes Mellitus Interagency Coordinating Committee, National Institute of Diabetes and Digestive and Kidney Diseases, 31 Center Drive, Building 31A, Room 9A19, MSC 2560, Bethesda, MD 20892-2560, telephone: 301-496-6623; FAX: 301-480-6741; email: [dmicc@mail.nih.gov](mailto:dmicc@mail.nih.gov).

**SUPPLEMENTARY INFORMATION:** The DMICC, chaired by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) comprising members of the Department of Health and Human Services and other federal agencies that support diabetes-related activities, facilitates cooperation, communication, and collaboration on diabetes among government entities. DMICC meetings, held several times a year, provide an opportunity for Committee members to learn about and discuss current and future diabetes programs in DMICC member organizations and to identify opportunities for collaboration. The March 12, 2014 DMICC meeting will focus on "Future Needs and Direction of Surveillance of Diabetes in Youth and Young Adults."

Any member of the public interested in presenting oral comments to the Committee should notify the contact person listed on this notice at least 10

days in advance of the meeting. Interested individuals and representatives or organizations should submit a letter of intent, a brief description of the organization represented, and a written copy of their oral presentation in advance of the meeting. Only one representative of an organization will be allowed to present; oral comments and presentations will be limited to a maximum of 5 minutes. Printed and electronic copies are requested for the record. In addition, any interested person may file written comments with the Committee by forwarding their statement to the contact person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person. Because of time constraints for the meeting, oral comments will be allowed on a first-come, first-serve basis.

Members of the public who would like to receive email notification about future DMICC meetings should register for the listserv available on the DMICC Web site, [www.diabetescommittee.gov](http://www.diabetescommittee.gov).

Dated: February 12, 2014.

B. Tibor Roberts,

Executive Secretary, DMICC, Office of Scientific Program and Policy Analysis, National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health.

[FR Doc. 2014-03634 Filed 2-19-14; 8:45 am]

BILLING CODE 4140-01-P

## DEPARTMENT OF THE INTERIOR

### Office of the Secretary

[DR.5B211.JA000713]

#### List of Programs Eligible for Inclusion in Fiscal Year 2014 Funding Agreements To Be Negotiated With Self-Governance Tribes by Interior Bureaus Other Than the Bureau of Indian Affairs

**AGENCY:** Office of the Secretary, Interior.  
**ACTION:** Notice.

**SUMMARY:** This notice lists programs or portions of programs that are eligible for inclusion in Fiscal Year 2014 funding agreements with self-governance Indian tribes and lists programmatic targets for each of the non-Bureau of Indian Affairs (BIA) bureaus in the Department of the Interior, pursuant to the Tribal Self-Governance Act.

**DATES:** This notice expires on September 30, 2014.

**ADDRESSES:** Inquiries or comments regarding this notice may be directed to

# **Attachment 5**

latimes.com/business/la-fi-lazarus-20140311,0,1949776.column

**latimes.com**

## **CVS probed in alleged loss of painkillers**

**CVS Caremark Corp. could face as much as \$29 million in fines for allegedly losing track of hydrocodone pills at four California stores. They may have been sold on the black market.**

David Lazarus

7:25 PM PDT, March 10, 2014

CVS Caremark Corp. could face as much as \$29 million in fines for allegedly losing track of prescription painkillers at four of its California stores, from which authorities said thousands of pills may have been sold on the black market. advertisement

Officials at the U.S. Drug Enforcement Administration and the California Board of Pharmacy told me Monday that more than 37,000 pills were apparently taken from CVS stores in Modesto, Fairfield, Dixon and Turlock.

Meanwhile, CVS pharmacists in Southern California said they've been instructed by the drugstore chain to get their paperwork in order so that no other prescription meds are found to be missing.

### **[Have a consumer question? Ask Laz](#)**

Casey Rettig, a special agent in the DEA's San Francisco office, said warrants were served on the four California CVS stores last May. She declined to comment further because the agency's investigation is still open.

Virginia Herold, executive officer of the state Board of Pharmacy, which licenses and oversees all drugstores in California, said each of the missing pills — all painkillers, such as Vicodin — could have a street value of as much as \$10.

Lauren Horwood, a spokeswoman for the U.S. attorney's office in Sacramento, said CVS faces 2,973 possible violations of the federal Controlled Substances Act for alleged discrepancies between the company's records and its inventory of prescription drugs.

The maximum fine for these violations could be \$29 million, she said.

Horwood said CVS has yet to respond to a letter sent last month by her office. The letter outlines the alleged violations and seeks more information from the company.

Officials, requesting anonymity because of the sensitivity of the matter, described the loss of painkillers as a big problem throughout the pharmacy business.

In some cases, the drugs have gone missing because pharmacists "self-medicate," they said. But in most cases, the officials said, lower-level pharmacy workers, such as technicians, have made off with the drugs and then sold them to others.

Such thefts typically come to light after pharmacies perform routine inspections of their inventory. They're required by law to report any missing meds within 14 days of discovery.

According to formerly sealed affidavits submitted as part of the DEA's application for search warrants, an investigator for the agency, Brian Glaudel, said the Sacramento district office became aware in late 2012 of losses of numerous hydrocodone tablets from CVS stores in the region.

Hydrocodone is a narcotic painkiller sold under various brand names, including Vicodin and Norco.

The pending investigations stem from a case involving a CVS store in Rocklin, northeast of Sacramento.

Glaudel said CVS notified officials in December 2012 that a pharmacy worker in the Rocklin store was seen hiding a bottle of hydrocodone in her pants.

The worker subsequently admitted to CVS managers that she had stolen more than 20,000 hydrocodone tablets, Glaudel said.

The worker was arrested and charged with embezzlement, he said. It's unclear whether the stolen hydrocodone was recovered in the Rocklin case.

Glaudel said DEA investigators went over records for other CVS stores in the area and found more than 16,000 hydrocodone tablets missing from the Turlock store, 11,000 from the Fairfield store and almost 5,000 each from the Modesto and Dixon stores.

Michael DeAngelis, a CVS spokesman, said the investigations are aimed at "assuring compliance with state and federal requirements for administrative record keeping related to invoices and inventory for controlled substances."

He said CVS regularly tells its pharmacists to "maintain certain records and paperwork," and recently sent them reminders.

This is the second time in the last year that CVS has found itself facing stiff fines for questionable oversight of prescription drugs.

The chain and its Oklahoma subsidiary agreed to pay \$11 million last April to avoid civil charges that they failed to keep accurate records of drugs being received from wholesalers and dispensed to customers.

Federal prosecutors had accused CVS pharmacies in Oklahoma of creating fake DEA license numbers on dispensing records, filling prescriptions for doctors without valid licenses and improperly labeling prescription vials.

CVS said after that settlement was announced that the allegations against the company involved "administrative record-keeping matters," and that "neither the DEA nor the U.S. attorney claimed that any patient's health or safety was put at risk."

The company did not admit any wrongdoing, saying it settled "to avoid the uncertainty of time-consuming litigation."

Michele M. Leonhart, the head of the DEA, was more forceful in her appraisal of the case.

She said last year's settlement with CVS "highlights DEA's steadfast resolve to combat the growing prescription drug abuse problem in this country by ensuring that all DEA registrants, including nationwide pharmacy chains, are in compliance with the law."

"Abuse of prescription drugs is one of the most critical issues we face today," she said. "The scope of this problem is alarming."

In June, the DEA disclosed that Walgreen Co. had agreed to pay \$80 million in fines to end a probe into allegations it failed to prevent prescription meds from going astray from some of its Florida stores. It was the largest-ever civil penalty paid under the Controlled Substances Act.

Pharmacies can be fined up to \$25,000 for each violation of the law.

Herold at the state Board of Pharmacy said her office issued 144 warnings, citations or fines against pharmacies last year. CVS accounted for 55 of those incidents, she said.

Herold said it's unclear whether the relatively high number of cases involving CVS was because the company is better at spotting troubles or "whether they have a bigger problem."

On its [website](#), CVS said that "prescription drug abuse in this country may be an epidemic, but it doesn't have to be."

It said it is "committed to advancing legislation, promoting technology and creating safer communities."

CVS is no stranger to official scrutiny. Investigations were launched by the U.S. Department of Justice and officials in California and New Jersey after I [reported](#) that pharmacists were refilling customers' prescriptions without their permission.

CVS blamed the practice on rogue drugstore managers and insisted that the company's official policy was that customers are always asked before being enrolled in ReadyFill, the chain's refill program.

But I subsequently obtained company documents showing that all CVS pharmacists were expected to enroll at least 40% of patients into ReadyFill. Failure to do so, pharmacists told me, could result in reduced compensation or even being fired.

The investigations into CVS' refill practices are pending.

*David Lazarus' column runs Tuesdays and Fridays. He also can be seen daily on KTLA-TV Channel 5 and followed on Twitter @Davidlaz. Send your tips or feedback to [david.lazarus@latimes.com](mailto:david.lazarus@latimes.com).*

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# **Attachment 6**

### **Procedure for Restocking of ADC:**

1. An ADC restocking report is generated and printed at the pharmacy.
2. Per the report, the appropriate pharmacy personnel packages medications in unit dose cards, places them in tamper evident secure container with a barcode label, and is verified.
3. The tamper-evident container is then transported to the specific facility.
4. The facility receives the container.
5. The health care professional designated and tracked by the pharmacy logs into the ADC and then scans the barcode on the container for restocking.
6. The ADC guides the user through the restock process by identifying and unlocking only the drawers and corresponding bins that require restock.
7. Once directed to a bin, the barcoded labeled bin is scanned to verify the correct medication is being restocked to the correct location, quantity is verified, and each unit dose is scanned and placed into bin.
8. Once the restock is complete; a restock confirmation report is available to the pharmacy and facility.

**HEALTH AND SAFETY CODE - HSC**

**DIVISION 2. LICENSING PROVISIONS [1200 - 1796.63]** ( *Division 2 enacted by Stats. 1939, Ch. 60. )*

**CHAPTER 2. Health Facilities [1250 - 1339.59]** ( *Chapter 2 repealed and added by Stats. 1973, Ch. 1202. )*

**ARTICLE 1. General [1250 - 1264]** ( *Article 1 added by Stats. 1973, Ch. 1202. )*

<sup>1250.</sup> As used in this chapter, “health facility” means any facility, place, or building that is organized, maintained, and operated for the diagnosis, care, prevention, and treatment of human illness, physical or mental, including convalescence and rehabilitation and including care during and after pregnancy, or for any one or more of these purposes, for one or more persons, to which the persons are admitted for a 24-hour stay or longer, and includes the following types:

(a) “General acute care hospital” means a health facility having a duly constituted governing body with overall administrative and professional responsibility and an organized medical staff that provides 24-hour inpatient care, including the following basic services: medical, nursing, surgical, anesthesia, laboratory, radiology, pharmacy, and dietary services. A general acute care hospital may include more than one physical plant maintained and operated on separate premises as provided in Section 1250.8. A general acute care hospital that exclusively provides acute medical rehabilitation center services, including at least physical therapy, occupational therapy, and speech therapy, may provide for the required surgical and anesthesia services through a contract with another acute care hospital. In addition, a general acute care hospital that, on July 1, 1983, provided required surgical and anesthesia services through a contract or agreement with another acute care hospital may continue to provide these surgical and anesthesia services through a contract or agreement with an acute care hospital. The general acute care hospital operated by the State Department of Developmental Services at Agnews Developmental Center may, until June 30, 2007, provide surgery and anesthesia services through a contract or agreement with another acute care hospital. Notwithstanding the requirements of this subdivision, a general acute care hospital operated by the Department of Corrections and Rehabilitation or the Department of Veterans Affairs may provide surgery and anesthesia services during normal weekday working hours, and not provide these services during other hours of the weekday or on weekends or holidays, if the general acute care hospital otherwise meets the requirements of this section.

A “general acute care hospital” includes a “rural general acute care hospital.” However, a “rural general acute care hospital” shall not be required by the department to provide surgery and anesthesia services. A “rural general acute care hospital” shall meet either of the following conditions:

(1) The hospital meets criteria for designation within peer group six or eight, as defined in the report entitled Hospital Peer Grouping for Efficiency Comparison, dated December 20, 1982.

(2) The hospital meets the criteria for designation within peer group five or seven, as defined in the report entitled Hospital Peer Grouping for Efficiency Comparison, dated December 20, 1982, and has no more than 76 acute care beds and is located in a census dwelling place of 15,000 or less population according to the 1980 federal census.

(b) “Acute psychiatric hospital” means a health facility having a duly constituted governing body with overall administrative and professional responsibility and an organized medical staff that provides 24-hour inpatient care for mentally disordered, incompetent, or other patients referred to in Division 5 (commencing with Section 5000) or Division 6 (commencing with Section 6000) of the Welfare and Institutions Code, including the following basic services: medical, nursing, rehabilitative, pharmacy, and dietary services.

(c) (1) “Skilled nursing facility” means a health facility that provides skilled nursing care and supportive care to patients whose primary need is for availability of skilled nursing care on an extended basis.

(2) “Skilled nursing facility” includes a “small house skilled nursing facility (SHSNF),” as defined in Section 1323.5.

(d) “Intermediate care facility” means a health facility that provides inpatient care to ambulatory or nonambulatory patients who have recurring need for skilled nursing supervision and need supportive care, but who do not require availability of continuous skilled nursing care.

(e) “Intermediate care facility/developmentally disabled habilitative” means a facility with a capacity of 4 to 15 beds that provides 24-hour personal care, habilitation, developmental, and supportive health services to 15 or fewer persons with developmental disabilities who have intermittent recurring needs for nursing services, but have been certified by a physician and surgeon as not requiring availability of continuous skilled nursing care.

(f) “Special hospital” means a health facility having a duly constituted governing body with overall administrative and professional responsibility and an organized medical or dental staff that provides inpatient or outpatient care in dentistry or maternity.

(g) “Intermediate care facility/developmentally disabled” means a facility that provides 24-hour personal care, habilitation, developmental, and supportive health services to persons with developmental disabilities whose primary need is for developmental services and who have a recurring but intermittent need for skilled nursing services.

(h) “Intermediate care facility/developmentally disabled-nursing” means a facility with a capacity of 4 to 15 beds that provides 24-hour personal care, developmental services, and nursing supervision for persons with developmental disabilities who have intermittent recurring needs for skilled nursing care but have been certified by a physician and surgeon as not requiring continuous skilled nursing care. The facility shall serve medically fragile persons with developmental disabilities or who demonstrate significant developmental delay that may lead to a developmental disability if not treated.

(i) (1) “Congregate living health facility” means a residential home with a capacity, except as provided in paragraph (4), of no more than 12 beds, that provides inpatient care, including the following basic services: medical supervision, 24-hour skilled nursing and supportive care, pharmacy, dietary, social, recreational, and at least one type of service specified in paragraph (2). The primary need of congregate living health facility residents shall be for availability of skilled nursing care on a recurring, intermittent, extended, or continuous basis. This care is generally less intense than that provided in general acute care hospitals but more intense than that provided in skilled nursing facilities.

(2) Congregate living health facilities shall provide one of the following services:

(A) Services for persons who are mentally alert, persons with physical disabilities, who may be ventilator dependent.

(B) Services for persons who have a diagnosis of terminal illness, a diagnosis of a life-threatening illness, or both. Terminal illness means the individual has a life expectancy of six months or less as stated in writing by his or her attending physician and surgeon. A “life-threatening illness” means the individual has an illness that can lead to a possibility of a termination of life within five years or less as stated in writing by his or her attending physician and surgeon.

(C) Services for persons who are catastrophically and severely disabled. A person who is catastrophically and severely disabled means a person whose origin of disability was acquired through trauma or nondegenerative neurologic illness, for whom it has been determined that active rehabilitation would be beneficial and to whom these services are being provided. Services offered by a congregate living health facility to a person who is catastrophically disabled shall include, but not be limited to, speech, physical, and occupational therapy.

(3) A congregate living health facility license shall specify which of the types of persons described in paragraph (2) to whom a facility is licensed to provide services.

(4) (A) A facility operated by a city and county for the purposes of delivering services under this section may have a capacity of 59 beds.

(B) A congregate living health facility not operated by a city and county servicing persons who are terminally ill, persons who have been diagnosed with a life-threatening illness, or both, that is located in a county with a population of 500,000 or more persons, or located in a county of the 16th class pursuant to Section 28020 of the Government Code, may have not more than 25 beds for the purpose of serving persons who are terminally ill.

(C) A congregate living health facility not operated by a city and county serving persons who are catastrophically and severely disabled, as defined in subparagraph (C) of paragraph (2) that is located in a county of 500,000 or more persons may have not more than 12 beds for the purpose of serving persons who are catastrophically and severely disabled.

(5) A congregate living health facility shall have a noninstitutional, homelike environment.

(j) (1) "Correctional treatment center" means a health facility operated by the Department of Corrections and Rehabilitation, the Department of Corrections and Rehabilitation, Division of Juvenile Facilities, or a county, city, or city and county law enforcement agency that, as determined by the department, provides inpatient health services to that portion of the inmate population who do not require a general acute care level of basic services. This definition shall not apply to those areas of a law enforcement facility that houses inmates or wards who may be receiving outpatient services and are housed separately for reasons of improved access to health care, security, and protection. The health services provided by a correctional treatment center shall include, but are not limited to, all of the following basic services: physician and surgeon, psychiatrist, psychologist, nursing, pharmacy, and dietary. A correctional treatment center may provide the following services: laboratory, radiology, perinatal, and any other services approved by the department.

(2) Outpatient surgical care with anesthesia may be provided, if the correctional treatment center meets the same requirements as a surgical clinic licensed pursuant to Section 1204, with the exception of the requirement that patients remain less than 24 hours.

(3) Correctional treatment centers shall maintain written service agreements with general acute care hospitals to provide for those inmate physical health needs that cannot be met by the correctional treatment center.

(4) Physician and surgeon services shall be readily available in a correctional treatment center on a 24-hour basis.

(5) It is not the intent of the Legislature to have a correctional treatment center supplant the general acute care hospitals at the California Medical Facility, the California Men's Colony, and the California Institution for Men. This subdivision shall not be construed to prohibit the Department of Corrections and Rehabilitation from obtaining a correctional treatment center license at these sites.

(k) "Nursing facility" means a health facility licensed pursuant to this chapter that is certified to participate as a provider of care either as a skilled nursing facility in the federal Medicare Program under Title XVIII of the federal Social Security Act (42 U.S.C. Sec. 1395 et seq.) or as a nursing facility in the federal Medicaid Program under Title XIX of the federal Social Security Act (42 U.S.C. Sec. 1396 et seq.), or as both.

(l) Regulations defining a correctional treatment center described in subdivision (j) that is operated by a county, city, or city and county, the Department of Corrections and Rehabilitation, or the Department of Corrections and Rehabilitation, Division of Juvenile Facilities, shall not become effective prior to, or if effective, shall be inoperative until January 1, 1996, and until that time these correctional facilities are

exempt from any licensing requirements.

(m) “Intermediate care facility/developmentally disabled-continuous nursing (ICF/DD-CN)” means a homelike facility with a capacity of four to eight, inclusive, beds that provides 24-hour personal care, developmental services, and nursing supervision for persons with developmental disabilities who have continuous needs for skilled nursing care and have been certified by a physician and surgeon as warranting continuous skilled nursing care. The facility shall serve medically fragile persons who have developmental disabilities or demonstrate significant developmental delay that may lead to a developmental disability if not treated. ICF/DD-CN facilities shall be subject to licensure under this chapter upon adoption of licensing regulations in accordance with Section 1275.3. A facility providing continuous skilled nursing services to persons with developmental disabilities pursuant to Section 14132.20 or 14495.10 of the Welfare and Institutions Code shall apply for licensure under this subdivision within 90 days after the regulations become effective, and may continue to operate pursuant to those sections until its licensure application is either approved or denied.

(n) “Hospice facility” means a health facility licensed pursuant to this chapter with a capacity of no more than 24 beds that provides hospice services. Hospice services include, but are not limited to, routine care, continuous care, inpatient respite care, and inpatient hospice care as defined in subdivision (d) of Section 1339.40, and is operated by a provider of hospice services that is licensed pursuant to Section 1751 and certified as a hospice pursuant to Part 418 of Title 42 of the Code of Federal Regulations.

*(Amended by Stats. 2012, Ch. 673, Sec. 2.5. Effective January 1, 2013.)*

**HEALTH AND SAFETY CODE - HSC**

**DIVISION 2. LICENSING PROVISIONS [1200 - 1796.63]** ( *Division 2 enacted by Stats. 1939, Ch. 60.*  )

**CHAPTER 2. Health Facilities [1250 - 1339.59]** ( *Chapter 2 repealed and added by Stats. 1973, Ch. 1202.*  )

**ARTICLE 1. General [1250 - 1264]** ( *Article 1 added by Stats. 1973, Ch. 1202.*  )

<sup>1261.6.</sup> (a) (1) For purposes of this section and Section 1261.5, an “automated drug delivery system” means a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of drugs. An automated drug delivery system shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability.

(2) For purposes of this section, “facility” means a health facility licensed pursuant to subdivision (c), (d), or (k), of Section 1250 that has an automated drug delivery system provided by a pharmacy.

(3) For purposes of this section, “pharmacy services” means the provision of both routine and emergency drugs and biologicals to meet the needs of the patient, as prescribed by a physician.

(b) Transaction information shall be made readily available in a written format for review and inspection by individuals authorized by law. These records shall be maintained in the facility for a minimum of three years.

(c) Individualized and specific access to automated drug delivery systems shall be limited to facility and contract personnel authorized by law to administer drugs.

(d) (1) The facility and the pharmacy shall develop and implement written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of stored drugs. Policies and procedures shall define access to the automated drug delivery system and limits to access to equipment and drugs.

(2) All policies and procedures shall be maintained at the pharmacy operating the automated drug delivery system and the location where the automated drug delivery system is being used.

(e) When used as an emergency pharmaceutical supplies container, drugs removed from the automated drug delivery system shall be limited to the following:

(1) A new drug order given by a prescriber for a patient of the facility for administration prior to the next scheduled delivery from the pharmacy, or 72 hours, whichever is less. The drugs shall be retrieved only upon authorization by a pharmacist and after the pharmacist has reviewed the prescriber’s order and the patient’s profile for potential contraindications and adverse drug reactions.

(2) Drugs that a prescriber has ordered for a patient on an as-needed basis, if the utilization and retrieval of those drugs are subject to ongoing review by a pharmacist.

(3) Drugs designed by the patient care policy committee or pharmaceutical service committee of the facility as emergency drugs or acute onset drugs. These drugs may be retrieved from an automated drug delivery system pursuant to the order of a prescriber for emergency or immediate administration to a patient of the facility. Within 48 hours after retrieval under this paragraph, the case shall be reviewed by a pharmacist.

(f) When used to provide pharmacy services pursuant to Section 4119.1 of the Business and Professions Code, the automated drug delivery system shall be subject to all of the following requirements:

(1) Drugs removed from the automated drug delivery system for administration to a patient shall be in

properly labeled units of administration containers or packages.

(2) A pharmacist shall review and approve all orders prior to a drug being removed from the automated drug delivery system for administration to a patient. The pharmacist shall review the prescriber's order and the patient's profile for potential contraindications and adverse drug reactions.

(3) The pharmacy providing services to the facility pursuant to Section 4119.1 of the Business and Professions Code shall control access to the drugs stored in the automated drug delivery system.

(4) Access to the automated drug delivery system shall be controlled and tracked using an identification or password system or biosensor.

(5) The automated drug delivery system shall make a complete and accurate record of all transactions that will include all users accessing the system and all drugs added to, or removed from, the system.

(6) After the pharmacist reviews the prescriber's order, access by licensed personnel to the automated drug delivery system shall be limited only to drugs ordered by the prescriber and reviewed by the pharmacist and that are specific to the patient. When the prescriber's order requires a dosage variation of the same drug, licensed personnel shall have access to the drug ordered for that scheduled time of administration.

(7) (A) Systems that allow licensed personnel to have access to multiple drugs and are not patient specific in their design, shall be allowed under this subdivision if those systems have electronic and mechanical safeguards in place to ensure that the drugs delivered to the patient are specific to that patient. Each facility using such an automated drug system shall notify the department in writing prior to the utilization of the system. The notification submitted to the department pursuant to this paragraph shall include, but is not limited to, information regarding system design, personnel with system access, and policies and procedures covering staff training, storage, and security, and the facility's administration of these types of systems.

(B) As part of its routine oversight of these facilities, the department shall review a facility's medication training, storage, and security, and its administration procedures related to its use of an automated drug delivery system to ensure that adequate staff training and safeguards are in place to make sure that the drugs delivered are appropriate for the patient. If the department determines that a facility is not in compliance with this section, the department may revoke its authorization to use automated drug delivery systems granted under subparagraph (A).

(C) This paragraph shall remain in effect only until January 1, 2012, unless a later enacted statute is enacted on or before January 1, 2012, deletes or extends that date.

(g) The stocking of an automated drug delivery system shall be performed by a pharmacist. If the automated drug delivery system utilizes removable pockets, cards, drawers, or similar technology, the stocking system may be done outside of the facility and be delivered to the facility if all of the following conditions are met:

(1) The task of placing drugs into the removable pockets, cards, or drawers is performed by a pharmacist or by an intern pharmacist or a pharmacy technician working under the direct supervision of a pharmacist.

(2) The removable pockets, cards, or drawers are transported between the pharmacy and the facility in a secure tamper-evident container.

(3) The facility, in conjunction with the pharmacy, has developed policies and procedures to ensure that the pockets, cards, or drawers are properly placed into the automated drug delivery system.

(h) Review of the drugs contained within, and the operation and maintenance of, the automated drug delivery system shall be done in accordance with law and shall be the responsibility of the pharmacy. The review shall be conducted on a monthly basis by a pharmacist and shall include a physical

inspection of the drugs in the automated drug delivery system, an inspection of the automated drug delivery system machine for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system.

(i) Drugs dispensed from an automated drug delivery system that meets the requirements of this section shall not be subject to the labeling requirements of Section 4076 of the Business and Professions Code or Section 111480 of this code if the drugs to be placed into the automated drug delivery system are in unit dose packaging or unit of use and if the information required by Section 4076 of the Business and Professions Code and Section 111480 of this code is readily available at the time of drug administration. For purposes of this section, unit dose packaging includes blister pack cards.

*(Amended by Stats. 2006, Ch. 775, Sec. 1. Effective January 1, 2007.)*

# **Attachment 7**

## Calendar No. 236

113TH CONGRESS  
1ST SESSION

# H. R. 3204

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IN THE SENATE OF THE UNITED STATES

SEPTEMBER 30, 2013

Received

NOVEMBER 4, 2013

Read the first time

NOVEMBER 5, 2013

Read the second time and placed on the calendar

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## AN ACT

To amend the Federal Food, Drug, and Cosmetic Act with respect to human drug compounding and drug supply chain security, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Drug Quality and Se-  
5 curity Act”.

1 **SEC. 2. REFERENCES IN ACT; TABLE OF CONTENTS.**

2 (a) REFERENCES IN ACT.—Except as otherwise spec-  
 3 ified, amendments made by this Act to a section or other  
 4 provision of law are amendments to such section or other  
 5 provision of the Federal Food, Drug, and Cosmetic Act  
 6 (21 U.S.C. 301 et seq.).

7 (b) TABLE OF CONTENTS.—The table of contents of  
 8 this Act is as follows:

Sec. 1. Short title.  
 Sec. 2. References in Act; table of contents.

TITLE I—DRUG COMPOUNDING

Sec. 101. Short title.  
 Sec. 102. Voluntary outsourcing facilities.  
 Sec. 103. Penalties.  
 Sec. 104. Regulations.  
 Sec. 105. Enhanced communication.  
 Sec. 106. Severability.  
 Sec. 107. GAO study.

TITLE II—DRUG SUPPLY CHAIN SECURITY

Sec. 201. Short title.  
 Sec. 202. Pharmaceutical distribution supply chain.  
 Sec. 203. Enhanced drug distribution security.  
 Sec. 204. National standards for prescription drug wholesale distributors.  
 Sec. 205. National standards for third-party logistics providers; uniform na-  
 tional policy.  
 Sec. 206. Penalties.  
 Sec. 207. Conforming amendment.  
 Sec. 208. Savings clause.

9 **TITLE I—DRUG COMPOUNDING**

10 **SEC. 101. SHORT TITLE.**

11 This Act may be cited as the “Compounding Quality  
 12 Act”.

13 **SEC. 102. VOLUNTARY OUTSOURCING FACILITIES.**

14 (a) IN GENERAL.—Subchapter A of chapter V (21  
 15 U.S.C. 351 et seq.) is amended—

1           (1) by redesignating section 503B as section  
2           503C; and

3           (2) by inserting after section 503A the fol-  
4           lowing new section:

5   **“SEC. 503B. OUTSOURCING FACILITIES.**

6           “(a) IN GENERAL.—Sections 502(f)(1), 505, and 582  
7 shall not apply to a drug compounded by or under the  
8 direct supervision of a licensed pharmacist in a facility  
9 that elects to register as an outsourcing facility if each  
10 of the following conditions is met:

11           “(1) REGISTRATION AND REPORTING.—The  
12 drug is compounded in an outsourcing facility that  
13 is in compliance with the requirements of subsection  
14 (b).

15           “(2) BULK DRUG SUBSTANCES.—The drug is  
16 compounded in an outsourcing facility that does not  
17 compound using bulk drug substances (as defined in  
18 section 207.3(a)(4) of title 21, Code of Federal Reg-  
19 ulations (or any successor regulation)), unless—

20           “(A)(i) the bulk drug substance appears on  
21 a list established by the Secretary identifying  
22 bulk drug substances for which there is a clin-  
23 ical need, by—

24           “(I) publishing a notice in the Federal  
25 Register proposing bulk drug substances to

1 be included on the list, including the ra-  
2 tionale for such proposal;

3 “(II) providing a period of not less  
4 than 60 calendar days for comment on the  
5 notice; and

6 “(III) publishing a notice in the Fed-  
7 eral Register designating bulk drug sub-  
8 stances for inclusion on the list; or

9 “(ii) the drug compounded from such bulk  
10 drug substance appears on the drug shortage  
11 list in effect under section 506E at the time of  
12 compounding, distribution, and dispensing;

13 “(B) if an applicable monograph exists  
14 under the United States Pharmacopeia, the Na-  
15 tional Formulary, or another compendium or  
16 pharmacopeia recognized by the Secretary for  
17 purposes of this paragraph, the bulk drug sub-  
18 stances each comply with the monograph;

19 “(C) the bulk drug substances are each  
20 manufactured by an establishment that is reg-  
21 istered under section 510 (including a foreign  
22 establishment that is registered under section  
23 510(i)); and

24 “(D) the bulk drug substances are each ac-  
25 companied by a valid certificate of analysis.

1           “(3) INGREDIENTS (OTHER THAN BULK DRUG  
2           SUBSTANCES).—If any ingredients (other than bulk  
3           drug substances) are used in compounding the drug,  
4           such ingredients comply with the standards of the  
5           applicable United States Pharmacopeia or National  
6           Formulary monograph, if such monograph exists, or  
7           of another compendium or pharmacopeia recognized  
8           by the Secretary for purposes of this paragraph if  
9           any.

10           “(4) DRUGS WITHDRAWN OR REMOVED BE-  
11           CAUSE UNSAFE OR NOT EFFECTIVE.—The drug does  
12           not appear on a list published by the Secretary of  
13           drugs that have been withdrawn or removed from  
14           the market because such drugs or components of  
15           such drugs have been found to be unsafe or not ef-  
16           fective.

17           “(5) ESSENTIALLY A COPY OF AN APPROVED  
18           DRUG.—The drug is not essentially a copy of one or  
19           more approved drugs.

20           “(6) DRUGS PRESENTING DEMONSTRABLE DIF-  
21           FICULTIES FOR COMPOUNDING.—The drug—

22                   “(A) is not identified (directly or as part  
23                   of a category of drugs) on a list published by  
24                   the Secretary, through the process described in  
25                   subsection (c), of drugs or categories of drugs

1           that present demonstrable difficulties for  
2           compounding that are reasonably likely to lead  
3           to an adverse effect on the safety or effective-  
4           ness of the drug or category of drugs, taking  
5           into account the risks and benefits to patients;  
6           or

7           “(B) is compounded in accordance with all  
8           applicable conditions identified on the list de-  
9           scribed in subparagraph (A) as conditions that  
10          are necessary to prevent the drug or category of  
11          drugs from presenting the demonstrable dif-  
12          ficulties described in subparagraph (A).

13          “(7) ELEMENTS TO ASSURE SAFE USE.—In the  
14          case of a drug that is compounded from a drug that  
15          is the subject of a risk evaluation and mitigation  
16          strategy approved with elements to assure safe use  
17          pursuant to section 505–1, or from a bulk drug sub-  
18          stance that is a component of such drug, the out-  
19          sourcing facility demonstrates to the Secretary prior  
20          to beginning compounding that such facility will uti-  
21          lize controls comparable to the controls applicable  
22          under the relevant risk evaluation and mitigation  
23          strategy.

24          “(8) PROHIBITION ON WHOLESALING.—The  
25          drug will not be sold or transferred by an entity

1 other than the outsourcing facility that compounded  
2 such drug. This paragraph does not prohibit admin-  
3 istration of a drug in a health care setting or dis-  
4 pensing a drug pursuant to a prescription executed  
5 in accordance with section 503(b)(1).

6 “(9) FEES.—The drug is compounded in an  
7 outsourcing facility that has paid all fees owed by  
8 such facility pursuant to section 744K.

9 “(10) LABELING OF DRUGS.—

10 “(A) LABEL.—The label of the drug in-  
11 cludes—

12 “(i) the statement ‘This is a com-  
13 pounded drug.’ or a reasonable comparable  
14 alternative statement (as specified by the  
15 Secretary) that prominently identifies the  
16 drug as a compounded drug;

17 “(ii) the name, address, and phone  
18 number of the applicable outsourcing facil-  
19 ity; and

20 “(iii) with respect to the drug—

21 “(I) the lot or batch number;

22 “(II) the established name of the  
23 drug;

24 “(III) the dosage form and  
25 strength;

1 “(IV) the statement of quantity  
2 or volume, as appropriate;

3 “(V) the date that the drug was  
4 compounded;

5 “(VI) the expiration date;

6 “(VII) storage and handling in-  
7 structions;

8 “(VIII) the National Drug Code  
9 number, if available;

10 “(IX) the statement ‘Not for re-  
11 sale’, and, if the drug is dispensed or  
12 distributed other than pursuant to a  
13 prescription for an individual identi-  
14 fied patient, the statement ‘Office Use  
15 Only’; and

16 “(X) subject to subparagraph  
17 (B)(i), a list of active and inactive in-  
18 gredients, identified by established  
19 name and the quantity or proportion  
20 of each ingredient.

21 “(B) CONTAINER.—The container from  
22 which the individual units of the drug are re-  
23 moved for dispensing or for administration  
24 (such as a plastic bag containing individual  
25 product syringes) shall include—

1 “(i) the information described under  
2 subparagraph (A)(iii)(X), if there is not  
3 space on the label for such information;

4 “(ii) the following information to fa-  
5 cilitate adverse event reporting:  
6 [www.fda.gov/medwatch](http://www.fda.gov/medwatch) and 1-800-FDA-  
7 1088 (or any successor Internet Web site  
8 or phone number); and

9 “(iii) directions for use, including, as  
10 appropriate, dosage and administration.

11 “(C) ADDITIONAL INFORMATION.—The  
12 label and labeling of the drug shall include any  
13 other information as determined necessary and  
14 specified in regulations promulgated by the Sec-  
15 retary.

16 “(11) OUTSOURCING FACILITY REQUIRE-  
17 MENT.—The drug is compounded in an outsourcing  
18 facility in which the compounding of drugs occurs  
19 only in accordance with this section.

20 “(b) REGISTRATION OF OUTSOURCING FACILITIES  
21 AND REPORTING OF DRUGS.—

22 “(1) REGISTRATION OF OUTSOURCING FACILI-  
23 TIES.—

24 “(A) ANNUAL REGISTRATION.—Upon  
25 electing and in order to become an outsourcing

1 facility, and during the period beginning on Oc-  
2 tober 1 and ending on December 31 of each  
3 year thereafter, a facility—

4 “(i) shall register with the Secretary  
5 its name, place of business, and unique fa-  
6 cility identifier (which shall conform to the  
7 requirements for the unique facility identi-  
8 fier established under section 510), and a  
9 point of contact email address; and

10 “(ii) shall indicate whether the out-  
11 sourcing facility intends to compound a  
12 drug that appears on the list in effect  
13 under section 506E during the subsequent  
14 calendar year.

15 “(B) AVAILABILITY OF REGISTRATION FOR  
16 INSPECTION; LIST.—

17 “(i) REGISTRATIONS.—The Secretary  
18 shall make available for inspection, to any  
19 person so requesting, any registration filed  
20 pursuant to this paragraph.

21 “(ii) LIST.—The Secretary shall make  
22 available on the public Internet Web site of  
23 the Food and Drug Administration a list  
24 of the name of each facility registered  
25 under this subsection as an outsourcing fa-

1 cility, the State in which each such facility  
2 is located, whether the facility compounds  
3 from bulk drug substances, and whether  
4 any such compounding from bulk drug  
5 substances is for sterile or nonsterile  
6 drugs.

7 “(2) DRUG REPORTING BY OUTSOURCING FA-  
8 CILITIES.—

9 “(A) IN GENERAL.—Upon initially reg-  
10 istering as an outsourcing facility, once during  
11 the month of June of each year, and once dur-  
12 ing the month of December of each year, each  
13 outsourcing facility that registers with the Sec-  
14 retary under paragraph (1) shall submit to the  
15 Secretary a report—

16 “(i) identifying the drugs compounded  
17 by such outsourcing facility during the pre-  
18 vious 6-month period; and

19 “(ii) with respect to each drug identi-  
20 fied under clause (i), providing the active  
21 ingredient, the source of such active ingre-  
22 dient, the National Drug Code number of  
23 the source drug or bulk active ingredient,  
24 if available, the strength of the active in-  
25 gredient per unit, the dosage form and

1 route of administration, the package de-  
2 scription, the number of individual units  
3 produced, and the National Drug Code  
4 number of the final product, if assigned.

5 “(B) FORM.—Each report under subpara-  
6 graph (A) shall be prepared in such form and  
7 manner as the Secretary may prescribe by regu-  
8 lation or guidance.

9 “(C) CONFIDENTIALITY.—Reports sub-  
10 mitted under this paragraph shall be exempt  
11 from inspection under paragraph (1)(B)(i), un-  
12 less the Secretary finds that such an exemption  
13 would be inconsistent with the protection of the  
14 public health.

15 “(3) ELECTRONIC REGISTRATION AND REPORT-  
16 ING.—Registrations and drug reporting under this  
17 subsection (including the submission of updated in-  
18 formation) shall be submitted to the Secretary by  
19 electronic means unless the Secretary grants a re-  
20 quest for waiver of such requirement because use of  
21 electronic means is not reasonable for the person re-  
22 questing waiver.

23 “(4) RISK-BASED INSPECTION FREQUENCY.—

24 “(A) IN GENERAL.—Outsourcing facili-  
25 ties—

1 “(i) shall be subject to inspection pur-  
2 suant to section 704; and

3 “(ii) shall not be eligible for the ex-  
4 emption under section 704(a)(2)(A).

5 “(B) RISK-BASED SCHEDULE.—The Sec-  
6 retary, acting through one or more officers or  
7 employees duly designated by the Secretary,  
8 shall inspect outsourcing facilities in accordance  
9 with a risk-based schedule established by the  
10 Secretary.

11 “(C) RISK FACTORS.—In establishing the  
12 risk-based schedule, the Secretary shall inspect  
13 outsourcing facilities according to the known  
14 safety risks of such outsourcing facilities, which  
15 shall be based on the following factors:

16 “(i) The compliance history of the  
17 outsourcing facility.

18 “(ii) The record, history, and nature  
19 of recalls linked to the outsourcing facility.

20 “(iii) The inherent risk of the drugs  
21 compounded at the outsourcing facility.

22 “(iv) The inspection frequency and  
23 history of the outsourcing facility, includ-  
24 ing whether the outsourcing facility has

1           been inspected pursuant to section 704  
2           within the last 4 years.

3           “(v) Whether the outsourcing facility  
4           has registered under this paragraph as an  
5           entity that intends to compound a drug  
6           that appears on the list in effect under sec-  
7           tion 506E.

8           “(vi) Any other criteria deemed nec-  
9           essary and appropriate by the Secretary  
10          for purposes of allocating inspection re-  
11          sources.

12          “(5) ADVERSE EVENT REPORTING.—Outsourc-  
13          ing facilities shall submit adverse event reports to  
14          the Secretary in accordance with the content and  
15          format requirements established through guidance or  
16          regulation under section 310.305 of title 21, Code of  
17          Federal Regulations (or any successor regulations).

18          “(c) REGULATIONS.—

19                 “(1) IN GENERAL.—The Secretary shall imple-  
20                 ment the list described in subsection (a)(6) through  
21                 regulations.

22                 “(2)           ADVISORY           COMMITTEE           ON  
23                 COMPOUNDING.—Before issuing regulations to im-  
24                 plement subsection (a)(6), the Secretary shall con-  
25                 vene and consult an advisory committee on

1       compounding. The advisory committee shall include  
2       representatives from the National Association of  
3       Boards of Pharmacy, the United States Pharma-  
4       copeia, pharmacists with current experience and ex-  
5       pertise in compounding, physicians with background  
6       and knowledge in compounding, and patient and  
7       public health advocacy organizations.

8               “(3) INTERIM LIST.—

9               “(A) IN GENERAL.—Before the effective  
10       date of the regulations finalized to implement  
11       subsection (a)(6), the Secretary may designate  
12       drugs, categories of drugs, or conditions as de-  
13       scribed such subsection by—

14               “(i) publishing a notice of such sub-  
15       stances, drugs, categories of drugs, or con-  
16       ditions proposed for designation, including  
17       the rationale for such designation, in the  
18       Federal Register;

19               “(ii) providing a period of not less  
20       than 60 calendar days for comment on the  
21       notice; and

22               “(iii) publishing a notice in the Fed-  
23       eral Register designating such drugs, cat-  
24       egories of drugs, or conditions.

1           “(B) SUNSET OF NOTICE.—Any notice  
2           provided under subparagraph (A) shall not be  
3           effective after the earlier of—

4                   “(i) the date that is 5 years after the  
5                   date of enactment of the Compounding  
6                   Quality Act; or

7                   “(ii) the effective date of the final reg-  
8                   ulations issued to implement subsection  
9                   (a)(6).

10           “(4) UPDATES.—The Secretary shall review,  
11           and update as necessary, the regulations containing  
12           the lists of drugs, categories of drugs, or conditions  
13           described in subsection (a)(6) regularly, but not less  
14           than once every 4 years. Nothing in the previous  
15           sentence prohibits submissions to the Secretary, be-  
16           fore or during any 4-year period described in such  
17           sentence, requesting updates to such lists.

18           “(d) DEFINITIONS.—In this section:

19                   “(1) The term ‘compounding’ includes the com-  
20                   bining, admixing, mixing, diluting, pooling, reconsti-  
21                   tuting, or otherwise altering of a drug or bulk drug  
22                   substance to create a drug.

23                   “(2) The term ‘essentially a copy of an ap-  
24                   proved drug’ means—

1           “(A) a drug that is identical or nearly  
2 identical to an approved drug, or a marketed  
3 drug not subject to section 503(b) and not sub-  
4 ject to approval in an application submitted  
5 under section 505, unless, in the case of an ap-  
6 proved drug, the drug appears on the drug  
7 shortage list in effect under section 506E at the  
8 time of compounding, distribution, and dis-  
9 pensing; or

10           “(B) a drug, a component of which is a  
11 bulk drug substance that is a component of an  
12 approved drug or a marketed drug that is not  
13 subject to section 503(b) and not subject to ap-  
14 proval in an application submitted under sec-  
15 tion 505, unless there is a change that produces  
16 for an individual patient a clinical difference, as  
17 determined by the prescribing practitioner, be-  
18 tween the compounded drug and the com-  
19 parable approved drug.

20           “(3) The term ‘approved drug’ means a drug  
21 that is approved under section 505 and does not ap-  
22 pear on the list described in subsection (a)(4) of  
23 drugs that have been withdrawn or removed from  
24 the market because such drugs or components of

1 such drugs have been found to be unsafe or not ef-  
2 fective.

3 “(4)(A) The term ‘outsourcing facility’ means a  
4 facility at one geographic location or address that—

5 “(i) is engaged in the compounding of ster-  
6 ile drugs;

7 “(ii) has elected to register as an outsource-  
8 ing facility; and

9 “(iii) complies with all of the requirements  
10 of this section.

11 “(B) An outsourcing facility is not required to  
12 be a licensed pharmacy.

13 “(C) An outsourcing facility may or may not  
14 obtain prescriptions for identified individual pa-  
15 tients.

16 “(5) The term ‘sterile drug’ means a drug that  
17 is intended for parenteral administration, an oph-  
18 thalmic or oral inhalation drug in aqueous format,  
19 or a drug that is required to be sterile under Federal  
20 or State law.”.

21 “(d) OBLIGATION TO PAY FEES.—Payment of the fee  
22 under section 744K, as described in subsection (a)(9),  
23 shall not relieve an outsourcing facility that is licensed as  
24 a pharmacy in any State that requires pharmacy licensing  
25 fees of its obligation to pay such State fees.”.

1 (b) FEES.—Subchapter C of chapter VII (21 U.S.C.  
2 379f et seq.) is amended by adding at the end the fol-  
3 lowing:

4 **“PART 9—FEES RELATING TO OUTSOURCING**  
5 **FACILITIES**

6 **“SEC. 744J. DEFINITIONS.**

7 “In this part:

8 “(1) The term ‘affiliate’ has the meaning given  
9 such term in section 735(11).

10 “(2) The term ‘gross annual sales’ means the  
11 total worldwide gross annual sales, in United States  
12 dollars, for an outsourcing facility, including the  
13 sales of all the affiliates of the outsourcing facility.

14 “(3) The term ‘outsourcing facility’ has the  
15 meaning given to such term in section 503B(d)(4).

16 “(4) The term ‘reinspection’ means, with re-  
17 spect to an outsourcing facility, 1 or more inspec-  
18 tions conducted under section 704 subsequent to an  
19 inspection conducted under such provision which  
20 identified noncompliance materially related to an ap-  
21 plicable requirement of this Act, specifically to deter-  
22 mine whether compliance has been achieved to the  
23 Secretary’s satisfaction.

1 **“SEC. 744K. AUTHORITY TO ASSESS AND USE OUTSOURC-**  
2 **ING FACILITY FEES.**

3 “(a) ESTABLISHMENT AND REINSPECTION FEES.—

4 “(1) IN GENERAL.—For fiscal year 2015 and  
5 each subsequent fiscal year, the Secretary shall, in  
6 accordance with this subsection, assess and collect—

7 “(A) an annual establishment fee from  
8 each outsourcing facility; and

9 “(B) a reinspection fee from each out-  
10 sourcing facility subject to a reinspection in  
11 such fiscal year.

12 “(2) MULTIPLE REINSPECTIONS.—An outsource-  
13 ing facility subject to multiple reinspections in a fis-  
14 cal year shall be subject to a reinspection fee for  
15 each reinspection.

16 “(b) ESTABLISHMENT AND REINSPECTION FEE SET-  
17 TING.—The Secretary shall—

18 “(1) establish the amount of the establishment  
19 fee and reinspection fee to be collected under this  
20 section for each fiscal year based on the method-  
21 ology described in subsection (c); and

22 “(2) publish such fee amounts in a Federal  
23 Register notice not later than 60 calendar days be-  
24 fore the start of each such year.

25 “(c) AMOUNT OF ESTABLISHMENT FEE AND REIN-  
26 SPECTION FEE.—

1           “(1) IN GENERAL.—For each outsourcing facil-  
2           ity in a fiscal year—

3                   “(A) except as provided in paragraph (4),  
4                   the amount of the annual establishment fee  
5                   under subsection (b) shall be equal to the sum  
6                   of—

7                           “(i) \$15,000, multiplied by the infla-  
8                           tion adjustment factor described in para-  
9                           graph (2); plus

10                           “(ii) the small business adjustment  
11                           factor described in paragraph (3); and

12                   “(B) the amount of any reinspection fee (if  
13                   applicable) under subsection (b) shall be equal  
14                   to \$15,000, multiplied by the inflation adjust-  
15                   ment factor described in paragraph (2).

16           “(2) INFLATION ADJUSTMENT FACTOR.—

17                   “(A) IN GENERAL.—For fiscal year 2015  
18                   and subsequent fiscal years, the fee amounts es-  
19                   tablished in paragraph (1) shall be adjusted by  
20                   the Secretary by notice, published in the Fed-  
21                   eral Register, for a fiscal year by the amount  
22                   equal to the sum of—

23                           “(i) 1;

24                           “(ii) the average annual percent  
25                           change in the cost, per full-time equivalent

1 position of the Food and Drug Administra-  
2 tion, of all personnel compensation and  
3 benefits paid with respect to such positions  
4 for the first 3 years of the preceding 4 fis-  
5 cal years, multiplied by the proportion of  
6 personnel compensation and benefits costs  
7 to total costs of an average full-time equiv-  
8 alent position of the Food and Drug Ad-  
9 ministration for the first 3 years of the  
10 preceding 4 fiscal years; plus

11 “(iii) the average annual percent  
12 change that occurred in the Consumer  
13 Price Index for urban consumers (U.S.  
14 City Average; Not Seasonally Adjusted; All  
15 items; Annual Index) for the first 3 years  
16 of the preceding 4 years of available data  
17 multiplied by the proportion of all costs  
18 other than personnel compensation and  
19 benefits costs to total costs of an average  
20 full-time equivalent position of the Food  
21 and Drug Administration for the first 3  
22 years of the preceding 4 fiscal years.

23 “(B) COMPOUNDED BASIS.—The adjust-  
24 ment made each fiscal year under subparagraph  
25 (A) shall be added on a compounded basis to

1 the sum of all adjustments made each fiscal  
2 year after fiscal year 2014 under subparagraph  
3 (A).

4 “(3) SMALL BUSINESS ADJUSTMENT FACTOR.—  
5 The small business adjustment factor described in  
6 this paragraph shall be an amount established by  
7 the Secretary for each fiscal year based on the Sec-  
8 retary’s estimate of—

9 “(A) the number of small businesses that  
10 will pay a reduced establishment fee for such  
11 fiscal year; and

12 “(B) the adjustment to the establishment  
13 fee necessary to achieve total fees equaling the  
14 total fees that the Secretary would have col-  
15 lected if no entity qualified for the small busi-  
16 ness exception in paragraph (4).

17 “(4) EXCEPTION FOR SMALL BUSINESSES.—

18 “(A) IN GENERAL.—In the case of an out-  
19 sourcing facility with gross annual sales of  
20 \$1,000,000 or less in the 12 months ending  
21 April 1 of the fiscal year immediately preceding  
22 the fiscal year in which the fees under this sec-  
23 tion are assessed, the amount of the establish-  
24 ment fee under subsection (b) for a fiscal year

1 shall be equal to  $\frac{1}{3}$  of the amount calculated  
2 under paragraph (1)(A)(i) for such fiscal year.

3 “(B) APPLICATION.—To qualify for the ex-  
4 ception under this paragraph, a small business  
5 shall submit to the Secretary a written request  
6 for such exception, in a format specified by the  
7 Secretary in guidance, certifying its gross an-  
8 nual sales for the 12 months ending April 1 of  
9 the fiscal year immediately preceding the fiscal  
10 year in which fees under this subsection are as-  
11 sessed. Any such application shall be submitted  
12 to the Secretary not later than April 30 of such  
13 immediately preceding fiscal year.

14 “(5) CREDITING OF FEES.—In establishing the  
15 small business adjustment factor under paragraph  
16 (3) for a fiscal year, the Secretary shall—

17 “(A) provide for the crediting of fees from  
18 the previous year to the next year if the Sec-  
19 retary overestimated the amount of the small  
20 business adjustment factor for such previous  
21 fiscal year; and

22 “(B) consider the need to account for any  
23 adjustment of fees and such other factors as  
24 the Secretary determines appropriate.

1       “(d) USE OF FEES.—The Secretary shall make all  
2 of the fees collected pursuant to subparagraphs (A) and  
3 (B) of subsection (a)(1) available solely to pay for the  
4 costs of oversight of outsourcing facilities.

5       “(e) SUPPLEMENT NOT SUPPLANT.—Funds received  
6 by the Secretary pursuant to this section shall be used  
7 to supplement and not supplant any other Federal funds  
8 available to carry out the activities described in this sec-  
9 tion.

10       “(f) CREDITING AND AVAILABILITY OF FEES.—Fees  
11 authorized under this section shall be collected and avail-  
12 able for obligation only to the extent and in the amount  
13 provided in advance in appropriations Acts. Such fees are  
14 authorized to remain available until expended. Such sums  
15 as may be necessary may be transferred from the Food  
16 and Drug Administration salaries and expenses appropria-  
17 tion account without fiscal year limitation to such appro-  
18 priation account for salaries and expenses with such fiscal  
19 year limitation. The sums transferred shall be available  
20 solely for the purpose of paying the costs of oversight of  
21 outsourcing facilities.

22       “(g) COLLECTION OF FEES.—

23               “(1) ESTABLISHMENT FEE.—An outsourcing  
24 facility shall remit the establishment fee due under  
25 this section in a fiscal year when submitting a reg-

1       istration pursuant to section 503B(b) for such fiscal  
2       year.

3               “(2) REINSPECTION FEE.—The Secretary shall  
4       specify in the Federal Register notice described in  
5       subsection (b)(2) the manner in which reinspection  
6       fees assessed under this section shall be collected  
7       and the timeline for payment of such fees. Such a  
8       fee shall be collected after the Secretary has con-  
9       ducted a reinspection of the outsourcing facility in-  
10      volved.

11              “(3) EFFECT OF FAILURE TO PAY FEES.—

12                      “(A) REGISTRATION.—An outsourcing fa-  
13       cility shall not be considered registered under  
14       section 503B(b) in a fiscal year until the date  
15       that the outsourcing facility remits the estab-  
16       lishment fee under this subsection for such fis-  
17       cal year.

18                      “(B) MISBRANDING.—All drugs manufac-  
19       tured, prepared, propagated, compounded, or  
20       processed by an outsourcing facility for which  
21       any establishment fee or reinspection fee has  
22       not been paid, as required by this section, shall  
23       be deemed misbranded under section 502 until  
24       the fees owed for such outsourcing facility  
25       under this section have been paid.

1           “(4) COLLECTION OF UNPAID FEES.—In any  
2 case where the Secretary does not receive payment  
3 of a fee assessed under this section within 30 cal-  
4 endar days after it is due, such fee shall be treated  
5 as a claim of the United States Government subject  
6 to provisions of subchapter II of chapter 37 of title  
7 31, United States Code.

8           “(h) ANNUAL REPORT TO CONGRESS.—Not later  
9 than 120 calendar days after each fiscal year in which fees  
10 are assessed and collected under this section, the Sec-  
11 retary shall submit a report to the Committee on Health,  
12 Education, Labor, and Pensions of the Senate and the  
13 Committee on Energy and Commerce of the House of  
14 Representatives, to include a description of fees assessed  
15 and collected for such year, a summary description of enti-  
16 ties paying the fees, a description of the hiring and place-  
17 ment of new staff, a description of the use of fee resources  
18 to support inspecting outsourcing facilities, and the num-  
19 ber of inspections and reinspections of such facilities per-  
20 formed each year.

21           “(i) AUTHORIZATION OF APPROPRIATIONS.—For fis-  
22 cal year 2014 and each subsequent fiscal year, there is  
23 authorized to be appropriated for fees under this section  
24 an amount equivalent to the total amount of fees assessed  
25 for such fiscal year under this section.”.

1 **SEC. 103. PENALTIES.**

2 (a) PROHIBITED ACTS.—Section 301 (21 U.S.C.  
3 331) is amended by adding at the end the following:

4 “(ccc)(1) The resale of a compounded drug that is  
5 labeled ‘not for resale’ in accordance with section 503B.

6 “(2) With respect to a drug to be compounded pursu-  
7 ant to section 503A or 503B, the intentional falsification  
8 of a prescription, as applicable.

9 “(3) The failure to report drugs or adverse events  
10 by an entity that is registered in accordance with sub-  
11 section (b) of section 503B.”.

12 (b) MISBRANDED DRUGS.—Section 502 (21 U.S.C.  
13 352) is amended by adding at the end the following:

14 “(bb) If the advertising or promotion of a com-  
15 pounded drug is false or misleading in any particular.”.

16 **SEC. 104. REGULATIONS.**

17 In promulgating any regulations to implement this  
18 title (and the amendments made by this title), the Sec-  
19 retary of Health and Human Services shall—

20 (1) issue a notice of proposed rulemaking that  
21 includes the proposed regulation;

22 (2) provide a period of not less than 60 cal-  
23 endar days for comments on the proposed regula-  
24 tion; and

25 (3) publish the final regulation not more than  
26 18 months following publication of the proposed rule

1 and not less than 30 calendar days before the effective date of such final regulation.

3 **SEC. 105. ENHANCED COMMUNICATION.**

4 (a) SUBMISSIONS FROM STATE BOARDS OF PHARMACY.—In a manner specified by the Secretary of Health  
5 and Human Services (referred to in this section as the  
6 “Secretary”), the Secretary shall receive submissions from  
7 State boards of pharmacy—

9 (1) describing actions taken against  
10 compounding pharmacies, as described in subsection  
11 (b); or

12 (2) expressing concerns that a compounding  
13 pharmacy may be acting contrary to section 503A of  
14 the Federal Food, Drug, and Cosmetic Act (21  
15 U.S.C. 353a).

16 (b) CONTENT OF SUBMISSIONS FROM STATE  
17 BOARDS OF PHARMACY.—An action referred to in sub-  
18 section (a)(1) is, with respect to a pharmacy that com-  
19 pounds drugs, any of the following:

20 (1) The issuance of a warning letter, or the im-  
21 position of sanctions or penalties, by a State for vio-  
22 lations of a State’s pharmacy regulations pertaining  
23 to compounding.

24 (2) The suspension or revocation of a State-  
25 issued pharmacy license or registration for violations

1 of a State’s pharmacy regulations pertaining to  
2 compounding.

3 (3) The recall of a compounded drug due to  
4 concerns relating to the quality or purity of such  
5 drug.

6 (c) CONSULTATION.—The Secretary shall implement  
7 subsection (a) in consultation with the National Associa-  
8 tion of Boards of Pharmacy.

9 (d) NOTIFYING STATE BOARDS OF PHARMACY.—The  
10 Secretary shall immediately notify State boards of phar-  
11 macy when—

12 (1) the Secretary receives a submission under  
13 subsection (a)(1); or

14 (2) the Secretary makes a determination that a  
15 pharmacy is acting contrary to section 503A of the  
16 Federal Food, Drug, and Cosmetic Act.

17 **SEC. 106. SEVERABILITY.**

18 (a) IN GENERAL.—Section 503A (21 U.S.C. 353a)  
19 is amended —

20 (1) in subsection (a), in the matter preceding  
21 paragraph (1), by striking “unsolicited”;

22 (2) by striking subsection (c);

23 (3) by redesignating subsections (d) through (f)  
24 as subsections (c) through (e), respectively; and

1           (4) in subsection (b)(1)(A)(i)(III), by striking  
2           “subsection (d)” and inserting “subsection (e)”.

3           (b) SEVERABILITY.—If any provision of this Act (in-  
4           cluding the amendments made by this Act) is declared un-  
5           constitutional, or the applicability of this Act (including  
6           the amendments made by this Act) to any person or cir-  
7           cumstance is held invalid, the constitutionality of the re-  
8           mainder of this Act (including the amendments made by  
9           this Act) and the applicability thereof to other persons and  
10          circumstances shall not be affected.

11 **SEC. 107. GAO STUDY.**

12          (a) STUDY.—Not later than 36 months after the date  
13          of the enactment of this Act, the Comptroller General of  
14          the United States shall submit to Congress a report on  
15          pharmacy compounding and the adequacy of State and  
16          Federal efforts to assure the safety of compounded drugs.

17          (b) CONTENTS.—The report required under this sec-  
18          tion shall include—

19                (1) a review of pharmacy compounding in each  
20                State, and the settings in which such compounding  
21                occurs;

22                (2) a review of the State laws and policies gov-  
23                erning pharmacy compounding, including enforce-  
24                ment of State laws and policies;

1           (3) an assessment of the available tools to per-  
2           mit purchasers of compounded drugs to determine  
3           the safety and quality of such drugs;

4           (4) an evaluation of the effectiveness of the  
5           communication among States and between States  
6           and the Food and Drug Administration regarding  
7           compounding; and

8           (5) an evaluation of the Food and Drug Admin-  
9           istration’s implementation of sections 503A and  
10          503B of the Federal Food, Drug, and Cosmetic Act.

11       **TITLE II—DRUG SUPPLY CHAIN**  
12                               **SECURITY**

13       **SEC. 201. SHORT TITLE.**

14          This title may be cited as the “Drug Supply Chain  
15       Security Act”.

16       **SEC. 202. PHARMACEUTICAL DISTRIBUTION SUPPLY**  
17                               **CHAIN.**

18          Chapter V (21 U.S.C. 351 et seq.) is amended by  
19       adding at the end the following:

20       **“Subchapter H—Pharmaceutical Distribution**  
21                               **Supply Chain**

22       **“SEC. 581. DEFINITIONS.**

23          “In this subchapter:

# **Attachment 8**

## Herold, Virginia@DCA

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**From:** Ingrid Hamel <ihamel@calhospital.org> on behalf of BJ Bartleson <BJbartleson@calhospital.org>  
**Sent:** Friday, March 07, 2014 10:09 AM  
**To:** Alicia Munoz-HASDIC; Amy Gutierrez; Woo, Art (CDPH-CHCQ-LNC-East Bay); BJ Bartleson; Candace Fong; Lee, Cari (CDPH-LNC-DO); Carolyn Brown; Dan Ross; Dana Radman; David Perrott; Dawn Benton; Eddie Avedikian; Edna DeLeon; Ingrid Hamel; Jan Kiely; Jeannette Hanni; Jeannette Hanni Assistant (Sybil Arevalo); Jenna Fischer -HC; Jerry Kim; Jim Hauenstein; Jim Hauenstein Assistant (Lisa Gouveia) ; Jonathan Nelson; Julia Slininger - HASC; Katie Choy; Kevin Dorsey-Tyler; Lisa Hall; Lori Woolsey; Lynne Whaley Welty; Lynne Whaley Welty Assistant (Martha Marroquin-Ceballos); Mahsa Farahani; Mary Foley; Michele Davenport Lambert; term 2/14 - HOLD per Rfillip - Mikaila Wedding; Nancy Blake; Nasim Karmali2; Pamela Richter; Patricia McFarland; Kajioka, Randy@CDCR; Rhonda Filipp; Richard Rabens; Menet, Robert (CDPH-LNC); Rory Jaffe; Sandra Jefferson (Asst. to A. Gutierrez); Sue Reed; Sue Reed; Terri Gately; Herold, Virginia@DCA  
**Subject:** Update on National Shortage of IV Solutions

### **TO: MEDIATION SAFETY COMMITTEE**

#### **Update on the National Shortage of IV Solutions**

AHA has shared with us the following information on the national shortage of IV solutions

The primary US manufacturers, Hospira, BBraun and Baxter cite increased national demand and flat supply as the reason for the normal saline shortage. In a letter to its customers, Hospira cited increased demand from this year's flu season and industry supply constraints.

All 3 manufacturers have placed normal saline on allocation based on historical demand in order to assist supplying those with whom they are contracted. This means manufacturers have placed limits on how much their contracted hospitals can receive so they can provide for fair distribution in times of limited supply and high demand periods. All are manufacturing at their maximum capacity and expect to resolve the situation by May/June 2014.

The product most affected at this time is the 1000 mL bags of normal saline. Shortage is also impacting other IV fluids due to shifting demand. The Food and Drug Administration (FDA) shortage list and other resources can be found at <http://www.fda.gov/Drugs/DrugSafety/DrugShortages/default.htm>. The American Society of Health-System Pharmacists (ASHP) (<http://www.ashp.org/shortages>) is currently reporting shortages of 0.9% NaCl, 0.45% NaCl, 5% Dextrose Injection, and Lactated Ringers solutions in large volume sizes (250-1000 ml).

The situation is serious, with a few reports of requests to state officials about tapping into their emergency management caches or requesting release from the Federal Strategic National Stockpile. However, federal officials say that there is no immediate plan to use stockpile supplies because the quantities of saline are insufficient to meet current needs for more than a few days and depleting them reduces the country's ability to respond to a national emergency.

In early Feb, ASHP conducted a survey of directors of pharmacy to gauge the scope of the problem. A preliminary report of the results is available at: <http://www.ashp.org/menu/AboutUs/ForPress/PressReleases/PressRelease.aspx?id=792>

The FDA is aware of the shortage situation for IV solutions and is working with the three manufacturers to help preserve the supply of these necessary products. FDA is committed to doing everything it can to address drug shortages, including finding alternative sources (including possibly importing supplies from overseas), so that patients can get the medicines they need when they need them. FDA has indicated that they will notify the AHA as soon as new information about additional supplies is available.

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