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STATE AND CONSUMERS AFFAIRS AGENCY  
DEPARTMENT OF CONSUMER AFFAIRS  
ARNOLD SCHWARZENEGGER, GOVERNOR

## **Enforcement Committee**

Robert Swart, PharmD, Chair and Board Member  
Jim Burgard, Board Member  
Stan Weisser, RPh, Board Member

The Enforcement Committee met on March 9, 2009, in San Diego. There was a Work Group on E-Pedigree Meeting held in conjunction with this meeting. Minutes of this meeting are provided in **Attachment 6**, near the back of this tab section.

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### **A. FOR INFORMATION: Report of the WorkGroup on E-Pedigree**

At this meeting, the Enforcement Committee convened a WorkGroup on E-Pedigree Meeting. Future meetings of the workgroup will be convened as necessary; at present, the plan is to host such meetings once or twice a year for the next few years.

#### Background:

The 2008 Legislative Session ended September 30, which is the date when the Governor signed SB 1307(Ridley-Thomas). This law now staggers implementation of e-pedigree requirements in California away from 2011 to:

- 50 percent of a manufacturer's products by 2015
- The remaining 50 percent of the manufacturer's products by 2016
- Wholesalers and repackagers must accept and pass e-pedigrees by July 1, 2016, and
- Pharmacies and pharmacy distribution centers must accept e-pedigrees by July 1, 2017

There is preemption language that would repeal California's provisions if federal law regarding e-pedigrees is enacted, or if federal standards are enacted, they would take effect in CA. There are provisions that define drop shipments, 3PLs, repackagers and manufacturers. Grandfathering provisions for drugs already in the supply chain are included.

The board will ultimately have to develop regulations for various components, including inference. No action on these regulations is planned for several years.

#### **A.1 Comments Submitted to the FDA on Standardized Numerical Identification of Prescription Drug Packages**

The committee discussed the FDA's request for comments on "Draft Guidance for Industry on Standards for Securing the Drug Supply Chain -- Standardized Numerical Identification for Prescription Drug Packages." These comments were due April 16, 2009.

Under 2007 federal law (Federal Food and Drug Administration Amendments Act of 2007 (FDAAA)), the FDA was charged to develop a standardized numerical identifier to be applied to a prescription drug at the point of manufacturing "sufficient to facilitate the identification, validation, authentication, and tracking and tracing of the prescription drug." This would be the serialized identifier referenced in California's e-pedigree law.

The Workgroup on E-Pedigree discussed the proposed identifier and whether an 8-digit random number, added to the NDC code, would be of sufficient size to track at the package level all drugs over the period of time a drug could remain in the supply chain coupled with record-keeping requirements. Instead several members suggested that an 8-digit alphanumeric identifier added to the NDC Code would substantially increase the number of items that could be tracked. The committee agreed to submit this as a recommendation, along with praise that the FDA is moving ahead nearly one year ahead of its deadline to specify this standard.

The board submitted comments to the FDA before the April 2009 deadline. These comments are provided in **Attachment 1**.

## **A.2 FDA's Proposed Guidance for Industry on Unique Device Identification Systems**

The committee was advised that on February 12, 2009, the FDA convened a hearing on "Unique Device Identification System." This hearing was convened to enable the FDA eventually to

"promulgate regulations establishing a unique device identification system for medical devices requiring the label of devices to bear a unique identifier, unless the Secretary [of HHS] requires an alternative placement or provides an exception for a particular device or type of device. The unique identifier shall adequately identify the device through distribution and use, and may include information on the lot or serial number."

While California's e-pedigree requirements exclude dangerous devices, the board still regulates the distribution of dangerous devices within, throughout and into California. Discussion of those present at the hearing indicated that serialization issues for dangerous devices are perhaps more complex than for dangerous drugs.

A proposed rule is expected to be released from the FDA by the end of the year.

### A.3 Presentations to the WorkGroup on Activities to Implement Electronic Pedigrees

The committee heard presentations from several individuals willing to present information about the status of pedigree laws and regulations nationally. The minutes for this meeting (**Attachment 6**) provide a detail account of these presentations. Additionally, where a PowerPoint Presentation was made, this presentation is also attached to the minutes.

Presentations were made by:

- FDA
- Congressman Buyer's Office
- GS1
- Oracle

Ilisa Bernstein of the FDA provided information about the FDA's request for guidance in identifying a unique identifier for drug packages at the unit level. She also advised that the FDA is considering a standard for tracking at the case and pallet level, and linking this to the serialization number of the unit packages.

The next speaker was Alison Hite of Congressman Buyer's Office, who in the past has co-authored federal legislation for drug supply security requirements via establishment of pedigree requirements.

She stated that while Congressman Buyer had hoped to use California's 2008 legislation as the model for federal pedigree requirements, the appointment of Mr. Waxman as Chair of the Energy and Commerce Committee has suspended efforts in this area until Mr. Waxman indicates the direction this committee will go. She expects that food safety and drug safety will be separate issues, and that food safety may be first. She encouraged those with contacts with Mr. Waxman, who has been supportive of California's requirements in the past, to encourage him to move forward with federal legislation for drug safety.

Bob Celeste of GS1 provided an update on the status standards development for serialization in the US and worldwide. Mr. Celeste indicated that while California's implementation dates have been moved back, work by the supply chain is continuing as there is much interest in such work, particularly in Europe.

John Danese provided an update of how Oracle is working with pharmaceutical manufacturers on serialization efforts and producing electronic pedigrees at the unit level for their products. He described in detail some of the products Oracle provides.

## ENFORCEMENT COMMITTEE:

### A. FOR ACTION: Implementation of the Ryan Haight Online Pharmacy Consumer Protection Act of 2008, Regarding Online Sales of Controlled Substances, As Listed in Docket No. DEA-3221

On April 6, 2009, the FDA released its interim rule on requirements to implement the Ryan Haight Online Pharmacy Consumer Protection Act of 2008. These provisions took effect April 13, 2009 as interim rules. The DEA is concurrently seeking comments on the perhaps temporary requirements; these comments are due June 5, 2009.

The board may wish to provide comments on these requirements which establish requirements for registration with the DEA for online pharmacies under specified conditions.

**Attachment 2** contains the *Federal Register* listing these provisions, and the DEA's request for comments.

The Ryan Haight Online Pharmacy Consumer Protection of 2008 was enacted on October 15, 2008. The act amends the federal Controlled Substance Act and Controlled Substances Import and Export Act by adding provisions to prevent the illegal distribution and dispensing of controlled substances via the Internet.

On April 13, 2009, it became illegal under federal law to deliver, distribute or dispense a controlled substance by means of the Internet, except as authorized by the Controlled Substances Act. The law applies to all controlled substances, in any schedule. In 2010, as Part 2 of this act, the DEA will establish requirements for issuance of a special permit to practitioners who practice telemedicine.

As part of this rule, the DEA cites a number of statistics documenting the high abuse of controlled drugs, and the "false sense of security" that some associate with abusing prescription drugs as safer than using street drugs, and a belief that there is nothing wrong with using prescription drugs without a prescription "once in a while."

The DEA cites as a growing problem rogue Internet sites that sell or facilitate the sale of these drugs. The DEA states that only 34 pharmacies in the US dispensed 98 million dosage units of hydrocodone in 2006, 2.9 million hydrocodone per pharmacy. The average pharmacy in the US dispenses 88,000 dosage units of hydrocodone per year.

The DEA notes that rogue Internet sites cater to drug seekers who are willing to pay a premium to obtain controlled substances without a medical need for them. The FDA states that criminals have enticed unscrupulous practitioners to become associated with the Internet criminals to write prescriptions without meeting standards of practice. Unscrupulous pharmacies agree to fill prescriptions, for a fee, for controlled substances with no questions asked, for as many prescriptions as are submitted. The pharmacy is

paid for both the drugs and a dispensing fee. Typically no information for patients is provided about how to contact the pharmacy with questions.

The law requires any person who operates a Web site of an "online pharmacy" to obtain a DEA special online pharmacy permit. The definition of online pharmacy includes any entity, whether in the US or not, that knowingly or intentionally delivers, distributes or dispenses, or offers or attempts to deliver, distribute or dispense a controlled substance by means of the Internet. It includes any Web site that sells, or offers to sell, any controlled substance or a prescription for controlled substances in the US. It also includes any person who operates such a site, any person who pays a practitioner to write prescriptions for controlled substances for customers or any person who pays a pharmacy to fill prescriptions for controlled substances that are issued to customers of a Web site, any pharmacy that knowingly or intentionally fills prescriptions for controlled substances and any person who sends an email offering to sell controlled drugs, or directs buyers to a Web site.

There are exemptions to this registration, including: a pharmacy registered under 21 USC 823(f) whose dispensing of controlled substances via the Internet consists solely of specified services, including:

1. refilling prescriptions for controlled substances in Schedules III, IV or V.
2. filling new prescriptions for controlled substances in Schedules III, IV or V.

A presentation on this requirement will be provided to the board at the board meeting.

California law for a number of years has required a good faith examination exam of a human or animal before dispensing a drug over the Internet. The board is able to cite and fine up to \$25,000 per incidence (not investigation) for violations.

4067. (a) No person or entity shall dispense or furnish, or cause to be dispensed or furnished, dangerous drugs or dangerous devices, as defined in Section 4022, on the Internet for delivery to any person in this state without a prescription issued pursuant to a good faith prior examination of a human or animal for whom the prescription is meant if the person or entity either knew or reasonably should have known that the prescription was not issued pursuant to a good faith prior examination of a human or animal, or if the person or entity did not act in accordance with Section 1761 of Title 16 of the California Code of Regulations.

(b) Notwithstanding any other provision of law, a violation of this section may subject the person or entity that has committed the violation to either a fine of up to twenty-five thousand dollars (\$25,000) per occurrence pursuant to a citation issued by the board or a civil penalty of twenty-five thousand dollars (\$25,000) per occurrence.

(c) The Attorney General may bring an action to enforce this Section and to collect the fines or civil penalties authorized by subdivision (b).

(d) For notifications made on and after January 1, 2002, the Franchise Tax Board, upon notification by the Attorney General or the board of a final judgment in an action brought under this

section, shall subtract the amount of the fine or awarded civil penalties from any tax refunds or lottery winnings due to the person who is a defendant in the action using the offset authority under Section 12419.5 of the Government Code, as delegated by the Controller, and the processes as established by the Franchise Tax Board for this purpose. That amount shall be forwarded to the board for deposit in the Pharmacy Board Contingent Fund.

(e) Nothing in this section shall be construed to permit the unlicensed practice of pharmacy, or to limit the authority of the board to enforce any other provision of this chapter.

f) For the purposes of this section, "good faith prior examination" includes the requirements for a physician and surgeon in Section 2242 and the requirements for a veterinarian in Section 2032.1 of Title 16 of the California Code of Regulations.

## **B. FOR ACTION AND DISCUSSION: Discussion of Policies Involving Home Generated Pharmaceutical Waste Take Back by Pharmacies**

### Background:

Last year, SB 966 (Simitian, Chapter 542, Statutes of 2007) directed the California Integrated Waste Management Board to develop the parameters for "model" drug take-back programs in pharmacies. These model programs are intended to provide consumers with the ability to dispose of unwanted prescription and OTC drugs (but NOT controlled substances) without flushing them down the toilet or tossing them into the garbage. Under SB 966, these guidelines were to be in place by December 2008.

State and federal law regulates prescription medicine until it is dispensed to patients. It is not regulated again unless it is collected at consolidated points, at which point it becomes medical waste or pharmaceutical, and must be handled and destroyed in specific, mandated ways.

Patients are often confounded about what to do with unwanted medicine. Californians increasingly want "green" options for disposing of unwanted medicine, which current law does not allow. There is no viable process, other than to make the discarded drug products unpalatable (mixing with kitty litter or other substance, wrapping in duct tape, etc.) and then placing them in the trash. Some drugs may be flushed down the toilet, and are specifically labeled by the manufacturer to be disposed of in this manner.

Pharmacies have in some cases agreed to take back unwanted drugs from patients. However, this acquisition by pharmacies is not yet authorized in law.

Some communities periodically offer community take-back events, or special days at landfills where the public can take back drugs.

Some drug manufacturers (and the state of Maine, where there is a pilot program underway for seniors) provide mailers that patients can use to send unwanted medicine to a predetermined location for destruction. This is the process preferred by the DEA for controlled drugs.

The greatest problem for the board with drug take-back programs is the potential for these drugs to be diverted to the streets. There is a serious prescription drug abuse problem in the US, and the uncontrolled aggregation of prescription medicine is an attractive enticement. Additionally, in some cases, drugs collected in collection bins could re-enter the prescription drug supply if pharmacies or wholesalers (or others) sell these items back into the supply chain.

Pharmacies are areas where health care is provided – concern has been expressed that it is difficult for this purpose to be combined with a recycling center, where high sanitation is not necessarily a priority.

Pharmacies also have expressed concern that they may be required to absorb the costs of paying for disposal of these returned drugs, for sorting out controlled drugs (which potentially would require a pharmacist's time) and for assuring the safety and periodic emptying of collection bins.

**1: FOR INFORMATION: Model Guidelines for Home-Generated Pharmaceutical Waste Approved by the California Integrated Waste Management Board**

At the January 2009 and October 2008 Board Meetings, the board discussed concern with the proposed model program guidelines as drafted by the California Integrated Waste Management Board (CIWMB). However, the board did express its continued support for such programs on a voluntary basis with appropriate, specified safeguards.

The CIWMB approved its Model Guidelines initially in November 2008, but agreed to consider additional changes at its February 2009 meeting.

Since the January 2009 Board of Pharmacy Meeting, Ms. Herold again provided written comments and testified before the CIWMB on February 18 (**Attachment 3**). Also provided in this attachment section are comments from the California Department of Public Health, and the final adopted model guidelines of the CIWMB.

The board will feature the Model Guidelines for pharmaceutical take back programs in its July 2009 *The Script*.

**2. FOR INFORMATION: Senate Bill 26**

Senator Simitian has introduced SB 26 (discussed under the Legislation and Regulation Committee Report), which would direct the board to coordinate with other state agencies, local governments, drug manufacturers and pharmacies to develop sustainable efficient policies to manage pharmaceutical wastes and the disposal of devices. The committee was reminded that this bill has been introduced during its March 9 meeting.

**3. FOR INFORMATION: Comments of the Board to the DEA in Response to Disposal of Controlled Substances by Persons Not Registered by the DEA**

The committee also discussed the disposal of controlled substances, which is a problem for drug-take back programs to handle, since only law enforcement agencies can take back these drugs.

The Drug Enforcement Administration recently sought comments for development of future requirements for the take back of controlled drugs in a public comment solicitation titled: "Disposal of Controlled Substances by Persons Not Registered with the Drug Enforcement Administration."

The committee discussed this opportunity and the board did submit comments for this item, which were due March 23, 2009.

Controlled drugs are the one item that cannot be returned to pharmacies or to community take back events. Instead, only law enforcement can accept these items. The involvement of the DEA in establishing policy in this area is another indicator of the movement underway to provide green methods of disposing of unwanted pharmaceuticals.

The board's comments, which highlighted the discussions the board has had on this topic since 2007, are provided in **Attachment 4**.

### **C. FOR INFORMATION: Activities to Implement E-Prescribing in California**

A number of patient and health care advocates have strongly pressed the need for increased use of e-prescribing. A principal reason is that statistics indicate that medication errors cost the health care system \$77 billion and cause 7,000 deaths annually. A number of these errors could be prevented by full implementation of e-prescribing. Other savings have been projected from redirected time currently spent by prescribers and pharmacies in verifying and switching prescription orders.

By the mid-1990s, the board had sponsored legislation and promulgated regulations to ensure that e-prescribing was authorized in California law. Since then, various provisions have been added or amended to keep law supportive of allowing electronic prescriptions. A current deterrent is that controlled substances cannot be e-prescribed.

On November 20, 2008, the Board of Pharmacy hosted an e-prescribing forum in conjunction with the Department of Consumer Affairs' Professionals Achieving Consumer Trust Summit. Other healing arts boards whose licensees prescribe drugs attended this forum as did our stakeholders and public interest groups. The Dental Board and Medical Board joined us as partners.

Also, the California HealthCare Foundation (CHCF) is strongly advocating adoption of e-prescribing. It also hosted a November 20 forum in San Francisco on e-prescribing.

Since then and among other projects, the CHCF has been working with the executive staff of the Medical Board and the Board of Pharmacy to host in a series of statewide

events where physicians and pharmacists at the local level could earn CE and simultaneously work through issues limiting adoption of e-prescribing. The Medical Board also has agreed to co-sponsor these local events.

At the end of March, the CHCF held its first "road show" on e-prescribing in Visalia. The California Pharmacists Association was very helpful in getting their members to this event.

The CHCF hopes to hold additional programs throughout California over the next few months.

Also on e-prescribing, Assembly Bill 718 has been introduced to require all prescribers and pharmacies to have the ability to transmit and receive prescriptions by electronic data transmission. The sponsor of this bill is a technology firm, Reed Elsevier, Inc.

**D. FOR INFORMATION: California's Controlled Substance Utilization Review and Evaluation System (CURES)**

In mid December, the board and California pharmacies were advised that effective January 1, 2009, the California Department of Justice would have a new data collection vendor for CURES, and that all California pharmacies were to submit data to this new vendor beginning January 1. This was a short transition, and the board learned that some pharmacies are having transmission issues submitting data to the new vendor.

In hopes of resolving these issues, the California Department of Justice attended the March 9 Enforcement Committee Meeting to hear and resolve issues involving the transition to the new vendor. The Department of Justice indicated that most of the implementation problems have been resolved.

The DOJ also advised the committee that its plans are still on track to offer via the Internet (with secured access) online, real time reports involving controlled substances dispensed to patients. This service should be available online to practitioners and pharmacies by July 1, 2009.

The Enforcement Committee will hear an updated report on the CURES system upgrades at its June 2009 meeting.

**F. FOR INFORMATION: Department of Consumer Affairs Policies Regarding Pursuit of Interim Suspension Orders**

The Enforcement Committee reviewed a copy of a December 15, 2008, memorandum from the Deputy Director of Legal Affairs Doreatha Johnson. In this memorandum, the department issued the department's policy to encourage the practice of licensing agencies to use Interim Suspension Orders (ISO) and provisions in the Penal Code (PC 23s) when the conduct of a licensee is such that the board cannot afford to wait for the completion of the administrative process, before taking action to ensure the safety of the public. This memo directs all DCA licensing agencies to institute procedures for ordering interim suspension orders as warranted as well as to make recommendations regarding specific

conditions when the agency shall pursue a suspension via a PC 23. The memo further provides suggested parameters.

The board uses all legal actions authorized, including both ISOs and PC 23s when a case is egregious and immediate public harm is eminent.

With the implementation of the Criminal Conviction Unit we anticipate an increase in the number of such actions as the board will have sufficient resources to more promptly address violations that warrant immediate suspension.

A copy of the memo is provided in **Attachment 5**.

**G. FOR INFORMATION: Minutes of the Enforcement Committee Meeting of March 9, 2009**

A copy of the minutes of March 9, 2009, Enforcement Committee Meeting is provided in **Attachment 6**.

**H. FOR INFORMATION: Enforcement Statistics 2008-09**

A copy of the board's enforcement statistics is provided in **Attachment 7**.

**I. FOR INFORMATION: Third Quarterly Report on Enforcement Committee Goals for 2008-09**

A copy of the third quarter's status of Enforcement Committee Goals is provided in **Attachment 8**.

# Attachment 1

*Comments of the Board of Pharmacy to the  
FDA on the Standardized Numerical  
Identifier for Serialization of Drug Packages*



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STATE AND CONSUMER SERVICES AGENCY  
DEPARTMENT OF CONSUMER AFFAIRS  
ARNOLD SCHWARZENEGGER, GOVERNOR

April 7, 2009

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

RE: **COMMENTS OF THE CALIFORNIA STATE BOARD OF PHARMACY**  
**Docket No. FDA-2009-D-0001**  
*(Draft) Guidance for Industry (on) Standards for Securing the Drug Supply Chain—  
Standardized Numerical Identification for Prescription Drug Packages*

To Whom It May Concern:

I write on behalf of the California State Board of Pharmacy. We are pleased to have this opportunity to respond to the Request for Information made in Docket No. FDA-2009-D-0001, titled "Guidance for Industry (on) Standards for Securing the Drug Supply Chain—Standardized Numerical Identification for Prescription Drug Packages." We are encouraged by and support expeditious action by the FDA in this vital standards-setting endeavor.

We previously submitted comments, dated May 12, 2008, on the precursor docket/request for comments on this subject, Docket No. FDA-2008-N-0120, titled "Standards for Standardized Numerical Identifier, Validation, Track and Trace, and Authentication for Prescription Drugs; Request for Comments." A copy of those prior comments is enclosed, and incorporated herein by reference. We have only a few additional remarks to add to what was said previously.

We first congratulate the FDA on moving forward in a timely fashion with this project, so vital to prescription product supply system security. We agree that the establishment of industry numerical identifier(s), plus standards for data carriers to link identifiers to the products, are vital components of a safe and secure prescription supply system, and necessary to implementation of an electronic pedigree and/or track and trace system for prescription products. We are pleased to see action by the FDA in advance of the full implementation deadline date for the identifier(s).

We also agree with your initial focus on developing standardized identifier(s) tracking the prescription products *at the unit/smallest package level*. We commend the FDA for recognizing the vital importance of unit-level tracking. While unit-level tracking also lays the foundation for case- and pallet-level tracking, it is only where aggregate tracking is rooted in unit-level tracking that substantial security (as well as recall) functionality can be assured. In this respect, the FDA Guidance mirrors the focus of the California pedigree legislation, which requires specification to a unit level. We are gratified to see this approach implemented at the federal level. As we stated near the conclusion of our May 12, 2008 response to Docket No. FDA-2008-N-0120:

And finally, with regard to the "Economic Impact" and/or "Harmonization with Other Countries" questions, we will again largely leave those to others to answer. However, we do observe that the economic impact(s) of universal item-level (mass) application of standard numerical identifiers, whatever they might be, are more than balanced by the dramatic impact on public health and safety this technology standard promises. A secure supply chain depends on an ability to reliably track and trace drug products, to prevent infiltration of counterfeit, misbranded, and/or adulterated products. And as is evidenced by the recent experience with Heparin, an effective recall also depends on a serialized-to-the-unit-level drug supply, that is absent now. Unit-level serialization will also bring the U.S. supply chain *more* in line with international standards, as it is much more the practice in other countries to have patient-level serialization (as well as packaging). It is high time that the U.S. employed a similar practice standard.

We do encourage the FDA to also create standards and/or identifiers for tracking at the case and/or pallet level. In our view, this aggregate tracking necessarily follows from tracking at the unit level, the mapping of hierarchical relationships between units and their packaging levels facilitating a fully interoperable electronic tracking system built "from the bottom up." In other words, aggregate-level tracking is not a sufficient *replacement* for unit-level tracking, but it is a healthy complement to tracking at the unit level. It seems likely the identifier(s) used to identify the aggregate packages (cases, pallets, etc.) need not be of the same type or have the same robustness/capacity for data storage as those used for tracking individual package units.

This last point brings us to our one expression of concern regarding the draft Guidance: it has been expressed to us, and we have read or heard rumblings within the industry, that a purely numeric 8-digit serialized extension is not sufficiently robust. We are informed that it may lack the capacity to handle the volume of pharmaceutical units without running out of numbers within a span of a few years. We therefore join those urging you to consider allowing an alphanumeric serialized extension and/or a greater number of digits, perhaps as many as twenty. It is vital that the industry have a sufficient universe of serialized identifiers to fully support unit-level tracking.

In part, these concerns about serialization capacity may be a function of a choice the FDA has made to embed the NDC code in the serialized identifier, as presumably a fully-randomized serial number of the same digit length would have far greater capacity. There is certainly some trade-off for this choice both in total serialization storage capacity and in interchangeability at the international level. However, as we expressed in our May 12, 2008 response, we believe the benefits of embedding the NDC number outweigh such concerns, and we commend the FDA for incorporating the preference we and many others expressed for embedding the NDC code. As to the lost serialization capacity, that can be compensated by a longer, fully-serialized extension.

In conclusion, we again commend the FDA for taking action to define the identifier(s) to be used for unit-level tracking, and encourage you to relate unit-level tracking to tracking at the aggregate (case/pallet/etc.) level. We hope that the FDA will assist in developing any necessary legislation and/or regulations to effectively require unit-level tracking/e-pedigree transmission at the federal level. As we said in our May 12, 2008 response, we believe the highest priorities for the FDA are development of standards for: (1) serialized numerical identifier(s) to be placed on the item-level (and case- and/or pallet-level) packaging for prescription products; and (2) data carrier(s) that should be used to encode and affix those numerical identifiers.

As we also stated in our May 12, 2008 response(s) (on this topic as well as on the topic of promising technologies (Docket No. FDA-2008-N-0121)), we recommend that the FDA settle on RFID tags and technology as the mandated/preferred carrier. To do so, we hope the FDA takes a leadership role in also settling the question of propriety of use of RFID tags on biologic products.

The Board looks forward to continuing its historical cooperation with the FDA as it sets forth on this standards-setting endeavor. The Board is very hopeful that the FDA can move very quickly to establish these national standards, as the FDA has indicated is its intent by moving to expeditiously publish the pertinent Docket event(s) and request(s) for comments/information.

Thank you for your attention to these matters, and for your willingness to hear our input. We look forward to continuing to work together to secure the nation's drug supply. Please feel free to contact the Board at any time if we can be of assistance. The best route for contact is via Executive Officer Virginia Herold, at (916) 574-7911, or [Virginia\\_Herold@dca.ca.gov](mailto:Virginia_Herold@dca.ca.gov).

Sincerely,



KENNETH H. SCHELL, Pharm.D.  
President, California State Board of Pharmacy

Enclosure: May 12, 2008 comments on Docket No. FDA-2008-N-0120



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May 2008/Prior Comments

STATE AND CONSUMER SERVICES AGENCY  
DEPARTMENT OF CONSUMER AFFAIRS  
ARNOLD SCHWARZENEGGER, GOVERNOR

May 12, 2008

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

RE: **RESPONSE OF THE CALIFORNIA STATE BOARD OF PHARMACY**  
**Docket No. FDA-2008-N-0120**  
*Standards for Standardized Numerical Identifier, Validation, Track and Trace, and Authentication for Prescription Drugs; Request for Comments*

To Whom It May Concern:

I write on behalf of the California State Board of Pharmacy. We are pleased to have this opportunity to respond to the Request for Comments included in Docket No. FDA-2008-N-0120, which has been titled "Standards for Standardized Numerical Identifier, Validation, Track and Trace, and Authentication for Prescription Drugs; Request for Comments." We are encouraged by and support expeditious action by the FDA in this vital standards-setting endeavor.

Our Historical Perspective in California

As you may know, the Board is the agency within California primarily responsible for the enforcement of California's drug pedigree law, a mandated serialization, electronic pedigree, and track and trace system designed to enhance the security of the drug supply chain. The California pedigree law was first enacted in 2004, with an initial effective date of January 1, 2007, and then modified and extended in 2006 by additional legislation that pushed the effective date to January 1, 2009. Recently, the Board exercised authority delegated to it by the 2006 legislation to further extend the effective date for implementation of the pedigree requirements to January 1, 2011.

The Board and its staff thus have several years experience developing and implementing pedigree laws. Further, since 2005 the Board and its staff have engaged in extensive outreach to all segments of the drug supply chain on the California pedigree law. Over that time, the Board has been grateful to receive invaluable support from the FDA in those efforts, and for its law.

This FDA support for California's pedigree law has mirrored a historical commitment at the FDA, as expressed for example in the 2004 and 2006 Reports by the FDA's Counterfeit Drug Task Force, to the same principles captured in California's pedigree law: a drug supply chain in which security is enhanced by a *universal* electronic pedigree requirement with full-system track and trace, and mass serialization *at the unit level* with standardized unique numerical identifiers. Both the FDA and California prefer, and assume this system will utilize, RFID technology.

The development of industry standards to accomplish an interoperable infrastructure is a necessary step in the implementation of any pedigree requirement. Standards for a standardized numerical identifier and for a technology or technologies to carry these identifiers (data carriers) are especially crucial. We therefore welcome and are enthusiastic about the FDA's efforts.

#### Response to Request for Comments

The Board has also been pleased to observe over the last several years that much if not all of the baseline work that would be required for development and implementation of national and international consensus industry standards has already been accomplished, at least in part during the industry's response to the imposition of the California and Florida pedigree requirements. As you are no doubt aware, nearly all of that effort has been conducted by or under the guidance and with the assistance of GS1 and/or GS1 US and/or EPCglobal Inc., the various incarnations of the centralized, national and international, neutral, and non-profit, standards-setting organization.

We expect and assume that GS1/EPCglobal will submit its own response(s), and will not attempt to provide the level of detail and specificity we assume will be provided therein. Instead, we will limit our comments to some basic principles and preferences we have developed over the last several years based on the vast quantity and variety of information we have collected.

#### **A. Standard Numerical Identifier**

Under the aegis of GS1/EPCglobal, the industry has already completed all or nearly all of the necessary work on development and implementation of a standardized numerical identifier to be used to identify individual products (and cases and pallets) in the supply chain. The standard identifier already in use within the industry is the Global Trade Item Number (GTIN), developed by GS1/EPCglobal. The Board is not aware of any competing or alternative standard identifier.

The Board strongly encourages the FDA to adopt the GS1/EPCglobal standard identifier. The GTIN is already in use and approved by the FDA for marking pharmaceutical products via a linear bar code. It has utility and extensibility for use with all other data carriers, as well. It is in use on packaging already with a significant majority of U.S. drug manufacturers and distributors.

We will not respond individually to all of the sub-categories or questions included in this sub-part (A), as standards-setting organization(s), industry participants, and technology vendors are better able to do so. We will be generally satisfied with urging adoption of the GTIN, except to note a few comments responsive to the specific questions posed in the notice:

- With regard to whether the standard numerical identifier should contain recognizable characteristics such as the National Drug Code (NDC) Directory number as part of its sequence or should be purely random, we note that the GTIN has the capacity to, and presently does, include/incorporate the NDC number. Though we recognize that this may reduce the full interchangeability of GTINs internationally due to inclusion of a U.S.-only NDC number, several of the professional pharmacist members of the Board have expressed a preference for inclusion of an NDC number in standard identifier(s). So much of the present tracking, billing, and payment infrastructure in the U.S. uses NDC number as a reference point that a certain level of comfort has developed with use of this identifier, and failure to include the NDC number may cause confusion.

- With regard to whether the standard numerical identifier should be in more than one place (e.g., at both the package and pallet level), we believe that full track and trace/pedigree capacity will require application of unique identifiers on *both* the individual item-level package *and* the case, pallet, or other aggregation. What is most crucial is that individual item-level (mass) serialization and application of unique identifiers be mandated by law; the application of identifiers to cases and pallets naturally follows.
- With regard to machine-readable versus human-readable, we feel strongly that it is of crucial importance to have machine-readable identifiers. Automatic data capture is an absolute necessity to preserve and extend the current processes and efficiencies in the drug supply chain. The fewer allowances that are made for human error the better. In fact, we also believe it critical to mandate or at least strongly encourage that standard numerical identifiers be encoded on carriers capable of non-line-of-sight data capture. This is the only means of transmission that is feasible for the entire supply chain.
- With regard to other questions posed under the “Characteristics” heading, we limit our comments to the observation that, as you have obviously realized, these are the kinds of decisions that must be made by industry consensus. In our view, there must be standards regarding whether or not to include a product type header/digit, how the parties in the supply chain ensure that numbers are unique and not duplicated, and/or whether or not the standard numerical identifier includes lot or batch number. What the particular decisions are with regard to those questions are of less concern to us.
- As for the “Standards” questions, we simply repeat our recommendation that the FDA strongly consider adoption of the GTIN as the pharmaceutical industry standard. The GTIN already enjoys that status within the industry, enjoying widespread adoption in the U.S. and internationally. There is no need to re-create this development process. We particularly encourage adoption of the SGTIN-96, which is the version applicable to serialization of drug products using RFID tag technology as the data carrier.
- And finally, with regard to the “Economic Impact” and/or “Harmonization with Other Countries” questions, we will again largely leave those to others to answer. However, we do observe that the economic impact(s) of universal item-level (mass) application of standard numerical identifiers, whatever they might be, are more than balanced by the dramatic impact on public health and safety this technology standard promises. A secure supply chain depends on an ability to reliably track and trace drug products, to prevent infiltration of counterfeit, misbranded, and/or adulterated products. And as is evidenced by the recent experience with Heparin, an effective recall also depends on a serialized-to-the-unit-level drug supply, that is absent now. Unit-level serialization will also bring the U.S. supply chain *more* in line with international standards, as it is much more the practice in other countries to have patient-level serialization (as well as packaging). It is high time that the U.S. employed a similar practice standard.

## **B. Standards for Validation**

We are not sure what is meant by use of the terms “Standards for Validation.” This is not a terminology we are accustomed to hearing, nor does it appear to clearly relate to any particular standard(s) or industry practice(s) we have encountered over the last several years.

To our knowledge, no such particular, specific “standards” for “validation of prescription drugs” presently exist, aside from those standards, practices and procedures developed to ensure and enable compliance with legal requirements such as those mandated in California and Florida, like the GS1/EPCglobal Pedigree and EPCIS standards. These standards *include* provisions and allowances for validations of prescription drugs, but would probably not be said to *be* such.

### **C. Standards for Track and Trace**

Likewise, we are not sure what is meant by “Standards for Track and Trace.” This is not a terminology we are accustomed to hearing, nor does it appear to clearly relate to any particular standard(s) or industry practice(s) we have encountered over the last several years.

Again, to our knowledge, no such particular, specific “standards” for “track and trace of products in the supply chain, generally” presently exist, aside from those standards, practices and procedures developed to ensure and enable compliance with legal requirements such as those set by California and Florida, like the GS1/EPCglobal Pedigree and EPCIS standards. Each of these standards *include* provisions and allowances for, or *enable*, tracking and tracing of drugs.

### **D. Standards for Authentication**

And finally, we are also not sure what is meant by “Standards for Authentication.” This is also not a terminology we are accustomed to hearing, nor does it appear to clearly relate to any particular standard(s) or industry practice(s) we have encountered over the last several years.

Again, to our knowledge, no such particular, specific “standards” for “authentication of products in the supply chain, generally” presently exist, aside from those standards, practices and procedures developed to ensure and enable compliance with legal requirements such as those set by California and Florida, like the GS1/EPCglobal Pedigree and EPCIS standards. Each of these standards *include* provisions and allowances for, or *enable*, authentication of drug products.

### **E. Prioritization**

What is clear to us, and requires no clarification, is that the highest priorities for the FDA, in this invaluable standards-setting venture, ought to be *immediate* and *concurrent* development of two standards: (1) the specification(s) for the standard numerical identifier to be placed on the item-level (and case- or pallet-level) packaging for prescription drugs; and (2) the standard(s) for the data carrier(s) that should be used to encode and affix those numerical identifiers.

As we have stated in our separate submission in response to the accompanying Docket on the specific subject of promising technologies, we believe it is imperative that the FDA settle on RFID tags and technology as the mandated/preferred carrier. To do so, we hope the FDA takes a leadership role in also settling the question of propriety of use of RFID tags on biologic products.

The Board looks forward to continuing its historical cooperation with the FDA as it sets forth on this standards-setting endeavor. The Board is very hopeful that the FDA can move very quickly to establish these national standards, as the FDA has indicated is its intent by moving to expeditiously publish the pertinent Docket event(s) and request(s) for comments/information.

Thank you for your attention to these matters, and for your willingness to hear our input. We look forward to continuing to work together to secure the nation's drug supply. Please feel free to contact the Board at any time if we can be of assistance. The best route for contact is via Executive Officer Virginia Herold, at (916) 574-7911, or [Virginia\\_Herold@dca.ca.gov](mailto:Virginia_Herold@dca.ca.gov).

Sincerely,

A handwritten signature in cursive script that reads "William Powers".

WILLIAM POWERS  
President, California State Board of Pharmacy

# Attachment 2

*Federal Register Listing of the DEA's  
Interim Rule on Implementation on the  
Ryan Haight Online Pharmacy Consumer  
Protection Act of 2008  
Docket No. DEA 3221*



# Federal Register

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Monday,  
April 6, 2009

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Part II

## Department of Justice

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Drug Enforcement Administration

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21 CFR Part 1300, 1301, 1304, et al.  
Implementation of the Ryan Haight  
Online Pharmacy Consumer Protection  
Act of 2008; Final Rule

## DEPARTMENT OF JUSTICE

## Drug Enforcement Administration

21 CFR Parts 1300, 1301, 1304, 1306

[Docket No. DEA-322]

RIN 1117-AB20

## Implementation of the Ryan Haight Online Pharmacy Consumer Protection Act of 2008

**AGENCY:** Drug Enforcement Administration (DEA), Department of Justice.

**ACTION:** Interim final rule with request for comments.

**SUMMARY:** The Ryan Haight Online Pharmacy Consumer Protection Act, which was enacted on October 15, 2008, amended the Controlled Substances Act and Controlled Substances Import and Export Act by adding several new provisions to prevent the illegal distribution and dispensing of controlled substances by means of the Internet. DEA is hereby issuing an interim rule to amend its regulations to implement the legislation and is requesting comments on the interim rule.

**DATES:** This interim rule is effective April 13, 2009, except §§ 1300.04, 1301.19, and 1304.40, which are effective April 6, 2009. Section 1300.04(i) (the definition of "practice of telemedicine") has an implementation date of January 15, 2010, unless such date is superseded by future regulatory actions as explained in the **SUPPLEMENTARY INFORMATION** section.

Written comments must be postmarked on or before June 5, 2009, and electronic comments must be sent on or before midnight Eastern time June 5, 2009.

**ADDRESSES:** To ensure proper handling of comments, please reference "Docket No. DEA-322" on all written and electronic correspondence. Written comments being sent via regular or express mail should be sent to the Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODL, 8701 Morrisette Drive, Springfield, VA 22152. Comments may be sent to DEA by sending an electronic message to [dea.diversion.policy@usdoj.gov](mailto:dea.diversion.policy@usdoj.gov). Comments may also be sent electronically through <http://www.regulations.gov> using the electronic comment form provided on that site. An electronic copy of this document is also available at the <http://www.regulations.gov> Web site. DEA will accept attachments to electronic

comments in Microsoft Word, WordPerfect, Adobe PDF, or Excel file formats only. DEA will not accept any file formats other than those specifically listed here.

Please note that DEA is requesting that electronic comments be submitted before midnight Eastern time on the day the comment period closes because <http://www.regulations.gov> terminates the public's ability to submit comments at midnight Eastern time on the day the comment period closes. Commenters in time zones other than Eastern time may want to consider this so that their electronic comments are received. All comments sent via regular or express mail will be considered timely if postmarked on the day the comment period closes.

**FOR FURTHER INFORMATION CONTACT:** Mark W. Caverly, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, VA 22152; Telephone: (202) 307-7297.

**SUPPLEMENTARY INFORMATION:** Posting of Public Comments: Please note that all comments received are considered part of the public record and made available for public inspection online at <http://www.regulations.gov> and in the DEA's public docket. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

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 posted online or made available in the public docket, you must include the phrase "PERSONAL IDENTIFYING INFORMATION" in the first paragraph of your comment. You must also place all the personal identifying information you do not want posted online or made available in the public docket 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 posted online or made available in the public docket, you must include the phrase "CONFIDENTIAL BUSINESS INFORMATION" in the first paragraph of your comment. You must also prominently identify 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 posted online or made available in the public docket.

Personal identifying information and confidential business information identified and located as set forth above will be redacted and the comment, in redacted form, will be posted online and placed in the DEA's public docket file. Please note that the Freedom of Information Act applies to all comments received. If you wish to inspect the agency's public docket file in person by appointment, please see the "For Further Information" paragraph.

**Preamble****I. Legislation Upon Which These Regulations Are Based**

The Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (Pub. L. 110-425) (hereafter, the "Ryan Haight Act" or the "Act") was enacted on October 15, 2008. The Act amended the Controlled Substances Act (CSA) and Controlled Substances Import and Export Act (CSIEA) by adding various provisions to prevent the illegal distribution and dispensing of controlled substances by means of the Internet.<sup>1</sup> The law becomes effective April 13, 2009 (except for one provision relating to telemedicine discussed below). Thus, as of April 13, 2009, it will be illegal under federal law to "deliver, distribute, or dispense a controlled substance by means of the Internet, except as authorized by [the CSA]" or to aid or abet such activity. 21 U.S.C. 841(h)(1). The Act applies to all controlled substances in all schedules.

This document serves three purposes: (1) To explain the new legislation; (2) to announce the amendments to the DEA regulations that implement the new legislation; and (3) to request comments on the amendments to the regulations, which are being issued as an interim rule as contemplated in the legislation.

**II. Authority in Ryan Haight Act To Issue Regulations**

The Ryan Haight Act contains various provisions that call upon the Attorney

<sup>1</sup> Consistent with the CSA itself, the Ryan Haight Act relates solely to controlled substances. Controlled substances are those psychoactive drugs and other substances—including narcotics, stimulants, depressants, hallucinogens, and anabolic steroids—that are placed in one of the five schedules of the CSA due to their potential for abuse and likelihood that they may cause psychological or physical dependence when abused.

Controlled substances constitute only a small percentage of all pharmaceutical drugs. Approximately 10 percent of all drug prescriptions written in the United States are for controlled substances, with the remaining approximately 90 percent of prescriptions being written for noncontrolled substances. The amendments to the CSA made by the Ryan Haight Act, as well as the regulations being issued here, do not apply to noncontrolled substances.

General to issue regulations to implement the Act. Among these is the following general grant of authority:

The Attorney General may promulgate and enforce any rules, regulations, and procedures which may be necessary and appropriate for the efficient execution of functions under this Act or the amendments made by this Act, and, with the concurrence of the Secretary of Health and Human Services where this Act or the amendments made by this Act so provide, promulgate any interim rules necessary for the implementation of this Act or the amendments made by this Act, prior to its effective date.<sup>2</sup>

This regulatory authority of the Attorney General has been delegated to the Administrator of DEA.<sup>3</sup> It is evident from the foregoing provision of the Act that Congress contemplated it would be necessary for DEA to issue regulations on an interim basis in order to implement the Act within the relatively short time period between the passage of the Act (October 15, 2008) and its effective date (April 13, 2009). Indeed, Congress envisioned that DEA would need to issue interim rules "prior to its effective date" (*i.e., before* April 13, 2009) to effectively implement the new requirements of the Act.<sup>4</sup> Accordingly, the rules published here are effective immediately while at the same time the agency is seeking public comment on them. Following the comment period, DEA will review the comments and make any modifications to the interim rule that are appropriate. Also, as explained below, the Act contemplates that DEA will, with the concurrence of the Secretary of Health and Human Services, promulgate regulations governing the issuance to practitioners of a special registration relating to the practice of telemedicine. Those regulations will be issued separately at a later date.

<sup>2</sup> Public Law 110-425, sec. 3(k)(1).

<sup>3</sup> Functions vested in the Attorney General under the CSA have been delegated to the Administrator of DEA. 28 CFR 0.100. Accordingly, in this document, "DEA Administrator" will be used in place of all statutory references to the Attorney General.

<sup>4</sup> Congress's express grant of authority under the Ryan Haight Act to issue interim rules as the DEA Administrator finds necessary to implement the Act prior to its effective date forms the basis for the DEA Administrator's conclusion, as is set forth in Section X below, that "good cause" exists under the Administrative Procedure Act (APA) for the issuance of interim rules (those which take effect immediately on an interim basis prior to the public comment period) because "notice and public procedure thereon are impracticable, \* \* \* [and] contrary to the public interest." See 5 U.S.C. 553(b)(B).

### III. Overview of the Legislation

#### A. Reasons for the Legislation

The unlawful use of pharmaceutical controlled substances has reached alarming levels in the United States in recent years, causing a substantial detrimental effect on the public health and safety. According to the most recently published National Survey on Drug Use and Health (2007),<sup>5</sup> 6.9 million Americans reported using psychotherapeutic drugs<sup>6</sup> nonmedically during the prior month.<sup>7</sup> With specific regard to pain relievers, 5.2 million respondents reported abusing these drugs,<sup>8</sup> which is an 18 percent increase from 2004.<sup>9</sup> This study further indicates that, in the United States, the abuse of prescription drugs is second only to that of marijuana and is higher than the abuse of cocaine, heroin and hallucinogens combined.<sup>10</sup> Among persons aged 12 and older who reported using illicit drugs for the first time in 2007, abuse of pain relievers was the most common category of first-time illicit drug use.<sup>11</sup>

The false sense of security that some associate with the abuse of these substances is also alarming. Many mistakenly believe that if a drug may be prescribed for medical use, abusing that drug cannot be as harmful as abusing more conventional "street" drugs, such as heroin or cocaine. According to the 2005 Partnership Attitude Tracking Study<sup>12</sup>, 40 percent of teens surveyed believe that prescription medicines are "much safer" to use than illegal drugs. Furthermore, the same study concluded that 31 percent believe there is "nothing wrong" with using prescription medicines without a prescription "once in awhile."<sup>13</sup>

One of the main factors contributing to the nationwide increase in the diversion of pharmaceutical controlled substances has been the rise in the number of Internet sites that sell or facilitate the sale of these drugs for other

than legitimate medical purposes. While in-person "prescription mills" (practitioners' offices that readily supply drug seekers with prescriptions for controlled substances without establishing a legitimate medical basis for doing so) have always been, and remain, a significant source of diversion, the advent of rogue Web sites that cater to those who abuse pharmaceutical controlled substances has allowed the criminal operators of these sites to exploit the anonymity of the Internet to generate illicit sales of controlled substances (and/or prescriptions therefor) that far exceed those of any in-person prescription mill. This is particularly evident when examining the data relating to the sales of hydrocodone, which is the most widely abused pharmaceutical controlled substance in the United States. According to data registered distributors of controlled substances provided to DEA<sup>14</sup> in 2006, 34 pharmacies in the United States that were supplying rogue Internet sites dispensed a total of more than 98 million dosage units of hydrocodone. Hence, these pharmacies each dispensed an average of approximately 2.9 million dosage units of hydrocodone per pharmacy in a single year. By means of comparison, the average pharmacy in the United States dispenses approximately 88,000 dosage units of hydrocodone per year.

Congress passed the Ryan Haight Act precisely because of "the increasing use of prescription controlled substances by adolescents and others for nonmedical purposes, which has been exacerbated by drug trafficking on the Internet."<sup>15</sup> The person for whom the Act was named, Ryan Haight, was "a California high school honors student and athlete who died in 2001 from an overdose of controlled substances that he had purchased from a rogue online pharmacy."<sup>16</sup> According to the Senate Report accompanying the legislation, "Ease of access to the Internet, combined with lack of medical supervision, has led to tragic consequences in the online purchase of prescription controlled substances."<sup>17</sup> The Senate Report then cited a list of examples of persons in the United States who had died from overdoses of controlled substances obtained via the Internet.<sup>18</sup>

<sup>5</sup> Available at <http://www.oas.samhsa.gov/nsduh/2k7nsduh/2k7Results.pdf>.

<sup>6</sup> The study states: "Psychotherapeutics include the nonmedical use of any prescription-type pain relievers, tranquilizers, stimulants, or sedatives. Over-the-counter substances are not included." *Id.* at 55.

<sup>7</sup> *Id.* at 1.

<sup>8</sup> *Id.*

<sup>9</sup> Compare 2004 National Survey on Drug Use and Health at 1, available at <http://www.oas.samhsa.gov/nsduh/2k4nsduh/2k4results.pdf>.

<sup>10</sup> See *id.* at 73.

<sup>11</sup> *Id.* at 4.

<sup>12</sup> Partnership for a Drug-Free America; Partnership Attitude Tracking Study, Teens in grades 7 through 12, 2005; [http://www.drugfree.org/Files/Full\\_Teen\\_Report](http://www.drugfree.org/Files/Full_Teen_Report) (page 21).

<sup>13</sup> *Id.* at 20-21.

<sup>14</sup> Distributors are required to submit certain reports to DEA's ARCOS unit, as provided in 21 CFR 1304.33.

<sup>15</sup> S. Rep. No. 110-521, at 1 (2008).

<sup>16</sup> *Id.* at 12.

<sup>17</sup> *Id.* at 5.

<sup>18</sup> *Id.* at 5-6.

### *B. Common Methods Employed by Operators of Rogue Web Sites That Sell Pharmaceutical Controlled Substances*

The rogue Web sites that the Ryan Haight Act seeks to eliminate take on a variety of appearances and use a variety of methods. One common factor is that all these Web sites are marketed toward drug seekers who are willing to pay a premium to obtain pharmaceutical controlled substances without having a legitimate medical need for them. While the "business models" that the operators of these sites employ to evade detection by law enforcement and/or to create the facade of compliance with the law have evolved significantly over time, there tend to be three categories of participants in these schemes: the prescribing practitioner; the pharmacy that fills the prescriptions; and the criminal facilitator (a non-DEA registrant) who runs the operation.<sup>19</sup>

While it has always been illegal to dispense a controlled substance without a legitimate medical purpose, prior to the Act, a rogue operator could design a site that would make it clear to drug seekers that pharmaceutical controlled substances could be obtained through the site without a legitimate medical purpose. For example, a typical rogue site would display prominently on its homepage a list of the pharmaceutical controlled substances that it sold and prompt customers to click on their desired drugs. These Web sites could easily be found by using any of various Internet search engines and entering search terms such as "hydrocodone no prescription." Unsolicited e-mails or other forms of online advertising and marketing often steered potential customers to these Web sites; the advertisements announced that controlled substances could be readily obtained through the Web site without an in-person medical evaluation and sometimes without even a prescription—thus insuring a drug seeking customer could obtain the controlled substance without a legitimate medical need.

Thus, prior to passage of the Act, attracting customers was relatively easy for these rogue Web sites. However, to deliver the goods that the customers were seeking (pharmaceutical controlled substances and/or prescriptions for such), the operator of the rogue Web site usually had to enlist the services of two types of DEA registrants: a practitioner and pharmacy. Thus, the typical

criminal facilitator had to recruit an unscrupulous practitioner willing to prescribe controlled substances without a legitimate medical evaluation obtained through a bona fide doctor-patient relationship. While the overwhelming majority of practitioners would want no part of this type of improper arrangement, criminal facilitators were able to find some unscrupulous practitioners willing to participate. Investigations have revealed that these facilitators often target practitioners who carry significant debt, such as those recently graduated from medical school, or those who have retired and are looking for some "extra income." Regardless of the motivations of the participating practitioners, the facilitator would persuade them to enter into an agreement whereby they would agree to write prescriptions for controlled substances without adhering to the standard professional practices employed by practitioners when evaluating the medical condition of patients and determining the appropriate treatment in return for payment from the facilitator based on the number of prescriptions they would write. These arrangements operated in several ways. In some instances, the facilitator would arrange for a practitioner to issue prescriptions for controlled substances based solely on reviewing online questionnaires the customers submitted to the Web site. Other schemes involved facilitators requiring the customers of the Web site to fax some documentation that purported to be the customers' "medical records" and then having an unscrupulous practitioner issue prescriptions for controlled substances based on a "review" of these faxed documents. A third type of scheme involved the facilitator having customers of the Web site call a telephone number staffed by employees of the site, answer a series of questions purporting to create a "medical history," and then have unscrupulous practitioners write the prescriptions based on these answers. Whatever the methods employed, these rogue Web site operations were merely a sham, as every step in the process was designed to sell customers controlled substances and/or prescriptions for controlled substances without regard to actual medical need.

Some criminal facilitators have been content to take in the profits associated with selling the prescriptions for controlled substances. (Some rogue Web sites charge customers a separate fee for arranging the issuance of prescriptions.) Others have sought to increase their

profits by also having customers fill the prescriptions through a pharmacy affiliated with the Web site. To achieve the latter, the criminal facilitator needed to enter into an agreement with an unscrupulous pharmacy that was willing—for a fee—to fill prescriptions for controlled substances with essentially no questions asked and for as many prescriptions as the Web site could steer toward the pharmacy.<sup>20</sup> In addition to paying the pharmacy for the cost of the drugs, the criminal facilitator would also typically pay the pharmacy an agreed upon amount that, in some instances, amounted to millions of dollars. Given the amount of money to be made from these arrangements, DEA has seen pharmacies close their doors completely to walk-in customers and convert their entire business to filling orders generated from rogue Web sites. In some instances, criminal facilitators have used multiple brick and mortar pharmacies to service their list of drug seeking customers. In other cases, a single pharmacy has supplied multiple rogue Web sites.

These rogue Web sites generally provide the customer with a wide variety of quick and easy payment methods, such as cash-on-delivery, lines of credit, and credit "gift" cards. They also typically structure the various steps of the ordering process so as to link and shift the buyer to different Web sites, making it difficult for investigators to connect payments, products, and Web providers together. Rarely do such rogue Web sites contain any identifying information about where the online pharmacy is located or who owns or operates the Web site. On the contrary, these Web sites frequently fluctuate in name and number minute by minute. Finally, the typical rogue Web site fails to provide any information on how a patient may contact the prescribing practitioner or the pharmacist to consult with them about the drug(s) ordered, including drug interactions and adverse reactions.

Recognizing that these rogue Web sites fuel the abuse of prescription controlled substances and thereby increase the number of resulting overdoses and other harmful consequences, Congress passed the Ryan Haight Act to prevent the Internet from being exploited to facilitate such unlawful drug activity.

<sup>20</sup> The small percentage of pharmacies who have so participated in these rogue Web site schemes have, in many cases, filled extraordinary numbers of prescriptions for controlled substances that dwarf the sales figures of walk-in pharmacies.

<sup>19</sup> The "business models" described here are not the only ones employed by operators of rogue sites; methods other than those described above have been utilized by those who divert controlled substances by means of the Internet.

#### IV. Brief Summary of Some of the Key Provisions of the Legislation

Before examining the legislation in detail, the following is a brief recitation of two of the most important new statutory requirements: the in-person medical evaluation requirement for prescribing practitioners and the modified registration requirement for online pharmacies.

**A. In-person medical evaluation requirement**—One of the primary ways in which the Ryan Haight Act combats the use of the Internet to facilitate illegal sales of pharmaceutical controlled substances is by mandating, with limited exceptions, that the dispensing of controlled substances by means of the Internet be predicated on a valid prescription involving at least one in-person medical evaluation. While the lack of an in-person medical evaluation has always been viewed as a “red flag” indicating that diversion might be occurring, the Ryan Haight Act makes it unambiguous that it is a *per se* violation of the CSA for a practitioner to issue a prescription for a controlled substance by means of the Internet without having conducted at least one in-person medical evaluation, except in certain specified circumstances. At the same time, it is crucial to bear in mind that, as Congress expressly stated under the Act, the mere fact that the prescribing practitioner conducted one in-person medical evaluation does *not* demonstrate that the prescription was issued for a legitimate medical purpose within the usual course of professional practice. Even where the prescribing practitioner has complied with the requirement of at least one in-person medical evaluation, a prescription for a controlled substance must still satisfy the additional, fundamental prerequisite that has been legally mandated for more than 90 years: it must be issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice.<sup>21</sup>

**B. Requirement of modified registration for online pharmacies**—Another of the core provisions of the Act is the requirement that any person who operates a Web site that fits within the definition of an “online pharmacy” must obtain from DEA a modification of its DEA pharmacy registration that expressly authorizes such online activity. Only DEA-registered pharmacies are eligible under the Act to

obtain such a modification of registration. One of the ramifications of this requirement is that those who are not DEA-registered pharmacies (for example, those nonregistrants who have heretofore facilitated unlawful Internet controlled substance sales by enlisting the services of unscrupulous pharmacies and/or prescribing practitioners) are prohibited from operating online pharmacies.

The Act’s definition of “online pharmacy” encompasses more than merely legitimate pharmacies that may obtain a modification of their DEA registrations allowing them to dispense controlled substances by means of the Internet. As explained below, the definition of “online pharmacy” includes, among others, those persons who operate the types of rogue Web sites that the Act was designed to eliminate. Consistent with the longstanding structure of the CSA (since it was enacted in 1970), the Ryan Haight Act prohibits all controlled substance activities by “online pharmacies” except those expressly authorized by the Act. Again, only DEA-registered pharmacies may obtain a modification of their registration authorizing them to operate as online pharmacies. In addition, a pharmacy that has obtained such a modification of its registration may not operate as an online pharmacy unless it has notified DEA of its intent to do so and its Web site contains certain declarations designed to provide clear assurance that it is operating legitimately and in conformity with the Act. (These requirements are discussed at length below.)

#### V. Detailed Explanation of the Legislation

Consistent with the structure of the CSA, the Ryan Haight Act sets out numerous regulatory requirements and other substantive provisions and makes it unlawful to “knowingly or intentionally \* \* \* deliver, distribute, or dispense a controlled substance by means of the Internet, except as authorized by [the Act].”<sup>22</sup> Thus, this explanation of the Act will be divided into two main parts: (1) Explaining the Act’s regulatory requirements and other substantive provisions and (2) explaining what it means to “knowingly or intentionally \* \* \* deliver, distribute, or dispense a controlled substance by means of the Internet.”

##### A. New definitions under the Act

The Act adds several new definitions to the CSA. These new statutory definitions are being added to the DEA

regulations as part of this Interim Rule. While many of the new definitions are self-explanatory, some are discussed in this preamble to assist in understanding the Act.

The following are two of the key definitions in the Act, which are set forth in 21 U.S.C. 802:

(51) The term “deliver, distribute, or dispense by means of the Internet” refers, respectively, to any delivery, distribution, or dispensing of a controlled substance that is caused or facilitated by means of the Internet.

This definition is plainly broad in scope, encompassing any activity utilizing the Internet that causes or facilitates the delivery, distribution, or dispensing of a controlled substance. This definition is incorporated into the Act’s definition of an “online pharmacy”:

(52) The term “online pharmacy” \* \* \* means [with certain exceptions discussed below] a person, entity, or Internet site, whether in the United States or abroad, that knowingly or intentionally delivers, distributes, or dispenses, or offers or attempts to deliver, distribute, or dispense, a controlled substance by means of the Internet.

The definition of “online pharmacy” is also broad in scope. First, it includes not only a “person”<sup>23</sup> but also any other “entity” or “Internet site”—“whether in the United States or abroad”—that otherwise meets the definition of an “online pharmacy.” Second, it also includes not only any such person, entity or Internet site “that knowingly or intentionally delivers, distributes, or dispenses \* \* \* a controlled substance by means of the Internet,” but also any such one who “offers or attempts” to do so.

Hence, the term “online pharmacy” includes, among other things: (i) Any Web site that sells, or offers to sell, any controlled substance or a prescription therefor to a person in the United States; (ii) any person who operates such a Web site;<sup>24</sup> (iii) any person who pays a practitioner to write prescriptions for controlled substances for customers of such a Web site; (iv) any person who pays a pharmacy to fill prescriptions for controlled substances that were issued

<sup>23</sup> As set forth in 1 U.S.C. 7, the word “person” includes “corporations, companies, associations, firms, partnerships, societies, and joint stock companies, as well as individuals.” Consistent therewith, the DEA regulations define “person” to include “any individual, corporation, government or governmental subdivision or agency, business trust, partnership, association, or other legal entity.” 21 CFR 1300.01(b)(34).

<sup>24</sup> The Act exempts certain categories of persons from the application of 21 U.S.C. 841(h)(1), such as Internet service providers and Web hosting services, so long as such persons do not act in concert with others who violate the Act.

<sup>21</sup> 21 CFR 1306.04(a); *United States v. Moore*, 423 U.S. 122 (1975). This requirement has been a part of federal law since the Harrison Narcotic Act of 1914. *Id.* at 131. For a detailed explanation of the “legitimate medical purpose requirement,” see 71 FR 52716, 52717 (2006 DEA policy statement).

<sup>22</sup> 21 U.S.C. 841(h)(1)(A).

to customers of such a Web site; (v) any pharmacy that knowingly or intentionally fills prescriptions for controlled substances that were issued to customers of such a Web site; and (vi) any person who sends an e-mail that: Offers to sell a controlled substance or a prescription for a controlled substance in a manner not authorized by the Act; directs buyers to a Web site operating in violation of the Act; or otherwise causes or facilitates the delivery, distribution, or dispensing of a controlled substance in a manner not authorized by the Act.

While the general scope of the definition of an "online pharmacy" is broad, the definition expressly excludes the following categories:

(i) Manufacturers or distributors registered under subsection (a), (b), (d), or (e) of [21 U.S.C. 823] who do not dispense controlled substances to an unregistered individual or entity;

(ii) Nonpharmacy practitioners who are registered under [21 U.S.C. 823(f)] and whose activities are authorized by that registration;

(iii) Any hospital or other medical facility that is operated by an agency of the United States (including the Armed Forces), provided such hospital or other facility is registered under [21 U.S.C. 823(f)];

(iv) A health care facility owned or operated by an Indian tribe or tribal organization, only to the extent such facility is carrying out a contract or compact under the Indian Self-Determination and Education Assistance Act;

(v) Any agent or employee of any hospital or facility referred to in clause (iii) or (iv), provided such agent or employee is lawfully acting in the usual course of business or employment, and within the scope of the official duties of such agent or employee, with such hospital or facility, and, with respect to agents or employees of health care facilities specified in clause (iv), only to the extent such individuals are furnishing services pursuant to the contracts or compacts described in such clause;

(vi) Mere advertisements that do not attempt to facilitate an actual transaction involving a controlled substance;

(vii) A person, entity, or Internet site that is not in the United States and does not facilitate the delivery, distribution, or dispensing of a controlled substance by means of the Internet to any person in the United States;

(viii) A pharmacy registered under [21 U.S.C. 823(f)] whose dispensing of controlled substances via the Internet consists solely of—

(I) Refilling prescriptions for controlled substances in schedule III, IV, or V, as defined in paragraph [21 U.S.C. 802(55)]; or

(II) Filling new prescriptions for controlled substances in schedule III, IV, or V, as defined in paragraph [21 U.S.C. 802(56)]; or

(ix) Any other persons for whom the [DEA Administrator] and the Secretary [of Health and Human Services] have jointly, by regulation, found it to be consistent with effective controls against diversion and otherwise consistent with the public health

and safety to exempt from the definition of an "online pharmacy".

21 U.S.C. 802(52)(B).

To elaborate briefly on these exceptions, under exception (i), a DEA-registered manufacturer or distributor<sup>25</sup> that uses the Internet to facilitate activities permitted by its DEA registration does *not* constitute an online pharmacy. Under exception (ii), a DEA-registered nonpharmacy practitioner (e.g., physician, dentist, veterinarian, scientific investigator, hospital, or other person authorized by his registration to dispense controlled substances) may do so by means of the Internet without being an online pharmacy. Under exceptions (iii) through (v), certain hospitals and other health care facilities associated with the United States government, as well as agents and employees acting in the course of their duties for such institutions, are not online pharmacies. Under exception (vi), an advertisement is not an online pharmacy, provided the advertisement does not "attempt to facilitate an actual transaction involving a controlled substance."

Under exception (vii), a person, entity, or Internet site located outside the United States is only exempted from the definition of an online pharmacy if it "does *not* facilitate the delivery, distribution, or dispensing of a controlled substance by means of the Internet to *any person in the United States*." (Emphasis added.) Thus, Web sites operated by persons located abroad, along with persons who operate the sites, *do* fall within the definition of an online pharmacy if they sell or offer to sell controlled substances to persons in the United States or otherwise "facilitate the delivery, distribution, or dispensing of a controlled substance by means of the Internet to any person in the United States."

Under exception (viii), a DEA-registered pharmacy is exempted from the definition of an online pharmacy if it dispenses controlled substances via the Internet solely by "refilling prescriptions for controlled substances in schedule III, IV, or V" and "filling new prescriptions for controlled substances in schedule III, IV, or V" (as those terms are defined in the Act). Finally, under exception (ix), the DEA Administrator and the Secretary of Health and Human Services have the authority to jointly decide to issue regulations making further exceptions to

<sup>25</sup> Under the CSA, a DEA-registered "distributor" delivers controlled substances to other DEA registrants; it may *not* administer, dispense, or otherwise deliver controlled substances to patients. See 21 U.S.C. 802(11), 822(a), 822(b), 828(a).

the definition of an online pharmacy, where they determine that doing so is "consistent with effective controls against diversion and otherwise consistent with the public health and safety." Pursuant to this clause, the regulations being issued here contain two exceptions to the definition of an online pharmacy: One relating to electronic prescribing of controlled substances and the other to the use of automated dispensing systems. These exceptions are explained below.

#### B. In-Person Medical Evaluation Requirement

To directly prohibit what had been the practice of many rogue Web sites—allowing customers to buy controlled substances and/or prescriptions for controlled substances via the Internet without ever seeing the prescribing practitioner in person—the Ryan Haight Act includes as one of its central features the "valid prescription" requirement. This requirement is set forth in 21 U.S.C. 829(e)(1): "No controlled substance that is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act<sup>26</sup> may be delivered, distributed, or dispensed by means of the Internet without a valid prescription."

The Act further defines the meaning of "valid prescription" in 21 U.S.C. 829(e)(2)(A): "The term 'valid prescription' means a prescription that is issued for a legitimate medical purpose in the usual course of professional practice by—(i) a practitioner who has conducted at least 1 in-person medical evaluation of the patient; or (ii) a covering practitioner." The Act explains the meaning of "in-person medical evaluation" in 21 U.S.C. 829(e)(2)(B):

(i) The term "in-person medical evaluation" means a medical evaluation that is conducted with the patient in the physical presence of the practitioner, without regard to whether portions of the evaluation are conducted by other health professionals.

(ii) Nothing in clause (i) shall be construed to imply that 1 in-person medical evaluation demonstrates that a prescription has been issued for a legitimate medical purpose within the usual course of professional practice.

Thus, for every controlled substance that is delivered, distributed, or dispensed by means of the Internet,

<sup>26</sup> Nearly every pharmaceutical controlled substance is a prescription drug under the Federal Food, Drug, and Cosmetic Act (FDCA). In the very rare instance where a drug contains a controlled substance but may be dispensed under the FDCA without a prescription, the DEA regulations specify the procedures a pharmacist must follow to dispense such a drug lawfully to a purchaser. 21 CFR 1306.26.

there must be a "valid prescription," which means not only that the prescription must comply with the longstanding requirement of being issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice, but also that the prescribing practitioner must either (i) have conducted at least one in-person medical evaluation of the patient or (ii) meet the definition of a "covering practitioner" (explained below). Any practitioner who writes a prescription for a controlled substance that fails to comply with this provision of the Act, as well as any pharmacy that knowingly or intentionally fills such a prescription, violates 21 U.S.C. 841(h)(1).

Hence, the Act makes it unambiguous that, except in limited and specified circumstances, it is a per se violation of the CSA for a practitioner to issue a prescription for a controlled substance by means of the Internet without having conducted at least one in-person medical evaluation. However, the Act also expressly provides that a prescribing practitioner does not automatically meet the requirement of issuing a prescription for a legitimate medical purpose while acting in the usual course of professional practice merely by having conducted a single in-person medical evaluation of the patient. Rather, as with all situations in which a prescription for a controlled substance is issued, all the facts and circumstances surrounding the issuance of the prescription must be evaluated in determining whether it was issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice.<sup>27</sup> A rogue Internet operation cannot, for example, defeat the purpose of the Act by establishing a method of operation in which a practitioner conducts a perfunctory in-person "evaluation" of each "patient" simply for the purpose of selling prescriptions for controlled substances to the patient in perpetuity with no follow-up visits. This topic is addressed further below in Section VII, which provides additional information for practitioners.

With respect to the term "covering practitioner," the Act states (21 U.S.C. 829(e)(2)(C)):

The term "covering practitioner" means, with respect to a patient, a practitioner who conducts a medical evaluation (other than an in-person medical evaluation) at the request of a practitioner who—(i) has conducted at least 1 in-person medical evaluation of the

patient or an evaluation of the patient through the practice of telemedicine, within the previous 24 months; and (ii) is temporarily unavailable to conduct the evaluation of the patient.

Thus, a prescribing practitioner who falls within the above definition of a "covering practitioner" need not conduct an in-person medical evaluation as a prerequisite to prescribing a controlled substance to a given patient, provided that the practitioner for whom the covering practitioner is covering has conducted an in-person medical evaluation of that patient and provided further that this covering arrangement is taking place on only a temporary basis. Moreover, just as with the primary practitioner, the requirement that the prescription must be issued in the usual course of professional practice for a legitimate medical purpose applies with equal force to a "covering practitioner."

The Act also provides for an exception to the requirement of an in-person medical evaluation for practitioners who are engaged in the "practice of telemedicine" within the meaning of the Act. 21 U.S.C. 829(e)(3)(A). Of course, a practitioner engaged in the "practice of telemedicine" remains subject to the requirement that every prescription for a controlled substance be issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. The Act provides a temporary definition of the "practice of telemedicine" pending issuance of new regulations addressing "telemedicine." The topic of "telemedicine" is further addressed in paragraph D below.

#### C. Requirements for Online Pharmacies

**Modified Registration Requirement—**The Act imposes various requirements for those persons and other entities that fit within the Act's definition of an online pharmacy. To begin with, an online pharmacy may only operate lawfully as an online pharmacy if it is a DEA-registered pharmacy that has obtained from DEA a modification of its registration authorizing it to engage in such activity. 21 U.S.C. 823(f), 841(h)(1). An online pharmacy that is not validly registered with a modification authorizing it to operate as an online pharmacy as required by 21 U.S.C. 823(f) will violate 21 U.S.C. 841(h)(1) if it knowingly or intentionally delivers, distributes, or dispenses a controlled substance by means of the Internet. Moreover, under the Act, the only type of online pharmacy that is eligible to apply to DEA for such modification of registration is a DEA-registered

pharmacy. 21 U.S.C. 823(f). Thus, any person, entity, or Internet site that falls within the definition of an online pharmacy—and is not a DEA-registered pharmacy that has obtained a modification of its registration authorizing it to operate as an online pharmacy—is necessarily violating the Act if it knowingly or intentionally delivers, distributes, or dispenses a controlled substance by means of the Internet.

The regulations being issued here set forth the process by which a DEA-registered pharmacy may apply online for a modification of its registration authorizing it to operate as an online pharmacy. Under the Act, DEA must base its decision on whether to grant or deny such an application for a modification of registration on the same statutory criteria that it must consider in evaluating an application for registration submitted by a pharmacy or other practitioner. 21 U.S.C. 823(f).

**Reporting Requirement—**A pharmacy that has obtained a modification of its registration authorizing it to dispense controlled substances by means of the Internet must report to DEA, on a monthly basis, the total amount of each controlled substance it dispenses. 21 U.S.C. 827(d)(2). For pharmacies that are subject to this requirement, the monthly report must include all controlled substances dispensed by any means—not just controlled substances dispensed by means of the Internet. *Id.* However, if a pharmacy with such a modified registration dispenses an amount that falls below the threshold in a given month, it is not required to submit a report for that month. *Id.* The monthly threshold is either (A) 100 or more prescriptions for controlled substances filled by the pharmacy or (B) 5,000 or more total dosage units of controlled substances dispensed. *Id.* Again, these threshold amounts include all controlled substances dispensed by the pharmacy by any means (through walk-in business, by mail, by means of the Internet, or otherwise). *Id.* If the pharmacy meets or exceeds either of the foregoing amounts in a given month, it must report to DEA the total amount of controlled substances it dispensed by any means during that month. *Id.* The regulations being issued here specify the time and manner in which such reports must be filed.

**Statements that must appear on an online pharmacy's Web site—**Every online pharmacy is required under the Act to "display in a visible and clear manner on its homepage a statement that it complies with the requirements of [21 U.S.C. 831] with respect to the delivery or sale or offer for sale of

<sup>27</sup> For a detailed explanation of the "legitimate medical purpose requirement," see 71 FR 52716, 52717 (2006 DEA policy statement). See also, 21 CFR 1306.04(a); *United States v. Moore*, 423 U.S. 122 (1975).

controlled substances and shall at all times display on the homepage of its Internet site a declaration of compliance in accordance with this section." 21 U.S.C. 831(a).

In addition, the Act requires every online pharmacy to satisfy the following requirement relating to what the Act refers to as the "Internet Pharmacy Site Disclosure Information." As set forth in 21 U.S.C. 831(c), each online pharmacy shall post in a visible and clear manner on the homepage of each Internet site it operates, or on a page directly linked thereto in which the hyperlink is also visible and clear on the homepage, the following information for each pharmacy that delivers, distributes, or dispenses controlled substances pursuant to orders made on, through, or on behalf of, that Web site:

- The name and address of the pharmacy as it appears on the pharmacy's Drug Enforcement Administration Certificate of Registration.
- The pharmacy's telephone number and e-mail address.
- The name, professional degree, and States of licensure of the pharmacist-in-charge, and a telephone number at which the pharmacist-in-charge can be contacted.
- A list of the States in which the pharmacy is licensed to dispense controlled substances.
- A certification that the pharmacy is registered under this part to deliver, distribute, or dispense by means of the Internet controlled substances.
- The name, address, telephone number, professional degree, and States of licensure of any practitioner who has a contractual relationship to provide medical evaluations or issue prescriptions for controlled substances, through referrals from the Web site or at the request of the owner or operator of the Web site, or any employee or agent thereof.

• The following statement, unless revised by the [DEA Administrator] by regulation: "This online pharmacy will only dispense a controlled substance to a person who has a valid prescription issued for a legitimate medical purpose based upon a medical relationship with a prescribing practitioner. This includes at least one prior in-person medical evaluation or medical evaluation via telemedicine in accordance with applicable requirements of section 309."

While the foregoing requirements are largely self-explanatory, some aspects warrant special emphasis. The requirement that an online pharmacy post the foregoing information "in a visible and clear manner on the homepage of each Internet site it

operates, or on a page directly linked thereto in which the hyperlink is also visible and clear on the homepage" is intended to ensure that members of the public who visit such Web sites are informed about the Ryan Haight Act's core requirements and to ensure that the DEA-registered pharmacies and prescribing practitioners affiliated with the site, if any, are clearly identified. Any effort by an online pharmacy to hide or reduce the visibility on the Web site of this required information will subject those responsible to potential criminal and civil liability and, in the case of DEA registrants, potential loss of registration. The required information must be displayed "for each pharmacy that delivers, distributes, or dispenses controlled substances pursuant to orders made on, through, or on behalf of, that Web site." Thus, if multiple pharmacies dispense controlled substances pursuant to orders made on, through, or on behalf of, that Web site, each required category of information must be displayed for each such pharmacy.

The requirement (under paragraph (4)) that an online pharmacy list the States in which it is licensed to dispense controlled substances is designed to ensure that an online pharmacy only dispenses controlled substances to patients in States in which it is authorized to practice pharmacy. Dispensing beyond the scope of State licensure is one of the recurring transgressions of some rogue online pharmacies and generally violates State law.<sup>28</sup>

*State licensure requirement*—The Act also requires that online pharmacies comply with State licensure requirements. Specifically, the Act requires that:

Each online pharmacy shall comply with the requirements of State law concerning the licensure of pharmacies in each State from which it, and in each State to which it, delivers, distributes, or dispenses or offers to deliver, distribute, or dispense controlled substances by means of the Internet, pursuant to applicable licensure requirements, as determined by each such State.

21 U.S.C. 831(b).

*Required notification to DEA*—The Act contains a provision that is designed to ensure that DEA, and the applicable State boards of pharmacy, are aware of the existence of an online pharmacy before it commences operation. The Act's notification requirements are set forth in 21 U.S.C. 831(d)(1):

<sup>28</sup> A State may bring a civil action in federal court to enjoin any violation of the Ryan Haight Act—not merely those violations of State law—and to obtain other appropriate legal or equitable relief. 21 U.S.C. 882(c).

Thirty days prior to offering a controlled substance for sale, delivery, distribution, or dispensing, the online pharmacy shall notify the [DEA Administrator], in such form and manner as the [Administrator] shall determine, and the State boards of pharmacy in any States in which the online pharmacy offers to sell, deliver, distribute, or dispense controlled substances.

Pursuant to this provision, the regulations being issued here provide that such notification to DEA shall be made by the pharmacy as part of the process by which it applies to DEA for a modification of its registration authorizing it to operate as an online pharmacy. The Act specifies that the foregoing notification must include the following information:

(A) The information required to be posted on the online pharmacy's Internet site under [21 U.S.C. 831(c)] and shall notify the [DEA Administrator] and the applicable State boards of pharmacy, under penalty of perjury, that the information disclosed on its Internet site under [21 U.S.C. 831(c)] is true and accurate;

(B) The online pharmacy's Internet site address and a certification that the online pharmacy shall notify the [Administrator] of any change in the address at least 30 days in advance; and

(C) the Drug Enforcement Administration registration numbers of any pharmacies and practitioners referred to in [21 U.S.C. 831(c)], as applicable.

21 U.S.C. 831(d)(2).

Thus, the information that an online pharmacy is required to post on its Web site must also be provided to DEA as part of the application for a modification of its DEA registration in order to satisfy part of the notification requirement.

*Declaration of compliance*—Beginning on the date on which the online pharmacy makes the notification to DEA required by 21 U.S.C. 831(d), and continuing thereafter, it must "display on the homepage of its Internet site, in such form as the [DEA Administrator] shall by regulation require, a declaration that it has made such notification to the [Administrator]." 21 U.S.C. 831(e). The regulations being issued here specify precisely the form in which this declaration must be made.

*Additional considerations regarding statements, declarations, notifications, and disclosures required under the Act*—As stated in 21 U.S.C. 831(f): "Any statement, declaration, notification, or disclosure required under [21 U.S.C. 831] shall be considered a report required to be kept under [the CSA]." One important effect of this provision is that, in conjunction with 21 U.S.C. 843(a)(4), it is a felony violation of the CSA to furnish false or fraudulent

material information in, or omit any material information from, any statement, declaration, notification, or disclosure required under 21 U.S.C. 831.<sup>29</sup>

#### D. Telemedicine

As indicated above, "a practitioner engaged in the practice of telemedicine" within the meaning of the Act is exempt from the requirement of an in-person medical evaluation as a prerequisite to prescribing or otherwise dispensing controlled substances by means of the Internet. Before explaining the meaning of the "practice of telemedicine," it bears repeated emphasis that all practitioners who prescribe controlled substances—even those engaged in the practice of telemedicine—remain subject to the requirement that the prescription be issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. Prescribing a controlled substance without conducting an in-person medical evaluation has always been, and remains under the Act, a strong indication (or "red flag") of likely diversion.<sup>30</sup> The Act simply made the failure to perform an in-person medical evaluation in certain circumstances<sup>31</sup> an automatic violation of the CSA, while leaving it as a factor indicative of possible diversion in all other circumstances.

The definition of the "practice of telemedicine" includes seven distinct categories that involve circumstances in which the prescribing practitioner might be unable to satisfy the Act's in-person medical evaluation requirement, yet nonetheless has sufficient medical information to prescribe a controlled substance for a legitimate medical purpose in the usual course of professional practice. In these circumstances, provided certain safeguards are in place to ensure that the practitioner who is engaged in the practice of telemedicine is able to conduct a bona fide medical evaluation of the patient at the remote location, and is otherwise acting in the usual course of professional practice, the Act contemplates that the practitioner will be permitted to prescribe controlled substances by means of the Internet

despite not having conducted an in-person medical evaluation. The Act defines these categories, through the definition of "practice of telemedicine," which is set forth in 21 U.S.C. 802(54).

The Act specifies that the definition of the "practice of telemedicine" found in 21 U.S.C. 802(54) does not take effect at the same time the rest of the Act takes effect (April 13, 2009). Rather, the Act provides for a temporary definition of the "practice of telemedicine" that will apply beginning April 13, 2009, and continuing until the *earlier* of two dates: (i) three months after the date on which regulations are promulgated to carry out 21 U.S.C. 831(h) [relating to the issuance of a special registration to practice telemedicine] or (ii) January 15, 2010.<sup>32</sup> Until the first of the foregoing two dates is reached, the Act states that the following definition applies:

[T]he term "practice of telemedicine" means the practice of medicine in accordance with applicable Federal and State laws by a practitioner (as that term is defined in section 102 of the Controlled Substances Act (21 U.S.C. 802)) (other than a pharmacist) who is at a location remote from the patient and is communicating with the patient, or health care professional who is treating the patient, using a telecommunications system referred to in section 1834(m) of the Social Security Act (42 U.S.C. 1395m(m)), if the practitioner is using an interactive telecommunications system that satisfies the requirements of section 410.78(a)(3) of title 42, Code of Federal Regulations.

The rule being issued today contains both definitions of the practice of telemedicine (temporary and permanent), with the respective effective dates indicated.

*Special registration for telemedicine*—A practitioner who is engaged in the practice of telemedicine within the meaning of the Act is not subject to the mandatory in-person medical evaluation requirement of 21 U.S.C. 829(e) (although such practitioner remains subject to the requirement that all prescriptions for controlled substances be issued for a legitimate medical purpose). The Act's permanent definition of the "practice of telemedicine" includes, as an example, "a practitioner who has obtained from the [DEA Administrator] a special registration under [21 U.S.C. 831(h)]." 21 U.S.C. 802(54)(E). The Act specifies certain criteria that DEA must consider when evaluating an application for such a registration. However, the Act contemplates that DEA must issue certain regulations to effectuate this special registration provision. Specifically, the Act states: "The [DEA Administrator] shall, with the

concurrence of the Secretary [of Health and Human Services], promulgate regulations specifying the limited circumstances in which a special registration under [21 U.S.C. 831(h)] may be issued and the procedures for obtaining such a special registration." DEA will issue a separate rule promulgating regulations consistent with this directive. As explained above, until such regulations are promulgated, or until January 15, 2010 (whichever comes first), the temporary definition of the practice of telemedicine recited above remains in effect.

#### E. Exemptions for Electronic Prescribing of Controlled Substances and Automated Dispensing Systems

*Electronic prescribing of controlled substances*—On June 27, 2008, DEA published in the **Federal Register** a Notice of Proposed Rulemaking that would amend the DEA regulations to allow practitioners to electronically prescribe controlled substances (73 FR 36722). DEA is currently developing a final rule on electronic prescribing of controlled substances that takes into account the numerous public comments that were submitted in response to the proposed rule. Once the rule is finalized and published in the **Federal Register**, practitioners will be permitted to electronically prescribe controlled substances in accordance with the requirements in the regulations. In most cases, electronic prescribing of controlled substances will occur by means of the Internet. Given the Act's definitions, a pharmacy that knowingly or intentionally fills an electronic prescription for a controlled substance would (in the likely event that such an electronic prescription were transmitted via the Internet) fall within the Act's definition of an online pharmacy.

As indicated above, the Act gives the DEA Administrator, acting jointly with the Secretary of Health and Human Services, authority to exempt by regulation certain persons from the definition of an "online pharmacy," where the Administrator and the Secretary have found that doing so is "consistent with effective controls against diversion and otherwise consistent with the public health and safety." 21 U.S.C. 802(52)(B)(ix). Pursuant to this authority, the regulations being issued here today contain a provision that exempts from the definition of an online pharmacy any DEA-registered pharmacy "whose delivery, distribution, or dispensing of controlled substances by means of the Internet consists solely of \* \* \* filling prescriptions that were electronically prescribed in a manner authorized by

<sup>29</sup> In addition, the Act lists the following as an example of a violation of 21 U.S.C. 841(h)(1): "making a material false, fictitious, or fraudulent statement or representation in a notification or declaration under [21 U.S.C. 831(d) or (e)]." 21 U.S.C. 841(h)(2)(E). Such conduct might also subject the offender to liability under 18 U.S.C. 1001(a).

<sup>30</sup> See, e.g., *United States v. Rosen*, 582 F.2d 1032, 1036 (5th Cir. 1978).

<sup>31</sup> These circumstances are specified in 21 U.S.C. 829(e) and discussed above.

<sup>32</sup> Public Law 110-425, section 3(j).

this chapter and otherwise in compliance with the Act." 21 CFR 1300.04(h)(9). To eliminate any possible confusion as to how this exception applies, this provision of the regulations further states: "A registered pharmacy will be deemed to meet this exception if, in view of all of its activities other than [the acceptance of electronic prescriptions for controlled substances transmitted in accordance with the requirements of this chapter], it would fall outside the definition of an online pharmacy." A DEA-registered pharmacy that is so exempted from the definition of an online pharmacy is not required to obtain a modified registration and is not subject to the reporting requirement of 21 U.S.C. 827(d)(2) or the additional requirements relating to online pharmacies set forth in 21 U.S.C. 831.

It should be understood that the exception provided in 21 CFR 1300.04(h)(9) cannot take effect until DEA issues regulations allowing for the electronic prescribing of controlled substances. Until then, electronic prescribing of controlled substances is not permitted by the DEA regulations and thus cannot form the basis for any exception to the requirement of a modified registration for DEA-registered pharmacies.

It should also be clear from the language of 21 CFR 1300.04(h)(9) that this exception provides no loophole for operators of rogue Internet Web sites or unscrupulous pharmacies that fill prescriptions generated through such sites. The mere fact that a pharmacy accepts electronic prescriptions does *not*, in any way, immunize the pharmacy from the requirements of the Act. Likewise, a rogue Web site that operates in violation of the Act cannot escape liability simply by having either (i) unscrupulous practitioners who have a contract to write prescriptions on behalf of the site issue such prescriptions electronically or (ii) unscrupulous pharmacies that have a contract to fill such prescriptions do so through the acceptance of electronic prescriptions. To the contrary, the regulation is written so that the exception cannot possibly be utilized by a rogue Web site; only a DEA-registered pharmacy is eligible for the exception and only to the extent it is otherwise acting in conformity with the CSA and the DEA regulations.

*Exemption for automated dispensing systems*—Under current DEA regulations, a DEA-registered retail pharmacy may install and operate an automated dispensing system at a long term care facility under certain specified conditions. 21 CFR 1301.27. Among other requirements, any retail pharmacy

that installs and operates an automated dispensing system at a long term care facility must maintain a separate registration at each long term care facility in which its automated dispensing systems are located. *Id.* Prescription information may be transmitted by the retail pharmacy to the automated dispensing system via the Internet. Therefore, a pharmacy that operates an automated dispensing system at a long term care facility could potentially fall within the Act's definition of an online pharmacy. Pursuant to 21 U.S.C. 802(52)(B)(ix), the DEA Administrator and the Secretary have jointly concluded that it would be consistent with effective controls against diversion and otherwise consistent with the public health and safety to issue the following exemption. As set forth in 21 CFR 1300.04(h)(10), if a DEA-registered retail pharmacy does not deliver, distribute, or dispense, or offer to deliver, distribute, or dispense, controlled substances by means of the Internet, other than to communicate prescription information to an automated dispensing system for which it holds a separate registration at a long term care facility, that retail pharmacy is exempted from the definition of an online pharmacy. As a result, such a pharmacy is not required to obtain a modified registration and is not subject to the reporting requirement of 21 U.S.C. 827(d)(2) or the additional requirements relating to online pharmacies set forth in 21 U.S.C. 831.

#### VI. Criminal Provisions of the Ryan Haight Act

The Ryan Haight Act adds two new criminal offenses to the CSA. The first new offense is set forth in 21 U.S.C. 841(h)(1), which states:

It shall be unlawful for any person to knowingly or intentionally—

(A) Deliver, distribute, or dispense a controlled substance by means of the Internet, except as authorized by [the CSA]; or

(B) Aid or abet (as such terms are used in section 2 of title 18, United States Code) any activity described in subparagraph (A) that is not authorized by [the CSA].

The Act contains specific examples of conduct which would violate 21 U.S.C. 841(h)(1). These examples in the Act, however, are *not* an exclusive list of the types of conduct that constitute violations of 21 U.S.C. 841(h)(1). With this proviso made clear, 21 U.S.C. 841(h)(2) lists the following as examples of violations:

(A) Delivering, distributing, or dispensing a controlled substance by means of the Internet by an online pharmacy that is not validly registered with a modification

authorizing such activity as required by [21 U.S.C. 823(f)] (unless exempt from such registration);

(B) Writing a prescription for a controlled substance for the purpose of delivery, distribution, or dispensation by means of the Internet in violation of [21 U.S.C. 829(e)];

(C) Serving as an agent, intermediary, or other entity that causes the Internet to be used to bring together a buyer and seller to engage in the dispensing of a controlled substance in a manner not authorized by [21 U.S.C. 823(f) or 829(e)];

(D) Offering to fill a prescription for a controlled substance based solely on a consumer's completion of an online medical questionnaire; and

(E) Making a material false, fictitious, or fraudulent statement or representation in a notification or declaration under [21 U.S.C. 831(d) or (e)].

As these examples are largely self-illuminating, and some have already been addressed in this preamble, only limited further amplification is provided here. Paragraph (C), in particular, reflects that the Act was intended not only to prohibit DEA registrants from using the Internet to facilitate the unlawful dispensing of controlled substances, but to also prohibit non-DEA registrants from doing so. Most notably, paragraph (C) is aimed squarely at the criminal facilitator whose "business plan" for operating a rogue online pharmacy is to recruit an unscrupulous practitioner to write prescriptions based on insufficient or nonexistent medical evaluations and/or an unscrupulous pharmacist to fill such prescriptions.

The Act contains certain categories of conduct that do not result in the participants falling within the Act's definition of an online pharmacy. Specifically, 21 U.S.C. 841(h)(3) states:

(A) This subsection [21 U.S.C. 841(h)(1)] does not apply to:

(i) The delivery, distribution, or dispensation of controlled substances by nonpractitioners to the extent authorized by their registration under [the CSA];

(ii) The placement on the Internet of material that merely advocates the use of a controlled substance or includes pricing information without attempting to propose or facilitate an actual transaction involving a controlled substance; or

(iii) except as provided in subparagraph (B), any activity that is limited to—

(I) the provision of a telecommunications service, or of an Internet access service or Internet information location tool (as those terms are defined in section 231 of the Communications Act of 1934) [47 U.S.C. 231]; or

(II) the transmission, storage, retrieval, hosting, formatting, or translation (or any combination thereof) of a communication, without selection or alteration of the content of the communication, except that deletion of a particular communication or material made

by another person in a manner consistent with section 230(c) of the Communications Act of 1934 [47 U.S.C. 230(c)] shall not constitute such selection or alteration of the content of the communication.

(B) The exceptions under subclauses (I) and (II) of subparagraph (A)(iii) shall not apply to a person acting in concert with a person who violates paragraph (1).

Thus, paragraph (A)(i) allows DEA-registered nonpractitioners (such as manufacturers and distributors) to utilize the Internet in carrying out activities authorized by their DEA registrations (and otherwise in conformity with the CSA) without being subject to liability under 21 U.S.C. 841(h)(1). Paragraph (A)(ii) allows for Web sites that advocate the use of controlled substances or contain pricing information "without attempting to propose or facilitate an actual transaction involving a controlled substance." Paragraph (A)(iii) exempts from application of 21 U.S.C. 841(h)(1) Internet service providers, Web hosting services, and certain other specified entities that do not alter content of Internet transmissions. However, it is crucial to bear in mind that the exception of paragraph (A)(iii) does not apply to "a person acting in concert with a person who violates [21 U.S.C. 841(h)(1)]." Thus, any person whose conduct would be sufficient to prove that he conspired to violate 21 U.S.C. 841(h)(1), or aided and abetted such violation, is not immune from prosecution under paragraph (A)(iii).

The second new criminal offense added by the Act is 21 U.S.C. 843(c)(2)(A). This provision expressly prohibits using the Internet to advertise illegal transactions in controlled substances. Specifically, this provision states:

It shall be unlawful for any person to knowingly or intentionally use the Internet, or cause the Internet to be used, to advertise the sale of, or to offer to sell, distribute, or dispense, a controlled substance where such sale, distribution, or dispensing is not authorized by [the CSA] or by the Controlled Substances Import and Export Act.

The Act further states:

Examples of activities that violate [21 U.S.C. 843(c)(2)(A)] include, but are not limited to, knowingly or intentionally causing the placement on the Internet of an advertisement that refers to or directs prospective buyers to Internet sellers of controlled substances who are not registered with a modification under [21 U.S.C. 823(f)].

Thus, for example, it is unlawful under the Act to knowingly or intentionally place an advertisement on the Internet that directs persons to a Web site that sells prescriptions for controlled substances where the operator of the

Web site is not a DEA-registered pharmacy with a modification authorizing it to operate as an online pharmacy. As another example, it is unlawful under the Act to knowingly or intentionally place an advertisement on the Internet that offers to sell a controlled substance without a prescription or that directs persons to a Web site through which a controlled substance may be purchased without a prescription.

Two important points should be noted with respect to 21 U.S.C. 843(c)(2)(A). First, to establish a violation of this felony provision, it is not necessary that the person placing the advertisement actually engage in a transaction involving a controlled substance. Rather, merely placing on the Internet an advertisement that is designed to facilitate, or offers to facilitate, an illegal sale of a controlled substance is sufficient to violate 21 U.S.C. 843(c)(2)(A). Second, the Act applies to advertisements relating to violations not only of the CSA, but also of the Controlled Substances Import and Export Act (CSIEA, which is found in 21 U.S.C. 951 through 971). Thus, it is a violation of 21 U.S.C. 843(c)(2)(A) to place an advertisement on the Internet that offers, for example, to ship controlled substances into the United States for personal medical use, since doing so would violate the CSIEA.<sup>33</sup> *What It Means to "Knowingly or intentionally deliver, distribute, or dispense a controlled substance by means of the Internet."*

The Ryan Haight Act is structured around the phrase "knowingly or intentionally deliver, distribute, or dispense a controlled substance by means of the Internet." The meaning of this phrase is therefore essential to the meaning of the Act. To explain its meaning, it is helpful to divide the phrase into two parts, starting with the latter half ("deliver, distribute, or dispense a controlled substance by means of the Internet"). The Act itself contains the following definition:

<sup>33</sup> Under the CSIEA, the importation of controlled substances into the United States is prohibited except by persons registered with DEA to do so or persons exempted from such requirement. 21 U.S.C. 952, 957, 960. In accordance with the CSIEA, DEA has issued a regulation authorizing a person to import certain controlled substances for personal medical use, provided the person has the drugs in his possession upon entering the United States, makes the required declaration to the U.S. Customs and Border Protection, and otherwise complies fully with the requirements of the regulation. 21 CFR 1301.26; 69 FR 55343 (2004). Under no circumstances is it permissible under the CSIEA or the regulations for a person to have controlled substances shipped into the United States for personal medical use.

The term "deliver, distribute, or dispense by means of the Internet" refers, respectively, to any delivery, distribution, or dispensing of a controlled substance that is caused or facilitated by means of the Internet.

21 U.S.C. 802(51) (emphasis added). Given that the phrase "deliver, distribute, or dispense by means of the Internet" has the foregoing definition, the next question is: What does it mean to "knowingly or intentionally" deliver, distribute, or dispense a controlled substance by means of the Internet?

The phrase "knowingly or intentionally" has been a part of the CSA since its enactment in 1970. Among other provisions, 21 U.S.C. 841(a)(1) (the most widely utilized criminal provision of the CSA) makes it an offense to "knowingly or intentionally \* \* \* manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance" except as authorized by the CSA. There are numerous reported federal cases, some of which are discussed below, in which practitioners and pharmacists have been convicted of violating 21 U.S.C. 841(a)(1). These cases establish clear precedent for interpreting the phrase "knowingly or intentionally" in the context of practitioners who unlawfully prescribe controlled substances and pharmacists who unlawfully fill prescriptions for controlled substances. Specifically, a practitioner may be convicted of knowingly or intentionally dispensing controlled substances in violation of the CSA where the practitioner either (i) had actual knowledge of the illegal activity or (ii) was presented with facts that put him on notice that criminal activity was particularly likely and yet intentionally failed to investigate those facts.<sup>34</sup> The following statement by one federal court of appeals exemplifies the standard under which pharmacists may be held liable for knowingly or intentionally dispensing controlled substances in violation of the CSA:

The question, then, in any case where a pharmacist is charged with illegal distribution of controlled substances, is whether he knew that the purported prescription was not issued for a legitimate medical purpose or in the usual course of medical practice. The key element of knowledge may be shown by proof that the defendant deliberately closed his eyes to the true nature of the prescription.<sup>35</sup>

Another federal court has similarly stated that a pharmacist may be

<sup>34</sup> *United States v. Katz*, 445 F.3d 1023, 1031 (8th Cir. 2006), cert. denied, 127 S.Ct. 421 (2006).

<sup>35</sup> *United States v. Lawson*, 682 F.2d 480, 482 (4th Cir. 1982) (citations omitted), cert. denied, 459 U.S. 991 (1982).

convicted of unlawfully dispensing controlled substances where the evidence establishes that the pharmacist "deliberately closed his eyes to wrongdoing that should have been obvious to him."<sup>36</sup> Courts have referred to such conduct as "willful blindness" or "deliberate ignorance." As one court has stated:

Ignorance is deliberate if the defendant was presented with facts that put her on notice that criminal activity was particularly likely and yet she intentionally failed to investigate those facts. \* \* \* If, in light of certain obvious facts, reasonable inferences support a finding that a defendant's failure to investigate is equivalent to 'burying one's head in the sand,' the jury may consider willful blindness as a basis for knowledge.<sup>37</sup>

Thus, a pharmacist who fills a prescription that was issued in violation of any provision of the Act may be held criminally liable under 21 U.S.C. 841(h)(1) if he did so knowingly or intentionally—that is, if he either (i) had actual knowledge of the violation or (ii) deliberately disregarded facts that would have led a reasonable pharmacist to be highly suspicious about the likelihood of such a violation. Likewise, a practitioner who writes a prescription in violation of the Act may be held criminally liable under 21 U.S.C. 841(h)(1) if he did so knowingly or intentionally—which can be proven by showing that either (i) the practitioner had actual knowledge of the violation or (ii) the practitioner deliberately disregarded facts that would have led a reasonable practitioner to be highly suspicious about the likelihood of such a violation.

#### VII. Additional Information About the Ryan Haight Act for Pharmacists, Practitioners, Other Registrants, and Members of the Public

This section provides additional information specifically tailored to various categories of persons who are likely to be affected by, or otherwise have an interest in, the Ryan Haight Act. This information must be read in conjunction with the general information explaining the Act provided above. For example, the definitions of the terminology used in the Act will not be repeated in this section (due to their length) and should be reviewed as necessary by returning to the appropriate sections of the preamble.

##### A. Additional Specific Information for Pharmacists

If you are a pharmacist, and your DEA-registered pharmacy falls within

the definition of an "online pharmacy," your pharmacy must, beginning on April 13, 2009, obtain from DEA a modification of its registration authorizing it to operate as an online pharmacy. (DEA will issue to the pharmacy a Certificate of Registration indicating the modification of registration.) The Ryan Haight Act contains several exceptions to the definition of an online pharmacy, so you should review carefully these exceptions before submitting an application for such modification of registration. Among other things, particular consideration should be given to the exception set forth in 21 U.S.C. 802(52)(B)(viii) that excludes from the definition of an online pharmacy those DEA-registered pharmacies "whose dispensing of controlled substances via the Internet consists solely of \* \* \* (I) refilling prescriptions for controlled substances in schedule III, IV, or V, as defined in paragraph [21 U.S.C. 802(55)] or (II) filling new prescriptions for controlled substances in schedule III, IV, or V, as defined in paragraph [21 U.S.C. 802(56)]."

Also, the regulations being issued here exempt from the definition of online pharmacy any registered pharmacy "whose delivery, distribution, or dispensing of controlled substances by means of the Internet consists solely of \* \* \* filling prescriptions that were electronically prescribed in a manner authorized by this chapter and otherwise in compliance with the Act." Given these exceptions to the definition of an online pharmacy, DEA anticipates that the overwhelming majority of pharmacies in the United States, if they follow their current practices, will not, as of April 13, 2009, fall within the definition of an online pharmacy. However, as of April 13, 2009, if a pharmacist knowingly or intentionally dispenses a controlled substance by means of the Internet, and the pharmacy fits within the definition of an online pharmacy, but does not hold a modified DEA registration authorizing it to operate as an online pharmacy, the pharmacy and the pharmacist are violating 21 U.S.C. 841(h)(1) and subject to potential criminal prosecution and loss of the pharmacy's DEA registration. Accordingly, if the anticipated activities of your pharmacy will render it an online pharmacy within the meaning of the Act, you should submit to DEA your application for a modified registration as early as possible, since you will not be permitted to engage in the activities of an online pharmacy until DEA has approved such application. To expedite matters, DEA has established an online

application process for registrants to apply for such modification of registration.

In addition, as explained earlier in this preamble, any pharmacy that fits within the Act's definition of an online pharmacy must display certain information on its Web site and make certain notifications to DEA, as required by the Act and the regulations being issued here. Also, if a pharmacy has applied for and been granted a modification of its registration authorizing it to operate as an online pharmacy, it is obligated to submit monthly reports of all controlled substances dispensed by any means (walk-in business, dispensing by mail, or any other type of dispensing—whether by means of the Internet or not), provided such dispensing meets or exceeds the threshold amounts.

A pharmacist has always had a corresponding responsibility to ensure that any dispensing of controlled substances conforms with the CSA and DEA regulations.<sup>38</sup> That same corresponding responsibility now applies with respect to the new requirements of the Ryan Haight Act and the implementing regulations. That is, a pharmacist's corresponding responsibility now includes ensuring that controlled substances are dispensed in conformity with the Ryan Haight Act. For example, under the Act, a pharmacist may not knowingly or intentionally fill a prescription for a controlled substance that was issued in violation of the inperson medical evaluation requirement of 21 U.S.C. 829(e).

How does a pharmacist, when presented with a prescription (whether it is a written prescription presented in person, an oral prescription, a faxed prescription, or otherwise) know whether the prescription was "dispensed by means of the Internet," and thus subject to the requirements of the Act? Again, under the law, a pharmacist has a corresponding responsibility to ensure that any prescription filled was issued in conformity with the law and regulations. The same legal standard that has always applied in determining whether a pharmacist met this responsibility will also apply in determining whether the pharmacist acted properly in filling a prescription subject to the requirements of the Ryan Haight Act. If the pharmacist either (i) had actual knowledge that the prescription was issued by means of the Internet and that the requirements of the Act were not met or (ii) in view of all

<sup>36</sup> *United States v. Veal*, 23 F.3d 985, 988 (6th Cir. 1994).

<sup>37</sup> *Katz*, 445 F.3d at 1031.

<sup>38</sup> See 21 CFR 1306.04(a).

the circumstances surrounding a particular prescription, and, in the exercise of proper professional practice, should have known of such violation, or deliberately closed his eyes to circumstances indicative of a possible violation, or otherwise failed to take appropriate steps that a professional pharmacist should take to investigate suspicious circumstances, the pharmacy and pharmacist may be deemed to have knowingly or intentionally violated 21 U.S.C. 841(h)(1).

Depending on the circumstances, the relevant factors for this inquiry might include: the number of prescriptions received from a practitioner; the practitioner's pattern of prescribing; the address of the patient in relation to that of the practitioner; and the distance from the practitioner to the pharmacy. If, taking factors such as these into account, the pharmacist either (a) actually knows that the patient to whom a prescription for a controlled substance was issued was steered to the practitioner through a Web site or (b) should reasonably suspect so and fails to verify, the pharmacist who fills such a prescription will have knowingly or intentionally dispensed a controlled substance by means of the Internet. If such dispensing occurs, both the pharmacy and the pharmacist fall within the definition of an online pharmacy, and both will automatically violate 21 U.S.C. 841(h)(1) if the pharmacy does not have a modified DEA registration authorizing it to operate as an online pharmacy. Again, such a violation, or any other transgression by a pharmacist of the corresponding responsibility as it pertains to the requirements of the Act may result in criminal prosecution of the pharmacist and/or administrative proceedings to revoke the pharmacy's registration.

Pharmacists should also note that the new requirements of the Act are in addition to, and not in lieu of, the longstanding requirement that all prescriptions for controlled substances be issued by a practitioner acting in the usual course of professional practice and otherwise in conformity with the CSA and DEA regulations. Thus, when a prescription for a controlled substance has been issued by means of the Internet, even if the pharmacy that fills the prescription has obtained from DEA a modification of its registration, and even if the pharmacist has confirmed that the prescribing practitioner has conducted at least one in-person medical evaluation of the patient, the pharmacist still has the corresponding responsibility to ensure that the prescription was issued for a legitimate

medical purpose in the usual course of professional practice. For example, if the pharmacist knows that a prescription for a controlled substance was issued by a practitioner who works for a Web site that sends its customers to practitioners for a one-time sham medical evaluation with the intent to sell prescriptions to the customers repeatedly thereafter with no in-person follow-up evaluations, the fact that the practitioner conducted an in-person "evaluation" purporting to comply with the Act does not excuse the pharmacist from fulfilling his corresponding responsibility to fill only those prescriptions for controlled substances that were issued for a legitimate medical purpose in the usual course of professional practice.

To list another common practice of rogue Internet site operators, if you are an owner of a pharmacy and you are approached by an "entrepreneur" who offers to funnel to you large quantities of prescriptions for filling in exchange for a fee, there is a strong possibility that you are being asked to serve as the supplier to a rogue Web site. This is especially so if such "entrepreneur" is not affiliated with a legitimate health care organization. Again, the rogue Web sites that the Act was designed to eliminate often depend on the assistance of DEA-registered pharmacies. If you as a pharmacy owner or pharmacist are asked to participate in a scheme that raises suspicions about compliance with the Act, you are risking potential criminal liability and loss of DEA registration if you agree to participate without taking reasonable steps to rule out the possibility that the scheme will violate the Act.

A pharmacist is not, however, obligated to know what cannot be known through the exercise of sound professional pharmacy practice. For example, it is conceivable that a customer could walk into a pharmacy with a prescription that was issued by means of the Internet (or such a prescription could be faxed to a pharmacy) with the pharmacist having no reasonable basis to know or suspect that it was issued by means of the Internet. As long as the pharmacist meets his corresponding responsibility to take reasonable steps under the circumstances to ensure that the prescription was issued in accordance with the requirements of the Ryan Haight Act (as well as all other applicable requirements of the CSA and DEA regulations), the pharmacist will not be held strictly liable for filling a prescription that he could not reasonably have known was issued by means of the Internet. Thus, it is

absolutely unnecessary for a pharmacy to apply for a modification of its DEA registration authorizing it to operate as an online pharmacy for the sole purpose of ensuring that it does not—despite the exercise of sound professional judgment—inadvertently fill a prescription that was issued by means of the Internet.

#### *B. Additional Specific Information for Practitioners*

If you are a physician, dentist, veterinarian, mid-level practitioner, or other practitioner registered with DEA to prescribe, administer, or dispense controlled substances, and your activities involving controlled substances are limited to those authorized by your registration, you are exempted under the Ryan Haight Act from the definition of an "online pharmacy." As a result, you are not subject to the requirement of obtaining a modified DEA registration that applies to pharmacies that dispense controlled substances by means of the Internet. Nonetheless, there are other requirements of the Act and the implementing regulations that, depending on the nature of your practice, might apply to you.

DEA believes that the overwhelming majority of practitioners in the United States, based on their current practices, do not engage in activities that constitute delivering, distributing, or dispensing controlled substances by means of the Internet.<sup>39</sup> Accordingly, the overwhelming majority of practitioners need not change their practices because of the enactment of the Ryan Haight Act. However, if you are a DEA-registered practitioner who prescribes or otherwise dispenses a controlled substance by means of the Internet, you must comply with the provisions of the Act that apply to you.

First, if you are a DEA-registered practitioner who prescribes or otherwise dispenses a controlled substance by means of the Internet, you must comply

<sup>39</sup> As discussed above, the electronic prescribing of controlled substances is not currently permitted under the DEA regulations, but DEA has proposed regulations that, once finalized, will allow such practice. The electronic prescribing of controlled substances through use of the Internet does, as explained above, constitute delivering, distributing, or dispensing controlled substances by means of the Internet. Nonetheless, since the overwhelming majority of practitioners only prescribe controlled substances to patients for whom they have conducted an in-person medical evaluation, and only for a legitimate medical purpose in the usual course of professional practice, it is anticipated that the overwhelming majority of practitioners will continue this practice once electronic prescribing of controlled substances becomes permissible under the DEA regulations. If so, such practitioners would satisfy the "valid prescription" requirement of the Ryan Haight Act.

with the provision of the Act relating to the in-person medical evaluation requirement, which is set forth in 21 U.S.C. 829(e). Certain exceptions apply to this requirement, as are discussed above in this preamble. Note, however, that the Act expressly states that compliance by a practitioner with the in-person medical evaluation requirement does not, by itself, satisfy the requirement that every prescription be issued for a legitimate medical purpose in the usual course of professional practice. Whether a prescription was issued for a legitimate medical purpose in the usual course of professional practice must, as always, be determined based on the totality of the circumstances under which a particular prescription was issued to a particular patient. As DEA has previously stated, "DEA recognizes that the overwhelming majority of American physicians who prescribe controlled substances do so for legitimate medical purposes [and] exercise the appropriate degree of medical supervision—as part of their routine practice during office visits."<sup>40</sup> However, this favorable characterization cannot be applied to the very small percentage of practitioners who write prescriptions on behalf of rogue Internet Web sites. Indeed, the main reason Congress enacted the Ryan Haight Act was to bring an end to the rogue Web sites that hire unscrupulous practitioners to write prescriptions without a legitimate medical purpose and outside the usual course of professional practice.

If you are a practitioner who knowingly or intentionally prescribes or otherwise dispenses controlled substances on behalf of a particular Web site, and if that Web site is not compliant with the requirements of the Act and the implementing regulations, you are dispensing controlled substances by means of the Internet in a manner not authorized by the Act. Doing so constitutes a violation of 21 U.S.C. 841(h)(1) and may result in criminal prosecution and/or administrative proceedings to revoke your DEA registration.

If you are a practitioner who writes prescriptions on behalf of a particular Web site, your name must appear prominently on that Web site. (This requirement helps to distinguish those Web sites that are compliant with the Act and the implementing regulations from those that are not compliant.) If such Web site is operated on behalf of a group medical practice in which you participate, it is sufficient that your

name (along with the names of your fellow practitioners who write prescriptions on behalf of the site) are posted in a visible and clear manner on the homepage of the Web site, or on a page directly linked thereto in which the hyperlink is also visible and clear on the homepage.<sup>41</sup> It is anticipated that most every medical office in the United States that currently has a Web site is already in compliance with this provision as it is common practice for such Web sites to post in such manner the names of the practitioners. If, however, you are one of what is anticipated to be a very small number of practitioners who, beginning on or after April 13, 2009 (the effective date of the Ryan Haight Act), writes prescriptions on behalf of a Web site of a DEA-registered pharmacy, the Act requires the Web site to post additional information identifying you. Specifically, the Web site must post the following information in a visible and clear manner on the homepage of each Internet site it operates, or on a page directly linked thereto in which the hyperlink is also visible and clear on the homepage: "The name, address, telephone number, professional degree, and States of licensure of any practitioner who has a contractual relationship to provide medical evaluations or issue prescriptions for controlled substances, through referrals from the Web site or at the request of the owner or operator of the Web site, or any employee or agent thereof."<sup>42</sup>

How does a practitioner know whether he is writing prescriptions that are issued through, or on behalf of, a Web site? In some cases, this will be obvious to the practitioner. For example, if a practitioner is approached by a person who offers to pay the practitioner to write prescriptions for "patients" who will be routed to the practitioner through the Web site, the practitioner has actual knowledge that

<sup>41</sup> As stated in 21 CFR 1304.50: "For a Web site to identify itself as being exempt from the definition of an online pharmacy by virtue of section 102(52)(B)(ii) of the Act (21 U.S.C. 802(52)(B)(ii)), the Web site shall post in a visible and clear manner on its homepage, or on a page directly linked thereto in which the hyperlink is also visible and clear on the homepage, a list of the DEA-registered nonpharmacy practitioners who are affiliated with the Web site. Any nonpharmacy practitioner affiliated with such a Web site is responsible for compliance with this section. An institutional practitioner that otherwise complies with the requirements of the Act and this chapter will be deemed to meet the requirements of this section if, in lieu of posting the names of each affiliated individual practitioner, it posts its name (as it appears on its Certificate of Registration) in a visible and clear manner on its homepage and in a manner that identifies itself as being responsible for the operation of the Web site."

<sup>42</sup> 21 U.S.C. 831(c)(6).

he is being asked to dispense controlled substances by means of the Internet within the meaning of the Act. (As most practitioners would immediately recognize, such a proposal is inherently suspect, since the legitimate practice of medicine is not structured around writing prescriptions for controlled substances and being compensated primarily or exclusively on that basis.)<sup>43</sup> The profitability of rogue Internet Web sites typically depends on the ability of the criminal facilitator who operates the site to recruit unscrupulous practitioners to enter into such types of contractual arrangements.

In response to the enactment of the Ryan Haight Act, some rogue Web sites have come up with the following approach in an effort to circumvent the new law. Drug-seeking customers who visit the rogue Web site are told that they should arrange a visit with one of the practitioners affiliated with the site to satisfy the Act's requirement of an in-person medical evaluation. Once the practitioner has gone through the motions of conducting what purports to be a medical evaluation, the "patient" will be permitted to purchase controlled substances (or prescriptions therefor) through the Web site in perpetuity, without having to see the practitioner in person again. A practitioner who might be inclined to consider entering into a contract with the operator of such a rogue Web site should consider that, in all likelihood, such an operation violates the Act—despite its purported compliance with the in-person medical evaluation requirement. For one, under the Act, the only persons who may operate Web sites through which controlled substances are prescribed or otherwise dispensed are DEA-registered practitioners (pharmacies and nonpharmacy practitioners).<sup>44</sup> Thus, a non-DEA registrant may not operate a Web site that constitutes an "online pharmacy" within the meaning of the Act (which includes, for example, a Web site that sells prescriptions for controlled substances or fills such prescriptions). Second, even in the unlikely event that the person who is offering the practitioner the opportunity to participate in such a Web site is a DEA registrant with the appropriate registration allowing it to dispense controlled substances by means of the

<sup>43</sup> Such an arrangement whereby compensation is based primarily or exclusively on the number of prescriptions for controlled substances issued is a "red flag" indicating that diversion of controlled substances into illicit channels might be occurring—regardless of whether the Internet is involved.

<sup>44</sup> See 21 U.S.C. 802(51), 802(52), 823(f), & 841(h)(1).

<sup>40</sup> 71 FR 52716, 52719 & 52723 (2006 DEA policy statement).

Internet, the prescribing practitioner must ensure that the Web site properly displays his name and the other required information in the manner required by the Act and the implementing regulations.

Further, even if the Web site has the required registration and posts the required information, it is difficult to envision how a conscientious practitioner could enter into a contract to provide medical evaluations and/or issue prescriptions through referrals from a Web site that is designed primarily to attract and supply persons seeking to obtain controlled substances for other than legitimate medical purposes (rather than to provide legitimate medical care to patients without a predetermined goal of selling drugs or prescriptions). Indeed, a Web site that operates in such a manner—such as by offering to arrange in-person “medical evaluations” for the purpose of allowing customers to obtain controlled substances through the Web site indefinitely thereafter—should be viewed by a practitioner as a “red flag” indicating that diversion of controlled substances to illicit channels might be occurring.

The same considerations apply if you, as a practitioner, are offered a contract or otherwise presented with a proposal to write prescriptions to customers of a Web site based on reviewing online questionnaires or faxed “medical records” or by answering telephone calls through a phone number affiliated with the Web site. If these customers are being referred to you through the Web site or at the request of the owner or operator of the Web site, any prescriptions for controlled substances you write for the customers constitute “dispensing by means of the Internet” within the meaning of the Act. As explained above, a practitioner who dispenses a controlled substance by means of the Internet in violation of the Act may be held criminally liable under 21 U.S.C. 841(h)(1) if he did so knowingly or intentionally—which can be proven by showing that either (i) the practitioner had actual knowledge of the violation or (ii) the practitioner deliberately disregarded facts that would have led a reasonable practitioner to be highly suspicious about the likelihood of such a violation. In addition, any transgression of the Act may result in administrative action to revoke the practitioner’s DEA registration.

With the foregoing considerations in mind, DEA again emphasizes that the current practices of the overwhelming majority of practitioners in the United States do not involve delivering,

distributing, or dispensing controlled substances by means of the Internet. This means that the vast majority of practitioners need not alter their current practices to conform to the requirements of the Ryan Haight Act.

#### *C. Additional Specific Information for DEA-Registered Distributors*

The ability of rogue Internet sites to supply controlled substances to persons who seek them for other than legitimate medical purposes depends largely on the existence of DEA-registered pharmacies that are willing to supply the customers of these Web sites. As the data provided at the beginning of this preamble illustrates, it takes only a relatively small number of unscrupulous pharmacies, working in conjunction with rogue Internet sites, to supply enormous quantities of hydrocodone and other controlled substances, causing a substantial detrimental effect on the public health and welfare. Accordingly, if you are a DEA-registered distributor, it is critical that you are vigilant in taking appropriate steps to avoid supplying the pharmacies that service the customers of rogue Web sites.

In a September 27, 2006, letter to all DEA-registered distributors, DEA specified a number of pharmacy practices that might be indicative of diversion. While all the considerations set forth in that letter remain valid today, the enactment of the Ryan Haight Act should further assist distributors in avoiding distributing controlled substances to pharmacies that are supplying customers of rogue Web sites. For example, if you are a distributor and you know that a pharmacy is soliciting buyers of controlled substances via the Internet, or is associated with an Internet site that solicits orders for controlled substances,<sup>45</sup> you are on notice that the pharmacy is an “online pharmacy” under the Act. If so, it is unlawful, per se, for the pharmacy to be operating without a modified DEA

<sup>45</sup> As explained earlier in this preamble, the Ryan Haight Act contains an exception from the definition of “online pharmacy” for any pharmacy registered under 21 U.S.C. 823(f) whose dispensing of controlled substances via the Internet consists solely of “refilling prescriptions for controlled substances in schedule III, IV, or V” or “filling new prescriptions for controlled substances in schedule III, IV, or V” (as those terms are defined in 21 U.S.C. 802(55) and (56)). 21 U.S.C. 802(52)(B)(viii). Given these and other exceptions in the Act, it is anticipated that most pharmacies, if they continue their current practices, will not fall within the definition of an online pharmacy. However, a pharmacy that actively solicits buyers of controlled substances via the Internet or is associated with a Web site that does so cannot fall within the foregoing exception and, therefore, does constitute an online pharmacy.

registration authorizing it to operate as an online pharmacy. Under such circumstances, if the pharmacy does not have such a modified registration, it would be unlawful for you as a distributor to supply the pharmacy with controlled substances. (The pharmacy’s Certificate of Registration will reflect its status as an online pharmacy in its business activity designation.)<sup>46</sup>

Even if you do not have actual knowledge that the pharmacy is operating through a Web site, if the pharmacy’s buying patterns are of a volume or otherwise of a nature indicating a reasonable likelihood that the pharmacy is supplying customers of a Web site or otherwise engaging in practices that render it an online pharmacy within the meaning of the Ryan Haight Act, the sound course of action for the distributor would be to confirm that the pharmacy is complying with the Act prior to supplying the pharmacy with controlled substances.<sup>47</sup>

#### *D. Additional Specific Information for Consumers*

The full title of the Ryan Haight Act is “The Ryan Haight Online Pharmacy Consumer Protection Act of 2008.” As this title implies, a primary purpose of the Act is to protect consumers by ensuring that only legitimate, law-abiding Web sites dispense controlled substances via the Internet. One of the ways the Act achieves this goal is by allowing only pharmacies who are properly registered with DEA to operate Web sites through which prescriptions for controlled substances are filled. In addition, the Act and the implementing regulations require such Web sites to fully disclose to consumers certain basic information, such as the name and telephone number of the pharmacist-in-charge, a list of the states in which the pharmacy is authorized to dispense controlled substances, the names of any

<sup>46</sup> DEA provides a “Registration Validation” tool on its Web site, through which DEA registrants may query DEA’s registration database regarding another DEA registrant to gather specific information about that registrant. Information available includes: The registrant’s name, address, and DEA registration number; the date of expiration of the registration; business activity; and the schedules of controlled substances the registrant is authorized to handle.

<sup>47</sup> As with all DEA registrants, distributors have a duty to maintain effective controls against diversion of controlled substances. 21 U.S.C. 823(b)(1), 823(e)(1); 21 CFR 1301.71(a). As part of this responsibility, all distributors must design and operate a system to disclose to the registrant suspicious orders of controlled substances and must report to DEA any such suspicious orders of controlled substances in accordance with 21 CFR 1301.74(b). Failure to comply with these or any other applicable regulatory requirements may, depending on the circumstances, result in civil monetary penalties and/or administrative revocation proceedings, among other things.

practitioners who have a contractual relationship to issue prescriptions for controlled substances through referrals from the Web site, and a certification that the Web site is acting in compliance with the Act. Accordingly, the Act should make it easier for consumers to differentiate between legitimate and illegitimate Web sites that sell controlled substances.

One strong indicator of an unlawful Web site is that it lets you as a customer pick the controlled substance and then charges you a fee to arrange for a practitioner to prescribe that controlled substance to you. An unlawful Web site might further offer to refund all or part of your fee if you are not sold the prescription for your drug of choice. A Web site that engages in such practices is virtually certain to be a rogue Web site that is not operating in compliance with the Ryan Haight Act.

Consumers should also be aware that the Act also prohibits certain advertising practices relating to the types of criminal activities the Act is designed to eliminate. Specifically, the Act makes it a crime to place an advertisement on the Internet that offers to sell a controlled substance or a prescription for a controlled substance in a manner that would be illegal (in violation of the CSA or the CSIEA).<sup>48</sup> For example, the Act makes it unlawful to place an advertisement on the Internet stating: "Hydrocodone! No Prescription Needed!" (or words to the same effect). This provision of the Act also makes it illegal to place an advertisement on the Internet that refers consumers to a Web site that is operating in violation of the Act (such as one that sells controlled substances but is not properly registered with DEA). This ban on illegal Internet advertising also applies to unsolicited commercial e-mail, which is sometimes referred to as "spam" or "junk e-mail." Consequently, beginning on April 13, 2009, if you as a consumer receive an unsolicited commercial e-mail with the subject line: "Hydrocodone! No Prescription Needed!," the sender of that e-mail has violated the law. Likewise, if you receive spam directing you to a Web site that is operating in violation of the Act, the spammer has also violated the Act.

Consumers should also be wary of rogue Web sites falsely claiming that they are allowed to sell controlled substances without complying with the Ryan Haight Act because they are located outside the United States. Any

such claim is flatly wrong. In fact, as explained earlier in this preamble, it has always been unlawful under the Controlled Substances Import and Export Act (CSIEA) (even prior to the Ryan Haight Act) to ship controlled substances into the United States for personal medical use. Any person who ships controlled substances from abroad into the United States illegally, along with the person in the United States who places the order for such a shipment and thereby causes the controlled substances to be illegally shipped into the United States, violates the CSIEA and is subject to criminal prosecution.<sup>49</sup>

#### VIII. Regulatory Changes To Implement the Ryan Haight Act

This section summarizes the regulations contained in this Interim Rule, which are being issued to implement the Ryan Haight Act. This section should be viewed as merely a summary provided for the convenience of the reader, and any registrant subject to the Ryan Haight Act should read carefully the entire preamble along with the text of the regulations being issued here.

##### A. Notification and Registration

As provided in 21 CFR 1304.40, all online pharmacies that intend to dispense controlled substances by means of the Internet must provide DEA with a thirty-day notice of such intent. To do this, they must apply for a modified registration via the online application process. The Administrator must approve the application for a modified registration and issue a Certificate of Registration indicating the modification before the online pharmacy may engage in any activity of an online pharmacy. As discussed previously in the preamble, the only entities that may apply for a modified registration are registrants with a valid Certificate of Registration (DEA Form 223) as a pharmacy. If you are not registered with DEA as a pharmacy and you intend to dispense controlled substances by means of the Internet, you must first apply for registration as a pharmacy in accordance with 21 CFR 1301.13. Upon receipt of the Certificate of Registration as a pharmacy from the Administrator, you may then apply for a modification to your registration to operate as an online pharmacy.

The Administrator may deny an application for such registration or such modification of registration if the Administrator determines that the issuance of such registration or

modification would be inconsistent with the public interest. 21 CFR 1301.19. The same statutory criteria used in determining the public interest for purposes of evaluating an application for registration—those found in 21 U.S.C. 823(f)—will be used in evaluating an application for a modification of registration to operate as an online pharmacy.

An online pharmacy must make a separate thirty-day advance notice to the State boards of pharmacy in each State in which it intends to offer to sell, deliver, distribute, or dispense controlled substances.

In accordance with 21 U.S.C. 831, the following information must be included in the notification to DEA that must be submitted as part of the Application for Modification of Registration:

- All Internet pharmacy site disclosure information as listed below.
- A certification, under penalty of perjury, that the Internet pharmacy site disclosure information that is posted on the online pharmacy's Web site is true and accurate.
- A listing of all Internet Web site addresses (also known as the uniform resource locator or URL) owned by the online pharmacy to conduct its online business activities.
- A certification that the online pharmacy will notify DEA of any changes to any of its Internet Web site addresses (URLs) at least 30 days in advance.
- The name, address, telephone number, professional degree, DEA registration numbers and States of licensure of any practitioner who has a contractual relationship to provide medical evaluations or issue prescriptions for controlled substances, through referrals from the Web site or at the request of the owner or operator of the Web site, or any employee or agent thereof.
- The DEA registration numbers of each pharmacy that delivers, distributes, or dispenses controlled substances pursuant to orders made on, through, or on behalf of the online pharmacy.

Pharmacies that intend to dispense controlled substances by means of the Internet must apply for the modified registration using the online registration process by going to the DEA Office of Diversion Control Web site at <http://www.deadiversion.usdoj.gov>. Registrants must positively acknowledge and agree to several statements during the application process. These acknowledgements will be printed on the registrant's receipt of registration for future reference. The following is a list of the acknowledgments with which a

<sup>48</sup> The exact wording of this provision is found in 21 U.S.C. 843(c)(2) and is recited above in this preamble.

<sup>49</sup> 21 U.S.C. 952, 957, 960(a)(1).

registrant must agree as part of the online pharmacy application process:

1. Pursuant to section 309(e) of the Controlled Substances Act (21 U.S.C. 829(e)), you, as an online pharmacy, acknowledge and agree that no controlled substance that is a prescription drug may be delivered, distributed, or dispensed by means of the Internet without a valid prescription.

2. Pursuant to 21 CFR 1306.09, you, as an online pharmacy, acknowledge and agree that a prescription for a controlled substance may only be dispensed by means of the Internet by a pharmacist, acting in the usual course of his professional practice, and employed in a pharmacy whose registration has been modified to authorize it to operate as an online pharmacy.

3. You, as an online pharmacy, acknowledge and understand that you may not engage in any activity of an online pharmacy, as defined in 21 CFR 1300.04(h), until your application for modified registration to operate as an online pharmacy is granted and a Certificate of Registration indicating the modification is issued by the Administrator (DEA Form 223).

4. You, as an online pharmacy, understand that the Administrator may deny an application for a modification of registration if the Administrator determines that the issuance of such modification would be inconsistent with the public interest. In determining the public interest, the Administrator considers the factors listed in 21 U.S.C. 823(f).

5. Pursuant to section 303(f) of the Controlled Substances Act (21 U.S.C. 823(f)), you, as an online pharmacy, certify that you are authorized by the appropriate state authority(ies) to modify your existing DEA registration to authorize you to dispense schedule II-V controlled substances by means of the Internet.

6. Pursuant to 21 CFR 1301.19, if you, as an online pharmacy, cease to dispense controlled substances by means of the Internet, you acknowledge and agree that you shall promptly notify the Administrator by modifying your registration to reflect the appropriate business activity.

7. Pursuant to section 307(d) of the Controlled Substances Act (21 U.S.C. 827(d)), you, as an online pharmacy, understand you are required to report the dispensing of controlled substances by means of the Internet to the Administrator in the manner set forth in 21 CFR 1304.55. This report will include the total quantity of each controlled substance that the pharmacy dispenses each calendar month. The report must be submitted to DEA electronically via online reporting, electronic file upload, or other means as approved by DEA. The monthly report shall include the date range of the reporting period, the NDC, and total quantity of each controlled substance dispensed. Reporting shall include all controlled substances dispensed via Internet transactions, mail-order, face-to-face transactions, or any other means. The report shall be submitted to DEA by the 15th day of the following month. (For threshold amounts refer to DEA Web site: <http://www.deadiversion.usdoj.gov>)

8. Pursuant to section 311(a) of the Controlled Substances Act (21 U.S.C. 831(a)), you, as an online pharmacy, agree to display at all times on your homepage, in a visible and clear manner, a statement that your online pharmacy complies with the requirements of section 311 of the Act (21 U.S.C. 831) with respect to the delivery or sale or offer for sale of controlled substances.

9. Pursuant to section 311(b) of the Controlled Substances Act (21 U.S.C. 831(b)), you, as an online pharmacy, acknowledge and agree to comply with the requirements of State law concerning the licensure of pharmacies in each State from which and to which you, deliver, distribute, or dispense, or offer to deliver, distribute, or dispense controlled substances by means of the Internet.

10. Pursuant to section 311(c) of the Controlled Substances Act (21 U.S.C. 831(c)), you, as an online pharmacy, acknowledge and agree to post the following Internet Pharmacy Site Disclosure information in a visible and clear manner on the homepage of each Internet site you operate, or on a page directly linked thereto in which the hyperlink is also visible and clear on the homepage:

(A) The name and address of the pharmacy as it appears on the pharmacy's DEA Certificate of Registration.

(B) The pharmacy's telephone number and e-mail address.

(C) Name of pharmacist-in charge, professional degree, States of licensure, and telephone number.

(D) List of States in which the pharmacy is licensed to dispense controlled substances.

(E) Certification that the pharmacy is registered to deliver, distribute, or dispense by means of the Internet, controlled substances.

(F) Practitioner's name, address, telephone number, professional degree, and States of licensure of any practitioner who has a contractual relationship to provide medical evaluations or issue prescriptions for controlled substances, through referrals from the Web site or at the request of the owner or operator of the Web site, or any employee or agent thereof.

(G) The following statement: "This online pharmacy is obligated to comply fully with the Controlled Substances Act and DEA regulations. As part of this obligation, this online pharmacy has obtained a modified DEA registration authorizing it to operate as an online pharmacy. In addition, this online pharmacy will only dispense a controlled substance to a person who has a valid prescription issued for a legitimate medical purpose based upon a medical relationship with a prescribing practitioner. This includes at least one prior in-person medical evaluation in accordance with section 309 of the Controlled Substances Act (21 U.S.C. 829), or a medical evaluation via telemedicine in accordance with section 102(54) of the Controlled Substances Act (21 U.S.C. 802(54))."

11. Pursuant to section 311(d)(2)(A) of the Controlled Substances Act (21 U.S.C. 831(d)(2)(A)), you, as an online pharmacy, certify that the Internet Pharmacy Site Disclosure information disclosed on your

Web site, under penalty of perjury, is true and accurate.

12. Pursuant to section 311(d) of the Controlled Substances Act (21 U.S.C. 831(d)), you, as an online pharmacy, acknowledge and agree that, thirty days prior to offering a controlled substance for sale, delivery, distribution, or dispensing, you must notify the Administrator and the State boards of pharmacy in any States in which you offer to sell, deliver, distribute, or dispense controlled substances. By fully completing and submitting this application, you will satisfy this requirement with respect to notifying the Administrator. However, you must separately notify the State boards of pharmacy as required by the Act. You understand that subsequent online pharmacy registration renewals will be accomplished by the online process and the appropriate renewal fee will apply.

13. You understand that in accordance with section 401(h) of the Act (21 U.S.C. 841(h)), as of April 13, 2009, it is unlawful for any online pharmacy to deliver, distribute, or dispense a controlled substance by means of the Internet unless such online pharmacy is validly registered with a modification of DEA registration authorizing the dispensing of controlled substances by means of the internet.

14. Pursuant to section 311(e) of the Controlled Substances Act (21 U.S.C. 831(e)), you, as an online pharmacy, understand and agree that on and after the date you apply for a modified registration, you will display on your homepage, in the manner described in 21 CFR 1304.40(d), a declaration that you have made the required notifications to the DEA Administrator.

There is no fee to apply for modification of an existing DEA registration. When a pharmacy makes application for a modified registration to conduct business as an online pharmacy, and the Administrator issues a Certificate of Registration for the modification to that pharmacy, the registration period continues from the date of the pharmacy's prior registration. When, however, an online pharmacy makes application to renew the modified registration, it will incur the appropriate application fee and, if approved, a new three-year registration period will begin.

An online pharmacy that seeks to discontinue its modification of registration authorizing it to dispense controlled substances by means of the Internet, but continue its business activity as a pharmacy, must so notify the Administrator through the online application process for modification of registration. The Administrator will issue a new Certificate of Registration to the pharmacy based on the changes made to its registration. Once the registration has been changed back to its previous status (retail pharmacy), the pharmacy is no longer authorized to dispense controlled substances by means of the Internet.

### B. Licensure

An online pharmacy must comply with the requirements of State law concerning the licensure of pharmacies in each State from which it, and in each State to which it, delivers, distributes, or dispenses or offers to deliver, distribute, or dispense controlled substances by means of the Internet. 21 U.S.C. 831(b).

### C. Online Pharmacy Internet Site Disclosure

Online pharmacies have a continual obligation under the Ryan Haight Act to make certain disclosures on their Web sites required by the Act. Consequently, an online pharmacy must maintain an active Web site to post the required information, statements, and other disclosures required by the Act and update the information as necessary.

### D. Statement of Compliance

The Act requires that each online pharmacy shall display, at all times and in a visible and clear manner, on its homepage a statement that it complies with the requirements of section 311(a) of the Act (21 U.S.C. 831(a)) with respect to the delivery or sale or offer for sale of controlled substances. This requirement is reiterated in the regulations being issued here in 21 CFR 1304.45(a). This regulation does not require specific language to be used for this statement, but the statement must include the name of the pharmacy as displayed on its DEA Certificate of Registration and clearly state that the pharmacy is in compliance with 21 U.S.C. 831(a). The following is an example of a statement a pharmacy may post on its Web site that would meet the requirements of this provision:

XYZ Pharmacy is in full compliance with the requirements of section 311(a) of the Controlled Substances Act (21 U.S.C. 831(a)) with respect to the delivery or sale or offer for sale of controlled substances.

### E. Internet Pharmacy Site Disclosure Information

The Act<sup>50</sup> and the regulations being issued here (21 CFR 1304.45(b)) require that each online pharmacy shall post in a visible and clear manner on the homepage of each Internet Web site it operates, or on a page directly linked thereto in which the hyperlink is also visible and clear on the homepage, the following information for each pharmacy that delivers, distributes, or dispenses controlled substances

pursuant to orders made on, through, or on behalf of, that Web site:

- The name and address of the pharmacy as it appears on the pharmacy's DEA Certificate of Registration.
- The pharmacy's telephone number and active business e-mail address.
- The name, professional degree, and States of licensure of the pharmacist-in-charge, and a telephone number at which the pharmacist-in-charge can be contacted.
- A list of the States in which the pharmacy is licensed to dispense controlled substances.
- A certification that the pharmacy is registered under 21 CFR Part 1301 to deliver, distribute, or dispense controlled substances by means of the Internet.
- The name, address, telephone number, professional degree, and States of licensure with State license number of any practitioner who has a contractual relationship to provide medical evaluations or issue prescriptions for controlled substances, through referrals from the Web site or at the request of the owner or operator of the Web site, or any employee or agent thereof.

• The following statement: "This online pharmacy is obligated to comply fully with the Controlled Substances Act and DEA regulations. As part of this obligation, this online pharmacy has obtained a modified DEA registration authorizing it to operate as an online pharmacy. In addition, this online pharmacy will only dispense a controlled substance to a person who has a valid prescription issued for a legitimate medical purpose based upon a medical relationship with a prescribing practitioner. This includes at least one prior in-person medical evaluation in accordance with section 309 of the Controlled Substances Act (21 U.S.C. 829) or a medical evaluation via telemedicine in accordance with section 102(54) of the Controlled Substances Act (21 U.S.C. 802(54))."

The following is a hypothetical example of a statement that would comply with all of the requirements of 21 CFR 1304.45(b) (assuming the assertions were true):

XYZ Pharmacy,  
1 Main Street,  
[City, State, zip code],  
[Area code and telephone number],  
pharmacist@xyzpharmacy.com.  
John H. Smith, R.Ph., Pharmacist-in-  
Charge, licensed in State.

The XYZ Pharmacy is in full compliance with the requirements of section 311(a) of the Controlled Substances Act (21 U.S.C. 831(a)).

XYZ Pharmacy is licensed in [State(s)] to dispense controlled substances. The pharmacist-in-charge may be contacted at the above telephone number. XYZ Pharmacy does not have any contractual relationships with any practitioner to provide medical evaluations or issue prescriptions for controlled substances through referrals from this Web site or at the request of the owner or operator of this Web site, or any employee or agent thereof. This online pharmacy is obligated to comply fully with the Controlled Substances Act and DEA regulations. As part of this obligation, this online pharmacy has obtained a modified DEA registration authorizing it to operate as an online pharmacy. In addition, this online pharmacy will only dispense a controlled substance to a person who has a valid prescription issued for a legitimate medical purpose based upon a medical relationship with a prescribing practitioner. This includes at least one prior in-person medical evaluation in accordance with section 309 of the Controlled Substances Act (21 U.S.C. 829) or a medical evaluation via telemedicine in accordance with section 102(54) of the Controlled Substances Act (21 U.S.C. 802(54)).

### F. Declaration of Compliance

On and after the date on which an online pharmacy makes the notification and applies for a modified registration, it must display, on the homepage of its Web site, a declaration that it has made such notification/application to the Administrator.

### G. Reporting

The Act requires,<sup>51</sup> and 21 CFR 1304.55 reiterates, that each online pharmacy must submit a monthly report to the Administrator of the total quantity of each controlled substance it has dispensed the previous calendar month. This report will be due on or before the 15th day of the following month. The report must include the total amount of such dispensing by any means, including all controlled substances dispensed via Internet transactions, mail-order transactions, face-to-face transactions, or any other means. It is not required that the online pharmacy identify the means of the dispensing in its report. The report is required for every month in which the total amount of dispensing of controlled substances by the pharmacy is either (i) over 100 prescriptions filled or (ii) 5,000 or more dosage units dispensed of all controlled substances combined.

Each online pharmacy shall report a negative response to the Administrator if, during a given calendar month, its total quantity of dispensing of controlled substances falls below both of the thresholds listed above.

The reporting required by online pharmacies under 21 CFR 1304.55 must

<sup>50</sup> 21 U.S.C. 831(c).

<sup>51</sup> 21 U.S.C. 827(d)(2).

be submitted to the Administrator electronically via online reporting, electronic file upload, or other means as approved by DEA. The report shall identify controlled substances by National Drug Code (NDC) number assigned to the product under the National Drug Code System of the Food and Drug Administration.

Online pharmacies must maintain these records for at least two years. The information must be easily accessible and available for inspection by authorized DEA employees.

A pharmacy that has changed its registration status from that of an online pharmacy back to a retail pharmacy remains responsible for submitting reports in accordance with § 1304.55 of this chapter with respect to any controlled substances that it dispensed while it was registered with a modification authorizing it to operate as an online pharmacy.

#### **IX. Section-by-Section Discussion of the Interim Final Rule**

In part 1300, new § 1300.04, containing definitions relating to the dispensing of controlled substances by means of the Internet, is added. These definitions are from the definitions contained in the Ryan Haight Act. This includes definitions of the terms "covering practitioner," "deliver, distribute or dispense by means of the Internet," "filling new prescriptions for controlled substances in Schedule III, IV, or V," "homepage," "in-person medical evaluation," "Internet," "online pharmacy," "practice of telemedicine," "refilling prescriptions for controlled substances in Schedule III, IV, or V," "valid prescription," and the temporary definition of "practice of telemedicine." However, please note that the regulations being issued here expand upon the exceptions to the definition of an online pharmacy contained in the Act. Specifically, as discussed above, the regulations add two exceptions to the definition of "online pharmacy": One relating to electronic prescriptions for controlled substances issued in a manner permitted by the DEA regulations and another relating to the utilization by retail pharmacies of automated dispensing systems at long term care facilities in a manner permitted by the DEA regulations.

In part 1301 (registration of manufacturers, distributors, and dispensers of controlled substances), new § 1301.11(b) restates the requirements of the Act that any person falling within the definition of an online pharmacy must be validly registered with a modification authorizing it to operate as an online pharmacy and that

only pharmacies registered under 21 U.S.C. 823(f) may apply for such modification.

To address the modification of registration as an online pharmacy, the table in § 1301.13(e)(1) is amended in "(iv) Dispensing or instructing" to specify the application for an online pharmacy. A comment has been added in the "Coincident activities allowed" column to explain that an online pharmacy may perform the activities of both a retail and online pharmacy.

New § 1301.19 (special requirements for online pharmacies) provides in paragraphs (a), (c), and (f) that a pharmacy must request a modification of its registration authorizing it to operate as an online pharmacy by completing the online application process. This section also provides, consistent with the Ryan Haight Act, that a pharmacy registrant may not operate as an online pharmacy until the DEA Administrator grants the modified registration. Paragraph (b) requires, consistent with the Ryan Haight Act, that an online pharmacy must comply with the pharmacy license requirements of not only the State where it is located, but also of any State to which it delivers, distributes, or dispenses controlled substances. Paragraph (d) requires a pharmacy that seeks to discontinue its authorization to operate as an online pharmacy to modify its registration to reflect this change in its business activity.

Section 1301.52, which addresses termination of registrations, is revised to include modification of registration within the meaning of the Act.

Four new sections are added to 21 CFR part 1304 (records and reports of registrants) to implement the reporting requirements of the Ryan Haight Act for online pharmacies, and to specify the information the Act requires to be posted on an online pharmacy's Web site. New § 1304.40(a) requires online pharmacies to notify the Administrator and State boards of pharmacy 30 days before offering to fill prescriptions for controlled substances. Notification to the DEA Administrator will be made by applying for a modification of DEA registration. Paragraph (b) of § 1304.40 contains a list of items that must be included in the notification. Paragraph (c) requires online pharmacies in operation at the time the Ryan Haight Act becomes effective (April 13, 2009) to make this notification by May 13, 2009, but this paragraph also makes clear that, as of April 13, 2009, it is unlawful for any person to operate as an online pharmacy unless it has obtained from DEA a modification of its registration authorizing it to do so. In

addition, paragraph (d) requires that on and after an online pharmacy makes notification under this section, it shall display a declaration that it has done so. Under § 1304.40(e), an online pharmacy must notify the Administrator of any changes to the information submitted in its notification thirty days prior to the change.

New section 1304.45 specifies the data elements required to be posted on the Web site of online pharmacies in a visible and clear manner, as provided in the Act.

To identify Web sites that are operating solely on behalf of DEA-registered nonpharmacy practitioners who are acting within the scope of their registrations (and thereby exempt from the definition of an online pharmacy), new § 1304.50 requires such Web sites that dispense controlled substances by means of the Internet to display in a visible and clear manner a list of those DEA-registered nonpharmacy practitioners affiliated with the Web site.

New § 1304.55 implements the requirement of the Act that each online pharmacy make a monthly report to DEA stating the total quantity of each controlled substance the pharmacy has dispensed the previous calendar month. This report must include not only the transactions made through the online pharmacy, but also any that the pharmacy made through mail order, face-to-face, or any other transaction when the pharmacy's total dispensing of controlled substances meets or exceeds the monthly threshold of either 100 prescriptions filled or 5,000 or more dosage units dispensed. Online pharmacies that do not meet this threshold in a given month are required to so notify DEA.

In part 1306 (prescriptions), new § 1306.09 includes requirements for prescriptions that track the requirements of the Act. Paragraph (a) specifies that no controlled substance may be delivered, distributed, or dispensed by means of the Internet without a valid prescription (using the definition of a valid prescription contained in the Act). Also consistent with the Act, paragraph (b) provides that a prescription may only be filled by a pharmacy whose registration has been modified as specified in the Act. Finally, paragraph (c) applies to online pharmacies the requirements of sections 1306.15 and 1306.25 regarding transfers of prescriptions between pharmacies.

## X. Regulatory Certifications

### A. Administrative Procedure Act

The Administrative Procedure Act (APA) generally requires agencies to publish a notice of proposed rulemaking and allow for a period of public comment prior to implementing new rules. The APA also provides, however, that agencies can be excepted from these requirements "when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest." 5 U.S.C. 553(b)(B). DEA has concluded that "good cause" exists to promulgate this rule as an Interim Final Rule rather than a proposed rule for the following reasons.

As explained above, the Ryan Haight Act contains the following provision specifically addressing the issuance of interim rules to implement the Act:

The [DEA Administrator] may promulgate and enforce any rules, regulations, and procedures which may be necessary and appropriate for the efficient execution of functions under this Act or the amendments made by this Act, and, with the concurrence of the Secretary of Health and Human Services where this Act or the amendments made by this Act so provide, promulgate any interim rules necessary for the implementation of this Act or the amendments made by this Act, prior to its effective date.<sup>52</sup>

It is evident from the foregoing provision that Congress envisioned that DEA might need to issue regulations on an interim basis to implement the Ryan Haight Act prior to the Act's effective date (April 13, 2009). This provision indicates that, given the 180 days between enactment of the Act and its effective date, Congress recognized it could be impracticable for DEA to complete notice-and-comment rulemaking within a time frame that would have allowed for regulations to become effective prior to the effective date of the Act. Similarly, this provision indicates that Congress believed it would be contrary to the public interest to delay the promulgation of regulations in a manner that would prevent implementation of the Act upon its effective date. Delaying the effective date of the regulations past the effective date of the Act would also be confusing to the public and would frustrate the intent of Congress to have the new provisions of the Act take effect on April 13, 2009. Accordingly, the rules published here are effective

immediately while at the same time the agency is seeking public comment on them.

Under the APA, 5 U.S.C. 553(d), agencies must generally provide a 30-day delayed effective date for final rules. An agency may dispense with the 30-day delayed effective date requirement "for good cause found and published with the rule." 5 U.S.C. 553(d)(3). For the reasons just discussed, DEA concludes that such good cause exists to justify an immediate effective date. In addition to the reasons provided above, DEA had to make this rule effective immediately to have in place regulatory procedures that will allow legitimate pharmacies that wish to conduct activity as an "online pharmacy" to do so upon the effective date of the Act. With the immediate effective date of these regulations, pharmacies may, sufficiently in advance of the effective date of the Act, submit applications to modify their registrations as required by the Act.

### B. Executive Order 12866

The Deputy Administrator certifies that this rulemaking has been drafted in accordance with the principles in Executive Order 12866 Section 1(b). It has been determined that this is "a significant regulatory action." Therefore, this action has been reviewed by the Office of Management and Budget. As discussed above, this action is largely codifying statutory provisions and involves limited agency discretion.

*Costs.* It should be noted that the costs identified here are costs associated with activities that online pharmacies are obligated to carry out to comply with the statutory requirements of the Ryan Haight Act. The regulatory provisions listed here are those which carry forward the statutory requirements mandated by the Act.

Pharmacies with existing online operations and those that wish to begin dispensing controlled substances by means of the Internet must apply to DEA to modify their registrations. Section 1304.40 requires notification to DEA. The application for modification of registration includes the notifications required by the Act; application to DEA is made with an online form. The information required is straightforward: Names, addresses, telephone numbers, the name, professional degree, and telephone number of the pharmacist-in-charge, and required certifications.

Assembly of this information and putting it in the online form in the proper manner can be accomplished by a pharmacist (Standard Occupational Code (SOC) 29-1051). The information required for the online pharmacy Web

site is largely the same as that required for the notification, so the pharmacist's work will also provide the information needed for the Web site.

Since an online pharmacy must have a Web site to operate, the initial cost of setting up the Web site is not a cost of the rule. (In fact, it is now commonplace for even small retail establishments to have Web sites.) The only cost is that of entering the required information and certifications on the site. Given that the site is already, or must be, in place, DEA estimates that such revisions will be relatively minor in nature. Modification of the Web site to include the required information will, however, require additional work—work that requires some technical expertise with computer systems and programs, including Web sites. DEA expects that a computer support specialist (SOC 15-1041) will be required for this work.

Completion of the online application for modification of registration will require fifteen minutes of the pharmacist's time and half an hour of the computer support specialist's time to update the Web site with the required information. The Web site will require ongoing maintenance as information changes. This will require one hour per year of the computer-support specialist's time.

Section 1304.55 requires online pharmacies to report to DEA the total quantity of each controlled substance that the pharmacy has dispensed each calendar month. The report must include the total quantity of such dispensing by any means, regardless of whether the controlled substances are dispensed by means of the Internet. Such reporting is required for every calendar month in which the total quantity of controlled substances dispensed by the pharmacy meets or exceeds one of the following thresholds: 100 or more prescriptions for controlled substances filled; or 5,000 or more dosage units dispensed of all controlled substances combined.

Such reporting is not required now from pharmacies of any kind. Based upon common industry practice, DEA believes that virtually all pharmacies will have internal electronic recordkeeping systems which will include the necessary data. A computer programmer (SOC 15-1021) will be required to set up a system that will extract the required data from existing records and put it in a form that meets the rule and is suitable for transmission to DEA. DEA estimates that the initial set-up will take two hours of the programmer's time. DEA expects that maintenance of the reporting system will not entail any increment in cost

<sup>52</sup> Public Law 110-425, sec. 3(k)(1).

beyond the initial work of setting up the system. DEA further assumes that a pharmacist will require ten minutes per month to transmit the monthly report to DEA.

Table 1 presents initial unit costs.

TABLE 1—INITIAL UNIT COSTS

Requirement	Unit time (in hours)	Hourly wage, fully loaded	Unit cost
Application for Modification of Registration (pharmacist) .....	0.25	\$104.40	\$26.10
Revision of pharmacy Web site (computer support specialist) .....	0.5	47.79	23.89
Establishing reporting system (programmer) .....	2.0	75.96	151.93
<b>Total</b> .....			<b>201.92</b>

Annual ongoing costs for online pharmacies comprise the cost of filing monthly reports with DEA and revising the pharmacy Web site as needed to comply with the requirements of the

Act. As noted previously, DEA assumes that Web site modifications can be handled by a computer support specialist. DEA assumes one hour per year of a computer support specialist's

time for those modifications and two hours a year for the pharmacist to file the reports. Table 2 presents annual ongoing costs for online pharmacies.

TABLE 2—ANNUAL ONGOING COSTS

Requirement	Unit time (in hours)	Hourly wage, fully loaded	Unit cost
Pharmacy Web site modification (computer support specialist) .....	1.0	\$47.79	\$47.79
Sending monthly report to DEA (pharmacist) .....	2.0	104.40	208.80
<b>Total</b> .....			<b>256.59</b>

**Total costs.** To estimate total costs, it is necessary to estimate the number of firms that will seek to modify their registration to that of online pharmacies. DEA estimates that 250 pharmacies will initially apply for such modification of registration. It is also necessary to estimate the number of pharmacies that will apply for such modification of registration in the future. DEA estimates that there would be a moderate number of registrants applying to modify their registrations in the two years after the first year as some other pharmacies find advantage in an online presence. After that, DEA estimates the number of pharmacies applying to modify their registrations will decline steadily, as few pharmacies will find benefit. Each year it is expected that a number of registrants applying to modify their registrations may drop out for various reasons. The total number of pharmacies in the United States has been declining. Data from the Economic Census indicate that the number of retail pharmacies fell at an annual rate of 1.7 percent from 1998 through 2006.<sup>53</sup> DEA estimates that the number of online pharmacy registrants will decline at a slightly faster rate, because some pharmacies will drop their online pharmacy registrations but stay in business as

retail pharmacies. DEA estimates an annual attrition rate of 2.0 percent for online pharmacies. The table below shows the estimated number of online pharmacy registrations and registrants in operation, year by year.

TABLE 3—ONLINE PHARMACY REGISTRANTS

	Registrations	Registrants in operation
Year 1 ...	250	250
Year 2 ...	30	275
Year 3 ...	25	295
Year 4 ...	20	309
Year 5 ...	20	322
Year 6 ...	10	326
Year 7 ...	10	329
Year 8 ...	10	333
Year 9 ...	9	335
Year 10	8	337
Year 11	7	337
Year 12	6	336
Year 13	5	334
Year 14	5	333
Year 15	5	331

To obtain undiscounted costs, year by year, the unit cost estimates—\$201.92 for initial start-up, \$256.59 for ongoing costs—are applied, respectively, to the number of online pharmacy registrations and the number of operating registrants in each year. The results are shown in the following table.

TABLE 4—UNDISCOUNTED TOTAL COSTS

	Initial	Ongoing	Total
Year 1 .....	\$50,480	\$64,147	\$114,628
Year 2 .....	6,058	70,562	76,620
Year 3 .....	5,048	75,566	80,614
Year 4 .....	4,038	79,186	83,225
Year 5 .....	4,038	82,734	86,773
Year 6 .....	2,019	83,646	85,665
Year 7 .....	2,019	84,538	86,558
Year 8 .....	2,019	85,414	87,433
Year 9 .....	1,817	86,015	87,832
Year 10 ...	1,615	86,347	87,962
Year 11 ...	1,413	86,416	87,830
Year 12 ...	1,212	86,227	87,439
Year 13 ...	1,010	85,786	86,795
Year 14 ...	1,010	85,353	86,363
Year 15 ...	1,010	84,929	85,939

Table 5 shows the present value and annualized cost at 7.0 percent and 3.0 percent discount rates, over fifteen years.

TABLE 5—PRESENT VALUE AND ANNUALIZED COSTS

	7.0 Percent	3.0 Percent
Year 1 .....	\$114,628	\$114,628
Year 2 .....	71,607	74,388
Year 3 .....	70,411	75,986
Year 4 .....	67,936	76,162
Year 5 .....	66,198	77,096
Year 6 .....	61,078	73,895
Year 7 .....	57,677	72,491
Year 8 .....	54,449	71,091

<sup>53</sup> Economic Census, Statistics of U.S. Businesses, 2006, available at <http://www.census.gov/epcd/sub/latest/us/US44.HTM#N446>.

TABLE 5—PRESENT VALUE AND ANNUALIZED COSTS—Continued

	7.0 Percent	3.0 Percent
Year 9 .....	51,119	69,335
Year 10 .....	47,846	67,416
Year 11 .....	44,648	65,354
Year 12 .....	41,542	63,168
Year 13 .....	38,538	60,877
Year 14 .....	35,837	58,809
Year 15 .....	33,328	56,816
Total .....	856,843	1,077,511
Annualized .....	94,077	90,259

The costs are relatively modest; the annualized sum of the present values is less than \$100,000 at both discount rates. Further, Table 4 shows that the undiscounted annual cost never exceeds \$100,000 after the first year with its relatively large number of registrations.

**Benefits.** The Ryan Haight Online Pharmacy Consumer Protection Act is designed to save lives by reducing deaths from drug overdoses and otherwise lessen the detrimental consequences of pharmaceutical controlled substance abuse by restricting the ability of rogue Internet pharmacies to illegally divert dangerous controlled substance prescription drugs to millions of people, including teens, without valid prescriptions issued under a legitimate physician's care.<sup>54</sup> The regulations promulgated based on this legislation will address the "wide-open channel of distribution" that currently exists for prescription controlled substances sold over the Internet, which represents an "easy availability [that] has enormous implications for public health, particularly the health of our children."<sup>55</sup> A key provision of this law, the requirement for practitioners to conduct at least one in-person medical evaluation of the patient before they prescribe a prescription for a controlled substance, is a major step toward combating the use of the Internet to facilitate illegal sales of pharmaceutical controlled substances. Also, requiring online pharmacies to post the required site disclosure information, certifications, and other information on their homepage provides consumers

with enhanced tools to determine the legitimacy of the online pharmacy.

#### C. Regulatory Flexibility Act

The Deputy Administrator hereby certifies that this rulemaking has been drafted in accordance with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612). The RFA applies to a rule that is published by the agency as a notice of proposed rulemaking. As explained above, the Ryan Haight Act expressly contemplates that DEA will issue interim rules under the "good cause" provision of the APA as the agency deems necessary to implement the Act prior to its effective date (April 13, 2009). Thus, Congress has expressly granted DEA authority to issue regulations to implement the Act that become effective immediately without the requirement of first seeking public comment through a notice of proposed rulemaking. Consequently, the requirements of the RFA do not apply to this rule.

It also should be noted that only a limited portion of the regulatory text being issued here is subject to modification following the comment period as the bulk of the regulatory text is taken verbatim from, and mandated by, the Ryan Haight Act. DEA is seeking public comment with respect to those parts of the regulatory text about which the agency has discretion.

Although the RFA does not apply to this Interim Final Rule, DEA has reviewed the potential impacts. The rule is likely to affect a substantial number of small entities, but DEA does not believe that it will have a significant economic impact on small entities.

DEA is uncertain which pharmacies will apply to modify their registrations to that of online pharmacies. While it is possible that such applicants will be a mixture of independent pharmacies and chains, DEA believes it unlikely that many chain pharmacies will fall within the definition of an online pharmacy and thereby need to apply for the modified registration. As discussed previously, the Ryan Haight Act contains several exceptions to the definition of "online pharmacy" including the exception set forth in 21 U.S.C. 802(52)(B)(viii) that excludes from the definition of an online pharmacy those DEA-registered pharmacies "whose dispensing of controlled substances via the Internet consists solely of \* \* \* (I) refilling

prescriptions for controlled substances in schedule III, IV, or V, as defined in paragraph [21 U.S.C. 802(55)] or (II) filling new prescriptions for controlled substances in schedule III, IV, or V, as defined in paragraph [21 U.S.C. 802(56)]." Also, the regulations being issued here exempt from the definition of online pharmacy any registered pharmacy "whose delivery, distribution, or dispensing of controlled substances by means of the Internet consists solely of \* \* \* filling prescriptions that were electronically prescribed in a manner authorized by this chapter and otherwise in compliance with the Act." Given these exceptions to the definition of an online pharmacy, DEA anticipates that the overwhelming majority of pharmacies in the United States, if they follow their current practices, will not, as of April 13, 2009, fall within the definition of an online pharmacy.

Further, as DEA stated previously, as long as the pharmacist meets his corresponding responsibility to take reasonable steps under the circumstances of the dispensing of any particular prescription to ensure that the prescription was issued in accordance with the requirements of the Ryan Haight Act (as well as all other applicable requirements of the CSA and DEA regulations), the pharmacist will not be held strictly liable for filling a prescription that he could not reasonably have known was issued by means of the Internet. Thus, it is absolutely unnecessary for a pharmacy to apply for a modification of its DEA registration authorizing it to operate as an online pharmacy for the sole purpose of ensuring that it does not—despite the exercise of sound professional judgment—inadvertently fill a prescription that was issued by means of the Internet.

The small-business size standard for retail pharmacies is annual revenue of \$7.0 million.<sup>56</sup> From the 2002 Economic Census, there are data on revenue of pharmacies by revenue class. The class with the lowest average revenue is pharmacies with sales of less than \$250,000 per year. Average revenue for this group is \$132,000. Table 6 shows Small Business Administration standards for these and larger firms that dispense controlled substances.

<sup>56</sup> Small Business Administration, Table of Small Business Size Standards, August 22, 2008.

<sup>54</sup> Office of National Drug Control Policy, Press Release, March 1, 2008, available at <http://www.oncdcp.gov/pda/030108.html>.

<sup>55</sup> S. Rep. No. 110–521, at 68 (2008).

TABLE 6—SBA DEFINITIONS OF SMALL ENTITIES

Industry description	NAICS code	Small business definition (sales in \$)
Pharmacies and Drug Stores .....	446110	7,000,000
Supermarkets and Other Grocery Stores .....	445110	27,000,000
Discount Department Stores .....	452112	27,000,000
Warehouse Clubs and Supercenters .....	452910	25,000,000
Mail Order Houses .....	454113	25,000,000

DEA estimates the annual cost of compliance with the Interim Final Rule for an individual pharmacy is the annualized sum of the present value of

a 15-year stream of ongoing costs and the initial start-up cost. Table 7 shows these values for 7.0 percent and 3.0 percent discount rates. The result is

annualized cost of about \$275. Even for the smallest pharmacies, that is not a significant economic impact.<sup>57</sup>

TABLE 7—ANNUALIZED COST FOR AN ONLINE PHARMACY

	7.0 Percent	3.0 Percent
Annual Ongoing Cost .....	\$256.59	\$256.59
PV of Ongoing Cost .....	2,337.00	3,063.15
Initial Cost .....	201.92	201.92
Sum of PV and Initial Cost .....	2,538.92	3,265.07
Annualized Cost .....	278.76	273.50

#### D. Paperwork Reduction Act

The Ryan Haight Act requires pharmacies that dispense controlled substances by means of the Internet to obtain a modification of their existing DEA registration to that of an online pharmacy (21 U.S.C. 823(f), 21 CFR 1301.11). To address this, DEA is revising its existing information collection, "Application for Registration (DEA Form 224), Application for Registration Renewal (DEA Form 224a), Affidavit for Chain Renewal (DEA Form 224b)" [information collection 1117-0014] to add an Application for Modification of Registration for Online Pharmacies (DEA Form 224c). This form will be completed online by pharmacies requesting to modify their registrations to that of an online pharmacy.

*Application for modification of registration*—The application for modification of registration will require an online pharmacy applicant to provide to DEA certain information, as discussed above. For purposes of this reporting, DEA believes that the Internet Pharmacy Site Disclosure information that applicants must supply will be immediately obtainable with minimal effort. Information such as the pharmacy's name, registration number, and contact information will be populated by DEA on the online form completed by the pharmacy applicant. Contact information for the pharmacist-in-charge should be readily available.

State licensure information should be readily available as well.

DEA believes that very few legitimate pharmacies (*i.e.*, those that comply with the law) will be affiliated with more than one Web site. Nor does it seem likely that such pharmacies will have contractual relationships with practitioners to issue prescriptions for controlled substances through referrals from the Web site or at the request of the owner or operator of the Web site, or any employee or agent thereof. Thus, DEA believes that the reporting of this type of information should be minimal, if at all, and will not be burdensome for the vast majority of the limited number of pharmacies likely to apply to modify their registrations.

DEA believes that the certifications required of the online pharmacies are straightforward and can easily be included on pharmacies' Web sites and reported to DEA. DEA has provided examples of those certifications for potential use by pharmacies applying to modify their registrations.

While the new reporting and application requirements will request information not previously requested by DEA (as the Ryan Haight Act mandates), DEA believes that much of the information required to be provided as part of the applications is readily available and retrievable, thus limiting the impact of the burden for completion of this application.

DEA estimates that 250 pharmacies will apply to modify their registrations to that of online pharmacies. DEA estimates that it will take a pharmacy 15 minutes (0.25 hours) to complete an Application for Modification of Registration for Online Pharmacies (DEA Form 224c), and that it will take an online pharmacy 15 minutes (0.25 hours) to renew its online pharmacy registration. DEA notes that the Application for Modification of Registration for Online Pharmacies (DEA Form 224c) is completed and submitted online through the DEA Office of Diversion Control Web site. Because those applying for a modification of registration must already be registered with DEA, the overall number of respondents will not change. To account for the new requirement, the number of respondents using DEA-224a has been reduced by the 250 respondents DEA estimates will apply for a modification using DEA-224c. As a result, the total burden for DEA-224a has been reduced by 16.7 hours. DEA estimates that DEA-224c will have a total of 62.5 burden hours for an overall increase of 46.2 burden hours.

*Reports of dispensing of controlled substances by online pharmacies*—The Ryan Haight Act requires those pharmacies with modified registrations to report certain information regarding their dispensing of controlled

<sup>57</sup> Economic Census, Establishment and Firm Size, 2002, Table 4.

substances to DEA. Specifically, online pharmacies are required to report to DEA the total quantity of controlled substances that the pharmacy has dispensed during each calendar month by any means, regardless of whether the controlled substances are dispensed by means of the Internet. Reports are required to be filed by every pharmacy that, at any time during a calendar month, holds a modified registration authorizing it to operate as an online pharmacy, regardless of whether the online pharmacy dispenses any controlled substances by means of the Internet during the month. Reports are required when the total quantity of controlled substances dispensed meets or exceeds either 100 or more prescriptions for controlled substances filled, or 5,000 or more dosage units dispensed of all controlled substances combined, in the calendar month for which reporting is required. If a pharmacy fills fewer than 100 prescriptions for controlled substances, and dispenses fewer than 5,000 dosage units of all controlled substances combined, in the calendar month for which reporting is required, a negative response indicating that reporting is not required must be received by DEA. Thus, each online pharmacy will report every month to DEA, either by providing actual dispensing information or by providing a negative response.

DEA believes that, of the limited number of pharmacies expected to be subject to the reporting requirement of the Act, few are likely to submit negative responses. It is reasonable to assume that online pharmacies subject to the reporting requirement will either fill 100 or more prescriptions for controlled substances, or 5,000 or more dosage units of all controlled substances combined, in any calendar month. Therefore, DEA has assumed for purposes of these estimates that all online pharmacies will report dispensing information to DEA.

DEA estimates that 250 online pharmacies will file monthly reports with DEA regarding their dispensing of controlled substances. DEA estimates that it will take each pharmacy 10 minutes to file this report.

The Department of Justice, Drug Enforcement Administration, has submitted the following information collection requests to the Office of Management and Budget (OMB) for review and clearance in accordance with the review procedures of the Paperwork Reduction Act of 1995. The information collections are published to obtain comments from the public and affected agencies.

All comments and suggestions, or questions regarding additional information, to include obtaining a copy of the proposed information collection instrument with instructions, should be directed to Mark W. Caverly, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, VA 22152, Telephone (202) 307-7297.

Written comments and suggestions from the public and affected agencies concerning the required collections of information are encouraged. Your comments on the information collection-related aspects of this rule should address one or more of the following four points:

- Evaluate whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility.
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.
- Recommendations to enhance the quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

*Overview of information collection 1117-0014:*

(1) *Type of Information Collection:* Revision of a currently approved collection.

- (2) *Title of the Form/Collection:*  
 Application for Registration (DEA Form 224);  
 Application for Registration Renewal (DEA Form 224a);  
 Affidavit for Chain Renewal (DEA Form 224b);  
 Application for Modification of Registration for Online Pharmacies (DEA Form 224c)

(3) Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:

*Form Number:* DEA Form 224, 224a, 224b, 224c;

*Component:* Office of Diversion Control, Drug Enforcement Administration, U.S. Department of Justice.

(4) Affected public who will be asked or required to respond, as well as a brief abstract:

*Primary:* Business or other for-profit.

*Other:* Not-for-Profit Institutions; State, Local or Tribal Government.

*Abstract:* All firms and individuals who distribute or dispense controlled substances must register with the DEA under the Controlled Substances Act. Pharmacies wishing to be online pharmacies must apply to modify their registrations. Such registration is mandatory under the law and needed for control measures over legal handlers of controlled substances and to monitor their activities.

(5) An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond is provided in the table below. Please note that the number of respondents using DEA-224a has been reduced by the 250 respondents that DEA estimates will apply for a modification using DEA-224c. Because those applying for a modification of registration must be currently registered with DEA, the overall number of respondents will not increase. The total response time has increased by 46.2 hours as a result of the 11 additional minutes it is estimated it will take each respondent to complete DEA-224c as compared to DEA-224a.

Form	Completed	Number of respondents	Time per response	Total (in hours)
Application for Registration (DEA-224)	Paper	12,094	0.2 hours (12 minutes)	2,418.8
Application for Registration (DEA-224)	Electronic	59,283	0.13 hours (8 minutes)	7,904.4
Application for Registration Renewal (DEA-224a)	Paper	159,678	0.2 hours (12 minutes)	31,935.6
Application for Registration Renewal (DEA-224a)	Electronic	209,285	0.06 hours (4 minutes)	13,952.3
Affidavit for Chain Renewals (DEA-224b)	Electronic	16	5 hours	80
Application for Modification of Registration for Online Pharmacies (DEA-224c)	Electronic	250	0.25 hours (15 minutes)	62.5

Form	Completed	Number of respondents	Time per response	Total (in hours)
Total .....	.....	440,606	.....	56,354

(6) An estimate of the total public burden (in hours) associated with the collection: It is estimated that this collection will create a burden of 56,354 annual burden hours.

*Overview of new information collection:*

(1) *Type of Information Collection:* New collection.

(2) *Title of the Form/Collection:* Reports of dispensing of controlled substances by online pharmacies.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:*

*Form Number:* DEA Form 332.  
*Component:* Office of Diversion Control, Drug Enforcement Administration, U.S. Department of Justice.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:*

*Primary:* Business or other for-profit.  
*Other:* Not-for-Profit Institutions; State, Local or Tribal Government.

*Abstract:* The Controlled Substances Act (21 U.S.C. 827(d)(2)) requires online pharmacies to report to DEA the total quantity of controlled substances that the pharmacy has dispensed during each calendar month by any means, regardless of whether the controlled substances are dispensed by means of the Internet. Reports are required to be filed by every pharmacy that, at any time during a calendar month, holds a modified registration authorizing it to operate as an online pharmacy, regardless of whether the online pharmacy dispenses any controlled substances by means of the Internet during the month. Such reporting is mandated by the Ryan Haight Act and permits DEA to monitor the dispensing of controlled substances by online pharmacies.

(5) An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond: It is estimated that 250 persons respond to this collection at 0.25 hours per person per month, for a total of 750 hours per year.

(6) An estimate of the total public burden (in hours) associated with the collection: 750 annual burden hours.

If additional information is required contact: Lynn Bryant, Department Clearance Officer, Information Management and Security Staff, Justice Management Division, Department of

Justice, Patrick Henry Building, Suite 1600, 601 D Street, NW., Washington, DC 20530.

*E. Executive Order 12988*

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform.

*F. Executive Order 13132*

This rulemaking does not impose enforcement responsibilities on any State; nor does it diminish the power of any State to enforce its own laws. Accordingly, this rulemaking does not have federalism implications warranting the application of Executive Order 13132.

*G. Unfunded Mandates Reform Act of 1995*

This rule will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$120,000,000 or more (adjusted for inflation) in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

*H. Congressional Review Act*

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act). This rule will not result in an annual effect on the economy of \$100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets. Further, as noted above in the Administrative Procedure Act certification, DEA has concluded that "good cause" exists to promulgate this rule as an Interim Final Rule effective as set forth in the DATES section of the preamble pursuant to 5 U.S.C. 553(b)(B) and 5 U.S.C. 553(d)(3).

**List of Subjects**

*21 CFR Part 1300*

Chemicals, Drug traffic control.

*21 CFR Part 1301*

Administrative practice and procedure, Drug traffic control, Security measures.

*21 CFR Part 1304*

Drug traffic control, Reporting and recordkeeping requirements.

*21 CFR Part 1306*

Drug traffic control, Prescription drugs.

■ For the reasons set out above, 21 CFR parts 1300, 1301, 1304, and 1306 are amended as follows:

**PART 1300—DEFINITIONS**

■ 1. The authority citation for part 1300 is revised to read as follows:

**Authority:** 21 U.S.C. 802, 821, 829, 871(b), 951, 958(f).

■ 2. Section 1300.04 is added to read as follows:

**§ 1300.04 Definitions relating to the dispensing of controlled substances by means of the Internet.**

(a) Any term not defined in this part or elsewhere in this chapter shall have the definition set forth in sections 102 and 309 of the Act (21 U.S.C. 802, 829).

(b) The term *covering practitioner* means, with respect to a patient, a practitioner who conducts a medical evaluation (other than an in-person medical evaluation) at the request of a practitioner who:

(1) Has conducted at least one in-person medical evaluation of the patient or an evaluation of the patient through the practice of telemedicine, within the previous 24 months; and

(2) Is temporarily unavailable to conduct the evaluation of the patient.

(c) The term *deliver, distribute, or dispense by means of the Internet* refers, respectively, to any delivery, distribution, or dispensing of a controlled substance that is caused or facilitated by means of the Internet.

(d) The term *filling new prescriptions for controlled substances in Schedule III, IV, or V* means filling a prescription for an individual for a controlled substance in Schedule III, IV, or V, if:

(1) The pharmacy dispensing that prescription has previously dispensed to the patient a controlled substance other than by means of the Internet and pursuant to the valid prescription of a practitioner that meets the applicable

requirements of subsections (b) and (c) of section 309 of the Act (21 U.S.C. 829) and §§ 1306.21 and 1306.22 of this chapter (for purposes of this definition, such a prescription shall be referred to as the "original prescription");

(2) The pharmacy contacts the practitioner who issued the original prescription at the request of that individual to determine whether the practitioner will authorize the issuance of a new prescription for that individual for the controlled substance described in paragraph (d)(1) of this section (*i.e.*, the same controlled substance as described in paragraph (d)(1)); and

(3) The practitioner, acting in the usual course of professional practice, determines there is a legitimate medical purpose for the issuance of the new prescription.

(e) The term *homepage* means the opening or main page or screen of the Web site of an online pharmacy that is viewable on the Internet.

(f) The term *in-person medical evaluation* means a medical evaluation that is conducted with the patient in the physical presence of the practitioner, without regard to whether portions of the evaluation are conducted by other health professionals. Nothing in this paragraph shall be construed to imply that one in-person medical evaluation demonstrates that a prescription has been issued for a legitimate medical purpose within the usual course of professional practice.

(g) The term *Internet* means collectively the myriad of computer and telecommunications facilities, including equipment and operating software, which comprise the interconnected worldwide network of networks that employ the Transmission Control Protocol/Internet Protocol, or any predecessor or successor protocol to such protocol, to communicate information of all kinds by wire or radio.

(h) The term *online pharmacy* means a person, entity, or Internet site, whether in the United States or abroad, that knowingly or intentionally delivers, distributes, or dispenses, or offers or attempts to deliver, distribute, or dispense, a controlled substance by means of the Internet. The term includes, but is not limited to, a pharmacy that has obtained a modification of its registration pursuant to §§ 1301.13 and 1301.19 of this chapter that currently authorizes it to dispense controlled substances by means of the Internet, regardless of whether the pharmacy is currently dispensing controlled substances by means of the Internet. The term does not include:

(1) Manufacturers or distributors registered under subsection (a), (b), (d), or (e) of section 303 of the Act (21 U.S.C. 823(a), (b), (d), or (e)) (§ 1301.13 of this chapter) who do not dispense controlled substances to an unregistered individual or entity;

(2) Nonpharmacy practitioners who are registered under section 303(f) of the Act (21 U.S.C. 823(f)) (§ 1301.13 of this chapter) and whose activities are authorized by that registration;

(3) Any hospital or other medical facility that is operated by an agency of the United States (including the Armed Forces), provided such hospital or other facility is registered under section 303(f) of the Act (21 U.S.C. 823(f)) (§ 1301.13 of this chapter);

(4) A health care facility owned or operated by an Indian tribe or tribal organization, only to the extent such facility is carrying out a contract or compact under the Indian Self-Determination and Education Assistance Act;

(5) Any agent or employee of any hospital or facility referred to in paragraph (h)(3) or (h)(4) of this section, provided such agent or employee is lawfully acting in the usual course of business or employment, and within the scope of the official duties of such agent or employee, with such hospital or facility, and, with respect to agents or employees of health care facilities specified in paragraph (h)(4) of this section, only to the extent such individuals are furnishing services pursuant to the contracts or compacts described in such paragraph;

(6) Mere advertisements that do not attempt to facilitate an actual transaction involving a controlled substance;

(7) A person, entity, or Internet site that is not in the United States and does not facilitate the delivery, distribution, or dispensing of a controlled substance by means of the Internet to any person in the United States;

(8) A pharmacy registered under section 303(f) of the Act (21 U.S.C. 823(f)) (§ 1301.13 of this chapter) whose dispensing of controlled substances via the Internet consists solely of:

(i) Refilling prescriptions for controlled substances in Schedule III, IV, or V, as defined in paragraph (k) of this section; or

(ii) Filling new prescriptions for controlled substances in Schedule III, IV, or V, as defined in paragraph (d) of this section;

(9)(i) Any registered pharmacy whose delivery, distribution, or dispensing of controlled substances by means of the Internet consists solely of filling prescriptions that were electronically

prescribed in a manner authorized by this chapter and otherwise in compliance with the Act.

(ii) A registered pharmacy will be deemed to meet this exception if, in view of all of its activities other than those referred to in paragraph (h)(9)(i) of this section, it would fall outside the definition of an online pharmacy; or

(10)(i) Any registered pharmacy whose delivery, distribution, or dispensing of controlled substances by means of the Internet consists solely of the transmission of prescription information between a pharmacy and an automated dispensing system located in a long term care facility when the registration of the automated dispensing system is held by that pharmacy as described in §§ 1301.17 and 1301.27 and the pharmacy is otherwise complying with this chapter.

(ii) A registered pharmacy will be deemed to meet this exception if, in view of all of its activities other than those referred to in paragraph (h)(10)(i) of this section, it would fall outside the definition of an online pharmacy.

(i) Effective January 15, 2010, the term *practice of telemedicine* means the practice of medicine in accordance with applicable Federal and State laws by a practitioner (other than a pharmacist) who is at a location remote from the patient and is communicating with the patient, or health care professional who is treating the patient, using a telecommunications system referred to in section 1834(m) of the Social Security Act (42 U.S.C. 1395m(m)), which practice falls within a category listed in the following paragraphs (i)(1) through (7):

(1) *Treatment in a hospital or clinic.* The practice of telemedicine is being conducted while the patient is being treated by, and physically located in, a hospital or clinic registered under section 303(f) of the Act (21 U.S.C. 823(f)) by a practitioner acting in the usual course of professional practice, who is acting in accordance with applicable State law, and who is registered under section 303(f) of the Act (21 U.S.C. 823(f)) in the State in which the patient is located, unless the practitioner:

(i) Is exempted from such registration in all States under section 302(d) of the Act (21 U.S.C. 822(d)); or

(ii) Is an employee or contractor of the Department of Veterans Affairs who is acting in the scope of such employment or contract, and registered under section 303(f) of the Act (21 U.S.C. 823(f)) in any State or is utilizing the registration of a hospital or clinic operated by the Department of Veterans Affairs registered under section 303(f);

(2) *Treatment in the physical presence of a practitioner.* The practice of telemedicine is being conducted while the patient is being treated by, and in the physical presence of, a practitioner acting in the usual course of professional practice, who is acting in accordance with applicable State law, and who is registered under section 303(f) of the Act (21 U.S.C. 823(f)) in the State in which the patient is located, unless the practitioner:

(i) Is exempted from such registration in all States under section 302(d) of the Act (21 U.S.C. 822(d)); or

(ii) Is an employee or contractor of the Department of Veterans Affairs who is acting in the scope of such employment or contract, and registered under section 303(f) of the Act (21 U.S.C. 823(f)) in any State or is using the registration of a hospital or clinic operated by the Department of Veterans Affairs registered under section 303(f);

(3) *Indian Health Service or tribal organization.* The practice of telemedicine is being conducted by a practitioner who is an employee or contractor of the Indian Health Service, or is working for an Indian tribe or tribal organization under its contract or compact with the Indian Health Service under the Indian Self-Determination and Education Assistance Act; who is acting within the scope of the employment, contract, or compact; and who is designated as an Internet Eligible Controlled Substances Provider by the Secretary of Health and Human Services under section 311(g)(2) of the Act (21 U.S.C. 831(g)(2));

(4) *Public health emergency declared by the Secretary of Health and Human Services.* The practice of telemedicine is being conducted during a public health emergency declared by the Secretary of Health and Human Services under section 319 of the Public Health Service Act (42 U.S.C. 247d), and involves patients located in such areas, and such controlled substances, as the Secretary of Health and Human Services, with the concurrence of the Administrator, designates, provided that such designation shall not be subject to the procedures prescribed by the Administrative Procedure Act (5 U.S.C. 551–559 and 701–706);

(5) *Special registration.* The practice of telemedicine is being conducted by a practitioner who has obtained from the Administrator a special registration under section 311(h) of the Act (21 U.S.C. 831(h));

(6) *Department of Veterans Affairs medical emergency.* The practice of telemedicine is being conducted:

(i) In a medical emergency situation:

(A) That prevents the patient from being in the physical presence of a practitioner registered under section 303(f) of the Act (21 U.S.C. 823(f)) who is an employee or contractor of the Veterans Health Administration acting in the usual course of business and employment and within the scope of the official duties or contract of that employee or contractor;

(B) That prevents the patient from being physically present at a hospital or clinic operated by the Department of Veterans Affairs registered under section 303(f) of the Act (21 U.S.C. 823(f));

(C) During which the primary care practitioner of the patient or a practitioner otherwise practicing telemedicine within the meaning of this paragraph is unable to provide care or consultation; and

(D) That requires immediate intervention by a health care practitioner using controlled substances to prevent what the practitioner reasonably believes in good faith will be imminent and serious clinical consequences, such as further injury or death; and

(ii) By a practitioner that:

(A) Is an employee or contractor of the Veterans Health Administration acting within the scope of that employment or contract;

(B) Is registered under section 303(f) of the Act (21 U.S.C. 823(f)) in any State or is utilizing the registration of a hospital or clinic operated by the Department of Veterans Affairs registered under section 303(f); and

(C) Issues a controlled substance prescription in this emergency context that is limited to a maximum of a five-day supply which may not be extended or refilled; or

(7) *Other circumstances specified by regulation.* The practice of telemedicine is being conducted under any other circumstances that the Administrator and the Secretary of Health and Human Services have jointly, by regulation, determined to be consistent with effective controls against diversion and otherwise consistent with the public health and safety.

(j) *Temporary definition of practice of telemedicine.* Prior to January 15, 2010, or as otherwise specified by regulation prior to that date, instead of the definition in paragraph (i), the term *practice of telemedicine* means the practice of medicine in accordance with applicable Federal and State laws by a practitioner (as that term is defined in section 102 of the Act (21 U.S.C. 802)) (other than a pharmacist) who is at a location remote from the patient and is communicating with the patient, or

health care professional who is treating the patient, using a telecommunications system referred to in section 1834(m) of the Social Security Act (42 U.S.C. 1395m(m)), if the practitioner is using an interactive telecommunications system that satisfies the requirements of section 410.78(a)(3) of title 42, Code of Federal Regulations.

(k) The term *refilling prescriptions for controlled substances in Schedule III, IV, or V:*

(1) Means the dispensing of a controlled substance in Schedule III, IV, or V in accordance with refill instructions issued by a practitioner as part of a valid prescription that meets the requirements of subsections (b) and (c) of section 309 of the Act (21 U.S.C. 829) and §§ 1306.21 and 1306.22 of this chapter, as appropriate; and

(2) Does not include the issuance of a new prescription to an individual for a controlled substance that individual was previously prescribed.

(l)(1) The term *valid prescription* means a prescription that is issued for a legitimate medical purpose in the usual course of professional practice by:

(i) A practitioner who has conducted at least one in-person medical evaluation of the patient; or

(ii) A covering practitioner.

(2) Nothing in this paragraph (l) shall be construed to imply that one in-person medical evaluation demonstrates that a prescription has been issued for a legitimate medical purpose within the usual course of professional practice.

#### **PART 1301—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES**

■ 3. The authority citation for part 1301 is revised to read as follows:

**Authority:** 21 U.S.C. 821, 822, 823, 824, 831, 871(b), 875, 877, 886a, 951, 952, 953, 956, 957, 958.

■ 4. Section 1301.11 is revised to read as follows:

#### **§ 1301.11 Persons required to register; requirement of modification of registration authorizing activity as an online pharmacy.**

(a) Every person who manufactures, distributes, dispenses, imports, or exports any controlled substance or who proposes to engage in the manufacture, distribution, dispensing, importation or exportation of any controlled substance shall obtain a registration unless exempted by law or pursuant to §§ 1301.22 through 1301.26. Except as provided in paragraph (b) of this section, only persons actually engaged in such activities are required to obtain a registration; related or affiliated

persons who are not engaged in such activities are not required to be registered. (For example, a stockholder or parent corporation of a corporation manufacturing controlled substances is not required to obtain a registration.)

(b) As provided in sections 303(f) and 401(h) of the Act (21 U.S.C. 823(f) and 841(h)), it is unlawful for any person who falls within the definition of "online pharmacy" (as set forth in section 102(52) of the Act (21 U.S.C. 802(52)) and § 1300.04(h) of this chapter) to deliver, distribute, or dispense a controlled substance by means of the Internet if such person is not validly registered with a modification of such registration authorizing such activity (unless such person is exempt from such modified registration requirement under the Act

or this chapter). The Act further provides that the Administrator may only issue such modification of registration to a person who is registered as a pharmacy under section 303(f) of the Act (21 U.S.C. 823(f)). Accordingly, any pharmacy registered pursuant to § 1301.13 of this part that falls within the definition of an online pharmacy and proposes to dispense controlled substances by means of the Internet must obtain a modification of its registration authorizing such activity following the submission of an application in accordance with § 1301.19 of this part. This requirement does not apply to a registered pharmacy that does not fall within the definition of an online pharmacy set forth in § 1300.04(h). Under the Act, persons other than registered pharmacies are not

eligible to obtain such a modification of registration but remain liable under section 401(h) of the Act (21 U.S.C. 841(h)) if they deliver, distribute, or dispense a controlled substance while acting as an online pharmacy without being validly registered with a modification authorizing such activity.

■ 5. Section 1301.13 is amended by revising paragraph (e)(1)(iv) and (e)(3) to read as follows:

**§ 1301.13 Application for registration; time for application; expiration date; registration for independent activities; application forms, fees, contents and signature; coincident activities.**

- \* \* \* \* \*
- (e) \* \* \*
- (1) \* \* \*

Business activity	Controlled substances	DEA application forms	Application fee (dollars)	Registration period (years)	Coincident activities allowed
* * *	*	*	*	*	*
(iv) Dispensing or instructing (includes Practitioner, Hospital/Clinic, Retail Pharmacy, Online Pharmacy, Central fill pharmacy, Teaching Institution).	Schedules II-V	New—224 ..... Renewal—224a Online Pharmacy—224c.	551 551	3	May conduct research and instructional activities with those substances for which registration was granted, except that a mid-level practitioner may conduct such research only to the extent expressly authorized under State statute. A pharmacist may manufacture an aqueous or oleaginous solution or solid dosage form containing a narcotic controlled substance in Schedule II-V in a proportion not exceeding 20% of the complete solution, compound or mixture. A retail pharmacy may perform central fill pharmacy activities. An online pharmacy may perform activities of retail pharmacy as well as online pharmacy activities.
*	*	*	*	*	*

\* \* \* \* \*

(3) Registrants will receive renewal notifications approximately 60 days prior to the registration expiration date. DEA Forms 224a, 225a, and 363a may be mailed, as applicable, to registrants; if any registered person does not receive such notification within 45 days before the registration expiration date, the registrant must promptly give notice of such fact and may request such forms by writing to the Registration Section, Drug Enforcement Administration.

\* \* \* \* \*

■ 6. Section 1301.19 is added to read as follows:

**§ 1301.19 Special requirements for online pharmacies.**

(a) A pharmacy that has been issued a registration under § 1301.13 may request that the Administrator modify its registration to authorize the pharmacy to dispense controlled substances by means of the Internet as an online pharmacy. The Administrator may deny an application for a modification of registration if the Administrator determines that the issuance of a modification would be inconsistent with the public interest. In determining the public interest, the Administrator will consider the factors

listed in section 303(f) of the Act (21 U.S.C. 823(f)).

(b) Each online pharmacy shall comply with the requirements of State law concerning licensure of pharmacies in each State from which it, and in each State to which it, delivers, distributes, or dispenses, or offers to deliver, distribute, or dispense controlled substances by means of the Internet.

(c) Application for a modified registration authorizing the dispensing of controlled substances by means of the Internet will be made by an online application process as specified in § 1301.13 of this part. Subsequent online pharmacy registration renewals

will be accomplished by an online process.

(d) A pharmacy that seeks to discontinue its modification of registration authorizing it to dispense controlled substances by means of the Internet as an online pharmacy (but continue its business activity as a non-online pharmacy) shall so notify the Administrator by requesting to modify its registration to reflect the appropriate business activity. Once the registration has been so changed, the pharmacy may no longer dispense controlled substances by means of the Internet. A pharmacy that has so changed its registration status back to that of a non-online pharmacy remains responsible for submitting reports in accordance with § 1304.55 of this chapter with respect to any controlled substances that it dispensed while it was registered with a modification authorizing it to operate as an online pharmacy.

(e) Registrants applying for modified registrations under this section must comply with notification and reporting requirements set forth in §§ 1304.40, 1304.45, 1304.50, and 1304.55 of this chapter.

(f) No person (including a registrant) required to obtain a modification of a registration under §§ 1301.11(b) and 1301.13 of this part authorizing it to operate as an online pharmacy may engage in any activity for which such modification of registration is required until the application for such modified registration is granted and an active Certificate of Registration indicating the modification of the registration has been issued by the Administrator to such person.

■ 7. Section 1301.52 is amended by revising paragraph (a) to read as follows:

**§ 1301.52 Termination of registration; transfer of registration; distribution upon discontinuance of business.**

(a) Except as provided in paragraph (b) of this section, the registration of any person, and any modifications of that registration, shall terminate if and when such person dies, ceases legal existence, or discontinues business or professional practice. Any registrant who ceases legal existence or discontinues business or professional practice shall notify the Administrator promptly of such fact.

\* \* \* \* \*

**PART 1304—RECORDS AND REPORTS OF REGISTRANTS**

■ 8. The authority citation for part 1304 is revised to read as follows:

**Authority:** 21 U.S.C. 821, 827, 831, 871(b), 958(e), 965, unless otherwise noted.

■ 9. Section 1304.01 is revised to read as follows:

**§ 1304.01 Scope of part 1304.**

Inventory and other records and reports required under section 307, section 311, or section 1008(e) of the Act (21 U.S.C. 827, 831, and 958(e)) shall be in accordance with, and contain the information required by, those sections and by the sections of this part.

■ 10. An undesignated heading and §§ 1304.40, 1304.45, 1304.50 and 1304.55 are added to read as follows:

**Online Pharmacies**

1304.40 Notification by online pharmacies.

1304.45 Internet Web site disclosure requirements.

1304.50 Disclosure requirements for Web sites of nonpharmacy practitioners that dispense controlled substances by means of the Internet.

1304.55 Reports by online pharmacies.

**Online Pharmacies**

**§ 1304.40 Notification by online pharmacies.**

(a) Thirty days prior to offering a controlled substance for sale, delivery, distribution, or dispensing by means of the Internet, an online pharmacy shall:

(1) Notify the Administrator of its intent to do so by submitting an application for a modified registration in accordance with §§ 1301.13 and 1301.19 of this chapter, with such application containing the information required by this section; and

(2) Notify the State boards of pharmacy in any States in which the online pharmacy offers to sell, deliver, distribute, or dispense controlled substances.

(b) The following information must be included in the notification submitted under paragraph (a) of this section:

(1) The pharmacy's Internet Pharmacy Site Disclosure information required to be posted on the homepage of the online pharmacy's Internet site under section 311(c) of the Act (21 U.S.C. 831(c)) and § 1304.45 of this part.

(2) Certification that the information disclosed on its Internet site under the Internet Pharmacy Site Disclosure is true and accurate. The statement shall be in a form similar to the following: "The above-named pharmacy, a DEA registrant, certifies, under penalty of perjury, that the information contained in this statement is true and accurate."

(3) Each Internet site address utilized by the online pharmacy and a certification that the online pharmacy shall notify the Administrator of any change in any such Internet address at least 30 days in advance. In the event that a pharmacy delivers, distributes, or dispenses controlled substances

pursuant to orders made on, through, or on behalf of, more than one Web site, the pharmacy shall provide, for purposes of complying with this paragraph, the Internet site address of each such site.

(4) The DEA registration numbers of:

(i) Every pharmacy that delivers, distributes, or dispenses controlled substances pursuant to orders made on, through, or on behalf of, each Web site referred to in paragraph (b)(3) of this section; and

(ii) Every practitioner who has a contractual relationship to provide medical evaluations or issue prescriptions for controlled substances, through referrals from the Web site or at the request of the owner or operator of the Web site, or any employee or agent thereof.

(c) An online pharmacy that is in operation at the time Public Law 110-425 becomes effective (April 13, 2009) must make the notifications required in this section on or before May 13, 2009. However, in accordance with section 401(h) of the Act (21 U.S.C. 841(h)), as of April 13, 2009, it is unlawful for any online pharmacy to deliver, distribute, or dispense a controlled substance by means of the Internet unless such online pharmacy is validly registered with a modification of such registration authorizing such activity.

(d) On and after the date an online pharmacy makes the notifications required under this section, each online pharmacy shall display on the homepage of its Internet site, a declaration that it has made such notifications to the Administrator in the following form: "In accordance with the Controlled Substances Act and the DEA regulations, this online pharmacy has made the notifications to the DEA Administrator required by 21 U.S.C. 831 and 21 CFR 1304.40."

(e)(1) Except as provided in paragraphs (e)(2) and (e)(3) of this section, if any of the information required to be submitted under this section changes after the online pharmacy submits the notification to the Administrator, the online pharmacy shall notify the Administrator of the updated information no later than 30 days before the change becomes effective via the online process.

(2) If a pharmacy referred to in paragraph (b)(4)(i) of this section ceases to deliver, distribute, or dispense controlled substances pursuant to orders made on, through, or on behalf of, each Web site referred to in paragraph (b)(3) of this section, the online pharmacy shall notify the Administrator no later than 30 days after the change becomes effective via the online process.

(3) If a practitioner referred to in paragraph (b)(4)(ii) of this section ceases to have a contractual relationship with the online pharmacy, the online pharmacy shall notify the Administrator no later than 30 days after the change becomes effective via the online process.

**§ 1304.45 Internet Web site disclosure requirements.**

(a) Each online pharmacy shall display, at all times and in a visible and clear manner, on its homepage a statement that it complies with the requirements of section 311 of the Act (21 U.S.C. 831) with respect to the delivery or sale or offer for sale of controlled substances. This statement must include the name of the pharmacy as it appears on the DEA Certificate of Registration.

(b) Each online pharmacy shall clearly display the following information on the homepage of each Internet site it operates, or on a page directly linked to the homepage. If the information is displayed on a page directly linked to the homepage, that link on the homepage must be visible and clear. The information must be displayed for each pharmacy that delivers, distributes, or dispenses controlled substances pursuant to orders made on, through, or on behalf of that Web site.

(1) The name and address of the pharmacy as it appears on the pharmacy's DEA Certificate of Registration.

(2) The pharmacy's telephone number and e-mail address.

(3) The name, professional degree, and States of licensure of the pharmacist-in-charge, and a telephone number at which the pharmacist-in-charge can be contacted.

(4) A list of the States in which the pharmacy is licensed to dispense controlled substances.

(5) A certification that the pharmacy is registered under part 1301 of this chapter with a modification of its registration authorizing it to deliver, distribute, or dispense controlled substances by means of the Internet.

(6) The name, address, telephone number, professional degree, and States of licensure with State license number of any practitioner who has a contractual relationship to provide medical evaluations or issue prescriptions for controlled substances, through referrals from the Web site or at the request of the owner or operator of the Web site, or any employee or agent thereof.

(7) The following statement: "This online pharmacy is obligated to comply fully with the Controlled Substances

Act and DEA regulations. As part of this obligation, this online pharmacy has obtained a modified DEA registration authorizing it to operate as an online pharmacy. In addition, this online pharmacy will only dispense a controlled substance to a person who has a valid prescription issued for a legitimate medical purpose based upon a medical relationship with a prescribing practitioner. This includes at least one prior in-person medical evaluation in accordance with section 309 of the Controlled Substances Act (21 U.S.C. 829) or a medical evaluation via telemedicine in accordance with section 102(54) of the Controlled Substances Act (21 U.S.C. 802(54))."

**§ 1304.50 Disclosure requirements for Web sites of nonpharmacy practitioners that dispense controlled substances by means of the Internet.**

For a Web site to identify itself as being exempt from the definition of an online pharmacy by virtue of section 102(52)(B)(ii) of the Act (21 U.S.C. 802(52)(B)(ii)) and § 1300.04(h)(2) of this chapter, the Web site shall post in a visible and clear manner on its homepage, or on a page directly linked thereto in which the hyperlink is also visible and clear on the homepage, a list of the DEA-registered nonpharmacy practitioners who are affiliated with the Web site. Any nonpharmacy practitioner affiliated with such a Web site is responsible for compliance with this section. An institutional practitioner that otherwise complies with the requirements of the Act and this chapter will be deemed to meet the requirements of this section if, in lieu of posting the names of each affiliated individual practitioner, it posts its name (as it appears on its Certificate of Registration) in a visible and clear manner on its homepage and in a manner that identifies itself as being responsible for the operation of the Web site.

**§ 1304.55 Reports by online pharmacies.**

(a) Each online pharmacy shall report to the Administrator the total quantity of each controlled substance that the pharmacy has dispensed each calendar month. The report must include the total quantity of such dispensing by any means, regardless of whether the controlled substances are dispensed by means of the Internet. Thus, such reporting shall include all controlled substances dispensed via Internet transactions, mail-order transactions, face-to-face transactions, or any other means. However, the pharmacy is not required to describe in its report to the Administrator such means of

dispensing. Such reporting is required for every calendar month in which the total quantity of controlled substances dispensed by the pharmacy meets or exceeds one of the following thresholds:

(1) 100 or more prescriptions for controlled substances filled; or

(2) 5,000 or more dosage units dispensed of all controlled substances combined.

(b) Each online pharmacy shall report a negative response if, during a given calendar month, its total dispensing of controlled substances falls below both of the thresholds in paragraph (a) of this section.

(c) The reporting requirements of this section apply to every pharmacy that, at any time during a calendar month, holds a modified registration authorizing it to operate as an online pharmacy, regardless of whether the online pharmacy dispenses any controlled substances by means of the Internet during the month.

(d) Reports will be submitted to DEA electronically via online reporting, electronic file upload, or other means as approved by DEA.

(e) Reports shall be filed every month not later than the fifteenth day of the month succeeding the month for which they are submitted.

(f) An online pharmacy filing a report under paragraph (a) of this section shall utilize the National Drug Code number assigned to the product under the National Drug Code System of the Food and Drug Administration, and indicate the total number of dosage units dispensed for each such National Drug Code number.

(g) Records required to be kept under this section must be kept by the registrant for at least two years from the date of such records. The information shall be readily retrievable from the ordinary business records of the registrant and available for inspection and copying by authorized employees of the Administration.

**PART 1306—PRESCRIPTIONS**

■ 11. The authority citation for part 1306 is revised to read as follows:

**Authority:** 21 U.S.C. 821, 829, 831, 871(b), unless otherwise noted.

■ 12. Section 1306.09 is added to read as follows:

**§ 1306.09 Prescription requirements for online pharmacies.**

(a) No controlled substance that is a prescription drug may be delivered, distributed, or dispensed by means of the Internet without a valid prescription.

(b) In accordance with the Act, it is unlawful for any person to knowingly or intentionally fill a prescription for a controlled substance that was issued in a manner that constitutes dispensing by means of the Internet unless such person is a pharmacist who is acting in the usual course of his professional

practice and is acting on behalf of a pharmacy whose registration has been modified under sections 1301.13 and 1301.19 of this chapter to authorize it to operate as an online pharmacy.

(c) Any online pharmacy that participates in the transfer between pharmacies of prescription information

must do so in accordance with the requirements of §§ 1306.15 and 1306.25 of this part.

Dated: April 1, 2009.

**Michele M. Leonhart,**

*Deputy Administrator.*

[FR Doc. E9-7698 Filed 4-3-09; 8:45 am]

BILLING CODE 4410-09-P

# Attachment 3

*Board of Pharmacy Comments to the  
CIWMB, February 2009, Comments of  
the California Department of Public  
Health and Final Model Guidelines for  
Take Back of Pharmaceuticals*



**California State Board of Pharmacy**  
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STATE AND CONSUMERS AFFAIRS AGENCY  
DEPARTMENT OF CONSUMER AFFAIRS  
ARNOLD SCHWARZENEGGER, GOVERNOR

To: California Integrated Waste Management Board

From: Virginia Herold, Executive Officer

A handwritten signature in black ink, appearing to read "V. Herold", written over the printed name.

Date: February 18, 2009

Subject: Model Guidelines for Home-Generated Pharmaceutical Waste  
Agenda Item C

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The California State Board of Pharmacy regulates those who ship, store, transport, sell and dispense prescription drugs to patients and practitioners in California, and ship prescription drugs and devices into, from and throughout California. We license approximately 6,600 pharmacies in California, 500 of which are hospital pharmacies. We license over 112,000 individuals and other businesses involved with prescription drug distribution.

Prescription drugs are tightly regulated down to the consumer level – the manufacturers are licensed, the wholesalers are licensed, the pharmacies are licensed, the practitioners who prescribe and sometimes dispense are licensed. However, once drugs are dispensed to the patient, there are no specified ways for the patient to destroy unwanted/unneeded drugs. Consumers often either toss them into the trash, or flush them down the toilet.

Prescription drugs are not regulated again unless they are aggregated, and then they become pharmaceutical or medical waste, and only licensed entities can handle this waste.

This regulation is important for a number of reasons. Foremost is to preserve the quality of our prescription medicine supply and the health of the public. Diversion of prescription drugs from highly regulated channels and prescription drug abuse are two reasons why aggregation and non-regulation of collection sites pose problems to society. However, the public is increasingly seeking green options for destruction of unwanted medicine.

For nearly one year, Board of Pharmacy staff has worked with a small working group of other state agencies, including the CIWMB, on the model programs. In November 2008, we provided comments on the proposed model program guidelines, and many of our recommendations have been incorporated into the guidelines before your board.

At this time, on behalf of the Board of Pharmacy, I wish to make the following statements:

1. The board remains greatly concerned with diversion of prescription drugs from these sites (whether in pharmacies themselves or at occasional community events) to pharmacies, where they will be re-dispensed to patients. Two such events have been highlighted in the media since November (where a pharmacy in Washington and a California physician were dispensing drugs acquired through a "take back" collection bin in their premises). Redispersing of medicine taken from collection bins is a serious threat to our drug supply and patient health. It

is also very difficult for regulators to identify such diversion. For this reason, we strongly assert that:

- Drugs should not be reviewed/received by staff at the collection site (whether a pharmacy or a community event) before being deposited into the collection device – the patients or patients' agents should do this themselves , and
- The drugs that are collected should be separated from their containers by patients or their agents before being placed in the containers.

This will aid in preventing diversion by pharmacy or collection site staff because no one is “reviewing” the drugs before they are placed in the container. Such practices will also reduce costs for disposal because the containers will not be part of the pharmaceutical waste. I am attaching a picture taken of a collection bin which shows the non-pharmaceutical material found in a bin.

2. Printed advertisements for community take back events should list who is responsible for the operation of the collection location, including the name, address, and phone number of the responsible party. All signage at collection sites should also clearly identify who is responsible for the collection operation.
3. Every operator of a model program must have written policies and procedures to document their operations and compliance with the guidelines.
4. At one-day or periodic events—we strongly advocate that the pharmaceutical waste must be picked up at the end of the day. It cannot be temporarily stored “for no longer than 90 days” (page 12 – top paragraph), and with permission for as long as one year. This conflicts with the more appropriate requirement that disposal occur on “the same day of the event” (page 13, item d).

I wish to note that on January 21, 2009, the Drug Enforcement Administration published in the Federal Register its intent to examine consumer disposal options for controlled substances. Whereas it appears that much of the DEA's interest lies in disposal of controlled substances from long-term care facilities, it is seeking comments from various designated entities including law enforcement agencies, publicly owned treatment works and pharmacies. These comments are due March 23.

We look forward to continuing to work on developing these programs so that they provide the public with the options they seek, and the safety and accountability needed to protect our prescription drug supply.

Thank you for your ongoing efforts in this area.

  
VIRGINIA MEROLD  
Executive Officer



MARK B HORTON, MD, MSPH  
Director

State of California—Health and Human Services Agency  
California Department of Public Health



ARNOLD SCHWARZENEGGER  
Governor

February 24, 2009

Ms. Margo Reid Brown, Chair and Board Members  
California Integrated Waste Management Board  
1001 I Street  
Sacramento, CA 95814

RE: Comment to the "Revised Criteria and Procedures for Model Home-Generated Pharmaceutical Waste Collection and Disposal Programs" dated February 24, 2009

Dear Madame Chair and Board Members,

We recently became aware that language modified in the SB 966 "Revised Criteria and Procedures for Model Home-Generated Pharmaceutical Waste Collection and Disposal Programs" dated February 24, 2009 may contain misleading information for entities that use the guidance for their program. Under Section I on page 4, paragraph 5, "Signage" the statement "Home-generated pharmaceutical wastes are generally classified as household waste and as such can be commingled in containers with other household waste or hazardous waste" may lead readers to manage consolidated pharmaceuticals as "household wastes" and result in the improper management and disposal of these wastes. As noted on page 1, number 8 the Minimum Criteria for management of these wastes requires "consolidated" home generated pharmaceutical waste to be managed as medical or hazardous waste. This paragraph was added to comply with the California Health and Safety Code.

We suggest the following addition to the statement in paragraph 5 for each of the recommendations in "I. Procedures for Model Permanent Home-Generated Pharmaceutical Waste Collection and Disposal Programs" and "II. Procedures for Model Pharmaceutical Waste Collection and Disposal Programs at Government-Sponsored One Time or Periodic Collection Events"

February 24, 2009

5. **Signage** ... Home-generated pharmaceutical wastes are generally classified as household waste and as such can be commingled in containers with other household waste or hazardous waste. Wastes commingled in this manner must be handled as medical or hazardous waste. However, if home-generated pharmaceutical wastes are mixed with other medical waste or managed as medical waste, the waste shall be segregated for storage in a separate container or secondary container, and that container shall be labeled with the words "INCINERATION ONLY" or other label approved by the CDPH on the lid and sides, so as to be visible from any lateral direction.

Thank you for your consideration regarding this latest comment. We appreciate the work that you and your staff have done to address this legislation.

Sincerely,



Kelvin Yamada, Chief  
Medical Waste Management Program

## Revised Criteria and Procedures for Model Home-Generated Pharmaceutical Waste Collection and Disposal Programs

Senate Bill 966 (Simitian, Chapter 542, Statutes of 2007) requires the California Integrated Waste Management Board (CIWMB) to develop model programs for the collection from consumers and proper disposal of unused or expired home-generated pharmaceuticals<sup>1</sup>. In developing model programs in California, the CIWMB is also required to evaluate programs used by other state, local, and other governmental entities. The CIWMB provided a survey to those entities that have collection programs and requested that they complete and return it to the CIWMB. The purpose of the survey was to acquire information on existing home-generated pharmaceutical waste collection programs in California. From the survey results, the Procedures for Model Home-Generated Pharmaceutical Waste Collection and Disposal Programs (Procedures) were developed that would help organizations or local governments create programs through which the public may return unused or expired home-generated pharmaceutical waste (typically a prescription drug dispensed to a consumer, or a non-prescription item, such as over the counter drugs, that are no longer wanted or needed by the consumer) and meet the following minimum criteria and goals of SB 966 and of the Pharmaceutical Working Group (staff from CIWMB, California Department of Public Health (CDPH), Board of Pharmacy, Department of Toxic Substances Control, and the State Water Resources Control Board).

The minimum criteria of SB 966 and of the Pharmaceutical Working Group for home-generated pharmaceutical waste collection model programs are as follows:

1. Requires, at no additional cost to the consumer, the safe and environmentally sound take back and disposal of unused or expired home-generated pharmaceuticals;
2. Ensures protection of the public's health and safety and the environment;
3. Ensures protection of the health and safety of consumers, and employees;
4. Report to the Board the amounts of home-generated pharmaceutical waste collected for purposes of program evaluation for safety, efficiency, effectiveness and funding sustainability, and incidents of diversion of drugs for use or sale;
5. Protects against the potential for the diversion of drug waste for unlawful use or sale;
6. Provides notices and informational materials about potential impacts of improper disposal of pharmaceutical waste and options for proper disposal;
7. Subjects persons or businesses to consequences for failure to comply with model programs per SB 966 and related state and federal pharmaceutical and waste management statutes at the point of transportation, deposition, and consolidation;
8. Requires that once home-generated pharmaceutical waste has been consolidated at a facility or place of business, the waste must be managed as medical or hazardous waste. This would include all statutory requirements for storage and handling as medical or hazardous waste, the use of registered medical or hazardous waste haulers and approved treatment technology for disposal; and
9. Requires collection locations to have written policies and procedures to document their operations and compliance with this home-generated pharmaceutical waste collection program.

Additional goals of SB 966 and the Pharmaceutical Working Group include:

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<sup>1</sup> Throughout this document, the terms "home-generated pharmaceuticals" or "home-generated pharmaceutical waste" are used. Although the term does not appear in the law establishing this program, it is the term commonly used by stakeholders to refer to unused or expired pharmaceuticals in the possession of consumers.

1. ~~Provides~~Providing for the collection of home-generated pharmaceuticals that is convenient for consumers;
2. ~~Maintains~~Maintaining privacy of all participants;
3. ~~Prevents~~Preventing the illegal collection of controlled substances through displaying signage or legally manages them if they are collected;
4. ~~Ensures~~Ensuring that medication information is legible, so that it can be identified in case of a poisoning;
5. ~~Develops~~Developing a sustainable funding source for collection and disposal of home-generated pharmaceuticals, such as grants, utility funding; or advanced disposal fees placed on home-generated pharmaceuticals and local general funds or via extended producer responsibility funding framework.
6. ~~Strives~~Striving to develop permanent collection programs rather than one-day events, so they will be more accessible to the public; ~~and~~
7. ~~Provides~~Providing recommendations for implementation of a statewide program; and
8. ~~Recommends~~Recommending statutory changes to, for example, the Medical Waste Management Act.

The following Procedures have been extracted from both the Pharmaceutical Collection Programs Survey collection program information on the internet, and from the Pharmaceutical Working Group and are ~~required~~recommended for pharmaceutical collection programs. The Procedures are not only a tool to determine if a program meets the minimum criteria of model programs, but also can be used as a model to develop a collection and disposal program for unused/expired home-generated pharmaceuticals. The Procedures are broken down by (I) Permanent Home-Generated Pharmaceutical Waste Collection and Disposal Programs, (II) One-Time or Periodic Events, and (III) Mail Back Programs.

#### I. Procedures for Model Permanent Home-Generated Pharmaceutical Waste Collection and Disposal Programs

As mentioned in the previous section on goals, it is preferable that permanent home-generated pharmaceutical collection programs be developed to provide the public with consistently accessible and convenient venues to drop off unused or expired home-generated pharmaceuticals. The following procedures are basic steps ~~that shall be taken~~ to implement permanent collection programs at these types of facilities.

1. **Types of Collection Facilities** – Only the following may maintain permanent collection locations for home-generated pharmaceuticals: pharmacies with active unrestricted licenses from the California State Board of Pharmacy, police and sheriff's stations, public/environmental health agencies, physician and other licensed health care prescribers' offices, Household Hazardous Waste (HHW) facilities, and healthcare collection sites. Healthcare collection sites are physical locations licensed or operated by individuals or entities licensed by an agency within the Department of Consumer Affairs (DCA), with these locations electing to collect or take-back home-generated pharmaceutical waste and/or sharps, as applicable. Examples of healthcare collection sites include but are not limited to physicians and surgeons' offices, dentists, veterinary offices and pharmacies. If a DCA licensee has their license revoked, suspended, placed on probation or otherwise limited in any way, it shall not operate a healthcare collection site. If collection is at a police station, law enforcement must agree to and be able to collect the controlled substances and other home-generated pharmaceutical waste.

Participation by any entity is voluntary and must be done in accordance with these provisions in these procedures in order to be considered a model program. Jurisdictions such as the City of Los Angeles, San Mateo County, Ventura County, Santa Cruz County, Marin County, Santa Clara County, and nonprofit groups such as the Teleosis Institute are current examples of entities implementing permanent and ongoing programs utilizing these types of venues.

A list of those facilities that collect home-generated pharmaceutical waste shall be provided to the CIWMB by the governmental entity, organization, or business that is implementing these programs. The list of collection facilities shall include the name, address, contact, and telephone number of the facility collecting and disposing of the home-generated pharmaceutical waste.

2. **Government Agency Authorization** – Any participating entity must determine what permits or approvals are needed for home-generated pharmaceutical waste collection. All relevant agencies and programs must authorize the collection and procedures at the collection location. Some agencies to contact are: local environmental health departments, California Department of Public Health Medical Waste Management Program, local hazardous waste departments, and zoning departments for use permits. As an example, medical waste generator permits are a requirement for collection programs, and are issued by local enforcement agencies, which can be the local environmental health department or the California Department of Public Health. The volume of pharmaceuticals collected will determine if a small quantity generator or large quantity generator permit is required.
3. **Medical/Hazardous Waste Hauler/Disposal Arrangements** – Advanced arrangements shall be made with the medical or hazardous waste hauler on the fee schedule, medical or hazardous waste incineration options, packing of materials, insurance, containers, payment, contract, EPA ID number, pick up schedule, and contact telephone numbers. All home-generated pharmaceutical waste transported to an offsite waste treatment facility shall be transported by a medical waste or hazardous waste transporter that has been issued a registration certificate in accordance with the Medical Waste Management Act. A complete list of approved medical waste transporters can be found on the CDPH webpage at <http://www.cdph.ca.gov/certlic/medicalwaste/Documents/MedicalWaste/Haulist.pdf>. A medical or hazardous waste transporter transporting medical waste shall have a copy of the transporter's valid hazardous waste transporter registration certificate in the transporter's possession while transporting medical waste. It is the responsibility of the collection site to ensure that all home-generated pharmaceutical waste is appropriately picked up and transported by registered waste haulers. Detailed information about each pickup from a collection site and invoices for these services shall be retained by the collection site for three years.
4. **What Can and Cannot Be Collected**
  - a. Home-generated prescription drugs dispensed to a consumer, or a non-prescription item in the possession of a consumer, such as over the counter drugs, vitamins and supplements, and veterinary pharmaceutical waste, may be accepted.
  - b. Sharps in ~~approved~~ containers approved by the local enforcement agency may be accepted at collection sites, but shall not be placed in the same containers as the home-generated pharmaceutical waste.
  - c. Medical waste such as human surgery specimens, blood samples, vaccines and serum, trauma scene waste, human surgery specimens, cultures from pathology laboratories, items containing human fluid blood vaccines, and serum shall not be accepted.

d. **Controlled Substances** - Controlled substances cannot be collected by these programs unless a sworn law enforcement officer is onsite to take custody of, document, and dispose of these controlled substances. Controlled substances are a specific category of prescription drugs and are defined as any substance listed in Sections 11053-11058 of the California Health and Safety Code. Some examples of controlled substances include opiates (morphine and codeine), painkillers, muscle relaxants, depressants and stimulants (amphetamines). ~~If a medication is not identifiable, it shall be assumed to be a controlled substance and handled accordingly.~~

5. **Signage** – Signage must be provided regarding what is acceptable for collection and what is not acceptable (controlled substances, sharps, garbage, etc.), as well as the hours during which collection is permitted. Home-generated pharmaceutical wastes are generally classified as household waste and as such can be commingled in containers with other household waste or hazardous waste. Wastes commingled in this manner must be handled as medical or hazardous waste. However, if home-generated pharmaceutical wastes are mixed with other medical waste or managed as medical waste, the waste shall be segregated for storage in a separate container or secondary container, and that container shall be labeled with the words “INCINERATION ONLY” or other label approved by the CDPH on the lid and sides, so as to be visible from any lateral direction. Home-generated pharmaceutical wastes shall be segregated for storage and when placed in a container or secondary container, that container shall be labeled with the words “INCINERATION ONLY” or other label approved by the CDPH on the lid and sides, so as to be visible from any lateral direction. A stand alone sign may be provided by the consolidation point (facility) which further describes the container as a waste pharmaceutical consolidation container. This sign shall be located in close proximity to the container to direct consumers to the container location. During periods of non-operation this sign ~~shall~~ may be removed and the container shall be stored in a secure ~~intermediate~~ storage area to prevent theft.

Signage should ~~also show~~ include instructions on how to deposit pharmaceuticals into the secured container, ~~since staff cannot assist the consumers. The~~. Any signage should also advise consumers to remove personal information from the medicine containers. ~~In addition, the signage should mention that the consumer must not be charged for this service, nor shall any collection site pay a consumer but leave information as to participate in a take back program.~~ the type of medication being deposited.

6. **How Home-Generated Pharmaceuticals Shall Be Collected** – Home-generated pharmaceuticals should be emptied from its original container into the secured container at the collection location. If home-generated pharmaceuticals are kept in the original, labeled container, ensure that personal information shall be removed or marked out, but information pertaining to the type of pharmaceutical is retained. The emptied containers and home-generated pharmaceuticals can then be placed in separate collection bins by the consumer for proper management. Staff of the collection site ~~other than pharmacies are not to~~ may assist consumers in placing home-generated pharmaceuticals in the bins. ~~This is the obligation of the consumer, if deemed necessary.~~ The collection location must ensure that the home-generated pharmaceutical licensed waste hauler or handler transports the home-generated pharmaceutical for proper destruction. Collected home-generated pharmaceuticals shall not be resold or reused. No individual or collection site shall purchase or offer to purchase home-generated pharmaceutical waste from consumers, nor shall such returned waste be sold, donated, or provided to anyone other than a registered medical or hazardous waste hauler as specified in these procedures.

a. **Packing Home-Generated Pharmaceutical Waste and Controlled Substances** – ~~If Home home-generated pharmaceutical waste, pills, liquids or other materials are not kept in their original container, they shall should be emptied from their containers by the consumer into the secured bin/container.~~ Collection site

staff may assist a consumer in opening a container but ~~shall~~should not otherwise assist consumers in placing pharmaceutical waste into the bins. With respect to controlled substances, the law enforcement agency whose officers are onsite have discretion over the exact details regarding the handling of controlled substances.

- b. Storage – ~~In accordance with Board of Pharmacy specifications requirements, A collection sites located in at pharmacies shall not commingle not allow storage of pharmaceutical waste outside of the collection containers, and shall not allow commingling of the pharmaceutical waste with active drug stock stored elsewhere on the premises. Home-generated pharmaceutical waste shall not be placed or commingled with expired, recalled or other quarantined drugs in the possession of a collection site.~~ Collected home-generated pharmaceuticals may only be stored in the secure sealed containers or in the custody of law enforcement. Once collected, home-generated pharmaceutical waste may be stored at an onsite location for not longer than 90 days when the container is ready for disposal. In certain circumstances, additional storage time may be obtained with prior written approval from the enforcement agency or the CDPH. The container shall be emptied at least once per year unless prior written approval from the enforcement agency or the CDPH is obtained.
- c. Sharps - Sharps may be accepted only if the location is also approved by the local enforcement agency or CDPH as a sharps consolidation point. Sharps and sharps in ~~approved containers, approved by the local enforcement agency~~ cannot be combined in collection bins with home-generated pharmaceutical waste. If the sharps are not brought in ~~approved a container approved by the local enforcement agency~~ and the collection site is willing to accept sharps, the consumer must place them in ~~an a container approved sharps disposal container. Never have employees by the local enforcement agency. Employees should never touch the sharps or assist in this process.~~
- d. Chain of Custody- When the home-generated pharmaceutical waste is collected by the facility, the facility becomes the ~~owner-generator~~ of the pharmaceutical waste, which is medical waste, and is responsible for assuring that ~~it is storageed, removal and transportation of full containers transported, and disposed are~~ in accordance with the Medical Waste Management Act by a licensed medical waste or hazardous waste transporter. Detailed information and invoices about each pick up from a home-generated pharmaceutical collection site shall be retained in a log by the collection site for three years after the life of the collection device. Each collection location must keep a log specific to that collection device. The log must contain (a) the name, address phone number and title of the collection site person authorized for the collection device; (b) the address, phone number and location number where device is located; (c) the date the collection device was installed at the location (d) the dates for every opening of the device and purpose of opening; (e) the names of the two persons that accessed the device (one column for collection site's personnel, and one column for the medical or hazardous waste hauler); (f) the weight of home-generated pharmaceutical waste removed from the device; and (g) additional columns for the final disposition of the drugs, and other security measures implemented to prevent unauthorized removals from the device. The log should indicate the name, address and hauler registration number of the waste hauler taking the drugs.

For controlled substances, the signed inventory must accompany the pharmaceutical waste and must stay with law enforcement in the evidence storage locker and through the point of destruction. Before the home-generated pharmaceutical waste is destroyed, the contents must be checked against the inventory to ensure that there has been no diversion. This is a U.S. Drug Enforcement Agency law.

- 7. Staffing** - The following staff are recommended at collection programs to implement the specified tasks:
- a. Pharmacist (at pharmacies) – The pharmacist ~~may or may not be able~~ has the discretion to assist any consumer who brings in home-generated pharmaceutical waste or review each consumer's deposit into the collection bin. ~~No pharmacist or pharmacy staff shall accept home-generated pharmaceutical waste directly from consumers.~~ The consumer shall deposit the items into the secured locked container. If a pharmacist, if he or she chooses, to assist consumers with the identification of drugs pharmaceuticals, the pharmacist should refer customers with pharmaceuticals that are unidentified, shall treat those drugs have been identified as controlled substances and consumers shall be referred to an appropriate collection location for those items. Alternatively, signage could be displayed stating that the pharmacy will not accept controlled substances for collection and disposal. Additional items that shall not be accepted into the pharmaceutical collection containers include sharps, medical waste and other items identified in the definition section of these procedures.
  - b. Law Enforcement – If a permanent home-generated pharmaceutical waste collection program decides to collect controlled substances, a police officer or other law enforcement officer is required to be present to monitor and collect the controlled substances.
  - c. Hazardous Waste Company Personnel (for collection at HHW facilities) - Hazardous waste personnel ~~will~~ should provide drums/containers for collection of non-controlled substances, seal containers, prepare paperwork, transport non-controlled substances for hazardous waste destruction, remove home-generated pharmaceutical waste, provide tracking paperwork from point of collection through destruction, incinerate non-controlled substances at a licensed hazardous waste incinerator, provide a certificate of destruction, and provide weight of materials collected. Do not allow home-generated pharmaceutical wastes that are hazardous waste (e.g. chemotherapy drugs) to be stored longer than 90 days at the facility as required for the management of hazardous waste.
  - d. Medical Prescriber Staff - No physician, dentist, veterinarian or other prescriber or the staff in these offices may accept home-generated pharmaceutical waste directly from consumers. It is the consumer's responsibility to deposit the items into the secured locked container. A prescriber may assist consumers with the identification of drugs.
- 8. Container Security** – It is the responsibility of the entity overseeing the collection location to provide for the security of the collected home-generated pharmaceuticals. The home-generated pharmaceutical waste must be deposited into secured containers to ~~limit~~ prevent diversion and theft opportunities and not allow staff or the entity overseeing the program from having access to the contents. Containers at permanent locations shall ~~either be locked and positioned so they are not moveable or~~ stored in an area that is either locked or under direct supervision or surveillance. The collection device must be within the physical plant of a pharmacy, prescriber's office, police department, or government agency operating the device so that it can only be accessed during operating hours.

~~The bins~~ Bins located at pharmacies shall require have a two key security system - one in the possession of the collection site's designated responsible person and the other in the possession of the licensed hauler who will pick up the contents for appropriate destruction. Containers may be stored in the following manner: a lockable cage on the container, lockable collection bins or kiosks, or lockable closets. Intermediate storage areas shall be marked with the international biohazardous symbol. These warning signs shall be readily legible from a distance of five feet.

Every collection site that provides for home-generated pharmaceutical waste collection shall keep contracts or ownership information for the collection device used for the program. These documents must be retained for the life of the device plus three years following discontinuation or replacement of the collection device. These records shall be readily retrievable at the request of a government enforcement agency.

Home-generated pharmaceutical waste may not be removed from a collection device and stored in a pharmacy, medical office or any other location. Instead, once the pharmaceuticals are removed by the waste hauler, they must be taken by the hauler. Once a collection device becomes full, no more pharmaceutical waste can be accepted from consumers by the collection site until a waste hauler has removed the pharmaceutical waste, and re-stocked the collection device with an empty container. Any theft of or loss from the collected home-generated pharmaceutical shall be reported ~~with~~ within 24 hours to the local police department, CDPH, California State Board of Pharmacy, and other agencies that have authorized the collection program.

**9. Essential Equipment and Supplies**

- a. Pharmacies, Physicians, Veterinarians and Other Prescribers' Offices and Police Stations – The following are examples of the types of equipment and supplies that ~~shall~~ should be provided: caged, lockable secure containers, lockable kiosks, lockable steel bins, refurbished lockable mail boxes with an internal container. These types of collection containers shall be located near a building entrance or in a lobby that allows people to drop off home-generated pharmaceuticals and not be able to retrieve them, in order to prevent theft. Other supplies include black markers to ~~cover up~~ obscure personal data, signage informing the public about what can and shall not be collected.
- b. Permanent HHW Collection Facility Equipment – The following are examples of equipment and supplies ~~shall should be~~ typically used at permanent HHW collection facilities provided: four container types (55 gallon lab packing containers, 30-gal cardboard with plastic liner, a 5-gal plastic container for inhalers, and a 5-gallon plastic container for mercury items), gloves, indelible markers, and sharps container and/or mail back sharps disposal kit.

**10. Budget** – In order to ensure that the program is properly run, a budget estimate should be developed so that the program is free for the public to dispose of unused and unwanted home-generated pharmaceuticals at the point of disposal. In doing so the facility will need to determine who will pay for the collection and disposal of home-generated pharmaceuticals and whether there are sufficient funds to pay for any large increases in rates or in amounts collected.

**11. Education and Advertising** - Collection locations operators shall provide educational materials to the community and to consumers dropping off home-generated pharmaceuticals. Educational materials must include information about the problem of pharmaceutical waste entering waterways and drinking water and accidental poisoning from home-generated pharmaceuticals. Operators shall develop and distribute materials advertising the availability of permanent collection programs. Examples of such advertising could include internet web site ads, newspaper ads, flyers (posted at transfer stations, municipal buildings, and pharmacies), press releases, community cable announcements, utility mailings, multi-lingual flyers distributed in utility bills in participating jurisdictions, movie theater advertisements, advertisements on buses and bus stops, print ads in recycling guides, or English and multi-lingual public service announcements. The advertisements should list who is responsible for operation of the collection location, including the name, address and phone number of the operator.

Collection location operators shall provide instructions and information for consumers ~~to use as they prepare to bring~~ prior to bringing items to the collection location. These instructions should include:

- a. ~~List~~ A list of what will and will not be accepted (address at a minimum the following: non-prescription drugs, prescription drugs, controlled substances, sharps, thermometers, medical waste).
- b. ~~All home-generated pharmaceutical waste must stay in their original containers; and~~ Instructions on type of personal information to render illegible and pharmaceutical information to retain for purposes of identification.
- c. ~~Patient name and any other personal information must be rendered unreadable on the prescription label, before turning items in for collection. Blacking out with a Sharpie or other marker is suggested. Leave the name of the drug on the container.~~

**12. Data Collection** - Data shall be kept on the total number of pounds collected, the number of residents utilizing the collection facility, and when possible, the types of materials collected for further study and analysis. Examples of collection forms can be accessed at [www.teleosis.org/pdf/Medicine\\_Return\\_Form.pdf](http://www.teleosis.org/pdf/Medicine_Return_Form.pdf) or [www.comofcom.com](http://www.comofcom.com). Security and confidentiality measures must be taken when retaining this data.

**13. Site Visits to Collection Sites** – For programs developed and overseen by public entities, those public entities shall visit collection locations periodically to help assure that procedures are being adhered to. A collection site shall make its premises available for inspection by government agencies with jurisdiction in this area.

## II. Procedures for Model Pharmaceutical Waste Collection and Disposal Programs at Government-Sponsored One Time or Periodic Collection Events

Although permanent collection programs are the preferred method to collect and properly manage home-generated pharmaceuticals, some jurisdictions such as Tuolumne County, Fresno County, City and County of Santa Cruz, and the City of Watsonville provide One-time or Periodic Collection Events. ~~Jurisdictions offering one~~ The following procedures are basic steps to implement One-time events shall adhere to the following requirements:

1. **Collection Site** - Access to the location must be restricted to only consumers dropping off home-generated pharmaceuticals. The designated operator shall observe consumers dropping off home-generated pharmaceuticals and shall ensure that ~~none of the home-generated pharmaceutical wastes are stolen.~~ stored in such a manner as to prevent theft. If any theft is observed or suspected, the operator shall contact the appropriate law enforcement agency and the Local Enforcement Agency of CDPH. The collection site should include the following:
  - a. Pharmacist (if a one day event is at a facility other than a pharmacy) ~~– Pharmacists are – It is recommended to be present at the event and must be that a licensed and pharmacist in good standing with the California State Board of Pharmacy~~ be present at the event.
  - b. Dedicated Collection Area - If the collection site is at an HHW facility and the home-generated pharmaceutical waste is being segregated, the facility must provide room to account for additional hazardous waste secured storage of pharmaceutical collection containers.
  - c. Law Enforcement - Law enforcement may participate in a collection event to provide security for event personnel; ~~this. This is optional and at the discretion of collection organizers and not required for all events.~~ A law enforcement officer is only required to attend and participate in a collection event only if

controlled substances are to be accepted at the event. ~~Only~~ Per U.S. Drug Enforcement Agency (DEA) law, only a law enforcement officer may accept controlled substances from the consumer. If controlled substances will be accepted, the operator of the event shall ask the law enforcement agency that is providing the officer if the agency has any specific requirements that the event must adhere to. For example, the law enforcement agency may specify the type of packaging that the drugs must be contained in to be accepted into their evidence locker, or if the containers the collection event will provide, are adequate for the law enforcement agency purposes. For controlled substances only, law enforcement must be on site at all times ~~be~~ and be able to see the collection and movement of the home-generated pharmaceutical wastes from the public to the collection location. Law enforcement must be able to see the transfer of home-generated pharmaceutical wastes from vehicles to the collection containers. The operator ~~shall~~ should coordinate with law enforcement to determine the appropriate position for law enforcement to be stationed.

2. **Government Agency Authorization** - Any participating entity must determine what permits or approvals are needed for home-generated pharmaceutical waste collection. All relevant agencies and programs must authorize the collection and procedures at the collection location. Some agencies to contact are: local environmental health departments, California Department of Public Health Medical Waste Management Program, local hazardous waste departments, and zoning departments for use permits. As an example, medical waste generator permits are a requirement for collection programs, and are issued by local enforcement agencies, which can be the local environmental health department or the California Department of Public Health. The volume of pharmaceuticals collected will determine if a small quantity generator or large quantity generator permit is required.
3. **Medical/Hazardous Waste Hauler/Disposal Arrangements** - Advanced arrangements shall be made with the medical or hazardous waste hauler on the fee schedule, medical or hazardous waste incineration options, packing of materials, insurance, containers, payment, contract, EPA ID number, pick up schedule, and contact telephone numbers. All home-generated pharmaceutical waste transported to an offsite waste treatment facility shall be transported by a medical waste or hazardous waste transporter that has been issued a registration certificate in accordance with the Medical Waste Management Act. A complete list of approved medical waste transporters can be found on the CDPH webpage at <http://www.cdph.ca.gov/certlic/medicalwaste/Documents/MedicalWaste/Haulist.pdf>. A medical or hazardous waste transporter transporting medical waste shall have a copy of the transporter's valid hazardous waste transporter registration certificate in the transporter's possession while transporting medical waste. It is the responsibility of the collection site to ensure that all home-generated pharmaceutical waste is appropriately picked up and transported by registered waste haulers. Detailed information about each pickup from a collection site and invoices for these services shall be retained by the collection site for three years.
4. **What Can and Cannot Be Collected**
  - a. These programs provide for the collection and disposal of home-generated prescription drugs dispensed to a consumer, or a non-prescription item in the possession of a consumer, such as over the counter drugs, vitamins and supplements, and veterinary pharmaceutical waste.
  - b. Sharps in ~~approved~~ containers approved by the local enforcement agency may be accepted at collection sites, ~~but shall not be placed in the same containers as the home-generated pharmaceutical waste.~~

- c. Medical waste such as human surgery specimens, blood samples, vaccines and serum, trauma scene waste, human surgery specimens, cultures from pathology laboratories, items containing human fluid blood vaccines, and serum shall not be accepted.
- e-d. Controlled Substances - Controlled substances cannot be collected by these programs unless a sworn law enforcement officer is onsite to properly collect, document, and dispose of these controlled substances. Controlled substances are a specific category of prescription drug and are defined as any substance listed in Sections 11053-11058 of the California Health and Safety Code. Some examples of controlled substances include opiates (morphine and codeine), painkillers, muscle relaxants, depressants and stimulants (amphetamines). ~~If a medication is not identifiable, it shall be assumed to be a controlled substance and handled accordingly.~~
5. **Signage** – Signage must be provided regarding describe what is acceptable for collection and what is not acceptable (controlled substances, sharps, garbage, etc.) ~~Home-generated pharmaceutical wastes shall be segregated for storage and, when placed in a container or secondary container, that container shall be labeled with the words "INCINERATION ONLY" or other labels approved by the CDPH on the lid and on the sides, so as to be visible from any lateral direction. A stand alone sign may be provided by the consolidation point (facility which further describes the container as a waste pharmaceutical consolidation container.). Home-generated pharmaceutical wastes are generally classified as household waste and as such can be commingled in containers with other household waste or hazardous waste. Wastes commingled in this manner must be handled as medical or hazardous waste. However, if home-generated pharmaceutical wastes are mixed with other medical waste or managed as medical waste, the waste shall be segregated for storage in a separate container or secondary container, and that container shall be labeled with the words "INCINERATION ONLY" or other label approved by the CDPH on the lid and sides, so as to be visible from any lateral direction. This sign shall be located in close proximity to the container to direct consumers to container location. During periods of non-operation this sign shall may be removed and the container shall be stored in a secure intermediate storage area.~~

~~Signage should also show include instructions on how to deposit pharmaceuticals into the secured container, since staff cannot assist the consumers. The. Any signage should also advise consumers to remove personal information from the medicine containers. In addition, the signage should mention that the consumer must not be charged for this service, nor shall any collection site pay a consumer to participate in a take back program.~~

6. **How Home-Generated Pharmaceuticals Shall Be Collected**

~~Advertise where the event will take place, when it will take place, the date, location, time, hours of the event, and who to contact for more information, for the event. Home-generated pharmaceuticals should be emptied from its original container into the secured container at the collection location. If home-generated pharmaceuticals are kept in the original, labeled container, personal information shall be removed or marked out, but leave information as to the type of medication being deposited. The emptied containers and home-generated pharmaceuticals can then be placed in separate collection bins by the consumer for proper management. Staff of the collection site other than pharmacies are not to may assist consumers in placing depositing home-generated pharmaceuticals in the bins. This is the obligation of the consumer, when needed. The collection location must ensure that the home-generated pharmaceutical licensed medical or hazardous waste hauler or handler transports the home-generated pharmaceutical waste for proper destruction. Collected home-generated pharmaceuticals shall not be resold or reused. No individual or collection site shall purchase or offer to purchase home-generated pharmaceutical waste from consumers,~~

nor shall such returned waste be sold, donated, or provided to anyone other than a registered waste hauler as specified in these procedures.

- a. Packing Home-Generated Pharmaceutical Waste and Controlled Substances ~~If Home-generated pharmaceutical waste, pills, liquids or other materials are not kept in their original container, they may shall be emptied from their containers by the consumer into the secured bin/container.~~ Collection site staff may assist a consumer in opening a container but ~~shall~~ should not otherwise assist consumers in placing pharmaceutical waste into the bins. With respect to controlled substances, the law enforcement agency whose officers are onsite have discretion over the exact details regarding the handling of controlled substances.
- b. Storage - ~~A collection site shall not allow storage of pharmaceutical waste outside of the collection containers, and shall not allow commingling of the pharmaceutical waste with active drug stock stored elsewhere on the premises. Home-generated pharmaceutical waste shall not be placed or commingled with expired, recalled or other quarantined drugs in the possession of a collection site.~~ Collected home-generated pharmaceuticals may only be stored in the secure sealed containers or in the custody of law enforcement. Once collected, home-generated pharmaceutical waste must be removed the same day from the location in which the one-day or periodic event was held but may be stored at a secure onsite location for not longer than 90 days when the container is ready for disposal. In certain circumstances, additional storage time may be obtained with prior written approval from the enforcement agency or the CDPH. The container shall be emptied at least once per year unless prior written approval from the enforcement agency or the CDPH is obtained.
- c. Sharps - Sharps may be accepted only if the location is also approved by the local enforcement agency or CDPH as a sharps consolidation point. Sharps and sharps in ~~approved~~ approved containers, approved by the local enforcement agency cannot be combined in collection bins with home-generated pharmaceutical waste. If the sharps are not brought in a container approved by the local enforcement agency and the collection site is willing to accept sharps, the consumer must place them in an approved sharps disposal container. Never have employees touch the sharps or assist in this process.
- d. Chain of Custody - When the home-generated pharmaceutical waste is collected by the facility, the facility becomes the ~~owner-generator~~ owner-generator of the pharmaceutical waste, which is medical waste, and is responsible for assuring that ~~it is stored, removal and transportation of full containers transported, and disposed~~ are ~~of~~ in accordance with the Medical Waste Management Act by a licensed medical waste or hazardous waste transporter. Detailed information and invoices about each pick up from a home-generated pharmaceutical collection site shall be retained in a log by the collection site for three years after the life of the collection device. Each collection location must keep a log specific to that collection device. The log must contain (a) the name, address phone number and title of the collection site person authorized for the collection device; (b) the address, phone number and location number where device is located; (c) the date the collection device was installed at the location (d) the dates for every opening of the device and purpose of opening; (e) the names of the two persons that accessed the device (one column for collection site's personnel, and one column for the medical or hazardous waste hauler); (f) the weight of home-generated pharmaceutical waste removed from the device; and (g) additional columns for the final disposition of the drugs, and other security measures implemented to prevent unauthorized removals from the device. The log should indicate the name, address and hauler registration number of the waste hauler taking the drugs.

For controlled substances, the signed inventory must accompany the pharmaceutical waste and must stay with law enforcement in the evidence storage locker and through the point of destruction. Before the home-generated pharmaceutical waste is destroyed, the contents must be checked against the inventory to ensure that there has been no diversion. This is a U.S. Drug Enforcement Agency law.

## 7. Staffing

The Event organizers are encouraged to have the following staff ~~are required~~ at collection sites to implement the specified tasks:

- a. Greeter - direct people to the collection location and answer questions. Greeters can also screen incoming people and wastes for problems. If the event is large enough, radios are useful.
- b. Law Enforcement Staff - to provide security, take possession of controlled substances ~~after determination by a pharmacist~~ if it has been determined that a controlled substance has been brought in by a consumer, transport controlled substances to evidence storage locker, document the collection of controlled substances, and arrange for and ensure U.S. ~~Drug Enforcement Agency~~ DEA authorized witnessed destruction of controlled substances. Law enforcement staff can also provide crowd control and watch for problem people. A law enforcement officer is required to attend and participate in a collection event only if controlled substances are to be accepted at the event. Only a law enforcement officer may accept controlled substances, not collection event personnel. If controlled substances will be accepted, confirm with the law enforcement agency providing an officer for the event, whether they have requirements for the type of packaging the drugs must be contained in to be accepted into their evidence locker, or if containers the collection event will provide are adequate for the law enforcement agency purposes. Law enforcement may participate in a collection event to provide security for event personnel. This is optional at the discretion of collection organizers and not required for all events.
- c. Pharmacist - to determine if a medication is a controlled substance, identify non-labeled home-generated pharmaceutical waste, inventory controlled substances, (if applicable), witness, and sign the inventory.
- d. Hazardous Waste Personnel - Provide drums/containers for collection of non-controlled substances. Seal containers, prepare paperwork, transport non-controlled substances for hazardous waste destruction, remove pharmaceutical waste on the same day as the event, provide tracking paperwork from point of collection through destruction, incinerate non-controlled substances in licensed hazardous waste incinerator, provide certificate of destruction, provide weight of materials collected, and complete data entry.

8. **Container Security** – It is the responsibility of the entity overseeing the collection event to provide for the security of the collected home-generated pharmaceuticals. The home-generated pharmaceutical waste must be deposited into secured containers to ~~limit~~ prevent diversion and theft opportunities and not allow staff or the entity overseeing the event from having access to the contents. The collection device must be within the physical plant of a pharmacy, prescriber's office, police department, or government agency operating the device so that it can only be accessed during operating hours.

Every collection event that provides for home-generated pharmaceutical waste collection shall keep contracts or ownership information for the collection device used for the program. These documents must be retained for the life of the device plus three years following discontinuation or replacement of the collection device. These records shall be readily retrievable at the request of a government enforcement agency.

Home-generated pharmaceutical waste may not be removed from a collection device and stored in a pharmacy, medical office or any other location. Instead, once the pharmaceuticals are removed by the waste hauler, they must be taken by the hauler. Once a collection device becomes full, no more pharmaceutical waste can be accepted from consumers by the collection site until a waste hauler has removed the pharmaceutical waste, and re-stocked the collection device with an empty container. Any theft of or loss from the collected home-generated pharmaceutical shall be reported with 24 hours to the local police department, CDPH, California State Board of Pharmacy, and other agencies that have authorized the collection program.

**9. ~~Essential~~ Recommended Equipment and Supplies**

- a. Tools for counting home-generated pharmaceutical waste (pharmacist should provide this);
- b. Hazardous waste containers;
- c. Gloves (Disposable latex or non-latex);
- d. Sealable plastic bags (One-gallon and snack size, with external slide mechanism);
- e. Extension cords, grounded;
- f. Survey forms (examples can be found at [www.teleosis.org/pdf/Medicine\\_Return\\_Form.pdf](http://www.teleosis.org/pdf/Medicine_Return_Form.pdf) or [www.comofcom.com](http://www.comofcom.com));
- g. Indelible markers;
- h. Packing tape;
- i. Containers- Check with your contracted medical or hazardous waste hauler for appropriate containers; ~~and~~
- j. Sharps disposal container -Provide sharps containers approved by the local enforcement agency to collect sharps if the location is also approved by the local enforcement agency or CDPH as a sharps consolidation point; and.
- k. Personal protective equipment – All staff must wear gloves (latex or non-latex) at all times when handling pharmaceutical waste. This is important as the containers may be powdery, sticky, and dirty. Accidental ingestion (even through skin or breathing) must be avoided. ~~Wearing~~The use of facemasks should be considered, especially for the pharmacist who ~~is doing~~may be conducting the physical ~~determination-examination~~ of the home-generated pharmaceutical waste. ~~-Do not eat or drink directly in the area that the home-generated pharmaceutical wastes are being collected. Discard used gloves.~~

**10. Budget** - An estimate of the budget should be developed and the program must be free to the public to dispose of unused and unwanted home-generated pharmaceuticals.

**11. Education and Advertising** – Collection event operators shall provide educational materials to the community and to consumers dropping off home-generated pharmaceuticals. These materials must include information about the problem of pharmaceutical waste entering waterways and drinking water and accidental poisoning from home-generated pharmaceutical waste. Event operators shall develop and distribute materials advertising for the collection event. Examples of such advertising could include internet web site ads, newspaper ads, flyers (posted at transfer stations, municipal buildings, and pharmacies), press releases, community cable announcements, utility mailings, multi-lingual flyers distributed in utility bills in participating

cities, movie theatre advertisements, advertisements on buses and at bus stops, print ads in recycling guides or English and multi-lingual public service announcements. The advertisements should list who is responsible for operation of the collection location, including the name, address and phone number of the operator.

Collection event operators shall provide instructions and information for consumers to use as they prepare to bring items to the collection event:

- a. List Date, Time, Location, operating hours, and contact information for the collection event.
- b. A list of what will and will not be accepted (address at a minimum the following: non-prescription drugs, prescription drugs, controlled substances, sharps, thermometers, medical waste-).
- c. Instructions on type of personal information to render illegible and pharmaceutical information to retain for purposes of identification.

- 12. Data Collection** - Determine amounts of home-generated pharmaceuticals collected along with the number of donators. If time allows, determine the types and amounts of home-generated pharmaceuticals collected. This information could be used for further studies and policy recommendations. Security and confidentiality measures should be taken when retaining this data.

Each collection event must have a log specific to that collection event. The log must contain (a) the name, address phone number and title of the collection site person authorized for the collection event (b) the address, phone number and location number where the event was located; (c) the date the collection event took place; (d) the names of at least one person from the event who witnessed the pickup by the licensed waste hauler (e) the name of the waste hauler's staff person who picked up the collected waste; (f) the weight of home-generated pharmaceutical waste removed from collection event; and (g) additional columns for the final disposition of the drugs, and other security measures implemented to prevent unauthorized removals. The log should indicate the name, address and hauler number of waste hauler taking the drugs. These records shall be kept for 3 years after the life of the collection event by the host agency.

- 13. Site Visits to Collection Sites** – The event organizer shall inspect the location to ensure compliance with all requirements. The CIWMB may request a report summarizing the activities of each collection location including amounts of home-generated pharmaceutical waste collected and the number of days in operation as a collection location for home-generated pharmaceuticals.

### III. Procedures for Model Pharmaceutical Waste Collection and Disposal Programs Through a Mail-Back Program

In some jurisdictions mailing back used and unused home-generated pharmaceuticals may be the only or most convenient option for the proper management of these items. An example is the State of Maine, which uses pre-paid mailing envelopes available at pharmacies, doctors' offices, and post offices. to collect home-generated pharmaceuticals that may include controlled substances. In addition, some pharmaceutical companies, such as Celgene, will take back their own home-generated pharmaceuticals via mail. Celgene allows patients to return unused drugs such as thalidomide purchased from the company, via UPS at no shipping cost to the patient. The following are some guidelines to look at when undertaking such a program:

Locations for Mail-Back Programs shall only be allowed if the following requirements are met:

1. Each entity overseeing either a Mail-Back Location or Mail-Back Program shall ensure that the home-generated pharmaceutical waste is destroyed in accordance with applicable regulations. CIWMB may request that each Mail-Back Location or Program provide information on the amounts of home-generated pharmaceuticals received and destroyed.
2. Determine locations where home-generated pharmaceuticals can be mailed for proper management and destruction. These facilities must be DEA-approved and able to accept controlled substances for destruction if controlled substances are mailed directly to the facility. In addition, these facilities must be able to provide data on the amounts of home-generated pharmaceuticals received and destroyed.
3. Operators of mail-back programs shall obtain self-sealing pre-addressed and pre-stamped envelopes that are approved by the U.S. Postal Service for containment and transportation of home-generated pharmaceutical waste. The envelopes shall also include an instruction sheet on how to package and send the home-generated pharmaceuticals.
4. Operators of mail back programs ~~shall~~ may provide postage-paid envelopes to pharmacies, one-time collection events, hospice care providers, doctors' offices, and post offices ~~to be provided to consumers that will be utilized by consumers~~ for the mailing and destruction of unused and expired home-generated pharmaceuticals.
5. Envelopes shall be tracked to assure that all envelopes are used for their intended purposes and that all of the home-generated pharmaceuticals get to the destruction facility.
6. ~~Operator~~ Operators ~~shall~~ may advertise its mail back program at pharmacies, convalescent homes, and retirement homes in order to inform potential users of the program of its availability and requirements for participation.
7. The operator shall review data on the amounts of home-generated pharmaceuticals collected to assure that the amounts are increasing and shall make changes to the program as needed to the program to assure continued growth.

## Appendix I-Definitions

1. **Controlled Substance**-any substance listed in Chapter 2 (commencing with Section 11053) of Davison 10 of the CA Health & Safety Code.
2. **Event** – Include programs and one- time events for the collection of home-generated pharmaceutical waste to assure appropriate disposal of these items.
3. **Collection Programs** – include permanent collection programs, temporary collection programs, and mail back collection programs
4. **Model Program** - CIWMB a[p[proved program through which the public may return unused or expired home-generated that meets statutory criteria.
5. **Over the Counter Drug** - a non-prescription drug a defined per CA Business & Professions Code Section 4025.1 which states “non-prescription drugs” means a drug which may be sold without a prescription and which is labeled for use by the consumer in accordance with the laws and rules of this state and the federal government.
6. **Collection Facility** - any entity CIWMB finds appropriate to implement or evaluate a model home-generated pharmaceutical waste program. The participant must agree to participate as a model program. Entities that may qualify to participate:
  - a. Governmental entities (includes police and sheriff’s stations, public/environmental health agencies and HHW facilities);
  - b. Pharmacies with active unrestricted licenses from the California State Board of Pharmacy;
  - c. Other Physician and other licensed health care prescribers’ offices; and
  - d. Healthcare Collection Sites that are licensed by the Department of Consumer Affairs
7. **Pharmaceutical Waste** - In this document it is considered to be a prescription drug dispensed to a consumer or a non-prescription item, no longer wanted or need by the consumer and includes home-generated pharmaceuticals in many delivery systems, such as pills, liquids, and inhalers.
8. **Prescription Drug** - is a dangerous drug as defined per California Business and Professions Code Section 4022 which means any drug unsafe for self-use in humans or animals, without the oversight of a licensed prescriber and includes the following:
  - a. any drug that bears the legend: “Caution: federal law prohibits dispensing without prescription, “Rx only”, or words of similar import.
  - b. any other drug that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to CA Business & Professions Code Section 4006.

# Attachment 4

*Comments to the DEA  
On Disposal of Controlled Substances  
by Persons Not Registered with the  
DEA  
Docket No. DEA 316-A*



**California State Board of Pharmacy**  
1625 N. Market Blvd, Suite N 219, Sacramento, CA 95834  
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STATE AND CONSUMERS AFFAIRS AGENCY  
DEPARTMENT OF CONSUMER AFFAIRS  
ARNOLD SCHWARZENEGGER, GOVERNOR

Docket No. DEA-316  
Sent Electronically to: dea.diversion.policy @usdoj.gov

March 23, 2009

Drug Enforcement Administration:  
Attention: DEA Federal Register Representative/ODL  
8701 Morrisette Drive  
Springfield, VA 22152

Dear Drug Enforcement Administration Staff:

Thank you for this opportunity to provide comments to your agency regarding patient disposal options for controlled substances.

The California State Board of Pharmacy regulates those who ship, store, transport, sell and dispense prescription drugs to patients and practitioners in California, and ship prescription drugs and devices into, from and throughout California. We license approximately 6,600 pharmacies in California, 500 of which are hospital pharmacies. We license over 112,000 individuals and other businesses involved with prescription drug distribution.

The Board of Pharmacy strongly believes that the public wants environmentally safe, designated means to dispose of unwanted prescription and nonprescription medicine, besides flushing medicine down the toilet or tossing it in the trash. As such, state and federal regulators need to ensure that the public has appropriate, convenient means to dispose of their medicines without creating other problems – most notably a divertible source of drugs that could return to the public or to the supply chain through the back doors of pharmacies and wholesalers, or become a public health hazard through the collection sites themselves.

So solutions that are convenient and simple for the public, yet provide secure and controlled collection and disposal of medicine are needed. The solutions must meet environment controls, and yet be inexpensive. Collected drugs need to be handled carefully and tracked by entities that are licensed to hand such wastes.

**108: What current laws or regulations does your State have regarding the disposal of dispensed controlled substances and noncontrolled substances by ultimate users?**

A: In California: California law is currently evolving in this area. Excluding legislation dealing with used sharps, the first take back law was enacted in 2007 (Simitian, Chapter 542, Statutes of 2007), which required the California Integrated Waste Management Board to develop guidelines for model take back programs, collect data and report back to the Legislature. The law included over-

the-counter and prescription drugs, and recognized that controlled drugs could not be returned, except to law enforcement agencies. The 2007 law was enacted in response to increasing demand by the public for an environmentally friendly solution of what to do with unwanted medicine.

The Model Guidelines were developed by December 1, 2008 as required, and amended again in February 2009. The California State Board of Pharmacy and the California Department of Public Health (which regulates integrated waste haulers) spent months working with the Integrated Waste Management Board and community waste disposal groups to develop these guidelines to ensure they did not create opportunities for diversion or permit unlicensed pick up of aggregated pharmaceutical waste.

The model guidelines are provided in Attachment 1. They are divided into provisions for ongoing programs, periodic programs and mail back programs. A major weakness of these guidelines is that as guidelines, they prevent regulatory agencies from enforcing the provisions. This year (see response to question 109 below) components of the model guidelines may be added to California law, and thus provide regulatory agencies with enforcement sanctions to ensure compliance.

Another major problem with the model guidelines is the manner in which they deal with controlled drugs. Federal law prohibits the return of controlled drugs to these programs unless the controlled drugs are separated and instead provided to law enforcement agencies. Although understandable, these requirements create a number of problems for most drug take-back programs. Most patients are not aware which of the drugs they may be returning are controlled drugs, so it is easy for patients to bring both controlled and noncontrolled substances to take-back sites for disposal. If patients ask for assistance from pharmacists or others in identifying whether their collection of returned drugs contains controlled substances, this results in highlighting the identification of the controlled drugs. If such identification results in a bag full of controlled substances that cannot be left at the pharmacy or collection event, what does the patient do with it? This creates the unintended but huge opportunity for someone to offer to "help" the consumer dispose of the controlled substances. A better solution is needed that prevents the identification and highlighting of controlled substances, but yet ensures that drugs deposited in take-back program bins are destroyed, and not somehow removed and diverted.

**109: What laws or regulations, if any, is your State considering regarding the disposal of dispensed controlled substances or noncontrolled substances by ultimate users?**

A: In California: this year, another bill has been just introduced (SB 26, Simitian) to deal with the take back of drugs and provide higher levels of control over the collection, storage and disposal of these drugs. Attachment 2 contains this bill, although it is early in the Legislative Session and amendments are expected. The bill will require that this board coordinate take back programs. The board believes that because diversion of drugs could occur from the inappropriate control over the collection processes that would endanger the public or result in the reintroduction of previously discarded medicine into the supply chain, strong regulatory oversight, record keeping, and sanctions are needed.

**110: Does your State agency participate in any initiatives (e.g., take-back or mail-back programs) regarding the disposal of dispensed controlled and noncontrolled substances by ultimate users at this time? If so, please describe.**

A: In California: the California State Board of Pharmacy will continue to oversee pharmacies that take back drugs, and work with waste management agencies, manufacturers and regulators regarding the use of the model guidelines in California. Many associations and work groups have formed to deal with take-back issues and the board will continue to participate in these forums. The board will work to secure changes needed to protect the public health, and will use the pending SB 26 or promulgate regulations to protect the state's drug supply.

Additionally I am a member of a committee formed by the National Association of Boards of Pharmacy to develop national policies for drug take-back programs nationwide.

**111: Is your State agency aware of any cases of diversion regarding take-back programs? If so, did the diversion result in the arrest or prosecution of any individuals?**

A: In California: the board is aware of cases involving drug diversion from take back programs. There are five instances we will describe in this letter:

1. A community pharmacy in Washington was caught "re-dispensing" drugs to patients collected in a pilot take-back program from the collection bins. This behavior is difficult to detect and the board is very concerned that California's take-back programs do not provide the opportunity for such diversion here. (Attachment 3)
2. A California physician redispensed drugs he collected from a collection bin to unknowing patients. (Attachment 4)
3. This board is currently prosecuting two pharmacies and the pharmacists involved in a fraud involving a reverse distributor who submitted claims on behalf of the pharmacies for return of drugs to manufacturers for refunds where the pharmacies claimed they returned the drugs, but which the reverse distributor actually got the drugs from other sources. (Attachment 5 and 6)
4. This is a picture of a pharmaceutical collection bin filled in California, being emptied by staff. (Attachment 7)
5. In a related matter: a California police sergeant was arrested at the end of February 2009 for stealing controlled substances from the family of a man who had recent died. (Attachment 8).

**112: If your State agency does not participate in any initiatives regarding the disposal of dispensed controlled and noncontrolled substances by ultimate users, why not?**

A: In California: not applicable; we are involved in this evolving area.

**113: If your State agency participates in any initiatives regarding the disposal of dispensed controlled and noncontrolled substances by ultimate users, what would you estimate to be the percentage, quantity or other measurable unit of controlled substances as compared to noncontrolled substances received?**

A: We have no way of knowing this figure for multiple reasons. First, the model guidelines have only just taken effect. Second, no agency has collected this figure, and the programs are set up to exclude controlled drugs.

However, the executive officer has heard estimates that up to 10 percent of the unwanted medicine patients seek to return to take-back programs are controlled substances. We are aware that families of hospice patients and those in long-term care facilities often have large quantities of drugs they wish to dispose of, but these families have had difficulty in finding appropriate disposal options. (They comprise a vocal group of supporters of take-back programs.) We suspect that there would be controlled drugs in such drug "collections."

**114: If your State agency participates in any initiatives regarding the disposal of dispensed controlled and noncontrolled substances by ultimate users, does your agency fund all or part of the initiative? If other funding is received, who provides the other funding?**

A: In California: the board does not fund such programs. However, some counties have been able to secure funds from waste management agencies to fund sharps and drug take-back programs. However, all these programs have only been able to offer limited-term funding. The Integrated Waste Management Board and county waste treatment programs are some of the temporary funding sources for these grants.

Senate Bill 966, which directed the development of model guidelines for drug take back programs, specifically prohibited pharmacies from charging patients for the return of drugs to these programs.

**115: If your State agency participates in any initiatives regarding the disposal of dispensed controlled and noncontrolled substances by ultimate users, what successes have you seen regarding these initiatives?**

A: In California: it is too soon to know the "successes" of these programs; however, there is high demand from the public in California for such programs, and the programs are likely here to stay. The adoption of state model program guidelines may well result in expanded use of these programs.

One mail return program operated by a drug manufacturer for a very dangerous product (thalidomide) seems to provide a good option for patients who need to dispose of this drug; however, as currently operated, this is an expensive program. We are unaware of other mail back programs for drugs.

**116: If your State agency participates in any initiatives regarding the disposal of dispensed and controlled and noncontrolled substances by ultimate users, what challenges or difficulties have you encountered?**

A: In California: Funding for pharmacies that take back drugs is a huge issue; most pharmacies that take back drugs pay for the programs themselves. This limits adoption and could prevent pharmacies from taking appropriate steps to properly handle and dispose of the pharmaceutical waste collected.

The product stewardship movement seeks to collect fees from manufacturers to fund the disposal of unwanted drug products from patients, but manufacturers do not currently support this philosophy. Other entities propose to deregulate pharmaceutical waste and allow common carriers to pick up these items as means to reduce program costs. The board has concerns that such cost cutting deregulation would lead to increased diversion from these programs.

Pharmacies should not be the only location where patients can take such items back. As locations where health care is delivered, it can be a problem to set up a "recycling center" in such a location. However, untended collection sites or unregulated community events can lead to inadequate security and thus lead to diversion.

Concern about how to identify and destroy controlled substances is a significant issue. Patients do not know what controlled drugs are. Separation of these drugs at a collection site is a problem and a possible source of diversion by the "sorter" whether a pharmacist or not. Moreover, patients often combine different medicines into containers so simply reading a label is not sufficient to be certain that controlled drugs are not deposited into collection bins.

Accordingly, the board suggests that drugs be deposited into collection bins by consumers, without their containers, and then pulverized or ground into an unidentifiable mass or mixed with fluid to prevent reuse (and destroy the attractiveness) of the collected drugs. This would render the aggregation worthless, and the separated containers can be independently recycled.

As stated previously, diversion and theft from unauthorized access to these bins remains a huge concern.

Lastly, those who handle waste at the county level sometimes lack the understanding of the value that aggregated pharmaceuticals create, in contrast to other waste streams such as recycled motor oil, paper and glass. This lack of knowledge results in the development of programs that fail to provide adequate security and safeguards to prevent diversion.

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Thank you for this opportunity to provide comments. The California State Board of Pharmacy would welcome the opportunity to work with you more fully if we can be of assistance to you. If you have questions, please do not hesitate to contact the board's executive officer, Virginia Herold, at (916) 574-7911.

Sincerely,



Kenneth Schell, PharmD  
President

Attachments

### Revised Criteria and Procedures for Model Home-Generated Pharmaceutical Waste Collection and Disposal Programs

Senate Bill 966 (Simitian, Chapter 542, Statutes of 2007) requires the California Integrated Waste Management Board (CIWMB) to develop model programs for the collection from consumers and proper disposal of unused or expired home-generated pharmaceuticals<sup>1</sup>. In developing model programs in California, the CIWMB is also required to evaluate programs used by other state, local, and other governmental entities. The CIWMB provided a survey to those entities that have collection programs and requested that they complete and return it to the CIWMB. The purpose of the survey was to acquire information on existing home-generated pharmaceutical waste collection programs in California. From the survey results, the Procedures for Model Home-Generated Pharmaceutical Waste Collection and Disposal Programs (Procedures) were developed that would help organizations or local governments create programs through which the public may return unused or expired home-generated pharmaceutical waste (typically a prescription drug dispensed to a consumer, or a non-prescription item, such as over the counter drugs, that are no longer wanted or needed by the consumer) and meet the following minimum criteria and goals of SB 966 and of the Pharmaceutical Working Group (staff from CIWMB, California Department of Public Health (CDPH), Board of Pharmacy, Department of Toxic Substances Control, and the State Water Resources Control Board).

The minimum criteria of SB 966 and of the Pharmaceutical Working Group for home-generated pharmaceutical waste collection model programs are as follows:

1. Requires, at no additional cost to the consumer, the safe and environmentally sound take back and disposal of unused or expired home-generated pharmaceuticals;
2. Ensures protection of the public's health and safety and the environment;
3. Ensures protection of the health and safety of consumers, and employees;
4. Report to the Board the amounts of home-generated pharmaceutical waste collected for purposes of program evaluation for safety, efficiency, effectiveness and funding sustainability, and incidents of diversion of drugs for use or sale;
5. Protects against the potential for the diversion of drug waste for unlawful use or sale;
6. Provides notices and informational materials about potential impacts of improper disposal of pharmaceutical waste and options for proper disposal;
7. Subjects persons or businesses to consequences for failure to comply with model programs per SB 966 and related state and federal pharmaceutical and waste management statutes at the point of transportation, deposition, and consolidation;
8. Requires that once home-generated pharmaceutical waste has been consolidated at a facility or place of business, the waste must be managed as medical or hazardous waste. This would include all statutory requirements for storage and handling as medical or hazardous waste, the use of registered medical or hazardous waste haulers and approved treatment technology for disposal; and
9. Requires collection locations to have written policies and procedures to document their operations and compliance with this home-generated pharmaceutical waste collection program.

Additional goals of SB 966 and the Pharmaceutical Working Group include:

<sup>1</sup> Throughout this document, the terms "home-generated pharmaceuticals" or "home-generated pharmaceutical waste" are used. Although the term does not appear in the law establishing this program, it is the term commonly used by stakeholders to refer to unused or expired pharmaceuticals in the possession of consumers.

1. Provides Providing for the collection of home-generated pharmaceuticals that is convenient for consumers;
2. Maintains Maintaining privacy of all participants;
3. Prevents Preventing the illegal collection of controlled substances through displaying signage or legally manages them if they are collected;
4. Ensures Ensuring that medication information is legible, so that it can be identified in case of a poisoning;
5. Develops Developing a sustainable funding source for collection and disposal of home-generated pharmaceuticals, such as grants, utility funding, or advanced disposal fees placed on home-generated pharmaceuticals and local general funds or via extended producer responsibility funding framework.
6. Strives Striving to develop permanent collection programs rather than one-day events, so they will be more accessible to the public; and
7. Provides Providing recommendations for implementation of a statewide program; and
8. Recommends Recommending statutory changes to, for example, the Medical Waste Management Act.

The following Procedures have been extracted from both the Pharmaceutical Collection Programs Survey collection program information on the internet, and from the Pharmaceutical Working Group and are required recommended for pharmaceutical collection programs. The Procedures are not only a tool to determine if a program meets the minimum criteria of model programs, but also can be used as a model to develop a collection and disposal program for unused/expired home-generated pharmaceuticals. The Procedures are broken down by (I) Permanent Home-Generated Pharmaceutical Waste Collection and Disposal Programs, (II) One-Time or Periodic Events, and (III) Mail Back Programs.

#### Procedures for Model Permanent Home-Generated Pharmaceutical Waste Collection and Disposal Programs

As mentioned in the previous section on goals, it is preferable that permanent home-generated pharmaceutical collection programs be developed to provide the public with consistently accessible and convenient venues to drop off unused or expired home-generated pharmaceuticals. The following procedures are basic steps that shall be taken to implement permanent collection programs at these types of facilities.

1. **Types of Collection Facilities** – Only the following may maintain permanent collection locations for home-generated pharmaceuticals: pharmacies with active unrestricted licenses from the California State Board of Pharmacy, police and sheriff's stations, public/environmental health agencies, physician and other licensed health care prescribers' offices, Household Hazardous Waste (HHW) facilities, and healthcare collection sites. Healthcare collection sites are physical locations licensed or operated by individuals or entities licensed by an agency within the Department of Consumer Affairs (DCA), with these locations electing to collect or take-back home-generated pharmaceutical waste and/or sharps, as applicable. Examples of healthcare collection sites include but are not limited to physicians and surgeons' offices, dentists, veterinary offices and pharmacies. If a DCA licensee has their license revoked, suspended, placed on probation or otherwise limited in any way, it shall not operate a healthcare collection site. If collection is at a police station, law enforcement must agree to and be able to collect the controlled substances and other home-generated pharmaceutical waste.

DEA  
Attachment 1

Participation by any entity is voluntary and must be done in accordance with these provisions in these procedures in order to be considered a model program. Jurisdictions such as the City of Los Angeles, San Mateo County, Ventura County, Santa Cruz County, Marin County, Santa Clara County, and nonprofit groups such as the Telesis Institute are current examples of entities implementing permanent and ongoing programs utilizing these types of venues.

A list of those facilities that collect home-generated pharmaceutical waste shall be provided to the CIWMB by the governmental entity, organization, or business that is implementing these programs. The list of collection facilities shall include the name, address, contact, and telephone number of the facility collecting and disposing of the home-generated pharmaceutical waste.

2. Government Agency Authorization – Any participating entity must determine what permits or approvals are needed for home-generated pharmaceutical waste collection. All relevant agencies and programs must authorize the collection and procedures at the collection location. Some agencies to contact are: local environmental health departments, California Department of Public Health Medical Waste Management Program, local hazardous waste departments, and zoning departments for use permits. As an example, medical waste generator permits are a requirement for collection programs, and are issued by local enforcement agencies, which can be the local environmental health department or the California Department of Public Health. The volume of pharmaceuticals collected will determine if a small quantity generator or large quantity generator permit is required.
3. Medical/Hazardous Waste Hauler/Disposal Arrangements – Advanced arrangements shall be made with the medical or hazardous waste hauler on the fee schedule, medical or hazardous waste incineration options, packing of materials, insurance, containers, payment, contract, EPA ID number, pick up schedule, and contact telephone numbers. All home-generated pharmaceutical waste transported to an offsite waste treatment facility shall be transported by a medical waste or hazardous waste transporter that has been issued a registration certificate in accordance with the Medical Waste Management Act. A complete list of approved medical waste transporters can be found on the CDPH webpage at <http://www.cdph.ca.gov/certlic/medicalwaste/Documents/MedicalWaste/Haulist.pdf>. A medical or hazardous waste transporter transporting medical waste shall have a copy of the transporter's valid hazardous waste transporter registration certificate in the transporter's possession while transporting medical waste. It is the responsibility of the collection site to ensure that all home-generated pharmaceutical waste is appropriately picked up and transported by registered waste haulers. Detailed information about each pickup from a collection site and invoices for these services shall be retained by the collection site for three years.
4. What Can and Cannot Be Collected
  - a. Home-generated prescription drugs dispensed to a consumer, or a non-prescription item in the possession of a consumer, such as over the counter drugs, vitamins and supplements, and veterinary pharmaceutical waste, may be accepted.
  - b. Sharps in approved containers approved by the local enforcement agency may be accepted at collection sites, but shall not be placed in the same containers as the home-generated pharmaceutical waste.
  - c. Medical waste such as human surgery specimens, blood samples, vaccines and serum, trauma scene waste, human surgery specimens, cultures from pathology laboratories, items containing human fluid blood vaccines, and serum shall not be accepted.

d. Controlled Substances - Controlled substances cannot be collected by these programs unless a sworn law enforcement officer is onsite to take custody of, document, and dispose of these controlled substances. Controlled substances are a specific category of prescription drugs and are defined as any substance listed in Sections 11053-11058 of the California Health and Safety Code. Some examples of controlled substances include opiates (morphine and codeine), painkillers, muscle relaxants, depressants and stimulants (amphetamines). ~~If a medication is not identifiable, it shall be assumed to be a controlled substance and handled accordingly.~~

5. Signage – Signage must be provided regarding what is acceptable for collection and what is not acceptable (controlled substances, sharps, garbage, etc.), as well as the hours during which collection is permitted. Home-generated pharmaceutical wastes are generally classified as household waste and as such can be commingled in containers with other household waste or hazardous waste. Wastes commingled in this manner must be handled as medical or hazardous waste. However, if home-generated pharmaceutical wastes are mixed with other medical waste or managed as medical waste, the waste shall be segregated for storage in a separate container or secondary container, and that container shall be labeled with the words "INCINERATION ONLY" or other label approved by the CDPH on the lid and sides, so as to be visible from any lateral direction. Home-generated pharmaceutical wastes shall be segregated for storage and when placed in a container or secondary container, that container shall be labeled with the words "INCINERATION ONLY" or other label approved by the CDPH on the lid and sides, so as to be visible from any lateral direction. A stand alone sign may be provided by the consolidation point (facility) which further describes the container as a waste pharmaceutical consolidation container. This sign shall be located in close proximity to the container to direct consumers to the container location. During periods of non-operation this sign shall may be removed and the container shall be stored in a secure intermediate storage area to prevent theft.

Signage should also ~~show~~ include instructions on how to deposit pharmaceuticals into the secured container, since staff cannot assist the consumers. ~~The~~ Any signage should also advise consumers to remove personal information from the medicine containers. ~~In addition, the signage should mention that the consumer must not be charged for this service, nor shall any collection site pay a consumer but leave information as to participate in a take-back program the type of medication being deposited.~~

6. How Home-Generated Pharmaceuticals Shall Be Collected – Home-generated pharmaceuticals should be emptied from its original container into the secured container at the collection location. If home-generated pharmaceuticals are kept in the original, labeled container, ensure that personal information shall be removed or marked out, but information pertaining to the type of pharmaceutical is retained. The emptied containers and home-generated pharmaceuticals can then be placed in separate collection bins by the consumer for proper management. Staff of the collection site other than pharmacies are not to may assist consumers in placing home-generated pharmaceuticals in the bins. ~~This is the obligation of the consumer, if deemed necessary.~~ The collection location must ensure that the home-generated pharmaceutical licensed waste hauler or handler transports the home-generated pharmaceutical for proper destruction. Collected home-generated pharmaceuticals shall not be resold or reused. No individual or collection site shall purchase or offer to purchase home-generated pharmaceutical waste from consumers, nor shall such returned waste be sold, donated, or provided to anyone other than a registered medical or hazardous waste hauler as specified in these procedures.
  - a. Packing Home-Generated Pharmaceutical Waste and Controlled Substances – ~~If Home-generated pharmaceutical waste, pills, liquids or other materials are not kept in their original container, they shall should be emptied from their containers by the consumer into the secured bin/container.~~ Collection site

staff may assist a consumer in opening a container but shall ~~should~~ not otherwise assist consumers in placing pharmaceutical waste into the bins. With respect to controlled substances, the law enforcement agency whose officers are onsite have discretion over the exact details regarding the handling of controlled substances.

- b. ~~Storage – In accordance with Board of Pharmacy specifications requirements, A collection sites located in at pharmacies shall not commingle not allow storage of pharmaceutical waste outside of the collection containers, and shall not allow commingling of the pharmaceutical waste with active drug stock stored elsewhere on the premises. Home-generated pharmaceutical waste shall not be placed or commingled with expired, recalled or other quarantined drugs in the possession of a collection site. Collected home-generated pharmaceuticals may only be stored in the secure sealed containers or in the custody of law enforcement. Once collected, home-generated pharmaceutical waste may be stored at an onsite location for not longer than 90 days when the container is ready for disposal. In certain circumstances, additional storage time may be obtained with prior written approval from the enforcement agency or the CDPH. The container shall be emptied at least once per year unless prior written approval from the enforcement agency or the CDPH is obtained.~~
- c. ~~Sharps – Sharps may be accepted only if the location is also approved by the local enforcement agency or CDPH as a sharps consolidation point. Sharps and sharps in approved containers, approved by the local enforcement agency cannot be combined in collection bins with home-generated pharmaceutical waste. If the sharps are not brought in approved a container approved by the local enforcement agency and the collection site is willing to accept sharps, the consumer must place them in a container approved sharps disposal container. Never have employees by the local enforcement agency. Employees should never touch the sharps or assist in this process.~~
- d. ~~Chain of Custody- When the home-generated pharmaceutical waste is collected by the facility, the facility becomes the owner-generator of the pharmaceutical waste, which is medical waste, and is responsible for assuring that it is stored, removal and transportation of full containers transported, and disposed are in accordance with the Medical Waste Management Act by a licensed medical waste or hazardous waste transporter. Detailed information and invoices about each pick up from a home-generated pharmaceutical collection site shall be retained in a log by the collection site for three years after the life of the collection device: Each collection location must keep a log specific to that collection device. The log must contain (a) the name, address phone number and title of the collection site person authorized for the collection device; (b) the address, phone number and location number where device is located; (c) the date the collection device was installed at the location (d) the dates for every opening of the device and purpose of opening; (e) the names of the two persons that accessed the device (one column for collection site's personnel, and one column for the medical or hazardous waste hauler); (f) the weight of home-generated pharmaceutical waste removed from the device; and (g) additional columns for the final disposition of the drugs, and other security measures implemented to prevent unauthorized removals from the device. The log should indicate the name, address and hauler registration number of the waste hauler taking the drugs.~~

For controlled substances, the signed inventory must accompany the pharmaceutical waste and must stay with law enforcement in the evidence storage locker and through the point of destruction. Before the home-generated pharmaceutical waste is destroyed, the contents must be checked against the inventory to ensure that there has been no diversion. This is a U.S. Drug Enforcement Agency law.

7. Staffing - The following staff are recommended at collection programs to implement the specified tasks:
- a. ~~Pharmacist (at pharmacies) – The pharmacist may or may not be able has the discretion to assist any consumer who brings in home-generated pharmaceutical waste or review each consumer's deposit into the collection bin. No pharmacist or pharmacy staff shall accept home-generated pharmaceutical waste directly from consumers. The consumer shall deposit the items into the secured locked container. If a pharmacist, if he or she chooses, to assist consumers with the identification of drugs pharmaceuticals, the pharmacist should refer customers with pharmaceuticals that are unidentified, shall treat those drugs have been identified as controlled substances and consumers shall be referred to an appropriate collection location for those items. Alternatively, signage could be displayed stating that the pharmacy will not accept controlled substances for collection and disposal. Additional items that shall not be accepted into the pharmaceutical collection containers include sharps, medical waste and other items identified in the definition section of these procedures.~~
- b. ~~Law Enforcement – If a permanent home-generated pharmaceutical waste collection program decides to collect controlled substances, a police officer or other law enforcement officer is required to be present to monitor and collect the controlled substances.~~
- c. ~~Hazardous Waste Company Personnel (for collection at HHW facilities) - Hazardous waste personnel will should provide drums/containers for collection of non-controlled substances, seal containers, prepare paperwork, transport non-controlled substances for hazardous waste destruction, remove home-generated pharmaceutical waste, provide tracking paperwork from point of collection through destruction, incinerate non-controlled substances at a licensed hazardous waste incinerator, provide a certificate of destruction, and provide weight of materials collected. Do not allow home-generated pharmaceutical wastes that are hazardous waste (e.g. chemotherapy drugs) to be stored longer than 90 days at the facility as required for the management of hazardous waste.~~
- d. ~~Medical Prescriber Staff - No physician, dentist, veterinarian or other prescriber or the staff in these offices may accept home-generated pharmaceutical waste directly from consumers. It is the consumer's responsibility to deposit the items into the secured locked container. A prescriber may assist consumers with the identification of drugs.~~
8. ~~Container Security – It is the responsibility of the entity overseeing the collection location to provide for the security of the collected home-generated pharmaceuticals. The home-generated pharmaceutical waste must be deposited into secured containers to limit prevent diversion and theft opportunities and not allow staff or the entity overseeing the program from having access to the contents. Containers at permanent locations shall either be locked and positioned so they are not moveable or stored in an area that is either locked or under direct supervision or surveillance. The collection device must be within the physical plant of a pharmacy, prescriber's office, police department, or government agency operating the device so that it can only be accessed during operating hours.~~

~~The bins located at pharmacies shall require have a two key security system-one in the possession of the collection site's designated responsible person and the other in the possession of the licensed hauler who will pick up the contents for appropriate destruction. Containers may be stored in the following manner: a lockable cage on the container, lockable collection bins or kiosks, or lockable closets. Intermediate storage areas shall be marked with the international biohazardous symbol. These warning signs shall be readily legible from a distance of five feet.~~

Every collection site that provides for home-generated pharmaceutical waste collection shall keep contracts or ownership information for the collection device used for the program. These documents must be retained for the life of the device plus three years following discontinuation or replacement of the collection device. These records shall be readily retrievable at the request of a government enforcement agency.

Home-generated pharmaceutical waste may not be removed from a collection device and stored in a pharmacy, medical office or any other location. Instead, once the pharmaceuticals are removed by the waste hauler, they must be taken by the hauler. Once a collection device becomes full, no more pharmaceutical waste can be accepted from consumers by the collection site until a waste hauler has removed the pharmaceutical waste, and re-stocked the collection device with an empty container. Any theft of or loss from the collected home-generated pharmaceutical shall be reported with within 24 hours to the local police department, CDPH, California State Board of Pharmacy, and other agencies that have authorized the collection program.

9. Essential Equipment and Supplies

- a. Pharmacies, Physicians, Veterinarians and Other Prescribers' Offices and Police Stations – The following are examples of the types of equipment and supplies that ~~shall~~ should be provided: caged, lockable secure containers, lockable kiosks, lockable steel bins, refurbished lockable mail boxes with an internal container. These types of collection containers shall be located near a building entrance or in a lobby that allows people to drop off home-generated pharmaceuticals and not be able to retrieve them, in order to prevent theft. Other supplies include black markers to ~~cover up~~ obscure personal data, signage informing the public about what can and shall not be collected.
- b. Permanent HHW Collection Facility Equipment – The following are examples of equipment and supplies ~~shall~~ should be typically used at permanent HHW collection facilities provided: four container types (55 gallon lab packing containers, 30-gal cardboard with plastic liner, a 5-gal plastic container for inhalers, and a 5-gallon plastic container for mercury items), gloves, indelible markers, and sharps container and/or mail back sharps disposal kit.

10. Budget – In order to ensure that the program is properly run, a budget estimate should be developed so that the program is free for the public to dispose of unused and unwanted home-generated pharmaceuticals at the point of disposal. In doing so the facility will need to determine who will pay for the collection and disposal of home-generated pharmaceuticals and whether there are sufficient funds to pay for any large increases in rates or in amounts collected.

11. Education and Advertising - Collection locations operators shall provide educational materials to the community and to consumers dropping off home-generated pharmaceuticals. Educational materials must include information about the problem of pharmaceutical waste entering waterways and drinking water and accidental poisoning from home-generated pharmaceuticals. Operators shall develop and distribute materials advertising the availability of permanent collection programs. Examples of such advertising could include internet web site ads, newspaper ads, flyers (posted at transfer stations, municipal buildings, and pharmacies), press releases, community cable announcements, utility mailings, multi-lingual flyers distributed in utility bills in participating jurisdictions, movie theater advertisements, advertisements on buses and bus stops, print ads in recycling guides, or English and multi-lingual public service announcements. The advertisements should list who is responsible for operation of the collection location, including the name, address and phone number of the operator.

Collection location operators shall provide instructions and information for consumers ~~to use as they prepare to bring~~ prior to bringing items to the collection location. These instructions should include:

- a. List A list of what will and will not be accepted (address at a minimum the following: non-prescription drugs, prescription drugs, controlled substances, sharps, thermometers, medical waste).
- b. All home-generated pharmaceutical waste must stay in their original containers; and Instructions on type of personal information to render illegible and pharmaceutical information to retain for purposes of identification.
- c. Patient name and any other personal information must be rendered unreadable on the prescription label, before turning items in for collection. Blacking out with a Sharpie or other marker is suggested. Leave the name of the drug on the container.

12. Data Collection - Data shall be kept on the total number of pounds collected, the number of residents utilizing the collection facility, and when possible, the types of materials collected for further study and analysis. Examples of collection forms can be accessed at [www.teleosis.org/pdf/Medicine\\_Return\\_Form.pdf](http://www.teleosis.org/pdf/Medicine_Return_Form.pdf) or [www.comofcom.com](http://www.comofcom.com). Security and confidentiality measures must be taken when retaining this data.

13. Site Visits to Collection Sites – For programs developed and overseen by public entities, those public entities shall visit collection locations periodically to help assure that procedures are being adhered to. A collection site shall make its premises available for inspection by government agencies with jurisdiction in this area.

Procedures for Model Pharmaceutical Waste Collection and Disposal Programs at Government Sponsored One-time or Periodic Collection Events

Although permanent collection programs are the preferred method to collect and properly manage home-generated pharmaceuticals, some jurisdictions such as Tuolumne County, Fresno County, City and County of Santa Cruz, and the City of Watsonville provide One-time or Periodic Collection Events. Jurisdictions offering one-time events shall adhere to the following requirements:

1. Collection Site - Access to the location must be restricted to only consumers dropping off home-generated pharmaceuticals. The designated operator shall observe consumers dropping off home-generated pharmaceuticals and shall ensure that ~~none of the home-generated pharmaceuticals wastes are stolen~~ stored in such a manner as to prevent theft. If any theft is observed or suspected, the operator shall contact the appropriate law enforcement agency and the Local Enforcement Agency of CDPH. The collection site should include the following:
- a. Pharmacist (if a one day event is at a facility other than a pharmacy) – Pharmacists are – It is recommended to be present at the event and must be that a licensed and pharmacist in good standing with the California State Board of Pharmacy be present at the event.
- b. Dedicated Collection Area - If the collection site is at an HHW facility and the home-generated pharmaceutical waste is being segregated, the facility must provide room to account for additional hazardous waste-secured storage of pharmaceutical collection containers.
- c. Law Enforcement - Law enforcement may participate in a collection event to provide security for event personnel; this is optional and at the discretion of collection organizers and not required for all events. A law enforcement officer is only required to attend and participate in a collection event only if

controlled substances are to be accepted at the event. ~~Only Per U.S. Drug Enforcement Agency (DEA) law, only~~ a law enforcement officer may accept controlled substances from the consumer. If controlled substances will be accepted, the operator of the event shall ask the law enforcement agency that is providing the officer if the agency has any specific requirements that the event must adhere to. For example, the law enforcement agency may specify the type of packaging that the drugs must be contained in to be accepted into their evidence locker, or if the containers the collection event will provide, are adequate for the law enforcement agency purposes. For controlled substances only, law enforcement must be on site at all times ~~be and~~ be able to see the collection and movement of the home-generated pharmaceutical wastes from the public to the collection location. Law enforcement must be able to see the transfer of home-generated pharmaceutical wastes from vehicles to the collection containers. The operator ~~shall~~ should coordinate with law enforcement to determine the appropriate position for law enforcement to be stationed.

2. Government Agency Authorization - Any participating entity must determine what permits or approvals are needed for home-generated pharmaceutical waste collection. All relevant agencies and programs must authorize the collection and procedures at the collection location. Some agencies to contact are: local environmental health departments, California Department of Public Health Medical Waste Management Program, local hazardous waste departments, and zoning departments for use permits. As an example, medical waste generator permits are a requirement for collection programs, and are issued by local enforcement agencies, which can be the local environmental health department or the California Department of Public Health. The volume of pharmaceuticals collected will determine if a small quantity generator or large quantity generator permit is required.
3. Medical/Hazardous Waste Hauler/Disposal Arrangements - Advanced arrangements shall be made with the medical or hazardous waste hauler on the fee schedule, medical or hazardous waste incineration options, packing of materials, insurance, containers, payment, contract, EPA ID number, pick up schedule, and contact telephone numbers. All home-generated pharmaceutical waste transported to an offsite waste treatment facility shall be transported by a medical waste or hazardous waste transporter that has been issued a registration certificate in accordance with the Medical Waste Management Act. A complete list of approved medical waste transporters can be found on the CDPH webpage at <http://www.cdph.ca.gov/certlic/medicalwaste/Documents/MedicalWaste/Haulist.pdf>. A medical or hazardous waste transporter transporting medical waste shall have a copy of the transporter's valid hazardous waste transporter registration certificate in the transporter's possession while transporting medical waste. It is the responsibility of the collection site to ensure that all home-generated pharmaceutical waste is appropriately picked up and transported by registered waste haulers. Detailed information about each pickup from a collection site and invoices for these services shall be retained by the collection site for three years.
4. What Can and Cannot Be Collected
  - a. These programs provide for the collection and disposal of home-generated prescription drugs dispensed to a consumer, or a non-prescription item in the possession of a consumer, such as over the counter drugs, vitamins and supplements, and veterinary pharmaceutical waste.
  - b. Sharps in approved containers approved by the local enforcement agency may be accepted at collection sites, ~~but shall not be placed in the same containers as the home-generated pharmaceutical waste.~~

c. Medical waste such as human surgery specimens, blood samples, vaccines and serum, trauma scene waste, human surgery specimens, cultures from pathology laboratories, items containing human fluid blood vaccines, and serum shall not be accepted.

~~e.d.~~ Controlled Substances - Controlled substances cannot be collected by these programs unless a sworn law enforcement officer is onsite to properly collect, document, and dispose of these controlled substances. Controlled substances are a specific category of prescription drug and are defined as any substance listed in Sections 11053-11058 of the California Health and Safety Code. Some examples of controlled substances include opiates (morphine and codeine), painkillers, muscle relaxants, depressants and stimulants (amphetamines). ~~If a medication is not identifiable, it shall be assumed to be a controlled substance and handled accordingly.~~

5. Signage - Signage ~~must be provided regarding describe~~ what is acceptable for collection and what is not acceptable (controlled substances, sharps, garbage, etc.) ~~Home-generated pharmaceutical wastes shall be segregated for storage and, when placed in a container or secondary container, that container shall be labeled with the words "INCINERATION ONLY" or other labels approved by the CDPH on the lid and on the sides, so as to be visible from any lateral direction. A stand-alone sign may be provided by the consolidation point (facility which further describes the container as a waste pharmaceutical consolidation container.). Home-generated pharmaceutical wastes are generally classified as household waste and as such can be commingled in containers with other household waste or hazardous waste. Wastes commingled in this manner must be handled as medical or hazardous waste. However, if home-generated pharmaceutical wastes are mixed with other medical waste or managed as medical waste, the waste shall be segregated for storage in a separate container or secondary container, and that container shall be labeled with the words "INCINERATION ONLY" or other label approved by the CDPH on the lid and sides, so as to be visible from any lateral direction. This sign shall be located in close proximity to the container to direct consumers to container location. During periods of non-operation this sign shall may be removed and the container shall be stored in a secure intermediate storage area.~~

Signage should ~~also show~~ include instructions on how to deposit pharmaceuticals into the secured container, ~~since staff cannot assist the consumers. The~~ Any signage should also advise consumers to remove personal information from the medicine containers. ~~In addition, the signage should mention that the consumer must not be charged for this service, nor shall any collection site pay a consumer to participate in a take-back program.~~

6. How Home-Generated Pharmaceuticals Shall Be Collected ~~Advertise where the event will take place, when it will take place, the date, location, time, hours of the event, and who to contact for more information, for the event. Home-generated pharmaceuticals should be emptied from its original container into the secured container at the collection location. If home-generated pharmaceuticals are kept in the original, labeled container, personal information shall be removed or marked out, but leave information as to the type of medication being deposited. The emptied containers and home-generated pharmaceuticals can then be placed in separate collection bins by the consumer for proper management. Staff of the collection site other than pharmacies are not to may assist consumers in placing depositing home-generated pharmaceuticals in the bins. This is the obligation of the consumer, when needed. The collection location must ensure that the home-generated pharmaceutical licensed medical or hazardous waste hauler or handler transports the home-generated pharmaceutical waste for proper destruction. Collected home-generated pharmaceuticals shall not be resold or reused. No individual or collection site shall purchase or offer to purchase home-generated pharmaceutical waste from consumers,~~

nor shall such returned waste be sold, donated, or provided to anyone other than a registered waste hauler as specified in these procedures.

- a. Packing Home-Generated Pharmaceutical Waste and Controlled Substances - ~~If home-generated pharmaceutical waste, pills, liquids or other materials are not kept in their original container, they may be emptied from their containers by the consumer into the secured bin/container.~~ Collection site staff may assist a consumer in opening a container but ~~shall~~ should not otherwise assist consumers in placing pharmaceutical waste into the bins. With respect to controlled substances, the law enforcement agency whose officers are onsite have discretion over the exact details regarding the handling of controlled substances.
- b. Storage - ~~A collection site shall not allow storage of pharmaceutical waste outside of the collection containers, and shall not allow commingling of the pharmaceutical waste with active drug stock stored elsewhere on the premises. Home-generated pharmaceutical waste shall not be placed or commingled with expired, recalled or other quarantined drugs in the possession of a collection site.~~ Collected home-generated pharmaceuticals may only be stored in the secure sealed containers or in the custody of law enforcement. Once collected, home-generated pharmaceutical waste must be removed the same day from the location in which the one-day or periodic event was held but may be stored at an secure onsite location for not longer than 90 days when the container is ready for disposal. In certain circumstances, additional storage time may be obtained with prior written approval from the enforcement agency or the CDPH. The container shall be emptied at least once per year unless prior written approval from the enforcement agency or the CDPH is obtained.
- c. Sharps - Sharps may be accepted only if the location is also approved by the local enforcement agency or CDPH as a sharps consolidation point. Sharps in ~~approved~~ approved containers, approved by the local enforcement agency cannot be combined in collection bins with home-generated pharmaceutical waste. If the sharps are not brought in a container approved by the local enforcement agency and the collection site is willing to accept sharps, the consumer must place them in an approved sharps disposal container. Never have employees touch the sharps or assist in this process.
- d. Chain of Custody - When the home-generated pharmaceutical waste is collected by the facility, the facility becomes the ~~owner~~ generator of the pharmaceutical waste, which is medical waste, and is responsible for assuring that ~~it is stored, removal and transportation of full containers transported, and disposed of~~ it is stored, removal and transportation of full containers transported, and disposed of in accordance with the Medical Waste Management Act by a licensed medical waste or hazardous waste transporter. Detailed information and invoices about each pick up from a home-generated pharmaceutical collection site shall be retained in a log by the collection site for three years after the life of the collection device. Each collection location must keep a log specific to that collection device. The log must contain (a) the name, address phone number and title of the collection site person authorized for the collection device; (b) the address, phone number and location number where device is located; (c) the date the collection device was installed at the location (d) the dates for every opening of the device and purpose of opening; (e) the names of the two persons that accessed the device (one column for collection site's personnel, and one column for the medical or hazardous waste hauler); (f) the weight of home-generated pharmaceutical waste removed from the device; and (g) additional columns for the final disposition of the drugs, and other security measures implemented to prevent unauthorized removals from the device. The log should indicate the name, address and ~~hauler~~ hauler registration number of the waste hauler taking the drugs.

For controlled substances, the signed inventory must accompany the pharmaceutical waste and must stay with law enforcement in the evidence storage locker and through the point of destruction. Before the home-generated pharmaceutical waste is destroyed, the contents must be checked against the inventory to ensure that there has been no diversion. This is a U.S. Drug Enforcement Agency law.

#### 7. Staffing

The Event organizers are encouraged to have the following staff ~~are required~~ at collection sites to implement the specified tasks:

- a. Greeter - direct people to the collection location and answer questions. Greeters can also screen incoming people and wastes for problems. If the event is large enough, radios are useful.
  - b. Law Enforcement Staff - to provide security, take possession of controlled substances after ~~determination by a pharmacist if it has been determined that a controlled substance has been brought in by a consumer~~, transport controlled substances to evidence storage locker, document the collection of controlled substances, and arrange for and ensure U.S. ~~Drug Enforcement Agency-DEA~~ Drug Enforcement Agency-DEA authorized witnessed destruction of controlled substances. Law enforcement staff can also provide crowd control and watch for problem people. A law enforcement officer is required to attend and participate in a collection event only if controlled substances are to be accepted at the event. Only a law enforcement officer may accept controlled substances, not collection event personnel. If controlled substances will be accepted, confirm with the law enforcement agency providing an officer for the event, whether they have requirements for the type of packaging the drugs must be contained in to be accepted into their evidence locker, or if containers the collection event will provide are adequate for the law enforcement agency purposes. Law enforcement may participate in a collection event to provide security for event personnel. This is optional at the discretion of collection organizers and not required for all events.
  - c. Pharmacist - to determine if a medication is a controlled substance, identify non-labeled home-generated pharmaceutical waste, inventory controlled substances, (if applicable), witness, and sign the inventory.
  - d. Hazardous Waste Personnel - Provide drums/containers for collection of non-controlled substances. Seal containers, prepare paperwork, transport non-controlled substances for hazardous waste destruction, remove pharmaceutical waste on the same day as the event, provide tracking paperwork from point of collection through destruction, incinerate non-controlled substances in licensed hazardous waste incinerator, provide certificate of destruction, provide weight of materials collected, and complete data entry.
8. Container Security - It is the responsibility of the entity overseeing the collection event to provide for the security of the collected home-generated pharmaceuticals. The home-generated pharmaceutical waste must be deposited into secured containers to ~~limit~~ prevent diversion and theft opportunities and not allow staff or the entity overseeing the event from having access to the contents. The collection device must be within the physical plant of a pharmacy, prescriber's office, police department, or government agency operating the device so that it can only be accessed during operating hours.

Every collection event that provides for home-generated pharmaceutical waste collection shall keep contracts or ownership information for the collection device used for the program. These documents must be retained for the life of the device plus three years following discontinuation or replacement of the collection device. These records shall be readily retrievable at the request of a government enforcement agency.

Home-generated pharmaceutical waste may not be removed from a collection device and stored in a pharmacy, medical office or any other location. Instead, once the pharmaceuticals are removed by the waste hauler, they must be taken by the hauler. Once a collection device becomes full, no more pharmaceutical waste can be accepted from consumers by the collection site until a waste hauler has removed the pharmaceutical waste, and re-stocked the collection device with an empty container. Any theft of or loss from the collected home-generated pharmaceutical shall be reported with 24 hours to the local police department, CDPH, California State Board of Pharmacy, and other agencies that have authorized the collection program.

9. Essential Recommended Equipment and Supplies

- a. Tools for counting home-generated pharmaceutical waste (pharmacist should provide this);
- b. Hazardous waste containers;
- c. Gloves (Disposable latex or non-latex);
- d. Sealable plastic bags (One-gallon and snack size, with external slide mechanism);
- e. Extension cords, grounded;
- f. Survey forms (examples can be found at [www.teleosis.org/pdf/Medicine\\_Return\\_Form.pdf](http://www.teleosis.org/pdf/Medicine_Return_Form.pdf) or [www.comofcom.com](http://www.comofcom.com));
- g. Indelible markers;
- h. Packing tape;
- i. Containers- Check with your contracted medical or hazardous waste hauler for appropriate containers; and
- j. Sharps disposal container -Provide sharps containers approved by the local enforcement agency to collect sharps if the location is also approved by the local enforcement agency or CDPH as a sharps consolidation point; and
- k. Personal protective equipment -- All staff must wear gloves (latex or non-latex) at all times when handling pharmaceutical waste. This is important as the containers may be powdery, sticky, and dirty. Accidental ingestion (even through skin or breathing) must be avoided. Wearing the use of facemasks should be considered, especially for the pharmacist who is doing may be conducting the physical determination examination of the home-generated pharmaceutical waste. Do not eat or drink directly in the area that the home-generated pharmaceutical wastes are being collected. Discard used gloves.

10. Budget - An estimate of the budget should be developed and the program must be free to the public to dispose of unused and unwanted home-generated pharmaceuticals.

11. Education and Advertising -- Collection event operators shall provide educational materials to the community and to consumers dropping off home-generated pharmaceuticals. These materials must include information about the problem of pharmaceutical waste entering waterways and drinking water and accidental poisoning from home-generated pharmaceutical waste. Event operators shall develop and distribute materials advertising for the collection event. Examples of such advertising could include internet web site ads, newspaper ads, flyers (posted at transfer stations, municipal buildings, and pharmacies), press releases, community cable announcements, utility mailings, multi-lingual flyers distributed in utility bills in participating

cities, movie theatre advertisements, advertisements on buses and at bus stops, print ads in recycling guides or English and multi-lingual public service announcements. The advertisements should list who is responsible for operation of the collection location, including the name, address and phone number of the operator.

Collection event operators shall provide instructions and information for consumers to use as they prepare to bring items to the collection event:

- a. List Date, Time, Location, operating hours, and contact information for the collection event.
- b. A list of what will and will not be accepted (address at a minimum the following: non-prescription drugs, prescription drugs, controlled substances, sharps, thermometers, medical waste,).
- c. Instructions on type of personal information to render illegible and pharmaceutical information to retain for purposes of identification.

12. Data Collection - Determine amounts of home-generated pharmaceuticals collected along with the number of donors. If time allows, determine the types and amounts of home-generated pharmaceuticals collected. This information could be used for further studies and policy recommendations. Security and confidentiality measures should be taken when retaining this data.

Each collection event must have a log specific to that collection event. The log must contain (a) the name, address phone number and title of the collection site person authorized for the collection event (b) the address, phone number and location number where the event was located; (c) the date the collection event took place; (d) the names of at least one person from the event who witnessed the pickup by the licensed waste hauler (e) the name of the waste hauler's staff person who picked up the collected waste; (f) the weight of home-generated pharmaceutical waste removed from collection event; and (g) additional columns for the final disposition of the drugs, and other security measures implemented to prevent unauthorized removals. The log should indicate the name, address and hauler number of waste hauler taking the drugs. These records shall be kept for 3 years after the life of the collection event by the host agency.

13. Site Visits to Collection Sites -- The event organizer shall inspect the location to ensure compliance with all requirements. The CIWMB may request a report summarizing the activities of each collection location including amounts of home-generated pharmaceutical waste collected and the number of days in operation as a collection location for home-generated pharmaceuticals.

Procedures for Model Pharmaceutical Waste Collection and Disposal Programs Through a Mail-Back Program

In some jurisdictions mailing back used and unused home-generated pharmaceuticals may be the only or most convenient option for the proper management of these items. An example is the State of Maine, which uses pre-paid mailing envelopes available at pharmacies, doctors' offices, and post offices. to collect home-generated pharmaceuticals that may include controlled substances. In addition, some pharmaceutical companies, such as Celgene, will take back their own home-generated pharmaceuticals via mail. Celgene allows patients to return unused drugs such as thalidomide purchased from the company, via UPS at no shipping cost to the patient. The following are some guidelines to look at when undertaking such a program:

Locations for Mail-Back Programs shall only be allowed if the following requirements are met:

1. Each entity overseeing either a Mail-Back Location or Mail-Back Program shall ensure that the home-generated pharmaceutical waste is destroyed in accordance with applicable regulations. CIWMB may request that each Mail-Back Location or Program provide information on the amounts of home-generated pharmaceuticals received and destroyed.
2. Determine locations where home-generated pharmaceuticals can be mailed for proper management and destruction. These facilities must be DEA-approved and able to accept controlled substances for destruction if controlled substances are mailed directly to the facility. In addition, these facilities must be able to provide data on the amounts of home-generated pharmaceuticals received and destroyed.
3. Operators of mail-back programs shall obtain self-sealing pre-addressed and pre-stamped envelopes that are approved by the U.S. Postal Service for containment and transportation of home-generated pharmaceutical waste. The envelopes shall also include an instruction sheet on how to package and send the home-generated pharmaceuticals.
4. Operators of mail back programs ~~shall~~ may provide postage-paid envelopes to pharmacies, one-time collection events, hospice care providers, doctors' offices, and post offices to be ~~provided to consumers that will be utilized by consumers~~ for the mailing and destruction of unused and expired home-generated pharmaceuticals.
5. Envelopes shall be tracked to assure that all envelopes are used for their intended purposes and that all of the home-generated pharmaceuticals get to the destruction facility.
6. ~~Operator~~ Operators shall may advertise its mail back program at pharmacies, convalescent homes, and retirement homes in order to inform potential users of the program of its availability and requirements for participation.
7. The operator shall review data on the amounts of home-generated pharmaceuticals collected to assure that the amounts are increasing and shall make changes to the program as needed to the program to assure continued growth.

#### Appendix I-Definitions

1. **Controlled Substance**-any substance listed in Chapter 2 (commencing with Section 11053) of Division 10 of the CA Health & Safety Code.
2. **Event** - Include programs and one-time events for the collection of home-generated pharmaceutical waste to assure appropriate disposal of these items.
3. **Collection Programs** - include permanent collection programs, temporary collection programs, and mail back collection programs
4. **Model Program** - CIWMB approved program through which the public may return unused or expired home-generated that meets statutory criteria.
5. **Over the Counter Drug** - a non-prescription drug as defined per CA Business & Professions Code Section 4025.1 which states "non-prescription drugs" means a drug which may be sold without a prescription and which is labeled for use by the consumer in accordance with the laws and rules of this state and the federal government.
6. **Collection Facility** - any entity CIWMB finds appropriate to implement or evaluate a model home-generated pharmaceutical waste program. The participant must agree to participate as a model program. Entities that may qualify to participate:
  - a. Governmental entities (includes police and sheriff's stations, public/environmental health agencies and HHW facilities);
  - b. Pharmacies with active unrestricted licenses from the California State Board of Pharmacy;
  - c. Other Physician and other licensed health care prescribers' offices; and
  - d. Healthcare Collection Sites that are licensed by the Department of Consumer Affairs
7. **Pharmaceutical Waste** - In this document it is considered to be a prescription drug dispensed to a consumer or a non-prescription item, no longer wanted or need by the consumer and includes home-generated pharmaceuticals in many delivery systems, such as pills, liquids, and inhalers.
8. **Prescription Drug** - is a dangerous drug as defined per California Business and Professions Code Section 4022 which means any drug unsafe for self-use in humans or animals, without the oversight of a licensed prescriber and includes the following:
  - a. any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription, "Rx only", or words of similar import.
  - b. any other drug that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to CA Business & Professions Code Section 4006.

Introduced by Senator Simitian

December 1, 2008

An act to add Sections 4001.2, 4068.1, and 4146 to the Business and Professions Code, to amend Sections 117700, 117935, 117945, 117960, 118000, 118040, 118147, and 118165 of, and to add Sections 117642, 117669, 117748, 117904.5, 118031, and 118041 to, the Health and Safety Code, and to amend Section 47200 of the Public Resources Code, relating to pharmaceutical waste.

LEGISLATIVE COUNSEL'S DIGEST

SB 26, as introduced, Simitian. Home-generated pharmaceutical waste.

The existing Pharmacy Law establishes the California State Board of Pharmacy, prescribes the licensing, regulatory, and disciplinary functions of the board, and authorizes the board to adopt rules and regulations necessary to administer laws governing the operation of pharmacies and the dispensing of drugs and devices to the public.

This bill would require the board to coordinate with other state agencies, local governments, drug manufacturers, and pharmacies to develop sustainable, efficient policies and programs to manage pharmaceutical wastes and the disposal of devices. The bill would authorize a pharmacy to accept the return of home-generated pharmaceutical waste and home-generated sharps waste, as defined.

Existing law, the California Integrated Waste Management Act of 1989, requires the California Integrated Waste Management Board to adopt regulations that set forth minimum standards for solid waste management and require assurance of financial ability to pay for specified injury and property damage claims resulting from the operation of a disposal facility. The act requires the board to expend moneys from

the Solid Waste Management Account in the Integrated Waste Management Fund, upon appropriation by the Legislature, for the making of grants to cities, counties, or other local agencies with responsibility for solid waste management, and for local programs to help prevent the disposal of hazardous wastes at disposal sites, as provided.

This bill would require that local programs to help prevent the disposal of home-generated sharps waste and home-generated pharmaceutical waste at disposal sites also be included among the types of local programs that may be funded by such a grant.

Existing law, the Medical Waste Management Act, requires the State Department of Public Health to regulate the management and handling of medical waste, as defined. Under existing law, certain items, such as household waste, are specifically excluded from the definition of medical waste.

This bill would also exclude home-generated pharmaceutical waste, as defined, from the definition of medical waste.

Existing law regulates the methods of consolidating, storing, and transporting medical waste and home-generated sharps waste. Violation of these provisions is a crime.

This bill would regulate consolidation points for home-generated pharmaceutical waste, as defined, as well as transportation and disposal of that waste by both hazardous waste haulers and common carriers, as defined. By expanding the definition of a crime, this 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.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

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

- 1 SECTION 1. Section 4001.2 is added to the Business and
- 2 Professions Code, to read:
- 3 4001.2. To further the purposes of Section 4001.1, and to
- 4 protect the public from hazards caused by the improper
- 5 management and disposal of waste drugs and devices, the

DEA  
ATTACHMENT  
2

1 California State Board of Pharmacy shall coordinate with other  
2 state agencies, local governments, drug manufacturers, and  
3 pharmacies to develop sustainable, efficient policies and programs  
4 to properly manage pharmaceutical wastes and the disposal of  
5 these wastes.

6 SEC. 2. Section 4068.1 is added to the Business and Professions  
7 Code, to read:

8 4068.1. A pharmacy may accept the return of home-generated  
9 pharmaceutical waste, as defined in Section 117769 of the Health  
10 and Safety Code, from the public.

11 SEC. 3. Section 4146 is added to the Business and Professions  
12 Code, to read:

13 4146. A pharmacy may accept the return of home-generated  
14 sharps waste, as defined in Section 117671 of the Health and Safety  
15 Code, from a person if the waste is contained in a sharps container.

16 SEC. 4. Section 117642 is added to the Health and Safety Code,  
17 to read:

18 117642. "Common carrier" means a person or company that  
19 hauls for hire goods, including, but not limited to, pharmaceutical  
20 waste or home-generated pharmaceutical waste. Home-generated  
21 pharmaceutical waste must have been consolidated at a location  
22 approved by the enforcement agency as a home-generated  
23 pharmaceutical waste consolidation point.

24 SEC. 5. Section 117669 is added to the Health and Safety Code,  
25 to read:

26 117669. "Home-generated pharmaceutical waste" means  
27 prescribed and over-the-counter drugs derived from a household.

28 SEC. 6. Section 117700 of the Health and Safety Code is  
29 amended to read:

30 117700. Medical waste does not include any of the following:

31 (a) Waste generated in food processing or biotechnology that  
32 does not contain an infectious agent as defined in Section 117675.

33 (b) Waste generated in biotechnology that does not contain  
34 human blood or blood products or animal blood or blood products  
35 suspected of being contaminated with infectious agents known to  
36 be communicable to humans.

37 (c) Urine, feces, saliva, sputum, nasal secretions, sweat, tears,  
38 or vomitus, unless it contains fluid blood, as provided in  
39 subdivision (d) of Section 117635.

1 (d) Waste ~~which~~ *that* is not biohazardous, such as paper towels,  
2 paper products, articles containing nonfluid blood, and other  
3 medical solid waste products commonly found in the facilities of  
4 medical waste generators.

5 (e) Hazardous waste, radioactive waste, or household waste,  
6 including, but not limited to, home-generated sharps waste, as  
7 defined in Section 117671, *and home-generated pharmaceutical*  
8 *waste, as defined in Section 117669.*

9 (f) Waste generated from normal and legal veterinarian,  
10 agricultural, and animal livestock management practices on a farm  
11 or ranch.

12 SEC. 7. Section 117748 is added to the Health and Safety Code,  
13 to read:

14 117748. "Pharmaceutical waste" means any pharmaceutical,  
15 prescription, or over-the-counter human or veterinary drug,  
16 including, but not limited to, a drug, as defined in Section 109925,  
17 or the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec.  
18 321(g)(1)) that meets any of the following requirements:

19 (a) The drug may no longer be sold or dispensed because it has  
20 expired.

21 (b) The drug can no longer be used for its intended purpose.

22 (c) The drug has been discarded.

23 (d) The drug has been consolidated at a location approved by  
24 the enforcement agency as a home-generated pharmaceutical waste  
25 consolidation point.

26 SEC. 8. Section 117904.5 is added to the Health and Safety  
27 Code, to read:

28 117904.5. (a) In addition to the consolidation points authorized  
29 pursuant to Section 118147, the enforcement agency may approve  
30 a location as a point of consolidation for the collection of  
31 home-generated pharmaceutical waste. These locations may  
32 include, but are not limited to, pharmacies, health care facilities,  
33 veterinarian offices, clinics, household hazardous waste programs,  
34 solid waste facilities, senior centers, or government offices.

35 (b) A consolidation location approved pursuant to this section  
36 shall be known as a home-generated pharmaceutical waste  
37 consolidation point.

38 (c) A home-generated pharmaceutical waste consolidation point  
39 is not subject to the requirements of Chapter 9 (commencing with  
40 Section 118275) of Part 14 of Division 4, to the permit

1 requirements of this part, or to any permit or registration fees, with  
2 regard to the activity of consolidating home-generated  
3 pharmaceutical waste pursuant to this section.

4 (d) A home-generated pharmaceutical waste consolidation point  
5 shall comply with all of the following requirements:

6 (1) It shall be approved by the enforcement agency for this  
7 purpose.

8 (2) The home-generated pharmaceutical waste collected and  
9 consolidated at the facility shall be collected and contained in a  
10 leak-resistant container and placed in a secure area that does not  
11 allow the waste to be accessed or salvaged by unauthorized persons.

12 (3) Containers ready for disposal shall not be held for more than  
13 90 days without the written approval of the enforcement agency.

14 (e) An operator of a home-generated pharmaceutical waste  
15 consolidation point that is approved pursuant to this section shall  
16 not be considered a generator of that waste.

17 (f) The end disposal facility that treats the home-generated  
18 pharmaceutical waste shall maintain the tracking documents  
19 required by Section 118040 or 118041, as applicable, and Section  
20 118165 with regard to the pharmaceutical waste.

21 (g) Nothing in this section shall exempt any person from any  
22 federal or state law governing pharmaceuticals.

23 SEC. 9. Section 117935 of the Health and Safety Code is  
24 amended to read:

25 117935. Any small quantity generator required to register with  
26 the enforcement agency pursuant to Section 117930 shall file with  
27 the enforcement agency a medical waste management plan, on  
28 forms prescribed by the enforcement agency containing, but not  
29 limited to, all of the following:

30 (a) The name of the person.

31 (b) The business address of the person.

32 (c) The type of business.

33 (d) The types, and the estimated average monthly quantity, of  
34 medical waste generated.

35 (e) The type of treatment used onsite.

36 (f) The name and business address of the registered hazardous  
37 waste hauler used by the generator for backup treatment and  
38 disposal, for waste when the onsite treatment method is not  
39 appropriate due to the hazardous or radioactive characteristics of  
40 the waste, or the name of the registered hazardous waste hauler

1 used by the generator to have untreated medical waste removed  
2 for treatment and disposal, and, if applicable, the name of the  
3 common carrier used by the generator to transport pharmaceutical  
4 waste offsite for treatment and disposal.

5 (g) A statement indicating that the generator is hauling the  
6 medical waste generated in his or her business pursuant to Section  
7 118030 and the name and any business address of the treatment  
8 and disposal facilities to which the waste is being hauled, if  
9 applicable.

10 (h) The name and business address of the registered hazardous  
11 waste hauler service provided by the building management to  
12 which the building tenants may subscribe or are required by the  
13 building management to subscribe and the name and business  
14 address of the treatment and disposal facilities used, if applicable.

15 (i) A statement certifying that the information provided is  
16 complete and accurate.

17 SEC. 10. Section 117945 of the Health and Safety Code is  
18 amended to read:

19 117945. Small quantity generators who are not required to  
20 register pursuant to this chapter shall maintain on file in their office  
21 all of following:

22 (a) An information document stating how the generator contains,  
23 stores, treats, and disposes of any medical waste generated through  
24 any act or process of the generator.

25 (b) Records of any medical waste transported offsite for  
26 treatment and disposal, including the quantity of waste transported,  
27 the date transported, and the name of the registered hazardous  
28 waste hauler or individual hauling the waste pursuant to Section  
29 118030, or the name of the common carrier hauling  
30 pharmaceutical waste pursuant to Section 118031. The small  
31 quantity generator shall maintain these records for not less than  
32 two years.

33 SEC. 11. Section 117960 of the Health and Safety Code is  
34 amended to read:

35 117960. Any large quantity generator required to register with  
36 the enforcement agency pursuant to Section 117950 shall file with  
37 the enforcement agency a medical waste management plan, on  
38 forms prescribed by the enforcement agency containing, but not  
39 limited to, all of the following:

40 (a) The name of the person.

- 1 (b) The business address of the person.
- 2 (c) The type of business.
- 3 (d) The types, and the estimated average monthly quantity, of
- 4 medical waste generated.
- 5 (e) The type of treatment used onsite, if applicable. For
- 6 generators with onsite medical waste treatment facilities, including
- 7 incinerators or steam sterilizers or other treatment facilities as
- 8 determined by the enforcement agency, the treatment capacity of
- 9 the onsite treatment facility.
- 10 (f) The name and business address of the registered hazardous
- 11 waste hauler used by the generator to have untreated medical waste
- 12 removed for treatment, if applicable, *or the name of the common*
- 13 *carrier hauling pharmaceutical waste pursuant to Section 118031.*
- 14 (g) The name and business address of the registered hazardous
- 15 waste hauler service provided by the building management to
- 16 which the building tenants may subscribe or are required by the
- 17 building management to subscribe, if applicable.
- 18 (h) The name and business address of the offsite medical waste
- 19 treatment facility to which the medical waste is being hauled, if
- 20 applicable.
- 21 (i) An emergency action plan complying with regulations
- 22 adopted by the department.
- 23 (j) A statement certifying that the information provided is
- 24 complete and accurate.
- 25 SEC. 12. Section 118000 of the Health and Safety Code is
- 26 amended to read:
- 27 118000. (a) Except as otherwise exempted pursuant to Section
- 28 118030 *or 118031*, all medical waste transported to an offsite
- 29 medical waste treatment facility shall be transported in accordance
- 30 with this chapter by a registered hazardous waste transporter issued
- 31 a registration certificate pursuant to Chapter 6 (commencing with
- 32 Section 118025) and Article 6.5 (commencing with Section
- 33 25167.1) of Chapter 6.5 of Division 20. A hazardous waste
- 34 transporter transporting medical waste shall have a copy of the
- 35 transporter's valid hazardous waste transporter registration
- 36 certificate in the transporter's possession while transporting
- 37 medical waste. The transporter shall show the certificate, upon
- 38 demand, to any enforcement agency personnel or authorized
- 39 employee of the Department of the California Highway Patrol.

- 1 (b) Except for small quantity generators transporting medical
- 2 waste pursuant to Section 118030 *or small quantity generators or*
- 3 *common carriers transporting home-generated pharmaceutical*
- 4 *waste pursuant to Section 118031*, medical waste shall be
- 5 transported to a permitted offsite medical waste treatment facility
- 6 or a permitted transfer station in leak-resistant and fully enclosed
- 7 rigid secondary containers that are then loaded into an enclosed
- 8 cargo body.
- 9 (c) A person shall not transport medical waste in the same
- 10 vehicle with other waste unless the medical waste is separately
- 11 contained in rigid containers or kept separate by barriers from
- 12 other waste, or unless all of the waste is to be handled as medical
- 13 waste in accordance with this part.
- 14 (d) Medical waste shall only be transported to a permitted
- 15 medical waste treatment facility, or to a transfer station or another
- 16 registered generator for the purpose of consolidation before
- 17 treatment and disposal, pursuant to this part.
- 18 (e) Facilities for the transfer of medical waste shall be annually
- 19 inspected and issued permits in accordance with the regulations
- 20 adopted pursuant to this part.
- 21 (f) Any persons manually loading or unloading containers of
- 22 medical waste shall be provided by their employer at the beginning
- 23 of each shift with, and shall be required to wear, clean and
- 24 protective gloves and coveralls, changeable lab coats, or other
- 25 protective clothing. The department may require, by regulation,
- 26 other protective devices appropriate to the type of medical waste
- 27 being handled.
- 28 SEC. 13. Section 118031 is added to the Health and Safety
- 29 Code, to read:
- 30 118031. Pharmaceutical waste may be shipped by a common
- 31 carrier if the generator or home-generated pharmaceutical waste
- 32 consolidation point meets the following requirements:
- 33 (a) The facility shall maintain documentation as required in
- 34 Sections 118040 and 118041.
- 35 (b) The waste products are transported to any of the following:
- 36 (1) A medical waste facility.
- 37 (2) A hazardous waste facility.
- 38 (3) A reverse distributor, with the final destination of a medical
- 39 or hazardous waste facility.

1 SEC. 14. Section 118040 of the Health and Safety Code is  
2 amended to read:

3 118040. (a) Except with regard to sharps waste consolidated  
4 by a home-generated sharps consolidation point approved pursuant  
5 to Section 117904, *pharmaceutical waste or home-generated*  
6 *pharmaceutical waste consolidated by a home-generated*  
7 *pharmaceutical waste consolidation point approved pursuant to*  
8 *Section 117904.5, or home-generated pharmaceutical waste*  
9 *transported pursuant to Section 118031*, a hazardous waste  
10 transporter or generator transporting medical waste shall maintain  
11 a completed tracking document of all medical waste removed for  
12 treatment or disposal. A hazardous waste transporter or generator  
13 who transports medical waste to a facility, other than the final  
14 medical waste treatment facility, shall also maintain tracking  
15 documents which show the name, address, and telephone number  
16 of the medical waste generator, for purposes of tracking the  
17 generator of medical waste when the waste is transported to the  
18 final medical waste treatment facility. At the time that the medical  
19 waste is received by a hazardous waste transporter, the transporter  
20 shall provide the medical waste generator with a copy of the  
21 tracking document for the generator's medical waste records. The  
22 transporter or generator transporting medical waste shall maintain  
23 its copy of the tracking document for three years.

24 (b) The tracking document shall include, but not be limited to,  
25 all of the following information:

26 (1) The name, address, telephone number, and registration  
27 number of the transporter, unless transported pursuant to Section  
28 118030.

29 (2) The type and quantity of medical waste transported.

30 (3) The name, address, and telephone number of the generator.

31 (4) The name, address, telephone number, permit number, and  
32 the signature of an authorized representative of the permitted  
33 facility receiving the medical waste.

34 (5) The date that the medical waste is collected or removed from  
35 the generator's facility, the date that the medical waste is received  
36 by the transfer station, the registered large quantity generator, or  
37 point of consolidation, if applicable, and the date that the medical  
38 waste is received by the treatment facility.

39 (c) Any hazardous waste transporter or generator transporting  
40 medical waste in a vehicle shall have a tracking document in his

1 or her possession while transporting the medical waste. The  
2 tracking document shall be shown upon demand to any  
3 enforcement agency personnel or officer of the Department of the  
4 California Highway Patrol. If the medical waste is transported by  
5 rail, vessel, or air, the railroad corporation, vessel operator, or  
6 airline shall enter on the shipping papers any information  
7 concerning the medical waste that the enforcement agency may  
8 require.

9 (d) A hazardous waste transporter or a generator transporting  
10 medical waste shall provide the facility receiving the medical waste  
11 with the original tracking document.

12 (e) Each hazardous waste transporter and each medical waste  
13 treatment facility shall provide tracking data periodically and in a  
14 format as determined by the department.

15 (f) Medical waste transported out of state shall be consigned to  
16 a permitted medical waste treatment facility in the receiving state.  
17 If there is no permitted medical waste treatment facility in the  
18 receiving state or if the medical waste is crossing an international  
19 border, the medical waste shall be treated in accordance with  
20 Chapter 8 (commencing with Section 118215) prior to being  
21 transported out of the state.

22 SEC. 15. Section 118041 is added to the Health and Safety  
23 Code, to read:

24 118041. (a) A person transporting pharmaceutical waste shall  
25 maintain a completed tracking document of all pharmaceutical  
26 waste removed for treatment or disposal. A copy of the tracking  
27 document shall be included with the container holding the  
28 pharmaceutical waste.

29 (b) The tracking document shall include, but not be limited to,  
30 all of the following information:

31 (1) The name, address, and telephone number of the generator.

32 (2) Specific information indicating that pharmaceutical waste  
33 is being transported.

34 (3) The name, address, and telephone number of the person  
35 transporting the waste.

36 (4) The name, address, telephone number, and permit number  
37 of the permitted treatment facility or transfer station to which the  
38 pharmaceutical waste is being sent.

1 (5) The date that the pharmaceutical waste was collected or  
2 removed from the generator or home-generated pharmaceutical  
3 waste consolidation point.

4 (c) A person tracking pharmaceutical waste shall have a tracking  
5 document for the waste in his or her possession while transporting  
6 the waste. The tracking document shall be shown, upon demand,  
7 to any enforcement agency personnel or officer of the Department  
8 of the California Highway Patrol.

9 (d) A medical waste treatment facility and transfer station shall  
10 date and sign a copy of the tracking document upon receipt,  
11 periodically provide data in a format determined by the department,  
12 and shall maintain a copy of the tracking document for three years.

13 (e) This section does not prohibit the use of a single document  
14 to verify the return of more than one container to a parent  
15 organization or another health care facility for the purpose of  
16 consolidation before treatment and disposal of the pharmaceutical  
17 waste over a period of time, if the form or log is maintained in the  
18 files of the parent organization or other health care facility that  
19 receives the waste.

20 (f) Pharmaceutical waste transported out of state shall be  
21 consigned to a permitted medical waste treatment facility in the  
22 receiving state. If there is no permitted medical waste treatment  
23 facility in the receiving state, or if the waste is crossing an  
24 international border, the home-generated pharmaceutical waste  
25 shall be treated pursuant to Section 118222 prior to being  
26 transported out of state.

27 SEC. 16. Section 118147 of the Health and Safety Code is  
28 amended to read:

29 118147. Notwithstanding any other provision of this chapter,  
30 a registered medical waste generator, which is a facility specified  
31 in subdivisions (a) and (b) of Section 117705, may accept  
32 home-generated sharps waste and home-generated pharmaceutical  
33 waste, to be consolidated with the facility's medical waste stream,  
34 subject to all of the following conditions:

35 (a) The generator of the home-generated sharps waste or  
36 home-generated pharmaceutical waste, a member of the  
37 generator's family, or a person authorized by the enforcement  
38 agency transports the sharps waste or pharmaceutical waste to the  
39 medical waste generator's facility.

1 (b) The home-generated sharps waste or home-generated  
2 pharmaceutical waste is accepted at a central location at the  
3 medical waste generator's facility.

4 (c) A reference to, and a description of, the actions taken  
5 pursuant to this section are included in the facility's medical waste  
6 management plan adopted pursuant to Section 117960.

7 SEC. 17. Section 118165 of the Health and Safety Code is  
8 amended to read:

9 118165. On and after April 1, 1991, all persons operating a  
10 medical waste treatment facility shall maintain individual records  
11 for a period of three years and shall report or submit to the  
12 enforcement agency upon request, all of the following information:

13 (a) The type of treatment facility and its capacity.

14 (b) All treatment facility operating records.

15 (c) Copies of the tracking documents for all medical waste it  
16 receives for treatment from offsite generators or from hazardous  
17 waste haulers or common carriers, pursuant to Section 118041.

18 SEC. 18. Section 47200 of the Public Resources Code is  
19 amended to read:

20 47200. (a) The board shall expend funds from the account,  
21 upon appropriation by the Legislature, for the making of grants to  
22 cities, counties, or other local agencies with responsibility for solid  
23 waste management, and for local programs to help prevent the  
24 disposal of home-generated sharps waste, as defined in Section  
25 117671 of the Health and Safety Code, home-generated  
26 pharmaceutical waste, as defined in Section 117669 of the Health  
27 and Safety Code, and hazardous wastes at disposal sites, including,  
28 but not limited to, programs to expand or initially implement  
29 household hazardous waste programs. In making grants pursuant  
30 to this section, the board shall give priority to funding programs  
31 that provide for the following:

32 (1) New programs for rural areas, underserved areas, and for  
33 small cities.

34 (2) Expansion of existing programs to provide for the collection  
35 of additional waste types, innovative or more cost-effective  
36 collection methods, or expanded public education services.

37 (3) Regional household hazardous waste programs.

38 (b) (1) The total amount of grants made by the board pursuant  
39 to this section shall not exceed, in any one fiscal year, three million  
40 dollars (\$3,000,000).

1 (2) Notwithstanding paragraph (1), the total amount of grants  
2 made by the board pursuant to this section may exceed three  
3 million dollars (\$3,000,000) but shall not exceed six million dollars  
4 (\$6,000,000), in any one fiscal year, if sufficient funds are  
5 appropriated from the Integrated Waste Management Account for  
6 this purpose.

7 SEC. 19. No reimbursement is required by this act pursuant to  
8 Section 6 of Article XIII B of the California Constitution because  
9 the only costs that may be incurred by a local agency or school  
10 district will be incurred because this act creates a new crime or  
11 infraction, eliminates a crime or infraction, or changes the penalty  
12 for a crime or infraction, within the meaning of Section 17556 of  
13 the Government Code, or changes the definition of a crime within  
14 the meaning of Section 6 of Article XIII B of the California  
15 Constitution.

**News Release**  
FOR IMMEDIATE RELEASE  
November 04, 2008  
Contact: Jodie Underwood  
Number: (206) 553-1162

**Edmonds Pharmacy "Manager of the Year" Pleads Guilty**  
*Thousands of Pills Involved, Including Oxycodone and Hydrocodone*

NOV 04 -- (Seattle) -- DEA Special Agent in Charge (SAC) Arnold R. Moorin and the United States Attorney for the Western District of Washington, Jeffrey Sullivan, announced that on October 31, 2008, Milton W. Cheung, a Washington State licensed pharmacist, entered guilty pleas to two felony offenses: Acquiring Controlled Substances by Deception and Misbranding Drugs. These offenses are punishable by up to four years in prison, a \$250,000 fine, and up to one year of supervised release. Cheung is set for sentencing on February 13, 2009.

Cheung, 55, of Lynnwood, Washington, has been employed for the last several years as a Pharmacy Manager at the Top Food Drug Store, in Edmonds, Washington. As pharmacy manager, Cheung was the principal pharmacist responsible for the daily activities and operations at the Edmonds Top Food Drug Store. From 2003 continuing through September 2008 (when he resigned), Cheung was named Pharmacy Manager of the Year, by Haggen Incorporated, the owner of Top Food Drug Store.

During 2007, and continuing through September 2008, Cheung solicited a number of Washington State medical providers, including doctors, hospices, and clinics, as well as Top Food Drug Store customers, to provide expired and unexpired drugs to him at the Edmonds Top Food Drug Store, on the alleged basis that he would provide these drugs to less developed countries as part of a philanthropic mission. While Cheung collected these drugs, he purposefully diverted much of the drugs collected by placing the drugs into the regular supply bottles at the Top Food Drug Store. This gave him a much larger inventory of drugs to distribute to pharmacy customers and made the pharmacy which he managed appear more profitable. Cheung then proceeded to distribute these returned drugs to customers at the Edmonds Top Food Drug Store when filling new customer prescriptions, even though a large portion of these drugs were expired, and despite the fact that all of the drugs had been adulterated in that they had already been distributed to and possessed by others, and were returned merchandise which Cheung was doing out as new inventory. Among the drugs deceptively collected by Cheung and later distributed by him, were such Schedule II through IV controlled substances as fentanyl, methadone, morphine, oxycodone, hydrocodone, and lorazepam, in addition to other drugs.

All prescription drugs carry an expiration date after which the drugs are no longer regarded as medically effective or safe to consumers. The entire drug re-distribution scheme conducted by Cheung, under the guise of providing drugs to developing nations, was unlawful; no such program had been sanctioned by the DEA or any other valid regulatory authority. In addition, all prescription medications in pharmacies are required by federal regulation to be maintained in stock containers which show their true lot number and expiration date. This is done to ensure the safety of what is being sold and distributed to the public. Cheung's prescription misbranding effectively countermanded and negated these safeguards.

In September 2008, in response to the criminal conduct by Cheung, Haggen Incorporated issued a drug recall, printed in the Seattle Times, advising customers of the Edmonds Top Food Drug Store to return all potentially expired drugs.

This case was investigated by the Drug Enforcement Administration, Internal Revenue Service and the Edmonds Police Department.

DEA  
Attachment  
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## DOCTOR ACCUSED OF DISPENSING SURPLUS PILLS

By David Hasemyer  
San Diego Union-Tribune  
February 3, 2009

EL CAJON — An 87-year-old El Cajon psychiatrist is facing disciplinary action by the Medical Board of California, accused of collecting surplus narcotics from patients and distributing them to other patients out of a basket on his office counter.

The Medical Board says Wayne Funk was negligent in handing out powerful and addictive pain pills and sedatives that had been prescribed for other patients but were returned to his office unused.

Funk, licensed in California since 1954, is facing the revocation of his license or other disciplinary action by the Medical Board. No hearing date has been set.

The doctor declined to comment. His wife said he is a compassionate man who would never harm his patients.

"He's helped so many people throughout the years," Mary Funk said. "It's a shame people don't know all of the good he's done. Wherever I go, somebody is always coming up to me and telling me how much he's helped them."

Funk's attorney, Robert Frank, declined to discuss the accusations but said the doctor denies any wrongdoing and will fight to keep his license.

Funk, who graduated from the University of Kansas school of medicine in 1947, was the subject of an inspection a year ago by agents with the Medical Board and the U.S. Drug Enforcement Administration.

"During the inspection, the investigators observed a counter with numerous sample medications and a basket containing prescription bottles, including controlled substances, which were returned by patients," according to the accusation filed in Administrative Law Court.

The investigators also found a drawer full of prescription bottles, many with expired dates, that Funk said had been returned by patients.

"(Funk) told the investigators that he collected unused medications from patients and then reissues the medications to other patients as a means of making the medications more affordable," according to the accusation.

Included in the grab bag of drugs were the painkiller Oxycodone and the sedatives Diazepam, Lorazepam and Temazepam.

During the inspection, Funk surrendered his DEA certificate to dispense controlled substances.

The Medical Board also has accused Funk of prescribing an addictive anti-anxiety drug to a patient without an appropriate examination and without reviewing the patient's medical records.

The doctor prescribed 870 Xanax pills for the patient over a two-month period in 2007, an amount not "medically indicated," according to the accusation. The patient later had to seek treatment from another doctor for detoxification.

David Hasemyer: (619) 542-4583; david.hasemyer@uniontrib.com

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of the State of California  
2 GREGORY J. SALUTE  
Supervising Deputy Attorney General  
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300 So. Spring Street, Suite 1702  
5 Los Angeles, CA 90013  
Telephone: (213) 897-5794  
6 Facsimile: (213) 897-2804  
7 Attorneys for Complainant

8 **BEFORE THE**  
**BOARD OF PHARMACY**  
9 **DEPARTMENT OF CONSUMER AFFAIRS**  
10 **STATE OF CALIFORNIA**

11 In the Matter of the Accusation Against:

Case No. 3082

12 **DAVID JUE FONG**  
502 S. Almansor St.  
13 Alhambra, CA 91801

**ACCUSATION**

14 Pharmacist License No. RPH 37204

15 Respondent.

16  
17 Complainant alleges:

18 **PARTIES**

19 1. Virginia Herold (Complainant) brings this Accusation solely in her official  
20 capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.

21 2. On or about August 26, 1982, the Board of Pharmacy issued Pharmacist  
22 License Number RPH 37204 to David Jue Fong (Respondent). The Pharmacist License was in  
23 full force and effect at all times relevant to the charges brought herein and will expire on  
24 September 30, 2009, unless renewed. Respondent is the Pharmacist-in-Charge of Cathay  
25 Medical Pharmacy, Inc. dba Cathay Medical Pharmacy, Pharmacy Permit No. PHY 36574,  
26 located at 626 W. College Street, Los Angeles, California.

27 ///  
28

1 **JURISDICTION**

2 3. This Accusation is brought before the Board of Pharmacy (Board),  
3 Department of Consumer Affairs, under the authority of the following laws. All section  
4 references are to the Business and Professions Code (Code) unless otherwise indicated.  
5 4. Section 118, subdivision (b), of the Code provides that the suspension,  
6 expiration, surrender, or cancellation of a license shall not deprive the Board of jurisdiction to  
7 proceed with a disciplinary action during the period within which the license may be renewed,  
8 restored, reissued or reinstated.  
9 5. Section 4300, subdivision (a) of the Code states: "Every license issued  
10 may be suspended or revoked."  
11 6. Code section 477, subdivision (b), states that "'License' includes  
12 certificate, registration or other means to engage in a business or profession regulated by this  
13 code."  
14 7. Section 480; subdivision (a)(2), provides that a board may deny a license if  
15 the applicant has committed dishonest, fraudulent, or deceitful acts with the intent to  
16 substantially benefit himself.  
17 8. Section 810 of the Code states:  
18 (a) It shall constitute unprofessional conduct and grounds for  
19 disciplinary action, including suspension or revocation of a license or certificate,  
20 for a health care professional to do any of the following in connection with his or  
21 her professional activities:  
22 ....  
23 (2) Knowingly prepare, make, or subscribe any writing, with intent to  
24 present or use the same, or to allow it to be presented or used in support of any  
25 false or fraudulent claim.  
26 9. Section 4301 of the Code states:  
27 The board shall take action against any holder of a license who is guilty of  
28 unprofessional conduct. . . . Unprofessional conduct shall include, but is not  
limited to, any of the following:  
....  
///

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1 (f) The commission of any act involving moral turpitude, dishonesty,  
2 fraud, deceit, or corruption, whether the act is committed in the course of relations  
as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.

3 (g) Knowingly making or signing any certificate or other document  
4 that falsely represents the existence or nonexistence of a state of facts.

5 (p) Actions or conduct that would have warranted denial of a license.  
6

7 COST RECOVERY

8 10. Section 125.3 of the Code provides that the Board may request the  
9 administrative law judge to direct a licensee found to have committed a violation or violations  
10 of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and  
11 enforcement of the case.

12 BACKGROUND

13 11. Cathay Medical Industries, Inc., owns Cathay Medical Pharmacy,  
14 Pharmacy Permit No. PHY 22806, and College Pharmacy, Pharmacy Permit No. PHY 36574.  
15 Cathay Medical Industries, Inc., is owned by Henry Fong (75%) and Gerald Wu (25%). Henry  
16 Fong is the Pharmacist-In-Charge of College Pharmacy, and Henry Fong's son, David Fong, is  
17 the Pharmacist-In-Charge of Cathay Medical Pharmacy.

18 12. Easy Returns Worldwide, Inc. (ERW) was a reverse distributor of  
19 pharmaceuticals. ERW returned expired drugs to the appropriate manufacturers for credit to its  
20 client pharmacies who purchased the drugs. ERW usually charged the pharmacies a 5-10% fee  
21 for said returns, which was based on the expected credits that the manufacturer would give to the  
22 pharmacies. Most manufacturers required the return of the actual products from ERW's retail  
23 pharmacies in order to give them credit.

24 13. In a criminal proceeding entitled *United States of America v. Richard J.*  
25 *Drury*, United States District Court, Eastern District of Missouri, Case No. S1-4:05 CR 33 ERW,  
26 Richard Drury, a corporate officer of ERW (Drury), was indicted, found guilty, and convicted of  
27 four counts of mail fraud for defrauding drug manufacturers by making false claims with  
28 pharmacies in connection with returned drugs. Pursuant to Drury's Indictment, between August

1 2000 and January 2002, Drury devised and participated in a scheme to create fraudulent returns  
2 of expired drugs to pharmaceutical manufacturers on behalf of pharmacies that had not purchased  
3 them with the false assertion that the pharmacies had purchased the drugs. This scheme caused  
4 the manufacturers to credit various pharmacies for returns that did not belong to them. The  
5 pharmacies paid approximately a 33% fee to Drury and ERW for the false returns credited to  
6 them.

7 14. David Fong agreed with ERW to participate in its fraudulent scheme in  
8 order to obtain easy profits for his family business. ERW returned dangerous drugs in November  
9 and December of 2000 under both Cathay Medical Pharmacy's and College Pharmacy's  
10 pharmacy permits and federal Drug Enforcement Administration (DEA) numbers, even though  
11 the returned drugs did not belong to either pharmacy. Based on the amount of the false returns  
12 on behalf of the two pharmacies, the Board investigator estimated that Respondent gained  
13 approximately \$14,000 for College Pharmacy and approximately \$19,000 for Cathay Medical  
14 Pharmacy by participating in ERW's fraudulent scheme.

15 FIRST CAUSE FOR DISCIPLINE

16 (Unprofessional Conduct / Commission of Fraudulent, Deceitful Acts)

17 15. Respondent is subject to disciplinary action under Code section 4301,  
18 subdivision (f), for committing fraudulent and deceitful acts constituting unprofessional conduct.  
19 In or about the year 2000, through ERW, a reverse distributor, Respondent presented false claims  
20 to drug manufacturers regarding returned drugs in order to obtain unearned financial benefit.  
21 Respondent's involvement in the fraudulent scheme is more fully described in paragraphs 11  
22 through 14, above.

23 SECOND CAUSE FOR DISCIPLINE

24 (Knowingly Creating a Document Containing Factual Misrepresentations)

25 16. Respondent is subject to disciplinary action under Code section 4301,  
26 subdivision (g), for knowingly creating documents containing factual misrepresentations, thus  
27 constituting unprofessional conduct. In or about the year 2000, Respondent presented claims  
28 through ERW to drug manufacturers that contained factual misrepresentations regarding

1 allegedly returned drugs in order to obtain unearned financial benefit. Respondent's involvement  
2 in the fraudulent scheme is more fully described in paragraphs 11 through 15, above.

3 **THIRD CAUSE FOR DISCIPLINE**

4 (Unprofessional Conduct / Commission of Acts That  
5 Would Have Warranted the Denial of a License)

6 17. Respondent is subject to disciplinary action under Code sections 480 and  
7 4301, subdivision (p), for engaging in unprofessional conduct, specifically, for committing acts  
8 that would have warranted the denial of a license. Section 480, subdivision (a)(2) provides that a  
9 board may deny a license if the applicant has committed dishonest acts in order to benefit himself  
10 financially. In or about the year 2000, Respondent presented false claims through ERW  
11 regarding allegedly returned drugs in order to obtain unearned financial benefit, thus constituting  
12 a valid ground for license denial under section 480 and constituting unprofessional conduct and a  
13 cause for discipline under section 4301, subdivision (p). Respondent's involvement in the  
14 fraudulent scheme is more fully described in paragraphs 11 through 16, above.

15 **FOURTH CAUSE FOR DISCIPLINE**

16 (Unprofessional Acts and Omissions Involving the Exercise of  
17 Pharmaceutical Education, Training, and Experience)

18 18. Respondent is subject to disciplinary action under Code section 4306.5 for  
19 committing unprofessional acts involving the exercise of professional pharmaceutical education,  
20 training, and experience. In or about the year 2000, Respondent fraudulently committed  
21 unprofessional acts when he presented false claims through ERW regarding allegedly returned  
22 drugs in order to obtain unearned financial benefit. The process of preparing false claims  
23 through ERW, and the utilization of a pharmaceutical specialty company, namely ERW, to  
24 process these claims, utilized specialized knowledge, which Respondent had gained through his  
25 pharmaceutical education, training, and experience, constituting unprofessional conduct and a  
26 cause for discipline under section 4306.5. Respondent's involvement in the fraudulent scheme is  
27 more fully described in paragraphs 11 through 17, above.

28 ///

1 **FIFTH CAUSE FOR DISCIPLINE**

2 (Preparing and Presenting False Claims for Payment)

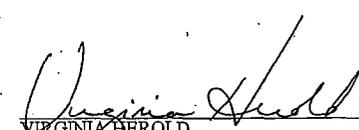
3 19. Respondent is subject to disciplinary action under section 810, subdivision  
4 (a)(2) for preparing and presenting false claims for payment, which constitutes a specifically  
5 identified form of unprofessional conduct. In or about the year 2000, Respondent fraudulently  
6 presented false claims through ERW regarding allegedly returned drugs in order to obtain  
7 unearned financial benefit. Respondent's involvement in the fraudulent scheme is more fully  
8 described in paragraphs 11 through 19, above.

9 **PRAYER**

10 WHEREFORE, Complainant requests that a hearing be held on the matters herein  
11 alleged, and that following the hearing, the Board of Pharmacy issue a decision:

- 12 1. Revoking or suspending Pharmacist License Number RPH 37204, issued  
13 to Respondent;  
14 2. Ordering Respondent to pay the Board of Pharmacy the reasonable costs of  
15 the investigation and enforcement of this case, pursuant to Business and Professions Code  
16 section 125.3; and  
17 3. Taking such other and further action as deemed necessary and proper.

18  
19 DATED: 7/22/08

20  
21  
22   
23 VIRGINIA HEROLD  
24 Executive Officer  
25 Board of Pharmacy  
26 Department of Consumer Affairs  
27 State of California  
28 Complainant

1 EDMUND G. BROWN JR. Attorney General  
of the State of California  
2 GREGORY J. SALUTE  
Supervising Deputy Attorney General  
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6 Facsimile: (213) 897-2804  
7 Attorneys for Complainant

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BOARD OF PHARMACY  
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8 **BEFORE THE**  
9 **BOARD OF PHARMACY**  
10 **DEPARTMENT OF CONSUMER AFFAIRS**  
11 **STATE OF CALIFORNIA**

11 In the Matter of the Accusation Against:  
12 CATHAY MEDICAL INC.  
d.b.a. COLLEGE PHARMACY  
13 HENRY FONG, Pharmacist-in-Charge  
626 W. College St.  
14 Los Angeles, CA 90012  
15 Pharmacy Permit No. PHY 36574  
16 and  
17 CATHAY MEDICAL INC.  
d.b.a. CATHAY MEDICAL PHARMACY  
18 DAVID FONG, Pharmacist-in-Charge  
711 W. College St.  
19 Los Angeles, CA 90012  
20 Pharmacy Permit No. PHY 22806  
21 Respondent.

Case No. 3086

11 **ACCUSATION**

22 Complainant alleges:

23 **PARTIES**

- 24 1. Virginia Herold (Complainant) brings this Accusation solely in her official  
25 capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.  
26 2. On or about March 1, 1983, the Board of Pharmacy (Board) issued  
27 Pharmacy Permit No. PHY 22806 to Cathay Medical Inc. d.b.a. Cathay Medical Pharmacy  
28

1 Pharmacy Permit No. PHY 22806 to Cathay Medical Inc. d.b.a. Cathay Medical Pharmacy  
2 (Respondent). The Pharmacy Permit was in full force and effect at all times relevant to the  
3 charges brought herein and will expire on March 1, 2009, unless renewed.  
4 3. On or about June 25, 1990, the Board issued Pharmacy Permit No. PHY  
5 36574 to Cathay Medical Inc. d.b.a. College Pharmacy (Respondent). The Pharmacy Permit was  
6 in full force and effect at all times relevant to the charges brought herein and will expire on June  
7 1, 2009, unless renewed.

8 **JURISDICTION**

- 9 4. This Accusation is brought before the Board of Pharmacy (Board),  
10 Department of Consumer Affairs, under the authority of the following laws. All Section  
11 references are to the Business and Professions Code (Code) unless otherwise indicated.  
12 5. Code section 4300, subdivision (a), states that "[e]very license issued may  
13 be suspended or revoked."  
14 6. Code section 477, subdivision (b), states that "'License' includes  
15 certificate, registration or other means to engage in a business or profession regulated by this  
16 code."  
17 7. Code section 480, subdivision (a)(2), provides that a board may deny a  
18 license if the applicant has committed dishonest, fraudulent, or deceitful acts with the intent to  
19 substantially benefit himself.  
20 8. Section 810 of the Code states:  
21 (a) It shall constitute unprofessional conduct and grounds for  
22 disciplinary action, including suspension or revocation of a license or certificate,  
23 for a health care professional to do any of the following in connection with his or  
24 her professional activities:  
25 (2) Knowingly prepare, make, or subscribe any writing, with intent to  
26 present or use the same, or to allow it to be presented or used in support of any  
27 false or fraudulent claim.  
28 9. Code section 4301 states:  
The board shall take action against any holder of a license who is guilty of

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6  
Attachment

1 is not limited to, any of the following:

2  
3 (f) The commission of any act involving moral turpitude, dishonesty,  
4 fraud, deceit, or corruption, whether the act is committed in the course of relations  
as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.

5 (g) Knowingly making or signing any certificate or other document that  
6 falsely represents the existence or nonexistence of a state of facts.

7  
8 (p) Actions or conduct that would have warranted denial of a license.

9 10. Code section 118, subdivision (b), provides that the suspension,  
10 expiration, surrender, or cancellation of a license shall not deprive the Board of jurisdiction to  
11 proceed with a disciplinary action during the period within which the license may be renewed,  
12 restored, reissued or reinstated.

#### 13 COST RECOVERY

14 11. Code section 125.3 provides that the Board may request the administrative  
15 law judge to direct a licensee found to have committed a violation or violations of the licensing  
16 act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the  
17 case.

#### 18 BACKGROUND

19 12. Cathay Medical Industries, Inc., owns Cathay Medical Pharmacy,  
20 Pharmacy Permit No. PHY 22806, and College Pharmacy, Pharmacy Permit No. PHY 36574.  
21 Cathay Medical Industries, Inc., is owned by Henry Fong (75%) and Gerald Wu (25%). Henry  
22 Fong is the Pharmacist-In-Charge of College Pharmacy, and Henry Fong's son, David Fong, is  
the Pharmacist-In-Charge of Cathay Medical Pharmacy.

23 13. Easy Returns Worldwide, Inc. (ERW) was a reverse distributor of  
24 pharmaceuticals. ERW returned expired drugs to the appropriate manufacturers for credit to its  
25 client pharmacies who purchased the drugs. ERW usually charged the pharmacies a 5-10% fee  
26 for said returns, which was based on the expected credits that the manufacturer would give to the  
27 pharmacies. Most manufacturers required the return of the actual products from ERW's retail  
28

1 pharmacies in order to give them credit.

2 14. In a criminal proceeding entitled *United States of America v. Richard J.*  
3 *Drury*, United States District Court, Eastern District of Missouri, Case No. S1-4:05 CR 33 ERW,  
4 Richard Drury, a corporate officer of ERW (Drury), was indicted, found guilty, and convicted of  
5 four counts of mail fraud for defrauding drug manufacturers by making false claims with  
6 pharmacies in connection with returned drugs. Pursuant to Drury's indictment, between August  
7 2000 and January 2002, Drury devised and participated in a scheme to create fraudulent returns  
8 of expired drugs to pharmaceutical manufacturers on behalf of pharmacies that had not purchased  
9 them with the false assertion that the pharmacies had purchased the drugs. This scheme caused  
10 the manufacturers to credit various pharmacies for returns that did not belong to them. The  
11 pharmacies paid approximately a 33% fee to Drury and ERW for the false returns credited to  
12 them.

13 15. David Fong agreed with ERW to participate in its fraudulent scheme in  
14 order to obtain easy profits for his family business. ERW returned dangerous drugs in November  
15 and December of 2000 under both Cathay Medical Pharmacy's and College Pharmacy's  
16 pharmacy permits and federal Drug Enforcement Administration (DEA) numbers, even though  
17 the returned drugs did not belong to either pharmacy. Based on the amount of the false returns  
18 on behalf of the two pharmacies, the Board investigator estimated that Respondent gained  
19 approximately \$14,000 for College Pharmacy and approximately \$19,000 for Cathay Medical  
20 Pharmacy by participating in ERW's fraudulent scheme.

#### 21 FIRST CAUSE FOR DISCIPLINE

##### 22 (False Claim for Pharmaceutical Refund)

23 16. Respondent is subject to disciplinary action under Code section 4301,  
24 subdivision (f), for committing fraudulent and deceitful acts constituting unprofessional conduct.  
25 In or about the year 2000, Respondent presented false claims for rebates to pharmaceutical  
26 manufacturers through ERW in order to obtain unearned financial benefit. The false claims  
27 provided that Respondent returned specified drugs, which were expired or otherwise unusable,  
28 to ERW, when, in fact, Respondent had never owned nor possessed these drugs. Respondent's

1 involvement in the fraudulent scheme is more fully described in paragraphs 11 through 15,  
2 above.

3 **SECOND CAUSE FOR DISCIPLINE**

4 (Knowingly Creating a Document Containing Factual Misrepresentations)

5 17. Respondent is subject to disciplinary action under Code section 4301,  
6 subdivision (g), for knowingly creating documents containing factual misrepresentations through  
7 ERW, thus constituting unprofessional conduct. Specifically, in or about the year 2000,  
8 Respondent through ERW created documents that falsely represented to drug manufacturers that  
9 Respondent returned specified drugs to ERW, which in fact, Respondent had not. Respondent's  
10 involvement in the fraudulent scheme is more fully described in paragraphs 11 through 16,  
11 above.

12 **THIRD CAUSE FOR DISCIPLINE**

13 (Unprofessional Conduct)

14 18. Respondent is subject to disciplinary action under Code sections 480 and  
15 4301, subdivision (p), for engaging in unprofessional conduct, specifically, for committing acts  
16 that would have warranted the denial of a license. Section 480, subdivision (a)(2) provides that a  
17 board may deny a license if the applicant has committed dishonest acts in order to benefit himself  
18 financially. In or about the year 2000, Respondent presented false claims through ERW  
19 regarding allegedly returned drugs in order to obtain unearned financial benefit, thus constituting  
20 a valid ground for license denial under section 480 and constituting unprofessional conduct and a  
21 cause for discipline under section 4301, subdivision (p). Respondent's involvement in the  
22 fraudulent scheme is more fully described in paragraphs 11 through 17, above.

23 **FOURTH CAUSE FOR DISCIPLINE**

24 (Preparing and Presenting False Claims for Payment)

25 19. Respondent is subject to disciplinary action under Code section 810,  
26 subdivision (a)(2), for preparing and presenting false claims for payment, which constitutes a  
27 specifically identified form of unprofessional conduct. In or about the year 2000, Respondent  
28 fraudulently presented false claims through ERW regarding allegedly returned drugs in order to

1 obtain unearned financial benefit. Respondent's involvement in the fraudulent scheme is more  
2 fully described in paragraphs 11 through 18, above.

3 **PRAYER**

4 WHEREFORE, Complainant requests that a hearing be held on the matter herein  
5 alleged, and that following the hearing, the Board of Pharmacy issue a decision:

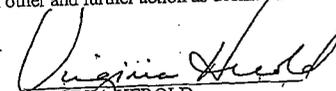
6 A. Revoking or suspending Pharmacy Permit No. PHY16574, issued to  
7 Cathay Medical Inc. d.b.a. College Pharmacy;

8 B. Revoking or suspending Pharmacy Permit No. PHY2806, issued to  
9 Cathay Medical Inc. d.b.a. Cathay Medical Pharmacy;

10 C. Ordering Cathay Medical Inc. to pay the Board of Pharmacy the  
11 reasonable costs of the investigation and enforcement of this case, pursuant to Business and  
12 Professions Code section 125.3; and,

13 D. Taking such other and further action as deemed necessary and proper.

14 DATED: 7/22/08

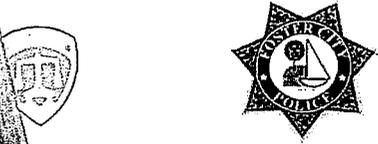
15   
16 VIRGINIA HEROLD  
17 Executive Officer  
18 Board of Pharmacy  
19 Department of Consumer Affairs  
20 State of California  
21 Complainant

DEA  
Attachment  
7

THE PHARMACEUTICAL  
DISPOSAL PROGRAM IS FOR  
RESIDENTIAL DISPOSAL ONLY.  
COMMERCIAL DISPOSAL  
FROM MEDICAL FACILITIES,  
DOCTORS' OFFICES,  
BOARD AND CARE  
FACILITIES, BUSINESSES,  
ETC., IS PROHIBITED BY  
STATUTE. VIOLATORS WILL  
BE REFERRED TO THE  
SAN MATEO COUNTY  
ENVIRONMENTAL  
HEALTH DEPARTMENT.



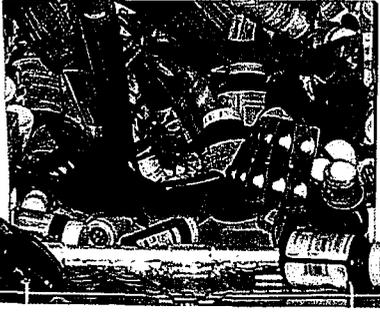
VAL  
SANTA ANITA  
SANTA ANITA



PHARMACEUTICAL DISPOSAL  
ONLY



DESCHOS FARMACEUTICOS  
SOLAMENTE



SFGate.com

### ALAMEDA OFFICER ACCUSED OF PAINKILLER SCAM

By Henry K. Lee, Staff Writer  
San Francisco Chronicle  
February 27, 2009

(02-26) 16:57 PST ALAMEDA -- A veteran Alameda police sergeant was arrested Thursday on suspicion of stealing prescription painkillers from the family of a man who recently died, authorities said.

Ronald R. Jones, a 26-year department veteran, was arrested on suspicion of two counts of fraud and misrepresentation to obtain a controlled substance, said Alameda police Lt. Bill Scott.

Jones, 48, was booked at a downtown Oakland jail and then released. He has been placed on paid administrative leave.

Jones allegedly told the family of a man who died of natural causes that police offered a disposal service for prescription medications, Scott said. The department does not provide such a service. Authorities suspect that Jones contacted the families of several other people who died recently and offered to take away prescription medicines. Authorities said their investigation is continuing.

Investigators did not disclose what, if anything, Jones did with the medications.

Jones' attorney, Alison Berry Wilkinson, called the case "a complete and utter misunderstanding. He wasn't doing anything improper. He was operating within his responsibilities."

E-mail Henry K. Lee at [hlee@sfchronicle.com](mailto:hlee@sfchronicle.com).

<http://sfgate.com/cgi-bin/article.cgi?f=/c/a/2009/02/27/BAOH165OKH.DTL>

This article appeared on page B - 3 of the San Francisco Chronicle

DEA  
Attachment  
8

# Attachment 5

*Department of Consumer Affairs  
Policies Regarding Pursuit of Interim  
Suspension Orders*



## MEMORANDUM

**DATE:** December 15, 2008

**TO:** Executive Officers  
Executive Directors  
Registrars  
Bureau Chiefs

**FROM:**   
**DOREATHEA JOHNSON**  
Deputy Director  
Legal Affairs

**SUBJECT:** Interim Suspension Orders

It is the purpose of the Department of Consumer Affairs (DCA) to ensure that those businesses and professions under its jurisdiction (hereafter licensee) are adequately regulated in order to protect the public health, safety, and welfare of the people of California. It has been a longstanding policy of the department to encourage the practice of the licensing agencies, to use Interim Suspension Orders and PC 23s when the conduct of a licensee is such that the board cannot afford to wait for the completion of administrative process, following the filing of an accusation, before taking action to ensure the safety of the general public. This memo is to reaffirm the department's position with respect to the use of these proceedings.

When licensees engage in conduct that poses an imminent risk of serious harm to the public health, safety, and welfare, it is the policy of the DCA to act swiftly and efficiently to protect the public by applying the provisions of Business and Professions Code section 495, relating to interim suspension, and Penal Code section 23, relating to criminal probation against licensees. To this end, every board, bureau, and commission in the DCA (licensing agencies) shall: (1) institute proceedings for ordering the interim suspension of a license or imposing license restrictions when such action is warranted; and (2) make recommendations regarding specific conditions of criminal probation pursuant to Penal Code section 23 for persons licensed under the provisions of the Business and Professions Code.

A. Interim Suspension Order

DCA expects its licensing agencies to seek an ISO pursuant to Business and Professions Code section 494 whenever a licensing agency can meet the requirements of that section by demonstrating both of the following:

- (1) There is a preponderance of evidence that a licensee has engaged in acts or omissions constituting violation of the Business and Professions Code or has been convicted of a crime substantially related to the licensed activity; **and**
- (2) Based on a **preponderance of evidence** it has been determined that permitting the licensee to continue to engage in licensed activity, or permitting the licensee to continue in licensed activity or practice without restrictions, **would endanger** the public health, safety, or welfare.

Factors to Consider When Deciding Whether to Issue an ISO

In assessing whether it can meet the requirements set forth in section 494, a licensing agency will need to answer the following questions:

- Is the alleged conduct or conviction substantially related to the occupational license? Each licensing agency must be guided by its own statutes and regulations in determining whether there is a substantial relationship between an act or crime and the qualifications, functions or duties of a particular license.
- How much time has passed since the conduct at issue? The recency of the conduct goes to the question of whether the licensing agency can demonstrate by a **preponderance of the evidence** that permitting the licensee to continue to engage in licensed activity, or permitting the licensee to continue in licensed activity or practice without restrictions, **would endanger** the public health, safety, or welfare. This determination necessarily depends on the specific facts and circumstances of each case and the character and nature of each licensed occupation. Generally, to immediately order the suspension or restriction on a license, a licensing agency must be able to provide evidence of imminent potential harm to the public either based on other similar acts by a licensee or on the fact that the conduct occurred a very short time ago.
- Is the licensee incarcerated? Is the licensee going to be released soon from custody? If so, a Penal Code section 23 recommendation may be more appropriate and a more efficient use of the licensing agency's resources.

- If the licensee was convicted of a crime, how old is the conviction and have there been any more recent complaints of a similar nature against the licensee? If the conduct that led to the conviction is recent, then an ISO is more likely to be successful.
- What is the nature of the crime or act? How egregious is the conduct? For example, a licensing agency should seek an ISO where the conduct or act is very recent and involves one of the following:
  - Licensed health care provider is accused of being under the influence of drugs or alcohol while treating patients.
  - Licensed health care provider is charged with DUI and the blood alcohol level is very high—e.g., .18 or greater.
  - Licensed health care provider allegedly has a consistent pattern of substance abuse.
  - Licensed health care provider has allegedly engaged recently in sexual misconduct with or sexually assaulted a patient.
  - Licensed security guard is recently convicted of a lewd act with a minor and will soon be released from custody.
  - Licensed health care practitioner is arrested for sexual assault against a patient.
  - Healing arts licensee is arrested for murder, aggravated rape or a similar type of assault.
  - Board has sufficient evidence to show that a licensed contractor's work on an ongoing project is substandard and is likely to compromise public safety.

This list is intended to provide some examples of situations where an ISO is appropriate. The list is not intended to be exhaustive, and you will need to review the specific facts and determine on a case-by-case basis whether an ISO should be requested. If you are unsure whether an ISO should be requested, please contact DCA Legal for assistance.

#### **B. Penal Code section 23 Petitions and Hearings**

Penal Code section 23 authorizes the DCA and its licensing agencies to appear in any criminal proceeding and make recommendations regarding specific conditions to be imposed on persons seeking to be released on their own recognizance, released on bail or being sentenced, including recommendations concerning conditions prohibiting the licensee from engaging in regulated licensed practice or restricting the licensee's

practice. In these circumstances, a licensing agency may recommend that a court order a licensee to surrender his or her license or practice under specified restrictions or conditions until such time as the criminal proceeding is concluded. At any stage during the criminal proceedings, a licensing agency may furnish pertinent information, make recommendations regarding specific conditions of probation, or provide any other assistance necessary to promote the interests of justice and protect the interests of the public.

A Penal Code section 23 petition may be presented in any court with appropriate jurisdiction during any criminal proceeding against a person licensed by DCA or one of its licensing agencies. A licensing agency that wishes to request the filing of a Penal Code section 23 petition must be able to demonstrate in the petition that the alleged crime is substantially related to the licensed activity and that suspending or restricting the license as a condition of bail, release or sentencing is necessary in order to ensure public safety while the criminal proceeding pending. The licensing agency's petition must delineate the specific recommendations by the licensing agency for suspending or restricting the license and explain how its specific recommendations would promote the interests of justice and protect the interests of the public while the criminal proceeding is pending. The following are some situations in which a licensing agency may wish to file a Penal Code section 23 petition:

---Licensed health care practitioner is arrested for being under the influence of drugs or alcohol while treating patients.

--Licensed health care practitioner is arrested for DUI and the blood alcohol level is very high -- e.g., .18 or greater.

--Licensed health care practitioner is arrested for sexually assaulting a patient.

--Licensed security guard is recently convicted of a lewd act with a minor and will soon be released from custody.

--Licensed health care practitioner is arrested for sexual assault against a patient.

--Licensed health care practitioner is arrested for murder, aggravated rape or a similar type of assault.

DCA encourages every licensing agency to file a Penal Code section 23 petition in the foregoing circumstances; e.g., whenever the likelihood of harm to the public would be great if the licensee was released and permitted either to practice or to practice without restrictions.

cc: Carrie Lopez  
Scott Reid

# Attachment 6

*Minutes of the March 9, 2009 Meeting of  
the Enforcement Committee*



**California State Board of Pharmacy**

1625 N. Market Blvd, Suite N219, Sacramento, CA 95834  
Phone (916) 574-7900  
Fax (916) 574-8618  
www.pharmacy.ca.gov

STATE AND CONSUMERS AFFAIRS AGENCY  
DEPARTMENT OF CONSUMER AFFAIRS  
ARNOLD SCHWARZENEGGER, GOVERNOR

**STATE BOARD OF PHARMACY  
DEPARTMENT OF CONSUMER AFFAIRS  
ENFORCEMENT COMMITTEE AND  
WORK GROUP ON E-PEDIGREE MEETING  
MINUTES**

**DATE:** March 11, 2009

**LOCATION:** Holiday Inn – San Diego Bayside  
4875 North Harbor Drive  
San Diego, CA 92106

**BOARD MEMBERS  
PRESENT:** Robert Swart, PharmD, Committee Chair  
Stanley C. Weisser, RPh  
James Burgard, Public Member

**STAFF PRESENT:** Virginia Herold, Executive Officer  
Anne Sodergren, Assistant Executive Officer  
Joshua Room, Deputy Attorney General  
Kristy Schieldge, DCA Senior Staff Counsel  
Tessa Fraga, Analyst

---

**Call to Order**

Chairperson Rob Swart called the meeting to order at 9:31 a.m.

The meeting began with a brief video created by Pfizer, Inc. which reveals the dangers of buying counterfeit medication online.

Dr. Swart provided background on e-pedigree. The 2008 legislative session ended September 30, which is the date when the Governor signed SB 1307(Ridley-Thomas). This law now staggers implementation of e-pedigree requirements in California away from 2011 to:

- 50 percent of a manufacturer's products by 2015
- The remaining 50 percent of the manufacturer's products by 2016
- Wholesalers and repackagers must accept and pass e-pedigrees by July 1, 2016
- Pharmacies and pharmacy distribution centers must accept e-pedigrees by July 1, 2017

Dr. Swart noted that there is preemption language that would repeal California's provisions if federal law regarding e-pedigrees is enacted, or if federal standards are enacted, they would take effect in California. He also noted that there are provisions that define drop shipments, 3PLs, repackagers and manufacturers. Grandfathering provisions for drugs already in the supply chain are included.

Dr. Swart stated that the board will ultimately have to develop regulations for various components, including inference. No action on these regulations is planned for several years.

## **A. Workgroup on E-Pedigree**

### **1. Discussion of Proposed Comments for the Food and Drug Administration's (FDA) "Proposed Guidance for Industry on Standards for Securing the Drug Supply Chain -- Standardized Numerical Identification of Prescription Drug Packages"**

Dr. Swart stated that the Enforcement Committee will now have an opportunity to discuss the FDA's request for comments on "Draft Guidance for Industry on Standards for Securing the Drug Supply Chain -- Standardized Numerical Identification for Prescription Drug Packages".

Dr. Swart explained that the FDA's document is fairly broad, but that the content is very similar to comments provided by California in regard to the e-pedigree standards. He stated that the FDA is now requesting additional comments specifically focused on the standardization of numerical identification of prescription drug packages. He noted that the comments are due to the FDA by April 16, 2009 and encouraged all in attendance to submit written comments.

Dr. Swart explained that, under 2007 federal law Federal Food and Drug Administration Amendments Act of 2007 (FDAAA), the FDA was charged with developing a standardized numerical identifier to be applied to a prescription drug at the point of manufacturing "sufficient to facilitate the identification, validation, authentication, and tracking and tracing of the prescription drug." He noted that this would be the serialized identifier referenced in California's e-pedigree law.

Dr. Swart provided his opinion that labeling should be required on all packaging down to the smallest unit and that this is more crucial than the visual appeal of the label.

Dr. Swart reiterated that, at today's meeting, the workgroup on e-pedigree will have the opportunity to discuss this request for comments and determine whether the board should submit comments in support of the FDA's identification of this identifier. Also, since the FDA will be attending this meeting, the Workgroup on e-pedigree will be able to ask questions of the FDA regarding this process

## **Public Comments:**

The committee generally discussed serialization issues. There was some concern regarding the eight-digit serialization number that would be the random portion of the unique identifier, and whether that is a sufficient number size to allow for lack of duplication and reuse over a period of time. The committee agreed that an alpha-numeric identifier for the 8-digit random number would be a better standard.

The committee expressed support for the FDA moving ahead with this standard, nearly one year early.

## 2. Discussion of Comments for FDA's Proposed Guidance for Industry on Unique Device Identification (UDI) Systems

Dr. Swart stated that, on February 12, 2009, the FDA convened a hearing on "Unique Device Identification System." The hearing was convened to enable the FDA to eventually "promulgate regulations establishing a unique device identification system for medical devices requiring the label of devices to bear a unique identifier, unless the Secretary [of Health and Human Services] requires an alternative placement or provides an exception for a particular device or type of device. The unique identifier shall adequately identify the device through distribution and use, and may include information on the lot or serial number."

Dr. Swart noted that, while California's e-pedigree requirements exclude dangerous devices, the board still regulates the distribution of dangerous devices within, throughout and into California. He also noted that the issue is being provided for the committee as information and for discussion.

Ms. Herold stated that the FDA will initiate a comment period within the next six months. She also noted that this will affect the Board of Pharmacy and its licensees as they regulate those that sell, ship and store dangerous devices within the state of California.

## **Public Comments:**

Ron Bone (McKesson Corp.) shared that the meeting held in Maryland, hosted by the FDA, was well attended by those within the supply chain. He noted that there were four panels discussing the issues and that submissions were provided following the meeting. The meeting promoted significant focus for UDI systems.

Mr. Room asked Mr. Bone whether he views the UDI requirements as a similar undertaking to e-pedigree.

Mr. Bone responded that, with UDI, the process is much more complicated and has many issues to address. The identification criteria will vary based on product. He also

noted that there had been discussion on the issue of risk-based products with relation to priority of recalls, etc.

### 3. Discussion and Updates to Implement Electronic Pedigree Requirements – Presentations

#### *a. Ilisa Bernstein – Food and Drug Administration (FDA)*

Dr. Bernstein provided an overview of the Guidance for Industry. She explained that 505D of the FDA Standards Development Act gives the FDA authority to develop standards for identification, validation, authentication, and tracking and tracing. She noted that the FDA is working to have standards finalized for serialization identification prior to the March 2010 deadline. Thus, the January 2009 draft was issued with opportunity for comments from the industry.

Dr. Bernstein reviewed the proposed Standardized Numerical Identifier (SNI), which would essentially result in a Serialized National Drug Code (NDC) as it is a combination of each product's NDC and a unique eight-digit serial number. She identified specific characteristics of the serialized NDC which were modified based on comments provided by industry.

Dr. Bernstein stated that the draft Guidance was announced in the Federal Register. She provided specific questions submitted by the FDA along with the draft which they are requesting comment on by industry.

Dr. Bernstein provided information for web site links to the draft Guidance Federal Register Notice and instructions for filing comments, which are due by April 16, 2009.

#### **Questions from the Board:**

Dr. Swart questioned the decision of excluding the lot number from the SNI. He stated concern about how that will effect patient safety in relation to e-pedigree and recall notification.

Dr. Bernstein responded that the SNI will link to a data base which will provide the expiration date, lot number, etc. She added that the information Dr. Swart is referring to would be a standard of track and trace.

Stan Weisser questioned whether it is feasible at this point in the decision process to reconsider the eight- digit number.

Dr. Bernstein responded that comments will be considered and changes will be made as necessary to the final draft. She added that nothing is final at this point.

Mr. Weisser questioned the FDA's decision not to address the case and pallet identifiers issue.

Dr. Bernstein responded that the law requires an SNI for pallets. She added that the FDA feels there should be an SNI for cases as well. However, more information is needed before they would be able to provide a recommendation in the future. Therefore, they are seeking comments from industry and are hoping to receive the necessary information.

Mr. Weisser mentioned that it was included in the comments submitted by the Board of Pharmacy.

Dr. Bernstein responded that they did receive some comments and information, but that it was not substantial enough to be able to provide an educated recommendation.

Ms. Herold explained that the board requested in their comments in 2008 that the NDC be part of a serialized number on the individual unit. She noted that the FDA appears to be including that in their Guidance. She stated that the ability to link the serialized number to a particular case or pallet is necessary for the wholesalers.

Mr. Room explained that the board requested that the serialization be included at the unit level, as that is the most crucial. There has been an assumption that, in order for the serialization system to be effective and workable, serialization would need to occur at the case and pallet level as well. He added that the board can choose to reaffirm by submitting additional comments in regards to case and pallet level serialization.

Mr. Weisser referenced the board's 2008 comments to the FDA. He quoted a section of the letter which states that the board believes that a full track and trace system would require SNI's on both levels – the individual unit and the case/pallet.

Mr. Room stated that the letter is a reflection of California law. He noted that California law does not state requirements relating specifically to case and pallets.

Ms. Herold added that if inference is allowed in the future, then it may be necessary to address SNI's at all levels within regulations.

Jim Burgard expressed concern regarding the individual serialization involving eight digits. He stated that, as large quantities of items are serialized, the process will become more complex for manufacturers. Mr. Burgard stated that this complexity should be considered.

Dr. Swart stated that it will be necessary for the manufacturers to provide input on what is the optimal amount of digits within the serialization.

Mr. Weisser reiterated that using only eight numerical digits is a limiting factor.

## **Public Comment:**

Mike Durschlag (Allermed Laboratories) commented that the standards are geared towards identifying drugs in the distribution system. He asked Dr. Bernstein if the same standards will apply when a manufacturer distributes directly to a physician.

Dr. Bernstein responded that that issue is outside the scope of the proposed Guidance and standards and would need to be addressed later.

Mr. Bone (McKesson) asked about the opportunity to have the UDI and SNI on the same package. This would be important for kits, where both a drug and a device are present.

Dr. Bernstein stated this has not been resolved. She did note, however, there has been discussion within both SNI and UDI workgroups on the subject and that they recognize the need for compatibility within the supply chain.

Steve Gray (Kaiser Permanente) asked if there is any significance in the pairing of the numbers within the eight digit structure of the SNI. He referenced the Generic Product Indicator (GPI) used on retail products, explaining that the numbers are paired to provide information on the type of product it is. He also asked if the SNI digits could be developed in a way to provide information on where the product originated.

Dr. Bernstein stated that the Guidance indicates the eight digit number is to be created by the manufacturer or repackager of the product. She added that, except for the requirement that the SNI must be unique for each package, the Guidance does not specify how the number is to be generated. She encouraged such suggested comments to be submitted.

Mr. Room identified that there is tension between those in the supply chain who want the number to have specific representation and those who want the number to be random because of the flexibility it provides. He stated that both GS1 and the FDA have indicated that it is by reference to the database to retrieve such identifying information, rather than by reference to the number itself.

Dr. Gray responded that the user is the consumer, and that they would not have access to the database. He added that consumers want to know where the product comes from, especially in relation to whether the drug originated from a manufacturer in another country. He reiterated his suggestion to consider this within the comments provided.

*b. Allison Hite - Congressman Buyer's Office*

Ms. Hite provided an update on e-pedigree implementation on a federal level. She stated that there is a bit of a standstill with the new chairman of Energy and Commerce. She encouraged any support and influence that any individuals or organizations in California may be able to provide in bringing the issue forward to Chairman Waxman, as the state has a strong representation with regard to e-pedigree of drugs. Ms. Hite stated that legislation at this time is indeterminable as how Chairman Waxman plans to handle food and drug regulation is not known. She indicated that there was a hearing regarding food safety, and foresees two separate bills as a result of that hearing, with food safety being addressed first and drug safety following.

Ms. Hite noted that they have made significant strides and have attempted to mirror California's efforts thus far in terms of the timeline of serializing drugs, as well as a track and trace system. Ms. Hite stated that Chairman Waxman is in support of having any related legislation which occurs at the federal level be influenced by legislation which is put in place in California. She explained that they are seeking assistance from the FDA on their legislation before moving forward.

Ms. Herold noted that, with regard to regulation development, the Congressman's office has been very clear thus far in not wanting to disrupt any efforts by states with respect to addressing serialization and pedigree. She stated that the early version of the bill seemed to directly follow the California model versus what other states have done. She asked if Congressman Buyer is going to continue with that plan of following the California model, or if they are waiting for input from Chairman Waxman.

Ms. Hite responded that the goal is to have one standardized pedigree standard. She stated that they are moving forward with flexibility in the language in order to meet the final goal. She noted that they felt the California timeline is more than adequate for the process.

*c. Bob Celeste - GS1*

Mr. Celeste provided an update on the standards development and adoption. He reviewed the reason for GS1's involvement in the serialization and global standardization process.

Mr. Celeste stated that, in order to achieve patient safety and healthcare supply chain efficiency, there are "foundational" steps to be addressed. Those steps include Standardized Product Identification (GTIN), Standardized Location Identification (GLN) and Standardized Product Definition (GDSN). Additionally, Mr. Celeste explained that the "pillars," which includes track and trace and e-pedigree, are the benefits which build on those foundational steps.

Mr. Celeste provided definitions for GS1's standards. He stated that the NDC is embedded within the GTIN number and a serial number is included. He explained that

the GTIN is then placed within a Global Data Synchronization network, where the information about that product can be obtained. Mr. Celeste also explained the creation of the Global Location Number and registry.

Mr. Celeste provided an example of how a product is ultimately tracked through the supply chain by use of identifiers. He added that GS1 is looking at the various issues raised by the pharmaceutical industry relating to traceability adoption and the use of identifiers versus carriers.

Mr. Celeste summarized the comments provided by GS1 to the FDA :

- Pallet and case level – GS1 is suggesting that the supply chain be able to use the serialized shipping container number as well as the Global Returnable Asset Identifier (GRAI)
- Blood and blood products serialization – conflicts with serial number standards
- Requested FDA to consider adopting GTIN's so that they can be accepted within their system
- Requested FDA to consider a sunset of duplicate data that is automated

Mr. Celeste noted that application identifiers can be added to bar codes.

Mr. Celeste stated that a number of hospitals and group purchasing organizations have established a deadline of 2010 for the GLN "sunrise." He added that 2012 is the "sunrise" date for GTIN, which has more impact for medical devices.

Mr. Celeste discussed the issue of bar code quality with relation to the use of a verifier, which reads and depicts the quality of a barcode. He explained that a test card is used to ensure that a readable bar code is produced. He explained that a good quality bar code ensures readability and prevents sending bad bar codes into the supply chain.

Mr. Celeste stated that the current pedigree standards allow for reliable movement and disposition, but also contains redundant product and location data. He indicated that, with the use of current and emerging standards, supply chain partners will have:

- Reliable product descriptions
- Reliable location hierarchy
- Reliable lookup and authentication

Mr. Room questioned whether the intent is for the data to be "pushed down" at each level, creating a static database at some point.

Mr. Celeste responded that China, for example, does not want their data in a US database. Therefore, the standards accommodate multiple Discovery Services.

Mr. Room asked if there would be a loophole for reliability of individual recipient data in that situation.

Mr. Celeste responded that the equivalence between the system and e-pedigree needs to be discussed further.

Mr. Weisser asked how manufacturers can protect their data from regions with more loose systems that allow for the potential of counterfeiting.

Mr. Celeste responded that the negotiations between Discovery Services and authentication procedures, as well as agreements that need to take place are involved and time consuming. He added that there is no guarantee that counterfeiting in another country would not occur, but noted that manufacturers have control over where they store their data. Mr. Celeste added that, currently, only the US is interested in having multiple Discovery Services, so it would only involve domestic pharmaceuticals and medical devices.

Mr. Celeste explained that an inference paper is being written and is currently in draft mode. He explained that the paper will discuss the general uses of inferences, how inference is currently being used, and risk mitigation. Mr. Celeste noted that the paper will take one more month for completion and provided a brief summary of what the inference paper encompasses. He noted that the paper will be finalized within a month to be published.

Mr. Celeste stated that GS1 is currently working on the subject of Radio Frequency Identification (RFID) with relation to providing supply chain security and privacy. They are also reviewing the business benefits of serialization and granular events. Mr. Celeste explained that this refers to the specific benefits to the supply chain, as well as patient safety, once serialization is in place.

Mr. Room asked if Mr. Celeste could provide insight to support why the FDA should adopt the GTIN as the standard for serialization.

Mr. Celeste responded that many countries have already adopted GTIN as the standard. He explained that the adoption to strictly GTIN (rather than native GTIN) would involve a lengthy conversion process. He added that the first step is to register a GTIN. Mr. Celeste referenced the peanut butter recall and how the standards were misused. He added concern over the difficulties in obtaining medication bedside within hospitals.

Mr. Room asked for a projected impact in using the SNI relating to global compatibility and distribution.

Mr. Celeste responded that there are currently explicit difficulties, as the NDC is only accepted within the US.

## Public Comments:

Steve Gray (Kaiser Permanente) referenced his earlier comment regarding the consideration by FDA to have the SNI be assigned digits that reflect its origin, for example, rather than being randomly assigned. He pointed out that, unlike other products such as clothes or toys, there is no way for a consumer to identify whether their prescription drugs were manufactured in another country.

Mr. Celeste responded that the GLN would identify where the item was manufactured. He also stated that one of their application identifiers is the country of origin. Therefore, a bar code can provide the information as Dr. Gray is suggesting. He added that it is up to the supply chain to decide what is included within the bar code.

Dr. Gray asked if GS1 sees the multiple Discovery Services referenced as an entity that would need to be licensed by the FDA or government regulated.

Mr. Celeste responded that he is unsure. He stated that discussions are needed to determine what process is necessary in order for Discovery Services to be trusted in terms of legitimacy and security of data.

Dr. Gray asked if proprietary privacy is also being incorporated into the discussions on security and privacy.

Mr. Celeste responded that discussions relating to proprietary privacy within the network are taking place.

### *d. John Danese - Oracle*

Mr. Danese provided a presentation on Oracle's drug supply chain integrity strategy. He noted that a presentation was made by Oracle to the board one year ago immediately prior to the deadline extension. Mr. Danese stated that, at that time, Oracle was not ready for a 2009 deadline, and that the extension to 2011 allowed Oracle and its customers the time needed to be fully prepared with implementation. Mr. Danese also provided a brief background on the company.

Mr. Danese reviewed the main "drivers" of the direction Oracle is taking in their strategy. They are:

- The US States – CA e-pedigree law now 1/1/15 and federal preemption language
- US Federal – FDA Amendments and Globalization Act
- Europe, Middle East and Africa (EMEA) – Countries are developing serialization databases and initiatives independently
- GS1 Healthcare – global traceability standards

Mr. Danese added that their customers are focused on product serialization as it is being addressed in Europe. He stated that Oracle has placed focus on their initial product release in terms of the serialization aspects, and indicated that they have taken a "wait and see" approach to see how the pedigree requirements evolve.

Mr. Danese explained that Oracle has been meeting regularly with a customer focus group in order to collaborate on the design of their product. He stated that, as a result of those meetings, they have been able to identify three main types of responses on what manufacturers are currently doing to prepare for implementation. Those are:

- Forge ahead with serialization efforts and lighten up effort around pedigree
- Refocus on European Union products and serialization
- Wait and see approach – putting projects on hold and doing nothing actively

Mr. Danese also provided specific responses from their customers, both large and smaller pharmaceutical companies, in relation to the current status of e-pedigree and serialization as well as how to address the European markets and their requirements.

Mr. Danese pointed out that the urgency around serialization remains high, based on a survey of their customers. He added that many are continuing with their serialization efforts, which is what drives Oracle's product development.

Mr. Danese reviewed the business benefits in addition to regulatory compliance, which includes product and channel integrity, regulatory compliance and better management of returns. He noted that returns are a huge cost. He emphasized that serialization allows a link between the return receipt and the original shipment/invoice, thus reducing the opportunity for illegitimate products being returned.

Mr. Danese provided information on a new product, the Oracle Pedigree and Serialization Manager (OPSM), which will be developed to ensure supply chain integrity. He explained that the software application will enable companies to implement mass-serialization of drug products and share serialized product data. Mr. Danese stated that the product will protect public health, achieve compliance with global electronic pedigree and related regulations, protect brand integrity and provide cost savings.

Mr. Danese stated that a partner/consumer serial validation portal will be provided so that manufacturers will get additional views into where their product is consumed while customers will be able to serial authenticity, check for recalls, etc.

Mr. Danese addressed the prior questions from the board and public regarding cases and pallets being serialized and unique identifiers for those levels. He explained that the OPSM will be able to generate the unique identifiers for product packaging at the smaller saleable unit levels (blister packs, boxes and cases). The system will not provide serialization on the pallet and container unit level. Those numbers can, however, be accepted from a warehouse management system and be captured as part of their packaging hierarchy. Mr. Danese noted that the OPSM will allow for cross-

referencing of codes (GTIN, GTIN, UPC) at each unit level, so that multiple identification numbers can be used.

Mr. Room asked if Oracle plans to submit FDA comments on the issue of the serialization number.

Mr. Danese responded that they have provided comments on the standards. He does anticipate that they will provide comments on the unique identifier aspect as well.

*e. Other Interested Manufacturers, Wholesalers, Pharmacies and their Associations*

No other comments from manufacturers, wholesalers, pharmacies and associations were provided.

Ms. Herold requested that the board provide additional comments to the FDA on this subject. She noted that the comments are due prior to the next board meeting. She suggested that the Enforcement Committee Chair collaborate with the Board President to determine additional comments to the FDA, addressing the issue of the quantity of digits and whether an eight digit format will be sufficient for the needs of the supply chain. She added that she feels comments should also be provided by the board in support of a unique identifier at the case and pallet level, as the board will be required to develop regulations on inference, but that the board should not be specific as to what the unique identifier should look like because they do not have the knowledge to determine that.

Mr. Room added that the board is pleased to see the FDA taking the same approach as required by California law to focus on serialization at the unit level first.

Motion: Dr. Swart and President Schell to collaborate and submit additional comments to the FDA on the board's support of the unique identifier at the case and pallet level as well as a potential format in terms of quantity of digits and alphanumeric layout.

MOTION: SW/JB

SUPPORT: 3                      OPPOSE: 0

**B. Enforcement Committee**

**1. Discussion of Policies Involving Home Generated Pharmaceutical Waste Take-Back by Pharmacies**

Dr. Swart provided background on drug take-back programs. He explained that last year, SB 966 (Simitian, Chapter 542, Statutes of 2007) directed the California Integrated

Waste Management Board (CIWMB) to develop the parameters for "model" drug take-back programs in pharmacies. These model programs are intended to provide consumers with the ability to dispose of unwanted prescription and over-the-counter drugs (but NOT controlled substances) without flushing them down the toilet or tossing them into the garbage. Under SB 966, these guidelines were to be in place by December 2008.

Dr. Swart explained that state and federal law regulates prescription medicine until it is dispensed to patients. It is not regulated again unless it is collected at consolidated points, at which point it becomes medical waste, and must be handled and destroyed in specific, mandated ways.

Dr. Swart stated that patients are often confounded about what to do with unwanted medicine. Californians increasingly want "green" options for disposing of unwanted medicine, which current law does not allow. He added that there is no viable process, other than to make the discarded drug products unpalatable (mixing with kitty litter or other substance, wrapping in duct tape, etc.) and then placing them in the trash. Dr. Swart noted, however, that some drugs may be flushed down the toilet, and are specifically labeled by the manufacturer to dispose of in this manner.

Dr. Swart indicated that pharmacies have in some cases agreed to take back unwanted drugs from patients. However, this acquisition by pharmacies is not authorized in law. He advised that some communities periodically offer community take-back events, or special days at landfills where the public can take back drugs.

Dr. Swart explained that some drug manufacturers (and the state of Maine, where there is a pilot program underway) provide mailers that patients can use to send unwanted medicine to a predetermined location for destruction. This is the process preferred by the DEA for controlled drugs.

Dr. Swart emphasized the greatest problem for the board with drug take-back programs, which is the potential for these drugs to be diverted to the streets. He stressed that there is a serious prescription drug abuse problem in the US, and the uncontrolled aggregation of prescription medicine is an attractive enticement. In some cases, drugs collected in bins could re-enter the prescription drug supply if pharmacies or wholesalers (or others) sell these items back into the supply chain.

Dr. Swart pointed out that pharmacies are areas where health care is provided. He shared that concern has been expressed that it is difficult for this purpose to be combined with a recycling center, where high sanitation is not necessarily a priority.

Dr. Swart stated that pharmacies have also expressed concern that they may be required to absorb the costs of paying for disposal of these returned drugs, for sorting out controlled drugs (which potentially would require a pharmacist's time) and for assuring the safety and periodic emptying of collection bins.

- Model Guidelines for Home Generated Pharmaceutical Waste Approved by the California Integrated Waste Management Board (CIWMB)

At the January 2009 and October 2008 Board Meetings, the board discussed concern with the proposed model program guidelines as drafted by the California Integrated Waste Management Board. However, the board did express its support for such programs on a voluntary basis with appropriate, specified safeguards.

Ms. Herold provided the board's concerns with provisions in the draft model program guidelines at a committee meeting of the Integrated Waste Management Board (CIWMB) on November 10. Specifically, Ms. Herold stressed the opinion of the board that the program should be established as voluntary.

Dr. Swart stated that, on November 13, the CIWMB adopted the Model Guidelines without incorporating the additional changes listed in the board's November letter. However, a number of other entities also provided comments to guidelines. For this reason, the CIWMB agreed to consider modifications to the Model Guidelines at its February 2009 meeting.

Ms. Herold again provided written comments and testified to the CIWMB on February 18.

- Senate Bill 26 (Simitian)

Dr. Swart indicated that Senator Simitian has introduced SB 26, which would direct the board to coordinate with other state agencies, local governments, drug manufacturers and pharmacies to develop sustainable efficient policies to manage pharmaceutical waste and the disposal of devices.

- Comments Sought by the Federal Drug Enforcement Administration on Disposal of Controlled Substances by Persons not Registered with the DEA – Docket No. DEA-316A

Underlying what is a national problem about how to deal with unwanted and unused drugs, the Drug Enforcement Administration is currently seeking comments on "Disposal of Controlled Substances by Persons Not Registered with the Drug Enforcement Administration." Dr. Swart advised that comments for this item are due March 23, 2009.

Ms. Herold explained that there is a new Integrated Waste Management Board. She stated that they view take-back drugs as a good thing, and are open to discussions on funding. Ms. Herold indicated that there are two versions of model guidelines available. There is question as to whether the guidelines will be feasible for the board to enforce. SB 26 provides amendments to address those issues.

Dr. Swart noted that the law to date has prohibited the take-back of drugs.

Ms. Herold responded that SB 26 addresses this issue and that provisions have been made.

Dr. Swart encouraged industry comments.

Ms. Herold shared that pharmacists are not to accept controlled drugs that are returned. Instead, only law enforcement can accept these items. The involvement of the DEA in establishing policy in this area is another indicator of the movement underway to provide green methods of disposing of unwanted pharmaceuticals.

Ms. Herold encouraged the board to provide comments to the DEA on this topic.

Dr. Swart suggested that the board provide input to Ms. Herold and board staff, which will in turn provide the comments to the DEA.

Discussion continued regarding drug take-back with respect to accountability and return receptacles.

#### **Public Comments:**

Dr. Gray (Kaiser Permanente) stated concern over this issue gaining publicity and leading to confusion and misinformation. He indicated that, aside from general confusion, there are actually two problems with relation to diversion of the unwanted and returned drugs. Not only might the drugs be resold by pharmacies or wholesalers, but they are sometimes also being gifted to non-profit programs, which is prohibited by law. Dr. Gray suggested that efforts be made to coordinate information provided by the DCA Boards. He also suggested that FDA coordinate their responses with those of the California Board of Pharmacy.

Ms. Herold stated that the DEA is moving in the right direction to stop this, but she is concerned about pushing the DEA too much on this topic. Unwanted drugs within long-term hospice care are the biggest concern, which is the DEA's focus.

In response to coordination of the other boards within DCA, Ms. Herold stated that she has been asked to meet with the other boards to discuss take-back and provide updates. She added that the donation of drugs is apparently not an issue.

There was discussion in relation to drug samples, and Ms. Herold stressed that pharmacies are not to take back drug samples.

Motion: Draft comments to the DEA regarding the disposal of controlled drugs by persons not registered with the DEA.

M/S: JB/SW

SUPPORT: 3            OPPOSE: 0

## 2. Update on Activities to Implement E-Prescribing in California

Dr. Swart explained that a number of patient and health care advocates have strongly pressed the need for increased use of e-prescribing. He stated that a principal reason is that statistics indicate that medication errors cost the health care system \$77 billion and cause 7,000 deaths annually. Dr. Swart stressed that a number of these errors could be prevented by full implementation of e-prescribing. Other savings have been projected from redirected time currently spent by prescribers and pharmacies in verifying and switching prescription orders.

Dr. Swart stated that by the mid-1990s, the board had sponsored legislation and promulgated regulations to ensure that e-prescribing was authorized in California law. Since then, various provisions have been added or amended to keep law supportive of allowing electronic prescriptions. He noted that a current deterrent is that controlled substances cannot be e-prescribed. This has caused additional problems and limited the usefulness of e-prescribing within doctor's offices. Dr. Swart indicated that the DEA provided guidelines in the past on the subject, which only made the process more cumbersome.

Dr. Swart advised that, on November 20, 2008, the Board of Pharmacy hosted an e-prescribing forum in conjunction with the Department of Consumer Affairs' Professionals Achieving Consumer Trust Summit. He noted that the other healing arts boards whose licensees prescribe drugs attended this forum, as did our stakeholders and public interest groups. The Dental Board and Medical Board joined the forum as partners.

Dr. Swart noted that the California HealthCare Foundation (CHCF) is strongly advocating adoption of e-prescribing. They also hosted a November 20 forum in San Francisco on e-prescribing.

Dr. Swart explained that, since then and among other projects, the CHCF has been working with the executive staff of the Medical Board and the Board of Pharmacy to host a series of statewide events where physicians and pharmacists could earn continuing education (CE) credits and simultaneously work through issues limiting adoption of e-prescribing. The CHCF is currently in the discussion phase and hope to have a "road show" they can take throughout California in the next few months.

Ms. Herold added that there is a forum scheduled for Visalia at the end of March. There will be two sessions on that day, with members of the Medical Board and physicians scheduled to attend. Additional forums to allow physicians and pharmacists the

opportunity to discuss and collaborate on the issues limiting the adoption of e-prescribing which will occur throughout the remainder of the year. The board has been asked if it is interested in participating and if so, the board will grant CE to pharmacists who attend these events. The Medical Board has already agreed to do this for their licensees. Ms. Herold will work on arranging for Board of Pharmacy licensees to be able to receive CE for attending the event.

Dr. Swart reiterated his support for providing CE to those who attend.

Additionally Assembly Bill 718 has been introduced to require all prescribers and pharmacies to have the ability to transmit and receive prescriptions by electronic data transmission. Dr. Swart noted that the sponsor of this bill is a technology firm, Reed Elsevier, Inc.

Dr. Swart stated that he was concerned about smaller pharmacies, as well as those located in rural areas, being able to comply with the ability to e-prescribe.

Ms. Herold provided information that the Governor's Healthcare Initiative has the same deadline of January 1, 2012, which will affect every prescriber and every pharmacy and thus will have wide impact.

There was discussion on the language of the legislation and the potential for enforcement discretion by the board and staff, as there is no specific consequence for the inability to e-prescribe.

Dr. Gray (Kaiser Permanente) noted that this is only a preliminary version of the bill and pointed out that it may evolve. He stated that federal law is already in place which establishes the standards and parameters for e-prescribing and transmission through the National Council for Prescription Drug Programs (NCPDP). He added that those may become the standards required in order for an entity to claim that they have the ability to e-prescribe. He also mentioned the incentives and penalties for e-prescribers if they are involved (or not) in federal billing. Dr. Gray added that this law will pertain to all prescribers. He raised the question of who would be the actual enforcement entity. Dr. Gray stated that there may be a requirement for the board to adopt regulations to further define what will be in effect by 2012. Dr. Gray recommended that future action in regards to this bill be discussed at the next Legislation and Regulation Committee meeting.

**MOTION:** To grant continuing education credit to licensees who participate in the events being held by the California Health Care Foundation throughout California.

M/S: RS/JB

APPROVE: 3      OPPOSE: 0

3. California's Controlled Substance Utilization Review and Evaluation System (CURES), a presentation and question and answer session led by the Department of Justice, Bureau of Narcotics Enforcement

Dr. Swart explained that, in mid-December, the board and California pharmacies were advised that effective January 1, 2009, the California Department of Justice would have a new data collection vendor for CURES, and that all California pharmacies were to submit data to this new vendor beginning January 1, 2009. He pointed out that this was a short transition, and the board has learned that some pharmacies are having transmission issues.

Kathy Ellis (Department of Justice – Bureau of Narcotic Enforcement “CURES” division) provided an overview and explanation of the CURES program, including the use of a vendor who collects the data submitted by pharmacies to create a database used by practitioners. Ms. Ellis discussed the recent change to a new data collection vendor after having the same vendor for the past 10 years. She explained that the State of California required them to go out for bids for a new vendor and that the turnaround time for switching vendors was very short. Ms. Ellis concurred with industry feedback that the transition has not been seamless as expected.

Ms. Ellis provided history on the development of the CURES and the program's database. She noted that, as a lesson learned in the recent transition, a turnaround in contracts is necessary in the future.

a. Implementation Issues Surrounding the New Data Collection Vendor for CURES

Ms. Ellis explained that, after implementation, many errors were noticed in the vendor's program. Specifically, the main issue was that the Department of Justice (DOJ) was receiving data in invalid formats. Additionally, there were errors involving patients' date of birth and gender. Ms. Ellis pointed out that the validation criteria have since been corrected to ensure erroneous input of those statistics will not be accepted.

Ms. Ellis indicated that the vendor has been tracking the complaint calls coming in because of the errors, and provided a log to the DOJ. Additionally, she noted that the vendor is receiving a large amount of faxes for data submissions; some which are numerous pages in length. She referenced pharmacy law regulations which state that if a pharmacist is providing more than twenty-five prescriptions within a six month period, they are to be sent electronically.

Ms. Ellis emphasized that they are working with the vendor to correct the issues. She stated that the DOJ is now receiving more data than they are rejecting, which is significant improvement. She also indicated that a letter will be sent to pharmacists in the near future to detail the implementation issues she has reviewed. Ms. Ellis indicated that the letter will stipulate a grace period to allow software vendors to make modification for the new vendor's format.

b. Moving to Provide Online, Near Real Time Reports to Practitioners on Controlled Substances Dispensed to Patients by July 1, 2009

Ms. Ellis stated that their automation project, which will automate the Patient Activity Report (PAR), will be rolling out in July, 2009. She explained that this will result in allowing authorized practitioners, prescribers and pharmacists to have access to patient activity information via web browser 24 hours a day in "real time." She noted that the project, which began in 2003, is currently in the test phase.

Ms. Ellis indicated that a notification system will also be rolled out. The alert system will be state wide and will allow for notifications to prescribers, physicians and pharmacists, on a voluntary basis, when there are potential doctor shoppers, theft, forgeries, inappropriate call-ins, etc. in their area

Ms. Ellis reviewed other projects in progress, but explained that the timeline for completion and rollout is unknown as they are dependent on funding and grant money. One such project is the "Direct Dispense", which will impact practitioners and veterinarians and allow them to enter their data online via web browser rather than sending it manually. Ms. Ellis added that another project in progress involves automation for an on line system for "0 fill" reporting when a pharmacist has no data to report. Ms. Ellis also indicated that integration is being developed to allow providers within hospitals to review patients' records during an office visit and have instant information on any controlled substances that have been prescribed and dispensed to that patient. She also noted a nationwide prescription drug program that is being developed which will result in a hub for prescribers to be able to share information between states.

Ms. Ellis concluded that by sharing that the automation of the PAR is in final testing stages at this time. Following testing, the DOJ will attempt to pilot the program by finding pharmacists and practitioners who would be willing to run test data prior to the actual rollout. She provided contact information for those who may be willing to assist with the pilot testing of the program.

**Questions from the Board:**

Dr. Swart asked if the formatting issues currently being seen with the CURES database are primarily preventable when the pharmacists are on the correct format.

Ms. Ellis confirmed, but that the vendor is also responsible for some of the formatting issues as well. She gave examples of relevant formatting issues that have since been addressed with the vendor.

Dr. Swart commented that he is hearing fewer complaints about the system. He clarified that most of the current errors are relating to the format being input by the users.

Ms. Ellis confirmed and noted that some pharmacists are providing data in the format as required by the 2005 ASAP format of the prior program. She added that the validation process has been "relaxed" as she has discussed the requirements in length with the vendor.

Mr. Weisser asked if there has been disruption in patients getting their medications

Ms. Ellis responded that there has not.

Ms. Herold referenced the reports provided by Ms. Ellis which list the formatting issues and database errors that were identified. She asked specifically about the errors relating to an invalid pharmacy identifier and asked whether those incidents would lead to lost data.

Ms. Ellis responded that they were losing the data initially, but that it was corrected within a couple of weeks.

Ms. Herold asked if the formatting issue has been corrected. She voiced concern over whether that data is making it into the database if that entry error can still be allowed to occur.

Ms. Ellis explained how an error message would be sent to the user as a result of the invalid entry. Those error messages resulted in a very high volume of calls to the DOJ. Ms. Ellis stated that the new letter being drafted to pharmacists will explain that adjustments have been made in the program which will remove the errors messages and that the data has, in fact, been collected and accepted into the database.

Ms. Herold asked if there is anything the board needs to share with pharmacies that would help reduce the amount of errors. She stated that the letter being drafted by the DOJ can be sent out via a subscriber alert. Ms. Herold asked if pharmacists can assume that the data being submitted is collected and accurate at this point.

Ms. Ellis confirmed that they can. She added that the earlier data that was rejected was saved and the vendor has been instructed to "rerun" that data in order to add it to the database.

Ms. Herold asked how the board can assist with informing pharmacists of the appropriate format that the data must be submitted, how they should clarify if there is a valid error occurring and who to contact for assistance with those errors.

Ms. Ellis responded that the DOJ will share the validation criteria with the pharmacists. She added that warnings will be given for user input error until July 1, 2009. Beyond

that, user errors on required data fields will be rejected, with a correction required and resubmitted within 14 days.

Ms. Herold stated that the report can be placed on the board website.

There was discussion as to whether pharmacists would have the required software as there is an issue with regard to proprietary software.

Ms. Herold asked Ms. Ellis if the letter is going through review at this point.

Ms. Ellis confirmed.

Ms. Herold stated that she wants to support the CURES program and assist in ensuring that pharmacists are clear on the data format requirements, as the program is such a valuable tool. She indicated that they will not take any action at this point while the DOJ moves forward with distribution of their letter. She reiterated that DOJ should contact the board if there is anything they can do to help.

Mr. Weisser asked about the likelihood of switching to a new vendor in the future.

Ms. Ellis responded that it is always a possibility. She explained that the new vendor was chosen because they were below the cost of the current vendor in the bid process. She stated that prescription monitoring programs are growing nationwide and want to be a part of the bidding. Ms. Ellis emphasized that CURES is taking the necessary efforts to avoid the aggravation that occurred with the recent transition of the new vendor.

Anne Sodergren asked how current the data will be when a user accesses the data once the "real time" automation project is in place.

Ms. Ellis responded that the new vendor uploads the submitted data several times a week.

Ms. Sodergren asked where the information comes from that will be provided in the notification alert system.

Ms. Ellis responded that it comes directly from the source. An example of one such source is from physicians calling and providing the information.

Ms. Herold asked if there is any lag in inputting the information being reported by prescribers as required by them.

Ms. Ellis confirmed that there is lag.

Ms. Herold asked if there is a "clear picture" of those people who are "doctor shopping."

Ms. Ellis responded that there is not. She stated, however, that staff workload should be reduced as a result of additional automation, which will allow for the opportunity to catch up on the input of information provided by pharmacists.

Ms. Herold asked if the Medical Board is involved in identifying prescribers who don't submit to CURES.

Ms. Ellis responding that she is unsure.

### **Public Comments:**

Janice Dang, Supervising Inspector, asked if the notification system can include physicians whose registration license has been revoked.

Ms. Ellis responded that she would need to discuss the addition with the IT department. She noted that they do obtain information from the DEA weekly which provides data on registrants whose licenses have been revoked, expired, etc. She agreed that the information would be valuable, but indicated that the DEA data is nationwide and, thus, may not be useable due to its large volume.

Ms. Dang referenced the CURES reports and explained that, with regard to compounding of controlled drugs, the active ingredient is not included or displays as "unknown" She asked if there is a way to reject those entries with an error message to the user.

Ms. Ellis responded that this is a requirement within the data entry to identify what the main ingredient of the controlled substance is. She reiterated that this is a requirement, but they are not getting the data accurately. CURES is trying to correct this issue.

Dr. Gray commented that Kaiser has experience with the DEA list which provides the information on expired, suspended and revoked licenses. He pointed out that there are several subcategories related to the reasons for a revoked license. Dr. Gray also stated that an expired DEA registration does not mean that the registrant is no longer authorized, as it may be due to delays in renewal processing. He noted other variances in expired registration. He stated that caution should be applied if CURES overreacts on such matters as it may affect patients.

Ms. Ellis responded that this was another validation issue. She also stated that, in the case of a DEA expired license, the vendor was originally rejecting the entry. CURES instructed them to stop rejecting those types of entries and to collect the data.

Dr. Gray noted the lag time within the DEA database which need to be taken into consideration as well.

## 5. Update Regarding Arrests and Criminal Convictions of Board Applicants and Licensees

Dr. Swart explained that the public and board licensees expect the board to act to remove from practice or deny licensure to those with substantially related convictions.

Dr. Swart stated that, as part of the board's regulatory process, the board requires fingerprint background checks on all applicants. In addition, the board recently implemented a change to the renewal forms for all individual licensees requiring self-certification of criminal convictions or discipline imposed by other regulatory agencies as part of the renewal process.

Dr. Swart pointed out that, in recent years the board has become inundated with fingerprint results. Whereas in 2000/01 the board received 608 arrest and conviction notifications, in 2007/08 the board received over 3,000. Additionally, Dr. Swart pointed out that about 30% of individual renewal applicants fail to complete the self-certification on the renewal form.

Dr. Swart indicated that, when it became clear that the board could not address this increased workload with existing resources, the board submitted a request to increase board staff through the Budget Change Proposal process. Board staff was recently advised that their request to establish a Criminal Conviction Unit was approved and included in the Governor's budget. Dr. Swart stated that the unit will consist of 6.5 positions and will be responsible for completing investigations on applicants and licensees who are either arrested and/or convicted of a crime and to determine if the arrest or conviction is substantially related to the duties and functions of the license obtained and therefore warrants action by the board.

Dr. Swart advised that board staff has begun recruitment to fill some of the Criminal Conviction Unit positions; however will not be able to fully staff this unit until July 2009, when the board's budget will be augmented to fully fund the unit.

Dr. Swart added that, more recently, SB 389 (Negrete McLeod) was introduced. He explained that this legislative proposal requires all specified agencies, including the board, to require state and federal level criminal background checks for all applicants as well require all licensees who have not previously undergone state and federal criminal background checks, to complete that as a condition of renewal.

Dr. Swart shared that this is going on throughout the Department of Consumer Affairs. He explained that there are approximately 150 pharmacist licensees who were licensed prior to the fingerprinting requirement established in September, 1949. He stressed that the Board of Pharmacy has moved further along than other boards in completing criminal background checks on licensees who were not previously conducted.

## 6. Department of Consumer Affairs' Policies Regarding Pursuit of Interim Suspension Orders Discussion

Dr. Swart explained that on December 15, 2008, the Deputy Director of Legal Affairs for the department, Doreathea Johnson, issued a memo reiterating the department's policy to encourage the practice of licensing agencies to use Interim Suspension Orders (ISO) and PC 23s when the conduct of a licensee is such that the board cannot afford to wait for the completion of the administrative process, before taking action to ensure the safety of the public. He added that the memo directs all DCA licensing agencies to institute procedures for ordering interim suspension orders as warranted as well as to make recommendations regarding specific conditions when the agency shall pursue a suspension via a PC 23. The memo further provides suggested parameters.

Dr. Swart stated that the board uses all legal actions authorized, including both ISOs and PC 23s when a case is egregious and immediate public harm is eminent. With the implementation of the Criminal Conviction Unit we anticipate an increase in the number of such actions as the board will have sufficient resources to more promptly address violations that warrant immediate suspension.

Dr. Swart advised that the board had received five PC 23 suspensions over the last fiscal year as appropriate, and that they are using them as encouraged.

Mr. Room stated that the low number of ISO's should not reflect poorly on the board. He added that, in his opinion, ISO's are typically used only in very specific and constraining circumstances. He noted that it is often more cost effective to go straight to the accusation and have a speedy hearing.

## 7. Public Comment for Items Not on the Agenda

The meeting was adjourned at 2:34 p.m.



## Standards Development and Adoption Update

California Board of Pharmacy  
March 11, 2009



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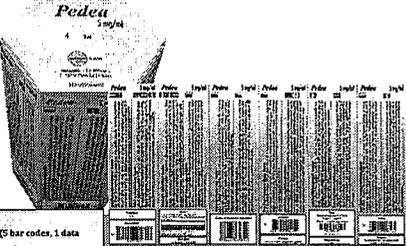
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- 12 different language texts (English, French and German are used in more than one country)

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**GS1 US Contents**

- The Fundamentals
- Significant Events
- Quality
- Pedigree future (DPMS, EPCIS, Discovery)
- Business Benefits and New Processes

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**GS1 Building Patient Safety**

The diagram shows a temple with a pediment labeled 'Patient Safety'. The columns are labeled: 'Healthcare Supply Chain Efficiency', 'Standardized Product Definition (GDSN)', 'Standardized Location Identification (GLN)', and 'Standardized Product Identification (GTIN)'. The base is labeled 'Standardization' and 'Interoperability'.

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**GS1 Building Patient Safety**

**The Fundamentals**

**Track & Trace Built on a Strong Foundation of the Fundamentals**

This diagram is similar to the previous one but includes callouts. A callout from 'The Fundamentals' points to the base (GDSN, GLN, GTIN). A callout from 'Track & Trace Built on a Strong Foundation of the Fundamentals' points to the 'Healthcare Supply Chain Efficiency' column.

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**GS1 STANDARDS IN ACTION**

The diagram features a central cartoon character with question marks above its head. Surrounding the character are the terms: 'GTIN', 'EPCIS', 'GLN', 'GDSN', 'DISCOVERY SERVICES', and 'GLN REGISTRY FOR HEALTHCARE'.

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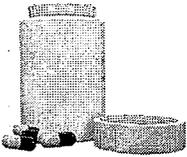
**GS1 STANDARDS IN ACTION**

**Definitions**

- GTIN® (Global Trade Item Number®)
- GDSN® (Global Data Synchronization Network®)
- GLN (Global Location Number)
- EPCIS (EPC Information Services)

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**GS1 STANDARDS IN ACTION**



© 2008 GS1 US Meriana ppt 14

**GS1 STANDARDS IN ACTION**



**NDC → GTIN:**  
(01) 003141419999 95

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**GS1 STANDARDS IN ACTION**



**NDC → GTIN:**  
(01) 003141419999 95  
SERIAL NUMBER: 16S APX3E

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**GS1 STANDARDS IN ACTION**



**GDSN:** STATIC DATA

- MANUFACTURER
- GTIN: (01) 00314141999995
- BRAND
- STRENGTH: 25mg
- 1000 PILLS
- ETC

**GDSN:**  
Global  
Data  
Synchronization  
Network

**NDC → GTIN:**  
(01) 003141419999 95  
SERIAL NUMBER: 165 APX3E

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**GS1 STANDARDS IN ACTION**



**GDSN:** STATIC DATA

- MANUFACTURER
- GTIN: (01) 00314141999995
- BRAND
- STRENGTH: 25mg
- 1000 PILLS
- ETC

**GLN:**  
Global  
Location Number

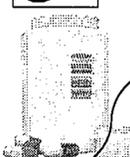
**NDC → GTIN:**  
(01) 003141419999 95  
SERIAL NUMBER: 165 APX3E

**DYNAMIC DATA**

SHIP DATE	2/1/09	2/15/09	3/1/09
SHIP FROM	MANUFACTURER GLN - A	WHOLESALER GLN - B	RETAIL CHAIN WAREHOUSE GLN - C
SHIP TO	WHOLESALER GLN - B	RETAIL CHAIN WAREHOUSE GLN - C	RETAIL STORE GLN - D
RECEIVED DATE	2/8/09	2/20/09	3/10/09

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**GS1 STANDARDS IN ACTION**



**GDSN:** STATIC DATA

- MANUFACTURER
- GTIN: (01) 00314141999995
- BRAND
- STRENGTH: 25mg
- 1000 PILLS
- ETC

**GTIN:**  
(01) 003141419999 95  
SERIAL NUMBER: 165 APX3E

**GLN Registry for Healthcare®**

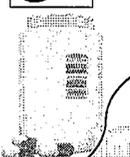
- GLN - B (110000457020 8)
- WHOLESALER NA ME
- ADDRESS
- PHONE NUMBER

**DYNAMIC DATA**

SHIP DATE	2/1/09	2/15/09	3/1/09
SHIP FROM	MANUFACTURER GLN - A	WHOLESALER GLN - B	RETAIL CHAIN WAREHOUSE GLN - C
SHIP TO	WHOLESALER GLN - B	RETAIL CHAIN WAREHOUSE GLN - C	RETAIL STORE GLN - D
RECEIVED DATE	2/8/09	2/20/09	3/10/09

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**GS1 STANDARDS IN ACTION**



**GDSN:** STATIC DATA

- MANUFACTURER
- GTIN: (01) 00314141999995
- BRAND
- STRENGTH: 25mg
- 1000 PILLS
- ETC

**Manufacturer's Database**

- GTIN - (01) 00314141999995
- SERIAL NUMBER: 165 APX3E
- PRODUCTION DATE
- EXPIRY DATE
- LOT NUMBER
- RAW MATERIAL DATA

**NDC → GTIN:**  
(01) 003141419999 95  
SERIAL NUMBER: 165 APX3E

**GLN Registry for Healthcare®**

- GLN - B (110000457020 8)
- WHOLESALER NA ME
- ADDRESS
- PHONE NUMBER

**DYNAMIC DATA**

SHIP DATE	2/1/09	2/15/09	3/1/09
SHIP FROM	MANUFACTURER GLN - A	WHOLESALER GLN - B	RETAIL CHAIN WAREHOUSE GLN - C
SHIP TO	WHOLESALER GLN - B	RETAIL CHAIN WAREHOUSE GLN - C	RETAIL STORE GLN - D
RECEIVED DATE	2/8/09	2/20/09	3/10/09

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**GS1 STANDARDS IN ACTION** DYNAMIC DATA

**GDSN:** STATIC DATA

- MANUFACTURER
- GTIN: (01) 00314141999995
- BRAND
- STRENGTH: 25mg
- 1000 PILLS
- ETC

**Manufacturer's Database**

- GTIN - (01) 00314141999995
- SERIAL NUMBER: 165APX3E
- PRODUCTION DATE
- EXPIRY DATE
- LOT NUMBER
- RAW MATERIAL DATA

**NDC → GTIN:**

(01) 00314141999995  
SERIAL NUMBER: 165APX3E

**GLN Registry for Healthcare®**

- GLN - B (110000457020 8)
- WHOLESALER NA ME
- ADDRESS
- PHONE NUMBER STATIC DATA

DYNAMIC DATA			
SHIP DATE	2/1/09	2/15/09	3/1/09
SHIP FROM	MANUFACTURER GLN - A	WHOLESALER GLN - B	RETAIL CHAIN WAREHOUSE GLN - C
SHIP TO	WHOLESALER GLN - B	RETAIL CHAIN WAREHOUSE GLN - C	RETAIL STORE GLN - D
RECEIVED DATE	2/8/09	2/20/09	3/10/09

**TRACEABILITY** DYNAMIC DATA

- EPCIS
- DISCOVERY SERVICES

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**GS1 STANDARDS IN ACTION** DYNAMIC DATA

**GDSN:** STATIC DATA

- MANUFACTURER
- GTIN: (01) 00314141999995
- BRAND
- STRENGTH: 25mg
- 1000 PILLS
- ETC

**Manufacturer's Database**

- GTIN - (01) 00314141999995
- SERIAL NUMBER: 165APX3E
- PRODUCTION DATE
- EXPIRY DATE
- LOT NUMBER
- RAW MATERIAL DATA

**NDC → GTIN:**

(01) 00314141999995  
SERIAL NUMBER: 165APX3E

**GLN Registry for Healthcare®**

- GLN - B (110000457020 8)
- WHOLESALER NA ME
- ADDRESS
- PHONE NUMBER STATIC DATA

DYNAMIC DATA			
SHIP DATE	2/1/09	2/15/09	3/1/09
SHIP FROM	MANUFACTURER GLN - A	WHOLESALER GLN - B	RETAIL CHAIN WAREHOUSE GLN - C
SHIP TO	WHOLESALER GLN - B	RETAIL CHAIN WAREHOUSE GLN - C	RETAIL STORE GLN - D
RECEIVED DATE	2/8/09	2/20/09	3/10/09

**TRACEABILITY** DYNAMIC DATA

- EPCIS
- DISCOVERY SERVICES

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**GS1 STANDARDS IN ACTION** DYNAMIC DATA

**GDSN:** STATIC DATA

- MANUFACTURER
- GTIN: (01) 00314141999995
- BRAND
- STRENGTH: 25mg
- 1000 PILLS
- ETC

**Manufacturer's Database**

- GTIN - (01) 00314141999995
- SERIAL NUMBER: 165APX3E
- PRODUCTION DATE
- EXPIRY DATE
- LOT NUMBER
- RAW MATERIAL DATA

**NDC → GTIN:**

(01) 00314141999995  
SERIAL NUMBER: 165APX3E

**GLN Registry for Healthcare®**

- GLN - B (110000457020 8)
- WHOLESALER NA ME
- ADDRESS
- PHONE NUMBER STATIC DATA

DYNAMIC DATA			
SHIP DATE	2/1/09	2/15/09	3/1/09
SHIP FROM	MANUFACTURER GLN - A	WHOLESALER GLN - B	RETAIL CHAIN WAREHOUSE GLN - C
SHIP TO	WHOLESALER GLN - B	RETAIL CHAIN WAREHOUSE GLN - C	RETAIL STORE GLN - D
RECEIVED DATE	2/8/09	2/20/09	3/10/09

**TRACEABILITY** DYNAMIC DATA

- EPCIS
- DISCOVERY SERVICES

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**GS1 STANDARDS IN ACTION** DYNAMIC DATA

**GDSN:** STATIC DATA

- MANUFACTURER
- GTIN: (01) 00314141999995
- BRAND
- STRENGTH: 25mg
- 1000 PILLS
- ETC

**Manufacturer's Database**

- GTIN - (01) 00314141999995
- SERIAL NUMBER: 165APX3E
- PRODUCTION DATE
- EXPIRY DATE
- LOT NUMBER
- RAW MATERIAL DATA

**NDC → GTIN:**

(01) 00314141999995  
SERIAL NUMBER: 165APX3E

**GLN Registry for Healthcare®**

- GLN - B (110000457020 8)
- WHOLESALER NA ME
- ADDRESS
- PHONE NUMBER STATIC DATA

DYNAMIC DATA			
SHIP DATE	2/1/09	2/15/09	3/1/09
SHIP FROM	MANUFACTURER GLN - A	WHOLESALER GLN - B	RETAIL CHAIN WAREHOUSE GLN - C
SHIP TO	WHOLESALER GLN - B	RETAIL CHAIN WAREHOUSE GLN - C	RETAIL STORE GLN - D
RECEIVED DATE	2/8/09	2/20/09	3/10/09

**TRACEABILITY** DYNAMIC DATA

- EPCIS
- DISCOVERY SERVICES

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2012 GTIN Sunrise "Adoption of GTIN by U.S. Healthcare by 2012" Voluntary US Healthcare Implementation Path					
PHASES	Phase One Awareness	Phase Two Notify Trading Partners	Phase Three Contract & Systems Testing event	Phase Four Transactions	Phase Five 2012 Implementation
Provider/ GRD	Know GS1 System Standards. Review internally what must be changed to accept.	Notify trading partners of need for GTIN, and possibly additional Application Identifiers (e.g. lot number, expiry date, serial number). Request ability to provide this information.	Terms and conditions of contracts specify applicable GS1 Standards, specifically GTINs. The Information Technology staff begins to align internal systems to GS1 specifications. Initial testing begins.	Testing continues to use GTINs and other GS1 Standards in a majority of, if not all, transactions.	All products ordered and received are marked in accordance with GS1 Standards.
Distributor	Know GS1 System Standards. Review incoming material and the ability of internal systems to accept.	Notify trading partners of ability to accept GS1 Standards; specifically GTIN and possibly additional Application Identifiers (e.g. lot number, expiry date, serial number). Notify trading partners of requirement for GS1 Standards from customers.	Terms and conditions of contracts specify applicable GS1 Standards on products, specifically GTIN and possibly lot number, expiry date and serial number. The Information Technology staff begins to align internal systems to GS1 specifications. Initial testing begins.	Testing continues to use GTINs and other GS1 Standards in a majority of, if not all, transactions.	All products ordered, received and shipped are marked in accordance with GS1 Standards.

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2012 GTIN Sunrise "Adoption of GTIN by U.S. Healthcare by 2012" Voluntary US Healthcare Implementation Path					
PHASES	Phase One Awareness	Phase Two Notify Trading Partners	Phase Three Contract & Systems Testing event	Phase Four Transactions	Phase Five 2012 Implementation
Supplier	Know of impending requirement. Determine the ability to meet or exceed requirement.	Notify trading partners of ability to accept GS1 Standards; specifically GTIN and possibly additional Application Identifiers (e.g. lot number, expiry date, serial number). Notify trading partners of requirement for GS1 Standards from customers.	Terms and conditions of contracts call for GS1 Standards on all products: GTIN and possibly lot number, expiry date and serial number. The Information Technology staff begins to align internal systems with this requirement. Initial testing begins.	Testing continues to use GTINs and other GS1 Standards in a majority of, if not all, transactions.	All products ordered and received are marked in accordance with GS1 Standards.
Business Provider	Know of impending requirement. Determine the ability to meet or exceed requirement.	Notify trading partners of ability to accept GS1 Standards; specifically GTIN and possibly additional Application Identifiers (e.g. lot number, expiry date, serial number). Notify trading partners of requirement for GS1 Standards from customers.	GS1 Standards are included in all products, specifically GTIN and possibly lot number, expiry date and serial number. The Information Technology staff begins to align internal systems with this requirement. Initial testing begins.	Testing continues to use GTINs and other GS1 Standards in a majority of software.	All products have specific segments identified for GS1 Standards, following allocation rules in the specifications.

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## Contents

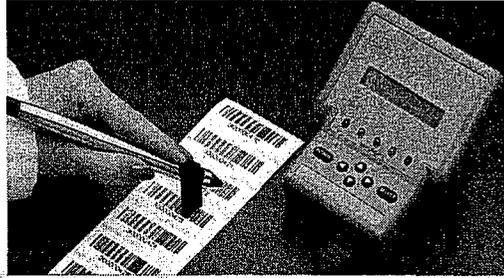
- The Fundamentals
- Significant Events
- **Quality**
- Pedigree future (DPMS, EPCIS, Discovery)
- Business Benefits and New Processes

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## Bar Code Quality

Where do all those measurements come from? ... Verification!



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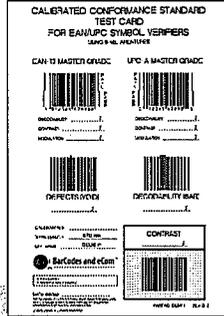
## Bar Code Quality Test Card for ISO/ANSI Based Verifiers

• Calibrated Conformance Standard is used to "verify the verifier"

• Traceable to National Institute of Standards and Technology (NIST)

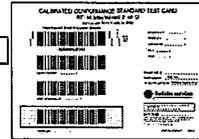
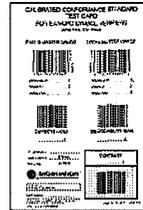
• Important training tool for personnel in the correct use of verifiers

• Stops all arguments



## Bar Code Quality Verifying the Verifier:

### Calibrated Conformance Standard Test Cards

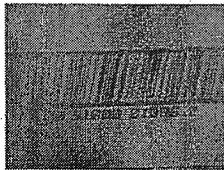


These cards stop all arguments and put you and your customer on the same page!



## Bar Code Quality What this does for you is:

- Prevents you from sending "bad" bar codes into the supply chain!
- Ensures readability of your bar codes throughout the supply chain.
- Lets you know what's happening before it's too late!



## Contents

- The Fundamentals
- Significant Events
- Quality
- Pedigree future (DPMS, EPCIS, Discovery)
- Business Benefits and New Processes

**GS1 STANDARDS IN ACTION** DYNAMIC DATA

**GDSN:** STATIC DATA

- MANUFACTURER
- GTIN: (01) 00314141999995
- BRAND
- STRENGTH: 25mg
- 1000 PILLS
- ETC

**Manufacturer's Database**

- GTIN - (01) 00314141999995
- SERIAL NUMBER: 165 APX3E
- PRODUCTION DATE
- EXPIRY DATE
- LOT NUMBER
- RAW MATERIAL DATA

**NDC → GTIN:**  
(01) 00314141999995  
SERIAL NUMBER: 165APX3E

**GLN Registry for Healthcare®**

- GLN - B (110000457020 8)
- WHOLESALER NA ME
- ADDRESS:
- PHONE NUMBER STATIC DATA
- ETC

SHIP DATE		2/1/09	2/15/09	3/1/09
SHIP FROM	MANUFACTURER GLN - A	WHOLESALER GLN - B	RETAIL CHAIN WAREHOUSE GLN - C	
SHIP TO	WHOLESALER GLN - B	RETAIL CHAIN WAREHOUSE GLN - C	RETAIL STORE GLN - D	
RECEIVED DATE	2/8/09	2/20/09	3/10/09	

**TRACEABILITY** DYNAMIC DATA

- EPCIS
- DISCOVERY SERVICES

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**GS1 STANDARDS IN ACTION** DYNAMIC DATA

**GDSN:** STATIC DATA

- MANUFACTURER
- GTIN: (01) 00314141999995
- BRAND
- STRENGTH: 25mg
- 1000 PILLS
- ETC

**Manufacturer's Database**

- GTIN - (01) 00314141999995
- SERIAL NUMBER: 165 APX3E
- PRODUCTION DATE
- EXPIRY DATE
- LOT NUMBER
- RAW MATERIAL DATA

**NDC → GTIN:**  
(01) 00314141999995  
SERIAL NUMBER: 165APX3E

**GLN Registry for Healthcare®**

- GLN - B (110000457020 8)
- WHOLESALER NA ME
- ADDRESS:
- PHONE NUMBER STATIC DATA
- ETC

SHIP DATE		2/1/09	2/15/09	3/1/09
SHIP FROM	MANUFACTURER GLN - A	WHOLESALER GLN - B	RETAIL CHAIN WAREHOUSE GLN - C	
SHIP TO	WHOLESALER GLN - B	RETAIL CHAIN WAREHOUSE GLN - C	RETAIL STORE GLN - D	
RECEIVED DATE	2/8/09	2/20/09	3/10/09	

**TRACEABILITY** DYNAMIC DATA

- EPCIS
- DISCOVERY SERVICES

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**GS1 STANDARDS IN ACTION** DYNAMIC DATA

**GDSN:** STATIC DATA

- MANUFACTURER
- GTIN: (01) 00314141999995
- BRAND
- STRENGTH: 25mg
- 1000 PILLS
- ETC

**Manufacturer's Database**

- GTIN - (01) 00314141999995
- SERIAL NUMBER: 165 APX3E
- PRODUCTION DATE
- EXPIRY DATE
- LOT NUMBER
- RAW MATERIAL DATA

**NDC → GTIN:**  
(01) 00314141999995  
SERIAL NUMBER: 165APX3E

**GLN Registry for Healthcare®**

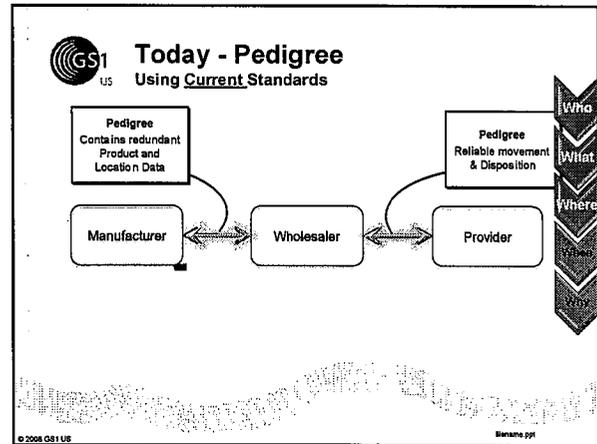
- GLN - B (110000457020 8)
- WHOLESALER NA ME
- ADDRESS:
- PHONE NUMBER STATIC DATA
- ETC

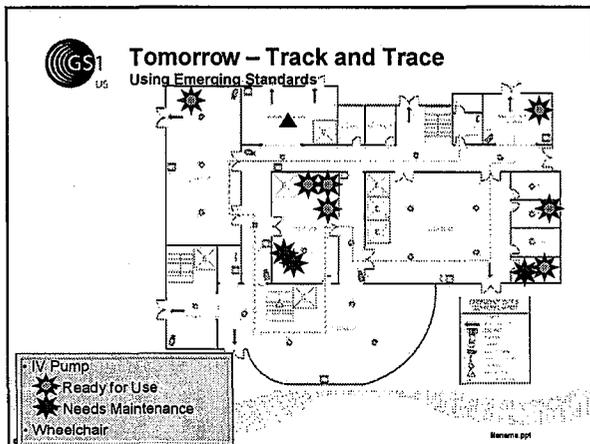
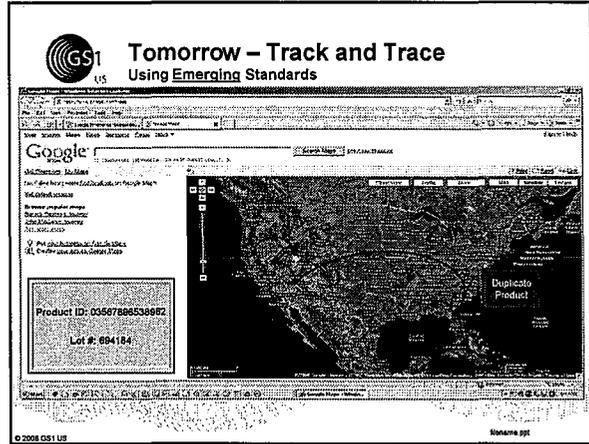
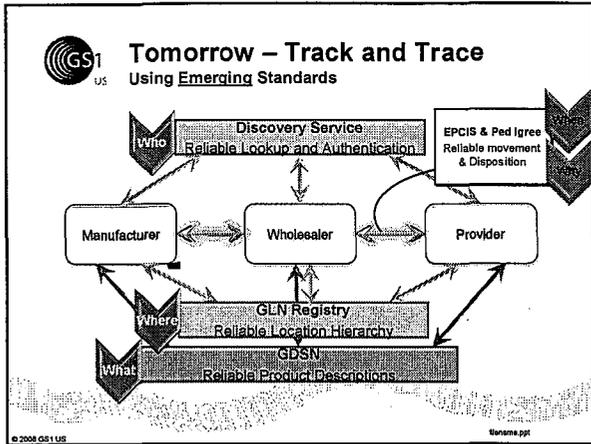
SHIP DATE		2/1/09	2/15/09	3/1/09
SHIP FROM	MANUFACTURER GLN - A	WHOLESALER GLN - B	RETAIL CHAIN WAREHOUSE GLN - C	
SHIP TO	WHOLESALER GLN - B	RETAIL CHAIN WAREHOUSE GLN - C	RETAIL STORE GLN - D	
RECEIVED DATE	2/8/09	2/20/09	3/10/09	

**TRACEABILITY** DYNAMIC DATA

- EPCIS
- DISCOVERY SERVICES

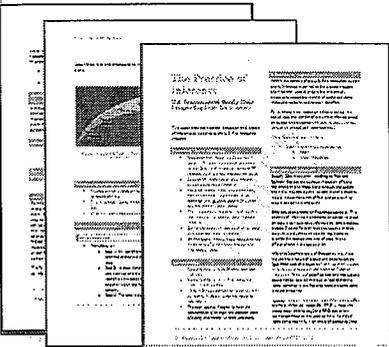
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  - **Business Benefits and New Processes**
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 **Inference Paper**



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 **Traceability Adoption**  
Support Use of RFID within the supply chain

**Security and Privacy Task Force**

# Work in Process

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 **Traceability Adoption**  
**Benefits beyond Regulatory Compliance**

Business benefits of serialization and granular events data

# Work in Process

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## Questions?

**Bob Celeste**  
 Director, Healthcare  
 GS1 Healthcare US  
[rceleste@gs1us.org](mailto:rceleste@gs1us.org)



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# Attachment 7

*Enforcement Statistics 2008-09*

# California State Board of Pharmacy Citation and Fine Statistics July 1, 2008 – March 31, 2009

**725 Citations were issued this fiscal year**

Total dollar amount of fines issued this fiscal year  
\$ 1,227,825.00

Total dollar amount of fines collected  
\$897,787.50\*

\*This amount also reflects payment of the citations issued before July 1, 2008.

The average number of days from date case is opened until a citation is issued is 175

Average number of days from date case is routed to Citation Unit to date citation is issued 16.59

437 citations are closed. The average number of days from date citation is issued to date citation is closed is 88.8

### Citation Breakdown by license type

Total issued	RPH with fine	RPH no fine	PHY with fine	PHY no fine	PIC with fine	PIC no fine	TCH with fine	TCH no fine
725	107	6	134	69	209	15	27	0

### Citation Breakdown by Miscellaneous license type

Wholesalers	Exemptee's	Clinics	Drug room	Exempt Hosp.	Hosp. pharmacy	Misc.	Unlicensed Premises	Unlicensed person
15	11	2	7	16	76	9	14	5

\*Intern Pharmacist, Licensed Correctional Facilities, Exempt Pharmacies, Non-Resident Pharmacies, and Vet Retailers

## Top Ten Violations by license type

Pharmacists	%	Pharmacies	%	Pharmacists in charge	%
1716 - Variation from prescription	33%	1716 - Variation from prescription	29%	4301(j)/111295/351- Adulterated Heparin Held at Pharmacy	41%
1732.5(b)- Renewal requirements for pharmacist - Retain certificates of completion for four years	12%	1714(b)- Operational standards and security; pharmacy responsible for pharmacy security	12%	1716 - Variation from prescription	12%
1732.5(a)- Renewal requirements for pharmacist - 30 hours of continuing education	4%	4115(e)-Pharmacy technician license required	7%	4169(a)(2) - Prohibited Acts; Purchase, trade, sell, or transfer dangerous drugs to that the person knew or reasonably should have known were adulterated...	9%
1732.5 - Renewal requirements for pharmacist	7%	4104-Procedures to take action when licensed individual is impaired or known to have diverted or used drugs; Written policies; Report; Immunity	5%	1714(d)- Operational standards and security; pharmacist responsible for pharmacy security	8%
1716/1761(a) – Variation from prescription/No pharmacist shall compound or dispense any prescription, which contains any significant error or omission...	7%	1716/1761(a) – Variation from prescription/No pharmacist shall compound or dispense any prescription, which contains any significant error or omission...	4%	4104-Procedures to take action when licensed individual is impaired or known to have diverted or used drugs; Written policies; Report; Immunity	5%
4301(j)/111295/351- Adulterated Heparin Held at Pharmacy	7%	4301(j)/111295/351- Adulterated Heparin Held at Pharmacy	4%	1715-Self-assessment of a pharmacy by the pharmacist in charge	4%
1761(a)/11170-No pharmacist shall compound or dispense any prescription, which contains any significant error or omission... /Prohibition on prescribing, etc. controlled substance for self	4%	1707.2(b)(1)(A)- In addition to the obligation to consult...a pharmacist shall provide oral consultation to his or her patients...whenever the prescription drug has not previously been dispensed to a patient...	3%	4169(a)(1) - Prohibited Acts; Purchase, trade, sell, or transfer dangerous drugs to unlicensed person or entity	3%
4342-Actions by board to prevent sale of preparations or drugs lacking quality or strength; penalties for knowing or willful violation of regulations governing those sales	4%	1711-Quality assurance program	3%	1304.11-Inventory requirements	3%
1707.2(b)(1)(A)- In addition to the obligation to consult...a pharmacist shall provide oral consultation to his or her patients...whenever the prescription drug has not previously been dispensed to a patient...	4%	1761(a)- No pharmacist shall compound or dispense any prescription, which contains any significant error or omission...	3%	1716/1761(a) – Variation from prescription/No pharmacist shall compound or dispense any prescription, which contains any significant error or omission...	2%
4051(a)- Conduct limited to a pharmacist; conduct authorized by pharmacist	3%	1716/1761(a) – Variation from prescription/No pharmacist shall compound or dispense any prescription, which contains any significant error or omission...	3%	4342-Actions by board to prevent sale of preparations or drugs lacking quality or strength; penalties for knowing or willful violation of regulations governing those sales	2%

# Contested Citations Office Conference

(These statistics also include contested Letters of Admonishment)

There have been twenty office conferences held so far this fiscal year

Number of requests	359
--------------------	-----

Number scheduled	359
------------------	-----

Number appeared	265
-----------------	-----

Number Postponed	83**
------------------	------

\*\*Please note these are added back into the number of requests and scheduled case totals above.

Total number of requests withdrawn	17
Failed to appear	7

## Office Conference between July 1, 2008 and March 31, 2009

Total number of citations affirmed	147
------------------------------------	-----

Decision	Total citations	Total dollar amount reduced
Modified	38	\$14,500.00
Dismissed	38	\$44,500.00
Reduced to Letter of Admonishment	0	\$0.00

Please note fifteen cases are pending decisions due to additional investigation being required.

# Board of Pharmacy Enforcement Statistics

## Fiscal Year 2008/2009

**Workload Statistics**                      July-Sept    Oct-Dec    Jan-Mar    Apr-June    Total 08/09

**Complaints/Investigations**

Initiated	638	514	479		1631
Closed	696	310	502		1508
Pending (at the end of quarter)	2162	1831	2343		2343

**Cases Assigned & Pending (by Team)**

Compliance Team	224	270	151		151
Drug Diversion/Fraud	160	182	112		112
Probation/PRP	12	125	53		53
Mediation/Enforcement	145	170	65		65
Criminal Conviction	497	508	1512		1512

**Application Investigations**

Initiated	81	120	97		298
Closed					
Approved	46	32	56		134
Denied	10	11	26		47
Total*	70	64	100		234
Pending (at the end of quarter)	257	323	328		328

**Citation & Fine**

Issued	424	87	210		721
Citations Closed	258	178	389		825
Total Fines Collected	\$418,500.00	\$240,975.00	\$238,312.50		\$897,787.50

\* This figure includes withdrawn applications.

\*\* Fines collected and reports in previous fiscal year.

# Board of Pharmacy Enforcement Statistics

## Fiscal Year 2008/2009

**Workload Statistics**                      **July-Sept**   **Oct-Dec**   **Jan-Mar**   **Apr-June**   **Total 08/09**

**Administrative Cases** (by effective date of decision)

Referred to AG's Office*	37	32	67	136
Pleadings Filed	29	28	15	72
<b>Pending</b>				
Pre-accusation	73	76	125	125
Post Accusation	76	84	74	74
<b>Total</b>	<b>153</b>	<b>160</b>	<b>205</b>	<b>205</b>
<b>Closed**</b>				
<b>Revocation</b>				
Pharmacist	0	1	2	3
Pharmacy	1	2	0	3
Other	3	5	11	19
<b>Revocation, stayed; suspension/probation</b>				
Pharmacist	3	3	2	8
Pharmacy	0	0	0	0
Other	0	0	0	0
<b>Revocation, stayed; probation</b>				
Pharmacist	0	2	3	5
Pharmacy	0	0	0	0
Other	1	2	0	3
<b>Suspension, stayed; probation</b>				
Pharmacist	0	0	0	0
Pharmacy	0	0	0	0
Other	0	0	0	0
<b>Surrender/Voluntary Surrender</b>				
Pharmacist	2	0	0	2
Pharmacy	0	0	0	0
Other	1	2	2	5
<b>Public Reprival/Reprimand</b>				
Pharmacist	0	0	0	0
Pharmacy	0	0	0	0
Other	0	0	0	0
Cost Recovery Requested	\$46,643.50	\$62,140.50	\$38,241.00	\$147,025.00
Cost Recovery Collected	\$25,856.54	\$45,622.15	\$24,226.65	\$95,705.34

\* This figure includes Citation Appeals

\*\* This figure includes cases withdrawn

# Board of Pharmacy Enforcement Statistics

## Fiscal Year 2008/2009

**Workload Statistics**                      **July-Sept**   **Oct-Dec**   **Jan-Mar**   **Apr-June**   **Total 08/09**

### Probation Statistics

Licenses on Probation

Pharmacist	96	95	106		106
Pharmacy	2	4	3		3
Other	13	16	14		14
Probation Office Conferences	10	8	15		33
Probation Site Inspections	41	26	50		117
Probationers Referred to AG for non-compliance	3	0	1		4

As part of probation monitoring, the board requires licensees to appear before the supervising inspector at probation office conferences. These conferences are used as 1) an orientation to probation and the specific requirements of probation at the onset, 2) to address areas of non-compliance when other efforts such as letters have failed, and 3) when a licensee is scheduled to end probation.

### Pharmacists Recovery Program (as of 3/31/09)

Program Statistics

In lieu of discipline	1	2	0		3
In addition to probation	3	2	1		6
Closed, successful	5	7	2		14
Closed, non-compliant	0	1	0		1
Closed, other	1	1	2		4
Total Board mandated Participants	59	59	58		58
Total Self-Referred Participants*	20	20	20		20
Treatment Contracts Reviewed	56	51	52		159

Monthly the board meets with the clinical case manager to review treatment contracts for scheduled board mandated participants. During these monthly meetings, treatment contracts and participant compliance is reviewed by the PRP case manager, diversion program manager and supervising inspector and appropriate changes are made at that time and approved by the executive officer. Additionally, non-compliance is also addressed on a needed basis e.g., all positive urines screens are reported to the board immediately and appropriate action is taken.

\* By law, no other data is reported to the board other than the fact that the pharmacists and interns are enrolled in the program.

As of March 31, 2009

# Attachment 8

*Third Quarterly Strategic Plan Update  
2008-09*

# GOALS, OUTCOMES, OBJECTIVES, AND MEASURES

## ENFORCEMENT COMMITTEE

Goal 1: Exercise oversight on all pharmacy activities.

Outcome: Improve consumer protection.

Objective 1.1	Achieve 100 percent closure on all cases within 6 months.						
Measure:	Percentage of cases closed.						
Tasks:	1. Mediate all complaints within 90 days (for cases closed during quarter).						
		<u>N</u>	< 90 days	< 120 days	< 180 days	Longer	<u>Average Days</u>
	Qtr 1	197	173	6	2	16	47
			88%	3%	1%	8%	
	Qtr 2	56	50	1	2	3	40
			89%	2%	4%	5%	
	Qtr 3	133	97	9	8	19	74
			73%	7%	6%	14%	
	Qtr 4						
	2. Investigate all cases within 120 days (for cases closed during quarter).						
		<u>N</u>	< 120 days	< 180 days	< 270 days	Longer	<u>Average Days</u>
	Qtr 1	499	378	79	28	14	63
			76%	16%	6%	3%	
	Qtr 2	223	171	25	17	10	93
			77%	11%	8%	4%	
	Qtr 3	368	268	19	40	41	116
			73%	5%	11%	11%	
	Qtr 4						

3. Close (e.g., no violation, issue citation and fine, refer to the AG's Office) all board investigations and mediations within 180 days.

<b>Qtr 1</b>	<b>N</b>	<b>&lt; 180</b>	<b>&lt; 270</b>	<b>&lt; 365</b>	<b>&gt; 365</b>
Closed, no additional action	186	170	10	5	1
Cite and/or fine letter of admonishment	476	447	18	3	8
Attorney General's Office	34	21	6	4	3
<b>Qtr 2</b>	<b>N</b>	<b>&lt; 180</b>	<b>&lt; 270</b>	<b>&lt; 365</b>	<b>&gt; 365</b>
Closed, no additional action	143	136	2	2	3
Cite and/or fine letter of admonishment	105	94	8	2	1
Attorney General's Office	31	19	7	3	2
<b>Qtr 3</b>	<b>N</b>	<b>&lt; 180</b>	<b>&lt; 270</b>	<b>&lt; 365</b>	<b>&gt; 365</b>
Closed, no additional action	198	157	20	10	11
Cite and/or fine letter of admonishment	230	203	15	7	5
Attorney General's Office	73	41	13	10	9
<b>Qtr 4</b>	<b>N</b>	<b>&lt; 180</b>	<b>&lt; 270</b>	<b>&lt; 365</b>	<b>&gt; 365</b>
Closed, no additional action					
Cite and/or fine letter of admonishment					
Attorney General's Office					

Objective 1.2	Manage enforcement activities for achievement of performance expectations.																																																																																																																																																																												
Measure:	Percentage compliance with program requirements.																																																																																																																																																																												
Tasks:	<p data-bbox="365 220 1015 252"><b>1. Administer the Pharmacists Recovery Program.</b></p> <table border="1" data-bbox="365 252 1510 535"> <thead> <tr> <th></th> <th>Voluntary Participants</th> <th>Participants Mandated Into Program</th> <th>Noncompliant, Terminated From Program</th> <th>Successfully Completed Program</th> </tr> </thead> <tbody> <tr> <td>Qtr 1</td> <td>20</td> <td>3</td> <td>0</td> <td>5</td> </tr> <tr> <td>Qtr 2</td> <td>20</td> <td>59</td> <td>1</td> <td>7</td> </tr> <tr> <td>Qtr 3</td> <td>20</td> <td>58</td> <td>0</td> <td>2</td> </tr> <tr> <td>Qtr 4</td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table> <p data-bbox="365 577 1015 609"><b>2. Administer the Probation Monitoring Program.</b></p> <table border="1" data-bbox="365 609 1234 913"> <thead> <tr> <th></th> <th>Qtr 1</th> <th>Qtr 2</th> <th>Qtr 3</th> <th>Qtr 4</th> </tr> </thead> <tbody> <tr> <td>Individuals</td> <td>108</td> <td>117</td> <td>119</td> <td></td> </tr> <tr> <td>Sites</td> <td>3</td> <td>6</td> <td>4</td> <td></td> </tr> <tr> <td>Tolled</td> <td>18</td> <td>14</td> <td>20</td> <td></td> </tr> <tr> <td>Inspections Conducted</td> <td>41</td> <td>26</td> <td>50</td> <td></td> </tr> <tr> <td>Successfully Completed</td> <td>9</td> <td>1</td> <td>1</td> <td></td> </tr> <tr> <td>Petitions to Revoke Filed</td> <td>1</td> <td>0</td> <td>0</td> <td></td> </tr> </tbody> </table> <p data-bbox="365 955 966 987"><b>3. Issue all citations and fines within 30 days.</b></p> <table border="1" data-bbox="365 987 1421 1375"> <thead> <tr> <th></th> <th><u>N</u></th> <th>30 days</th> <th>60 days</th> <th>90 days</th> <th>&gt; 90 days</th> <th><u>Average Days</u></th> </tr> </thead> <tbody> <tr> <td>Qtr 1</td> <td>423</td> <td>389</td> <td>29</td> <td>3</td> <td>2</td> <td>15</td> </tr> <tr> <td></td> <td></td> <td>92%</td> <td>7%</td> <td>1%</td> <td>.5%</td> <td></td> </tr> <tr> <td>Qtr 2</td> <td>85</td> <td>50</td> <td>31</td> <td>5</td> <td>0</td> <td>29</td> </tr> <tr> <td></td> <td></td> <td>59%</td> <td>36%</td> <td>5%</td> <td>0%</td> <td></td> </tr> <tr> <td>Qtr 3</td> <td>725</td> <td>457</td> <td>100</td> <td>45</td> <td>33</td> <td>24</td> </tr> <tr> <td></td> <td></td> <td>79%</td> <td>14%</td> <td>6%</td> <td>4%</td> <td></td> </tr> <tr> <td>Qtr 4</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table> <p data-bbox="365 1428 1006 1459"><b>4. Issue letters of admonishment within 30 days.</b></p> <table border="1" data-bbox="365 1459 1421 1848"> <thead> <tr> <th></th> <th><u>N</u></th> <th>30 days</th> <th>60 days</th> <th>90 days</th> <th>&gt; 90 days</th> <th><u>Average Days</u></th> </tr> </thead> <tbody> <tr> <td>Qtr 1</td> <td>31</td> <td>22</td> <td>6</td> <td>3</td> <td>0</td> <td>24</td> </tr> <tr> <td></td> <td></td> <td>71%</td> <td>19%</td> <td>10%</td> <td>0%</td> <td></td> </tr> <tr> <td>Qtr 2</td> <td>15</td> <td>6</td> <td>9</td> <td>0</td> <td>0</td> <td>29</td> </tr> <tr> <td></td> <td></td> <td>40%</td> <td>60%</td> <td>0%</td> <td>0%</td> <td></td> </tr> <tr> <td>Qtr 3</td> <td>77</td> <td>41</td> <td>26</td> <td>8</td> <td>2</td> <td>30</td> </tr> <tr> <td></td> <td></td> <td>54%</td> <td>35%</td> <td>10%</td> <td>1%</td> <td></td> </tr> <tr> <td>Qtr 4</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table>		Voluntary Participants	Participants Mandated Into Program	Noncompliant, Terminated From Program	Successfully Completed Program	Qtr 1	20	3	0	5	Qtr 2	20	59	1	7	Qtr 3	20	58	0	2	Qtr 4						Qtr 1	Qtr 2	Qtr 3	Qtr 4	Individuals	108	117	119		Sites	3	6	4		Tolled	18	14	20		Inspections Conducted	41	26	50		Successfully Completed	9	1	1		Petitions to Revoke Filed	1	0	0			<u>N</u>	30 days	60 days	90 days	> 90 days	<u>Average Days</u>	Qtr 1	423	389	29	3	2	15			92%	7%	1%	.5%		Qtr 2	85	50	31	5	0	29			59%	36%	5%	0%		Qtr 3	725	457	100	45	33	24			79%	14%	6%	4%		Qtr 4								<u>N</u>	30 days	60 days	90 days	> 90 days	<u>Average Days</u>	Qtr 1	31	22	6	3	0	24			71%	19%	10%	0%		Qtr 2	15	6	9	0	0	29			40%	60%	0%	0%		Qtr 3	77	41	26	8	2	30			54%	35%	10%	1%		Qtr 4						
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**5. Obtain immediate public protection sanctions for egregious violations.**

	Interim Suspension Orders	Automatic Suspension Based on Conviction	Penal Code 23 Restriction
Qtr 1	0	0	2
Qtr 2	0	0	2
Qtr 3	0	0	1
Qtr 4			

**6. Submit petitions to revoke probation within 30 days for noncompliance with terms of probation.**

	30 days	60 days	> 60 days	N
Qtr 1	0	0	3	3
Qtr 2	0	0	0	0
Qtr 3	1	0	0	1
Qtr 4				

**Objective 1.3**

**Achieve 100 percent closure on all administrative cases within 1 year.**

**Measure:**

**Percentage of administrative cases closed within 1 year.**

	N	1 Year	1.5 Year	2 Year	2.5 Year	>2.5 Years	Average
Qtr 1	13	4 30%	2 15%	5 38%	0 0%	2 15%	553
Qtr 2	16	2 13%	8 50%	2 13%	3 19%	1 6%	680
Qtr 3	27	14 52%	10 37%	2 7%	1 4%	0 0%	390
Qtr 4							

Objective 1.4	Inspect 100 percent of all facilities once every 3 year inspection cycle ending 6/30/08.																				
Measure:	Percentage of licensed facilities inspected once every 3 year cycle.																				
Tasks:	1. Inspect licensed premises to educate licensees proactively about legal requirements and practice standards to prevent serious violations that could harm the public.																				
	<table border="1"> <thead> <tr> <th></th> <th>Number of Inspections</th> <th>Aggregate Inspections This Cycle</th> <th>Percent Complete</th> </tr> </thead> <tbody> <tr> <td>Qtr 1</td> <td>345</td> <td>4271</td> <td>59%</td> </tr> <tr> <td>Qtr 2</td> <td>373</td> <td>4530</td> <td>56%*</td> </tr> <tr> <td>Qtr 3</td> <td>295</td> <td>4299</td> <td>60%</td> </tr> <tr> <td>Qtr 4</td> <td></td> <td></td> <td></td> </tr> </tbody> </table>		Number of Inspections	Aggregate Inspections This Cycle	Percent Complete	Qtr 1	345	4271	59%	Qtr 2	373	4530	56%*	Qtr 3	295	4299	60%	Qtr 4			
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	* Decrease due to new licenses issued for CVS/Long's buyout.																				
	2. Inspect sterile compounding pharmacies initially before licensure and annually before renewal.																				
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Qtr 2	67	0																			
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Qtr 4																					
3. Initiate investigations based upon violations discovered during routine inspections.																					
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Objective 1.5	Initiate policy review of 25 emerging enforcement issues by June 30, 2011.
Measure:	The number of issues.
Tasks:	<p>1. Monitor the implementation of e-pedigree on all prescription medications sold in California.</p> <p><i>Sept. 28, 2006: Board convenes third Workgroup on Implementation of E-Pedigree Meeting. Presentations provided by EPCglobal, McKesson, Supervising Inspector Nurse and Johnson and Johnson.</i></p> <p><i>Sept. 30, 2006: Governor signs SB 1476 which delays implementation of e-pedigree requirements until 2009, requires serialization and interoperability and notification to the board whenever counterfeit drugs are discovered.</i></p> <p><i>Oct. 6, 2006: FDA provides presentation on federal pedigree requirements at board-hosted NABP District 7 &amp; 8 Meeting.</i></p> <p><i>Dec. 2006: Board convenes fourth Workgroup on Implementation of E-Pedigree Meeting. Presentations made by EPCglobal, McKesson, AmerisourceBergen and Cardinal. Pilot testing e-pedigree systems underway at each of the three large wholesalers. Standards for electronic pedigree to be finalized by January 2007 by EPCglobal.</i></p> <p><i>Jan. 2007: EPCglobal finalizes electronic messaging standards for electronic pedigrees.</i></p> <p><i>Feb. 2007: EPCglobal convenes regional meeting with hospitals to discuss implementation issues of e-pedigree in these facilities. Hospitals are encouraged to join the board's Workgroup on Implementation of E-Pedigree Meetings.</i></p> <p><i>March 2007: Two board members and executive staff meet with nine EPCglobal representatives to walk through EPCglobal's messaging standards and business scenarios. The standard complies with California's e-pedigree requirements although some questions remain about situation-specific criteria.</i></p> <p><i>Board convenes fifth Workgroup on Implementation of E-pedigree Meeting. Presentations are made by EPCglobal, AmerisourceBergen and SupplyScape.</i></p> <p><i>May 2007: Board presents information at the National Association of Boards of Pharmacy annual meeting on California's electronic pedigree requirements in both a poster session and a full presentation to the full assembly.</i></p> <p><i>June 2007: Board convenes sixth Workgroup on E-Pedigree Meeting, with the largest attendance of any prior meeting. Presentations were made by EPCglobal, Pfizer, Walgreens and PhRMA. Hospital pharmacies were specifically invited to attend this meeting.</i></p> <p><i>July 2007: Board hears presentations on EPCglobal standards.</i></p> <p><i>Sept. 2007: Enforcement Meeting has large audience (200 people). Presentations by PhRMA, GSK, Bracco, CPhA, EPCglobal, Walgreens, Rite Aid, CVS, rfXcel, and HDMA.</i></p> <p><i>Federal legislation enacted for the FDA supports California requirements. Major presentations made on California's standards to LogiPharma (Philadelphia) and HDMA Subcommittee of board meets with EPCglobal representatives on standards.</i></p> <p><i>Oct. 2007: Major presentations at EPCglobal Conference in Chicago. At Board Meeting, presentations made by IBM/Amerisource Bergen, Alien Technology and EPCglobal on readiness of technology.</i></p>

- Dec. 2007:** Enforcement Committee Meeting solely dedicated to Workgroup on E-Pedigree (an eight-hour meeting). Largest meeting to date involving over 400 individuals representing all members in the pharmaceutical supply chain. Board encourages discussion of grandfathering and inference, and seeks information via a template. Industry seeks delay. Many request board to specify technology. Board releases template for readiness assessment.
- Jan. 2008:** Board reviews requests for delay until 2011 from members of the pharmaceutical supply chain.
- Feb. 2008:** Questions and Answers released. Specialized area of the board's website is created to consolidate e-pedigree information.
- March 2008:** Board delays implementation date for e-pedigree requirements from January 1, 2009 until January 1, 2011.
- April 2008:** Board sponsors legislation that will enhance some of the pedigree requirements, allowing for staggered implementation, as well as provisions for regulations on inference and grandfathering.
- June 2008:** Board meets as a public meeting rather than an Enforcement Committee Meeting to hear discussions and presentations on the status of e-pedigree implementation and to discuss and review the amendments to its e-pedigree legislation, SB 1307.
- Sept. 2008:** Governor signs SB 1307, which delays implementation until 2015-2017, and makes other modifications.
- Oct. 2008:** Board convenes workgroup on e-pedigree meeting.
- March 2009:** Board convenes workgroup on e-pedigree as part of the Enforcement Committee. Presentation made by FDA, Congressman Buyer's office, GS1 and Oracle.
- April 2009:** Board submits comments to the FDA regarding nomenclature for the unique identifier.
- 2. Implement federal restrictions on ephedrine, pseudoephedrine or phenylpropanolamine products.**
- Sept. 2006:** Final phase-in of federal requirements takes effect on September 30. Board newsletter provides information for licensees.
- Oct. 2006:** Board adds Consumer friendly materials regarding sales of these drugs to its website.
- 3. Monitor the efforts of the DEA and DHHS to implement electronic prescribing for controlled substances.**
- Sept. 2006:** DEA releases proposed rule to allow prescribers to issue 90 days' worth of Schedule II prescriptions at one time.
- Oct. 2006:** Board considers proposed rule.
- Nov. 2006:** Board submits letter supporting change in DEA policy allowing prescribers to write multiple prescriptions for Schedule II drugs with "Do not fill before (date)" at one time, eliminating the need for patients to revisit prescribers merely to obtain prescriptions.
- 2nd Qtr 07/08:** DEA agrees to allow a 90-day supply of Schedule II drugs to be prescribed at one time in serial prescriptions.
- June 2008:** DEA published proposed regulations that would provide physicians and other authorized prescribers with the option of issuing electronic prescriptions for controlled substances.
- July 2008:** Board to discuss Federal Drug Enforcement Administration's proposed rule to allow e-prescribing for controlled substances at its July board meeting.
- Sept. 2008:** Board submits comments on DEA proposed requirements for e-prescribing of controlled substances.

- 4. Evaluate establishment of an ethics course as an enforcement option.**
- June 2007: Subcommittee meets with ethicist trainer for Dental Board.*
- Aug. 2007: Subcommittee meets with Medical Boards Ethics course provider (Institute for Medical Quality).*
- Oct. 2007: Institute for Medical Quality provides information to board about program; recommendation of committee is to move forward with the specialized program. Board approves development of program at board meeting.*
- Jan. 2008: Staff compile resource materials and begin steps to develop framework for program. Board agrees to establish program.*
- April 2008: Legislation/Regulation Committee to develop draft language for a regulatory proposal. Draft language for a new regulation to be presented and reviewed at July 2008 Board Meeting.*
- July 2008: Board moves ethics regulation for 45 day notice and plans action at the October Board Meeting.*
- Oct. 2008: Board holds regulation hearing on proposed requirements for the ethics class.*
- Dec. 2008: Board releases regulation for 15 day comment.*
- Jan. 2009: Board adopts regulation.*
- April 2009: Rulemaking file compiled and submitted to the Department of Consumer Affairs for review.*
- 5. Participate in emerging issues at the national level affecting the health of Californians regarding their prescription medicine.**
- May 2007: Board staff provides presentation at National Association of Boards of Pharmacy annual meeting on California's pedigree requirements.*
- June 2007: Board works with Center for Medicare and Medicaid Services on security prescription forms that will be required in only four months for all written Medicaid and Medicare prescriptions.*
- Nov. 2007: Staff meets with FDA officials to discuss California's e-pedigree requirements and new federal law for FDA's action involving pharmaceutical chain security.*
- May 2008: The Executive Officer gives a poster presentation on the board's e-pedigree requirements at the annual National Associations of Boards of Pharmacy (NABP) meeting.*
- May 2008: The Executive Officer attends a drug tracking conference of manufacturers and wholesalers and presents status of California's e-pedigree efforts.*
- June 2008: Executive staff and supervising inspector provide a presentation via videoconference at the Fourth Global Forum on Pharmaceutical AntiCounterfeiting.*
- Nov. 2008: Executive Officer Herold provides information about SB 1307 to a conference of drug manufacturers and wholesalers.*
- Dec. 2008: Executive Officer Herold provides information about SB 1307 to a conference of drug manufacturers and wholesalers and at a conference on drug distribution chain security.*
- Executive Officer Herold participates on a National Association of Boards of Pharmacy Task Force on designing patient-centered labels.*
- Board President Schell participates on a National Association of Boards of Pharmacy Task Force on drug take-back programs.*

	<p><b>6. Provide information about legal requirements involving e-prescribing to support the Governor's Health Care Initiative and its promotion of e-prescribing.</b></p> <p><i>Sept. 2007: Provided comments on proposed statutory requirements.</i></p> <p><i>Dec. 2007: Sought DCA's support for involvement in e-prescribing by the Administration. Provided comments on proposed e-prescribing initiatives.</i></p> <p><i>Oct. 2008: Executive Officer Herold joins a task force to achieve e-prescribing coordinated by the California HealthCare Foundation.</i></p> <p><i>Nov. 2008: Board hosts conference on e-prescribing as part of department's Professionals Achieving Consumer Trust Summit. The Medical Board and Dental Board join us as sponsors.</i></p> <p><i>Jan. 2009: Executive Officer Herold works with California HealthCare Foundation and Medical Board to plan joint activities with licensees to facilitate e-prescribing.</i></p> <p><i>March 2009: Pharmacists and physicians in Visalia attend first of California HealthCare Foundation's public forums on e-prescribing.</i></p> <p><b>7. Implement in California the Center for Medicare and Medicaid Service requirements for security prescription forms that will be required in only four months for all written Medicaid and Medicare prescriptions.</b></p> <p><i>June - Oct. 2007: Board works with the Department of Health Care Services to implement security forms until subsequent federal legislation delays implementation until April 2008.</i></p> <p><i>Dec. 2007: Meeting with Department of Health Care Services on issues involving security forms for MediCal prescriptions.</i></p> <p><i>April 1, 2008: Requirements that all written prescriptions for MediCal prescriptions be written on security forms containing at least one specified security component takes effect.</i></p> <p><i>April 2008: Subscriber alert released with information for contact resources from the California Department of Health Care Services about security forms for MediCal prescriptions.</i></p> <p><i>Oct. 2008: Requirements for security forms in place.</i></p>
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	<p><b>8. Liaison with other state and federal agencies to achieve consumer protection.</b></p> <p><i>1st Qtr 07/08: Bimonthly meetings initiated with Department of Health Care Services audit staff to investigate pharmacies and pharmacists involved in MediCal fraud and drug diversion. Several joint investigations underway with state and federal agencies.</i></p> <p><i>2nd Qtr 07/08: Bimonthly meeting with the Department of Health Care Services continue. Board inspectors attend 3-day-training with federal and state regulations on items involving fraud provided by the Office of Inspector General of the Department of Health and Human Services. Joint investigations with other state and federal agencies continue that involve the board's jurisdiction.</i></p> <p><i>3rd Qtr 07/08: Bimonthly meetings with the Department of Health Care Services continue. Board works with the Drug Enforcement Administration on joint investigations and receives specialized training.</i></p> <p><i>4th Qtr 07/08: Board staff meets with staff of the California Department of Public Health regarding joint inspections of licensed healthcare facilities in California to identify and remove recalled drugs.</i></p> <p><i>3rd Qtr 08/09: Executive staff meet with Department of Health Care Services investigators on cases of mutual concern. Board investigators work with federal and state drug enforcement officers on search warrants and mutual investigations.</i></p>
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9. **Work with the California Integrated Waste Management Board to implement requirements for model programs to take back unwanted prescription medicine from the public.**
- March 2008:* Second meeting with state agency stakeholders on developing components for model programs that conform with diverse state agency security and safety requirements.
- June 2008:* Supervising pharmacist inspector attended a two-day multi-disciplinary conference hosted by the Integrated Waste Management Board on drug take-back programs.
- Aug. 2008:* Executive Officer Herold speaks at conferences sponsored by the California Integrated Waste Management Board.
- Oct. 2008:* Enforcement Committee hears presentations on drug take-back programs, medical waste management processes and the take-back of sharps. Board to submit comments to California Integrated Waste Management Board on model programs for take-back programs.
- Nov. 2008:* Executive Officer provides written and verbal testimony at California Integrated Waste Management Board hearing on the model guidelines.
- Dec. 2008:* Executive Officer participates in public hearing at the California Integrated Waste Management Board on possible changes to the model guidelines adopted by the California Integrated Waste Management Board in November.
- Feb. 2009:* California Integrated Waste Management Board amends model guidelines to include provisions advanced by the Board.
10. **Inspect California hospitals to ensure recalled heparin has been removed from patient care areas.**
- 4th Qtr 07/08:* Board initiates inspections of 40 California hospitals looking for counterfeit heparin and unlicensed sales but discovers recalled heparin still in 40 percent of hospitals inspected. Board notifies FDA and California Department of Public Health and initiates inspections of 533 hospitals during April-June. Recalled heparin is found in 94 of these facilities. Data reported to board during June Board Meeting.
- 1st Qtr 08/09:* The Script highlights problems found in heparin inspections. Citations and fines issued to facilities with recalled heparin. Work with hospitals begins to strengthen drug control within facilities.
- 2nd Qtr 08/09:* Hospitals and Pharmacists-in-Charge fined where recalled heparin was discovered by the Board.
- 3rd Qtr 08/09:* First stakeholder meeting scheduled to discuss drug distribution within hospitals.
- March 08/09:* First stakeholder meeting convened.