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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  
D. Timothy Dazé, Esq., Board Member  
Stan Weisser, RPh, Board Member

The Enforcement Committee met on December 9, 2008, in Sacramento. There was no Work Group on E-Pedigree Meeting held in conjunction with this meeting. Minutes of this meeting are provided in **Attachment 8**, near the back of this tab section.

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### **A. FOR ACTION: Presentation and Request from San Diego County for an Exemption to Distribute Prophylaxis Drugs to Emergency Response Staff Prior to a Declared Emergency**

#### Background:

In 2007, the board received a request from San Diego County to provide an unspecified number of up to 500,000 bottles of a 7-14 day dosing regiment of doxycycline or ciprofloxacin to first responders, that would be stored in their homes for their and their families' use, with the remainder being stored somewhere (unmentioned) else. The county was seeking an exemption from patient-specific labeling because it would be "difficult, if not impossible" to label these containers. This request was later withdrawn.

In September 2008, the board received a new request from San Diego County. This is the proposal being submitted to the board for action at this meeting.

This plan calls for doxycycline 100mg #20 to be prescribed to approximately 100,000 first responders and critical access employees and their family members. A total of about 500,000 individuals are estimated to be covered under this plan. Each prescription will be written by the Public Health Officer (a licensed California prescriber) and transmitted to a pharmacy for dispensing. The pharmacy would label the container and dispense the medication.

San Diego County is seeking confirmation from the board that this model satisfies the requirements in pharmacy law. In **Attachment 1** are materials submitted by San Diego in support of their proposal. This will be the first opportunity for the proponents of this request to address the board.

There are several problems with this proposal as submitted:

1. The Medical Board of California has informally advised the Board of Pharmacy's executive officer that a prescription written by a public health officer in this manner

would not be a valid prescription because there would have been no prescriber-patient relationship established pursuant to an examination.

2. During a declared emergency, California law provides the board with broad waiver authority to ensure care of patients. California Business and Professions Code section 4062 provides:

**4062.** (a) Notwithstanding Section 4059 or any other provision of law, a pharmacist may, in good faith, furnish a dangerous drug or dangerous device in reasonable quantities without a prescription during a federal, state, or local emergency, to further the health and safety of the public. A record containing the date, name, and address of the person to whom the drug or device is furnished, and the name, strength, and quantity of the drug or device furnished shall be maintained. The pharmacist shall communicate this information to the patient's attending physician as soon as possible. Notwithstanding Section 4060 or any other provision of law, a person may possess a dangerous drug or dangerous device furnished without prescription pursuant to this section.

(b) During a declared federal, state, or local emergency, the board may waive application of any provisions of this chapter or the regulations adopted pursuant to it if, in the board's opinion, the waiver will aid in the protection of public health or the provision of patient care.

However, unless there is a declared emergency, a pharmacy needs a valid prescription to provide prescription medicine to patients (with limited exceptions that would not be in play in this proposal).

3. The board lacks the authority to waive requirements for the dispensing of drugs in such a manner – a statutory amendment to the Business and Professions Code would be needed.

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The board has been innovative in its support to encourage disaster response training and preparedness, especially by its licensees. This has included not only the statutory authority identified above in section 4062 (which the board sponsored), but also development of a disaster response policy, published in the board's newsletter two years ago, to alert board licensees what it expects once a declared emergency occurs. The board has worked with the California Department of Public Health to ensure preplanning and training for disasters, encourage pharmacists and others to become trained first responders, and the board has been publicly recognized and commended for this activity.

San Diego's proposal is being offered as part of the pre-planning process for a public health disaster to ensure the more immediate availability of disaster response workers. However, as proposed, the board lacks the authority to approve it.

Very recently, San Diego County has verbally advised the executive officer of a revised proposal that would seemingly solve the statutory problems associated with this request. The amended proposal would involve the county health officer providing a written notice to emergency responders that they would take to their personal health care providers, encouraging the prophylactic prescribing of doxycycline. The personal health care providers (who do have a patient-prescriber relationship) could determine whether to write such a prescription, but if written, the responders could take the prescription to their own pharmacies. The county would pay for the drug prescribed by the responder's own health care provider.

**B. FOR INFORMATION: New Data Collection Vendor Secured for the Controlled Substances Utilization Review and Evaluation System (CURES) Effective January 1, 2009**

In mid December, the board was 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 January 1.

Despite the very short notice to California pharmacies during the holiday season, the board is not aware that there have been monumental problems with the transition. Nevertheless, two board staff have been assisting callers and redirecting them to the California Department of Justice.

Here is a copy of the subscriber alert that the board sent to its subscribers on December 12, as soon as we learned of the forthcoming change:

The Department of Justice has announced that there is a new vendor for submission of CURES data, effective January 1, 2009.

The new vendor is Infinite Solutions, and information about this new vendor can be found at:

[http://www.pharmacy.ca.gov/licensing/cures\\_ltr.pdf](http://www.pharmacy.ca.gov/licensing/cures_ltr.pdf)

All pharmacies in California that dispense controlled substances and report data electronically to CURES will by January 1, 2009, need to establish an account with Infinite Solutions and modify their software to send CURES data to the new vendor. The letter provided via the link above provides basic directions on how to do this.

The Department of Justice indicates that the new contract provides for no grace period, and that after January 1, 2009, all CURES data needs to be sent to Infinite Solutions.

If you have questions about this, please contact the Department of Justice, and specifically Ronna Kephart at [Ronna.Kephart@doj.ca.gov](mailto:Ronna.Kephart@doj.ca.gov) Phone calls should be made to the CURES line at the Department of Justice (916) 319-9062.

We will share additional information in future subscriber alerts as we gain it.

**C. FOR ACTION: Department of Consumer Affairs Professionals Achieving Consumer Trust Policy Statement**

This year the Department of Consumer Affairs sponsored its first Professionals Achieving Consumer Trust (PACT) Summit in November. At this conference, departmental regulatory board members and staff joined with Schwarzenegger Administration officials, consumers, consumer advocates, professional associations and others to discuss topics that would advance the protection of the public. The Board of Pharmacy held two board meetings during this conference, one on e-prescribing, the other on designing patient-centered prescription container labels.

Out of this summit a policy statement was prepared by the department. This statement is provided in **Appendix 2**. President Schell signed the statement on behalf of the board.

The board may wish to discuss and ratify this statement.

**D. FOR INFORMATION: Presentation by Jan Hirsch, PhD, UCSD on Research Regarding Use of Automated Dispensing Machines in Community Pharmacies**

In 2005 and 2006, the board discussed and eventually promulgated a regulation to allow automated dispensing machines in pharmacies to dispense refill medications -- if requested by the patient and approved by the pharmacist. This was a use of emerging technology and several pharmacies had sought the board's authority to install such machines in their pharmacies to provide patients with after-hours access (as well as access during times when the pharmacy was open) to refills. Basically, a patient could pick up refill medication, if approved, from a vending-like machine using a credit card for payment and not specifically deal with the pharmacy staff. The machine was to be located near the physical area of the pharmacy.

A number of conditions were built into the regulations to provide for assurance patients would not be required to use these machines for refills if they were not supportive. A copy of the final regulation is provided in **Attachment 3**.

During the discussions to develop and promulgate the regulations, UCSD proposed initiating a consumer satisfaction survey of how patients felt about use of these machines. While the results of the study were not available in time for adopting the regulation (which took effect in January 2007), UCSD continued the study. The study is now completed and will be published very shortly.

At this meeting, the board will hear a presentation from Dr. Hirsch on the satisfaction of patients who use the automated dispensing machines versus regular interaction with pharmacies. **Attachment 3** also contains an abstract of Dr. Hirsch's paper.

**E. Report of the Enforcement Committee Meeting of December 9, 2008**

**1. FOR ACTION: Model Programs for Take Back of Drugs from the Public (SB 966, Simitian, Chapter 542, Statutes of 2007)**

Background:

Senate Bill 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 (a copy of SB 966 is provided in **Attachment 4**). 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 required 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, 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 dispose of in this manner. Water quality advocates are strongly opposed to this practice.

Pharmacies have in some cases agreed to take back unwanted drugs from patients. However, this acquisition by pharmacies is not 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. 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. This has occurred in Washington where a pharmacy operating a take-back program was selling returned drugs to patients as new medicine (**Attachment 4**).

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. Senate Bill 9666 specifically prohibits pharmacies from charging for drug take back.

Update for this meeting:

At the October 2008 Board Meeting, the board discussed concern with the initial proposed model program guidelines as drafted by the Integrated Waste Management Board. However, the board did express its support for such programs on a voluntary basis.

Since April 2008, board staff have been working with the California Integrated Waste Management Board, the California Department of Public Health and other agencies on the model program parameters specified by SB 966.

Immediately before the October Board Meeting, the Integrated Waste Management Board issued new guidelines, incorporating some of the changes suggested by the staff. The board directed Executive Officer Herold to provide the board's concerns with provisions in the second draft model program guidelines at a committee meeting of the Integrated Waste Management Board (CIWMB) on November 10. Ms. Herold provided this testimony and submitted written comments (**Attachment 4**).

On November 13, the CIMWB adopted the Model Guidelines (**Attachment 5**), 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 CIMWB agreed to consider modifications to the Model Guidelines, perhaps at its February 2009 meeting.

During the December Enforcement Committee Meeting, Jim Cropper of the CIWMB spoke about the comments they had received on the model guidelines. He stated that proposed comments on the adopted guidelines that were submitted to the CIMWB would be evaluated during a public meeting on December 19. This summary document is also provided in **Attachment 5**.

Ms. Herold and Ms. Schiedge attended this meeting and provided comments regarding the board's and Department of Consumer Affairs' perspective on the guidelines. Additionally,

Ms. Herold will meet with CIWMB staff on January 22. As such, she will provide an update to the board at its January Board Meeting about what the CIWMB plans on doing with its Model Guidelines.

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 wastes and the disposal of devices. The board will discuss this legislation during the Legislation and Regulation Committee Report.

The board needs to determine whether it wishes to provide additional comments and/or testimony on the proposed modifications to the model guidelines.

At future Enforcement Committee Meetings, the board will discuss how it will enforce these voluntary guidelines.

## **2. FOR INFORMATION: Sharps Take Back By Pharmacies**

### Background and Update:

A related, but separate issue to the problem of how society will dispose of unwanted drug products is the issue of disposal of used sharps.

According to estimates by the California Integrated Waste Management Board, California patients use hundreds of millions of needles and syringes each year. This does not include lancets. This is a disposal issue and a public health and safety issue.

Since September 1, 2008, California law has prohibited the disposal of sharps in trash or recycling containers. Pharmacies are listed on the CIWMB's Web site as one of the disposal locations. However, pharmacy law does not authorize pharmacies to take back sharps, unless there is a county-adopted needle exchange program in place.

At the October 2008 Board Meeting, the board approved a policy statement that:

California law does not authorize pharmacies to accept the return of sharps when appropriately contained in an approved sharps container.

The board reserves its enforcement discretion about whether to intervene with any pharmacy that takes back sharps containers inappropriately.

However, until this matter is fully resolved, the board does not anticipate

intervening in such practices. Nevertheless, this policy may change as a result of a complaint or public safety issue.

This policy statement will be published in the January 2009 *The Script* newsletter.

Additionally, at the October 3008 Board Meeting, the board agreed to sponsor a statutory amendment to allow pharmacies to take back sharps. This proposal was proposed as an amendment to section 4146:

A pharmacy may accept the return of needles and syringes from the public if contained in a sharps container as defined by Health and Safety Code section 117750.

A similar provision is contained in this year's SB 26 (Simitian).

During the Enforcement Committee meeting, the committee asked for clarification of disposal options of these returned products. Jim Cropper (CIWMB), Kelvin Yamada and Steve Kubo (CDPH) described the three methods: Household Hazard Waste collection facilities, use of mail back container or collection at consolidations centers (including pharmacies).

The CDPH advised the committee that individual agencies can have the products sent to an incineration facility. The CDPH also highlighted some problems during transportation of the products, including occasional cases where returned products have fallen from trucks. There are also investigations resulting from stolen containers and sharps showing up at recycling centers because people put them in bottles that are turned in to the recycling center. The CDPH anticipates seeing more problems now that the ban has been implemented.

Discussion at the meeting also included the question of the cost and who will pay for these programs. While some counties are providing grants to cover the costs, typically one to two years of grant money is required to establish the program. At that point, however, the grant money is gone.

Members of industry indicated that they are complying with local ordinances in conformance with sharps take back requirements. Longs, specifically, indicated that they are receiving not only returned needles, but also drugs. In addition, needles are being returned in unauthorized containers. While Longs Drugs have sharps containers available for sale, many consumers are not returning the used needles in sharps containers. San Luis Obispo (SLO) is providing Longs with containers to place the sharps units directly into the container. Consumers do put other items in the containers. SLO is also arranging for the disposal of the needles and is paying for it with a two-year grant. Marin County has a similar program and also pays for the disposal. In Marin County, the county also pays for the sharps container.

According to comments at the Enforcement Committee Meeting, patients appear resistant to purchasing mail back containers, which cost over \$20. Also, there is a company that is promoting the ability of pharmacies to melt sharps units. To do this, a specific sharps container is used that when returned by the customer, can be melted at the pharmacy. The cost of each unit is about \$1,800 and the pharmacy would be left with the cost to implement.

Longs provided some "lessons learned" from their efforts in various parts of the California and stated that the costs for these solutions make the programs cost prohibitive. They also indicated that public education is a key component to ensure that needles are returned in sharps containers. Longs suggested that there be a uniform public education and outreach.

The CPhA stated that CIWMB may not be aware of some of the hidden costs and all of the different laws that cover such disposal, and expressed willingness to work with the board and the other interested parties in finding solutions.

### 3. **FOR DISCUSSION: Future Activities to Support E-Prescribing Implementation**

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.

The board hosted this forum to provide information about e-prescribing in hopes of fostering its implementation in California. A number of patient and health care advocates have strongly pressed the need for increased use of e-prescribing for prescription medicine. 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. In mid-2008, the DEA sought comments on its proposal to allow e-prescribing of controlled substances. The board submitted comments, and while supporting e-prescribing of controlled substances noted that the DEA's proposed requirements made e-prescribing much more stringent than written orders.

The California HealthCare Foundation also sponsored a forum on e-prescribing on November 20 in San Francisco. Generally, the two forums were comprised of similar presentations. Moreover, the two forums provided opportunities for strong policy initiatives to move forward encouraging e-prescribing in California.

Executive Officer Herold is a member of the group formed by the California HealthCare Foundation to work towards achieving e-prescribing in California by 2012, which was one goal in Governor Schwarzenegger's 2008 health reform package that was not enacted.

Recently, Ms. Herold and the executive officer of the Medical Board met with the California HealthCare Foundation to discuss future activities to bring our licensees together to implement e-prescribing.

### 4. **FOR ACTION: Fingerprinting Initiative of the Department of Consumer Affairs**

#### Background:

For a number of years the board has fingerprinted all applicants to secure criminal background information before issuing a license. This is not true of all our sister boards.

Since the fall, Department Director Carrie Lopez has been advocating a department-wide initiative to ensure that health board licensees have all been fingerprinted. One of the specific

requirements detailed by the director is that all health boards within the department implement a plan for securing fingerprints from all licensees regardless of when they were first licensed.

When researching the possible impact to board operations to implement such a change, staff learned that the board was fingerprinting pharmacist applicants as early as September 1949, and we estimate that approximately 150 pharmacists licensed before this date still hold active licenses but who were not fingerprint cleared with the Department of Justice. The board has been researching criminal backgrounds of applicants longer than any other agency in the department.

Meanwhile to ensure thorough, complete and expedient review of convictions and arrests of board applicants and licensees, the board is seeking establishment of a Criminal Conviction Unit to investigate subsequent arrest and conviction information received from the Department of Justice on board licensees. This unit will be comprised of six staff dedicated to the retrieval, review and investigation of subsequent arrests and convictions – “rap sheets.” In addition, the unit will be responsible for the immediate review of a rap sheet to determine the category of conviction, whether it is substantially related to the duties, qualifications and functions of a licensee, the seriousness of the offense and the imminent threat to the health and safety of the public.

The board receives approximately 3,000 arrest notifications a year. The creation of this unit will ensure the timely review and investigation of such notifications and allow the board to pursue administrative action as necessary in the interest of public protection. The projected costs for this unit are approximately \$640,000 annually, and this budget augmentation has been added to the Governor’s Budget for 2009-10, reflecting the Administration’s interest in securing such timely review as a public protection initiative. The board hopes to initiate this unit in several months, and fund the staffing until July 2009 from redirections from other board programs.

**5. FOR INFORMATION: Citation and Fine Program Overview 2006-08**

During the Enforcement Committee Meeting, Supervising Inspector Bob Ratcliff provided an overview of the citations and fines issued by the board during fiscal years 2006-07 and 2007-08. This presentation was requested by President Schell and CPhA, following the board’s specific presentation on citations and fines that focused on prescription errors that was presented at the July 2008 Board Meeting.

Following the presentation, the committee discussed with the audience whether citation and fines should be issued, whether this was appropriate for a first offense, and the role of the board as a consumer protection agency. At the end of the discussion, CPhA emphasized its desire for compliance inspections by the board, to ensure pharmacies and pharmacists are compliant with California’s requirements, and strongly pressed the need for these inspections at least once every three years.

**6. FOR INFORMATION: DEA Policy on Correcting Schedule II Prescriptions**

In October 2008, the board received clarification from the Drug Enforcement Administration on the Final Rule *entitled Issuance of Multiple Prescriptions for Schedule II Controlled Substances* (72 FR 64921) as it relates to the changes that can be made by a pharmacist.

As highlighted by the DEA, the preamble to the final rule is in conflict with information posted on the DEA's website regarding changes a pharmacist may make to a Schedule II prescription after oral consultation with the prescriber.

In light of this confusion, the DEA is instructing pharmacists to adhere to state regulations or policy until this matter is resolved through a future rulemaking.

California law does not specifically indicate what changes a pharmacist can make to a Schedule II prescription. Rather our law provides that both the date and signature of the physician must be in the prescriber's handwriting. California Code of Regulations Section 1761 (a) allows for a pharmacist to contact a prescriber for oral clarification on a prescription that is ambiguous, erroneous, irregular, uncertain or contains an omission, unless that omission is the prescriber's signature or date.

A copy of the DEA notification is provided in **Attachment 6**. An article on this topic will be published in the January 2009 *The Script*.

**7. FOR INFORMATION: Theft of Dangerous Drugs from the Pharmaceutical Supply Chain**

At the Enforcement Committee Meeting, discussion included that California Pharmacy Law requires that all deliveries of dangerous drugs and devices may only be received by and signed for by a pharmacist or designated representative. Further, the law specifies that delivery of such products to a hospital's central receiving area must be subsequently delivered to the hospital pharmacy within one working day, and the pharmacist on duty must immediately inventory the products. (Business and Professions Code Section 4059.5(a) and (c))

Board staff received correspondence from Kaiser Permanente requesting the board's assistance in communicating the delivery requirements for dangerous drugs and devices to pharmacies. According to information received from Kaiser, despite numerous attempts to address this issue with common carriers like FedEx and UPS, deliveries are still made to unauthorized locations.

The board does not regulate common carriers, nor is there any requirement in pharmacy law requiring such licensure to handle dangerous drugs and devices. However, board licensees are responsible for ensuring the appropriate delivery, receipt and handling of such products.

In July 2008, the board included an article in *The Script*, which highlighted the problem of drug diversion from common carriers and stated that the board, as well as the DEA, holds licensees/registrants accountable for failing to take actions to prevent, discover, and report in-transit thefts as required by law. This article highlighted that as a result of these thefts, dangerous drugs are sold on the street, on the Internet, or introduced into the medication supply chain by being sold to pharmacies and wholesalers. **Attachment 7** contains a copy of the article included in the July 2008 as well as the correspondence received from Kaiser.

**8. FOR INFORMATION: Summary of the Enforcement Committee Meeting of December 9, 2008**

A copy of the minutes of December 9, 2008, Enforcement Committee Meeting is provided in **Attachment 8**.

**F. FOR INFORMATION: Second Quarterly Report on Enforcement Committee Goals for 2008-09**

A copy of the second quarter's status of Enforcement Committee Goals is provided in **Attachment 9**.

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

A copy of the board's enforcement statistics is provided in **Attachment 10**.

# Attachment 1

*Request from San Diego County to Provide  
Doxycycline First Responders and Their  
Families in Advance of a Declared  
Emergency*



# County of San Diego

JEAN M. SHEPARD  
ACTING DIRECTOR

## HEALTH AND HUMAN SERVICES AGENCY

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Disease Prevention/Health Promotion  
Emergency Medical Services  
HIV/AIDS Services  
Medical Quality Assurance  
Public Health Laboratory  
PH Nursing/Border Health  
TB & STD Control  
Vital Records

<Month / Year>

**Subject:** ProphyKit Participation Information Letter

Dear Employee,

You are receiving this letter and a Screening and Consent Form because you have been identified as a "First Responder or Critical Access Employee" (FRCAE). A FRCAE is someone involved in the initial response to a public health emergency and must physically respond to such an event within the first 6 to 8 hours. As such, you are critical to the continuity of government and provide critical services as a part of the agency, department, division, or jurisdiction at any level of government.

### **Background**

The County of San Diego, Health and Human Services Agency (HHS) through support from the California Department of Public Health (CDPH) and the Centers for Disease Control and Prevention (CDC), is implementing the FRCAE Home Emergency Prophylaxis Kit (ProphyKit) program to improve Public Health Emergency Preparedness and readiness. This letter is provided to help you make an informed decision on whether or not to participate in this program which may involve taking medication if a public health emergency occurs. If this letter or the attached consent contains words or information that you do not understand please ask your employer to explain it to you. Along with this letter, you have an unsigned copy of this *FRCAE Screening and Consent Form* to review and think about or discuss with family or friends before making your decision to participate or not.

When reading the FRCAE Screening and Consent Form, the words "you" and "your" refer to each person taking part in the program, including your immediate household members. To participate in this program, you must be familiar with the risks and benefits of this program. This process is known as informed consent.

You will be required to sign the *FRCAE Screening and Consent Form* if you decide to take part in this program. This program can involve everyone in your household, or just yourself if you so choose. All adults who live in your household (18 years of age and older) who wish to participate must agree to take part in this program. If there are participants who are minors (less than 18 years of age) or adults not able to consent for themselves in the household, a parent or legally authorized representative must give permission for them to take part. This is accomplished by the legally authorized representative signing the informed consent form on behalf of the person unable to consent for themselves.

### **Purpose**

The purpose of this program is to place medicine, in a (ProphyKit, in people's homes, so that the medicines would be immediately available if a public health emergency were to occur involving an anthrax exposure event. The ProphyKit is a clear bag that contains individual emergency medicine for each member of your household participating in this program. The ProphyKit contains prepackaged-child-resistant bottles of antibiotics containing an antibiotic named doxycycline. This medicine is used to treat people who have been exposed to anthrax. Anthrax is a germ that causes severe infections.

The ProphyKit contains a brochure which highlights:

- How and when to use this drug
- Information about doxycycline

- Directions **not** to use the drug unless instructions are given by the Public Health Officer of the County of San Diego or a representative for a specific public health emergency.

**The medicine in the PropyKit is to be used ONLY in the event of a specific public health emergency if you are told to do so by the County of San Diego Public Health Officer.**

The only reason you may be excluded from participating in this program, is if you or your household member(s) know they are allergic to doxycycline. If any member has a known allergy to doxycycline, the entire household will not be eligible to participate in this program for public safety reasons. If the FRCAE employee is not allergic to doxycycline, the FRCAE employee alone will remain eligible to participate. You may receive a signed and dated copy of all pages of the *FRCAE Screening and Consent Form* and any other necessary written information before you receive any medications, if you make a formal request for the copies..

### **Procedures**

The *FRCAE Screening and Consent form* contains information to help HSA decide if you and your household members are medically eligible to participate in this program. If so, you will be asked to sign the consent portion of the form. You will also be asked to identify anyone under 89 pounds. If you agree to take participate in this program, you and your household members will be asked a series of questions about each member's medical history, especially medications and allergies. You will also be given a brief questionnaire inquiring about your opinions about preparing for a public health emergency.

Your responses will be entered into a computer by clinical personnel. You may refuse or skip any question you do not wish to answer. Your refusal to answer some questions may prevent your participation in the program. These questions will determine if your household is medically eligible to participate in the PropyKit program. If you and your household members agree to participate, you will all be asked to sign this consent form. Approximately 1-3 months later, a PropyKit bag will be shipped to your listed household location.

You will be instructed to:

- Leave the inner packet sealed and closed
- Keep the PropyKit out of the reach of children and pets in your home
- Store the PropyKit bag in a cool, dry place and not in your bathroom or medicine cabinet

**The best location to store your PropyKit is the top shelf of a bedroom closet.**

You will be expected to bring your PropyKit back into your work location **annually** on the date of your performance evaluation. During this time, you will be required to complete a questionnaire regarding this program that may include:

- The experiences you have had since having the PropyKit in your home
- How you stored the PropyKit
- Your opinions about preparing for a public health emergency
- If opened, why the bag was opened

### **Caution**

**Unless directed to do so by the County of San Diego Public Health Officer for a public health emergency, do not open the sealed bag or take the antibiotic medicine contained in the PropyKit for any reason.**

### **Risks**

If the PropyKit is stored, not opened and the medicines not taken by anyone, there will be no health risks from this program. If the medicines are taken, certain side effects are possible with the antibiotics in the PropyKit.

#### **Common Side Effects**

- upset stomach, vomiting, diarrhea
- yeast infection in women
- increased sensitivity to sun and sunburn

#### **Allergic Reaction**

Doxycycline may cause an allergic reaction, such as a skin rash or, in very rare instances, allergic shock or other serious side effects. Serious allergic reaction may be life threatening.

### Additional Risks

Some participants may feel stress from having the ProphyKit in their home. Some subjects may feel guilt because they will have medicine in the event of a public health emergency when others do not. Participants may also feel uneasy due to the ProphyKit being in their home for use during a terrorist attack. Care should be taken to avoid frightening young children in the household that do not understand discussions about emergencies and terrorism. The ProphyKit must be kept out of the reach of children and persons who may not be able to read or understand the label.

### Warnings

Special Note for Participants that meet any of the following criteria:

- If taking Accutane (isotretinoin) stop isotretinoin if headache develops
- If you are taking Coumadin (warfarin), or Lanoxin (digoxin) you and members of your household are still eligible to take part in the program but should not begin prophylaxis with the doxycycline until contacting a physician or calling 211 first. Once contacted, a doctor may direct you or your household member to adjust the dosing of these medications if appropriate. If you are allergic to doxycycline, you and your household members will be ineligible to participate in the program. If one of the household members is allergic to doxycycline, the entire household will be ineligible to participate and only you may participate if not allergic.
- Women who are pregnant or of childbearing age, may take part in the program if you or women in the household are of childbearing age, even if pregnant. However, please note that there is limited information about side effects of these drugs during pregnancy. If the mother of an unborn baby takes doxycycline, permanent staining of your child's teeth or poor bone development can result. In addition, there is a small chance of liver disease in some pregnant women.
- Birth control pills may not work as well as intended when taking doxycycline. It is advised to use another form of birth control if you are taking doxycycline to reduce the possibility of an unwanted pregnancy. If you suspect that you are pregnant when instructed to take the medicine, notify your primary care provider or the Public Health Officer or the representative immediately for further instructions.
- Taking anti-seizure medicines Dilantin (phenytoin), or Tegretol (carbamazepine) may decrease the effectiveness of doxycycline and will not work as well. If you are taking these medications, you and members of your household are still eligible to take part in the program but you should not begin taking the doxycycline until contacting a your primary care provider or calling 211 first. Once contacted, a doctor may direct you or your household member to adjust the dosing of the doxycycline.
- Do not take antacids with aluminum or magnesium, vitamin supplements with calcium, magnesium or iron, dairy products, colestipol or sucralfate within 4 hours before or after taking doxycycline as this will reduce the effect of the doxycycline.

### Special Note for Households with Children

Your household may take part in the program, even if you have children in the household. Doxycycline has not generally been approved by the FDA for treating children under the age of 9 except for treatment due to exposure to Anthrax. Please note that the medicine in the ProphyKit may cause permanent staining of the teeth in children younger than 9 years old. This means that their teeth can become grayish in color and this color does not go away. This medicine can also cause bone growth delay in premature infants, but this side effect goes away after the medicine is finished.

### New Findings

You will be notified of any findings that might change your decision to be in this program.

### Benefits

By participating in this program, you will learn about preparing for emergencies. This program will provide information about the use of ProphyKit stored in homes to protect people if an Anthrax exposure event should ever occur. If an Anthrax exposure event ever occurs in your area, the medicines in your ProphyKit will protect you and your household members from developing an Anthrax infection. However, the possibility of an anthrax exposure event in your area is very low, and the ProphyKit does not provide complete protection if an Anthrax event should occur.

### Costs

The County of San Diego is providing the drugs contained in the ProphyKit is provided at no cost to you and your household during this initial program period. ProphyKit replacement costs are to being determined.

### Alternatives

Your alternative is to not participate in this program. You may wish to speak to your personal physician about alternatives to doxycycline.

## **Confidentiality**

This section explains how personal health information and other information collected about you for the program may be used. Your personal health information includes, but is not limited to, information that was collected for your entry into this program and information that is collected during the program.

Federal regulations give you certain rights related to your health information. These include the right to know who will be able to get the information and why they may be able to get it. The County Public Health Officer must get your authorization (permission) to use or give out any health information that might identify you.

### **What information may be used and given to others?**

If you choose to be in this program, the clinical screening health personnel will receive the *FRCAE Screening and Consent form*, which includes personal information about you and your household participants.

### **Who may use and give out information about you?**

Information about your health may be used and given to others by the clinical screening health personnel and staff. They might see the screening forms and questionnaires completed during and after the program. This information is used to determine your eligibility to participate in the program and your safety.

### **Information about you and your health which might identify you may be given to:**

- The County Public Health Officer or designee
- Your jurisdiction's Human Resources Office
- The ProphyKit Dispensing Pharmacy
- The California Department of Public Health

### **Why will this information be used and/or given to others?**

Information about you and your health that might identify you may be given to others that are directly involved in this program to protect your health or to report a serious side effect experienced after you take this antibiotic. The information may also be used to meet the reporting requirements of governmental agencies. The results of this program may be published in scientific journals or presented at medical or health related meetings, but your identity will not be disclosed when used for this purpose.

### **What if I decide not to give permission to use and give out my health information?**

By signing this consent form, you are giving permission to use and give out the health information contained on the *FRCAE Screening and Consent form*, and the *Baseline Evaluation Questionnaire* and the *Follow-up Evaluation Questionnaire* for the purposes described above. If you refuse to give permission, you and your household members will be ineligible to participate in the ProphyKit program.

### **May I review or copy the information obtained from me or created about me?**

Yes, you have the right to review and copy your health information.

### **May I withdraw or revoke (cancel) my permission?**

Yes, but this permission will not stop automatically. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to your employer. If you withdraw your permission, you will not be able to continue your participation in the ProphyKit program. When you withdraw your permission, no new health information which might identify you will be gathered after that date. Information that has already been gathered may still be used and given to others.

## **Program Related Injury**

It is important that you follow the instructions. DO NOT take the medicine contained in the ProphyKit unless instructed to do so by the County of San Diego Public Health Officer or his/her representative during a declared public health emergency. In the event these instructions are not followed and a member of your household is injured or becomes ill, the cost of treating such injury or illness will be billed to you or your medical insurance. Your health insurance company may or may not pay for treatment of injuries as a result of your participation in this program.

## **Voluntary Participation**

The participation of each member of your household in this program is based on their personal choice unless they are a minor or unable to consent. Any member of your household may personally decide not to participate or may leave the program at any time. No member of the household must feel pressure from other members about participating. A decision to not participate in the program or to leave the program will not result in any penalty. You may also refuse or skip any question if you do not wish to answer; however, your refusal to answer certain questions may prevent you from

participating in this program. If you decide not to participate, it will not affect your employment or current benefits or services that you are receiving. If you decide to stop taking part in the program after you receive a ProphyKit, you will be asked to return it to your employer.

### **Questions**

Please ask as many questions as you have about the program before agreeing to participate. If you have additional questions about the program you can call 211 at any time and ask to speak to the HHSA ProphyKit Program point of contact.

### **For More Information**

The County of San Diego community information number, 211, can be used for community, health, and disaster related information questions that you or a household member can call if you have any questions about the program. You will be referred to the HHSA ProphyKit point of contact. You should the poison control center at 800-222-1222 if someone in your household opens the ProphyKit or takes any of the medicine, no matter what the reason if the County Public Health Officer of San Diego or his/her representative has instructed you to take it during a declared public health emergency. If you or someone else takes the medicine ProphyKit, without the County Health Officer's instruction to do so, you should seek report the event to the poison control number and then seek medical assistance if instructed to do so.

If I have any questions about my rights to disclose medical information I may contact the San Diego County SNS/CRI Coordinator:

San Diego County SNS/CRI Coordinator: Jack Walsh  
Strategic National Stockpile Coordinator, Cities Readiness Initiative Coordinator  
County of San Diego, Health and Human Services Agency, Public Health Services  
Disaster Medical & Health Emergency Preparedness  
6255 Mission Gorge Road, Mailstop: S-555, San Diego, CA 92120  
Office: 619-285-6591 Cell: 619-572-4298 Fax: 619-285-6531  
Email: Jack.Walsh@sdcounty.ca.gov

## 6. Acknowledgements

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- *<insert comment about review from the California State Board of Pharmacy (when applicable)>*
- *<insert comment about review from the California Medical Board (when/if applicable)>*
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## 7. References

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<sup>1</sup> For doxycycline approval, see *Federal Register*, Nov 2, 2001, Vol 66, No. 213, pp. 55679-55682; for ciprofloxacin, see [http://www.fda.gov/cder/foi/nda/2000/19-537S038\\_Cipro.htm](http://www.fda.gov/cder/foi/nda/2000/19-537S038_Cipro.htm) (accessed March 30, 2006).

<sup>2</sup> Brouillard JE, Terriff CM, Tofan A, Garrison MW. Antibiotic selection and resistance issues with fluoroquinolones and Doxycycline against bioterrorism agents. *Pharmacotherapy*. 2006 Jan; 26(1):3-14.

<sup>3</sup> <http://www.bt.cdc.gov/agent/anthrax/faq/preventive.asp>

<sup>4</sup> [http://www.fda.gov/CDER/drug/infopage/penG\\_doxy/doxypreg.htm#P5\\_169](http://www.fda.gov/CDER/drug/infopage/penG_doxy/doxypreg.htm#P5_169) and <http://www.fda.gov/cder/drug/infopage/cipro/ciproreg.htm>

<sup>5</sup> Friedman J, Polifka J. *Teratogenic effects of drugs: a resource for clinicians (TERIS)*. Baltimore, Maryland: Johns Hopkins University Press, 2000:149-195.

<sup>vi</sup> <http://www.hhs.gov/ocr/hipaa/>

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**FIRST RESPONDER AND CRITICAL ACCESS  
EMPLOYEE HOME EMERGENCY  
PROPHYLAXIS KIT PLAN**

**County of San Diego  
Health and Human Services Agency  
Disaster Medical and Health Emergency  
Preparedness**

**November 2008**

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Note: Attach this official document to the County Local  
Pharmaceutical Cache Plan as a reference

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**APPROVAL PAGE**

County of San Diego  
Health and Human Services Agency  
Disaster Medical and Health Emergency Preparedness

**First Responder and Critical Access Employee Home Emergency Prophylaxis Kit**

**Submitted by:**

---

Jack Walsh Date  
*Strategic National Stockpile Coordinator*  
*Cities Readiness Initiative Coordinator*

**Reviewed by:**

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Patrick Buttron Date  
*Bioterrorism Coordinator*

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Marcy Metz, RN Date  
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*Legal Counsel, San Diego County*

**Approved by:**

---

Wilma Wooten, MD, MPH Date  
*Public Health Officer*

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## PLAN DISTRIBUTION

- California Emergency Preparedness Office
- California Department of Public Health
- California County SNS/CRI Coordinator
- County of San Diego Public Health Officer
- County of San Diego Director, OES
- County of San Diego Chief, Community Epidemiology
- County of San Diego Chief, HHS/PHSA Pharmacist
- County of San Diego Bioterrorism Coordinator
- County of San Diego SNS/CRI Coordinator
- County of San Diego Alternate SNS/CRI Coordinator
- County of San Diego Lead, Bioterrorism Public Health Nurse
- Emergency Medical Alert Network (EMAN)
- Emergency Medical Services Department Operations

# COUNTY OF SAN DIEGO

## Health and Human Services Agency Disaster Medical and Health Preparedness Unit

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Disclaimer

This document shall serve as a general recommendation based on available data relevant to likely bioterrorism scenarios at the time of writing. There may be situations or scenarios where these recommendations may not be applicable. In the event of an actual bioterrorism event, readers must exercise clinical judgment and modify according to the specific unique situation or scenario.

## Executive Summary

In the aftermath of a suspected or confirmed bioterrorism attack, the County of San Diego Public Health Officer (PHO) is responsible for the overall management of emergency public health operations within the Operational Area (OA). The County of San Diego Health and Human Services Agency (HHS) is preparing local area First Responders and Critical Access Employees (FRCAE) and members of their immediate household with a ten day supply of doxycycline to be stored in the home. The medication will be distributed as a Emergency Prophylaxis Kit (ProphyKit) to a proposed 100,000 FRCAE households to provide immediate emergency access to antibiotics for the intended recipients (proposed 500,000 people) within 2 to 3 hours after order by the PHO. The medication inside the ProphyKit is intended to be used only for post exposure prophylaxis (PEP) under order (announcement) from the PHO in the event of a public health emergency involving the release of a biological organism such as *bacillus anthracis*, the bacteria that causes anthrax. This supply is intended to provide protection during the initial phase of the exposure. If additional medication is required beyond the ten days provided, it will be made available by HHS.

The reason for this approach is that weaponized anthrax can cause catastrophic loss of life within 72 hours. It follows that the response time to administer prophylaxis to the public is compressed to forty-eight (48) hours. For this mass prophylaxis operation to effectively mitigate public morbidity and mortality, FRCAE's must receive priority prophylaxis to ensure their availability and ability to respond and initiate the massive countywide public health response operation. By forward placing the ProphyKit in the homes of the FRCAE, the probability that the FRCAE will report for duty in a timely manner improves because the responder and their household members will already be protected. Furthermore, the time required to commence response activities for the public will decrease substantially, allowing more time to set up public dispensing sites and rapidly deploy other public dispensing modalities to meet the compressed time frame for the total response.

## Acronyms

The following list of acronyms will be used throughout the document:

ADR	Adverse Drug Reaction
CAO	Chief Administrative Officer
CDC	Centers for Disease Control (and Prevention)
CRI	Cities Readiness Initiative
DOC	Departmental Operations Center
DP-POC	Dispensing Pharmacy Point of Contact
FRCAE	First Responder and Critical Access Employee
EMS DOC(MOC)	Emergency Medical Services Department Operations Center/ Medical Operations Center
EMS	Emergency Medical Services
EOC	Emergency Operations Center
HAZMAT	Hazardous Material Response
HHSA	Health and Human Services Agency (County of San Diego)
ICS	Incident Command System
LJ/RE-POC	Local Jurisdiction / Response Entity - Point of Contact
OA	Operational Area
PHO	Public Health Officer (County of San Diego)
POC	Point of Contact
POD	Point of Dispensing
SNS	Strategic National Stockpile

## Glossary

- Contraindication - condition which makes a particular treatment or procedure inadvisable. A contraindication may be absolute or relative
  - An absolute contraindication is a situation which makes a particular treatment or procedure absolutely inadvisable and prohibited.
  - A relative contraindication is a condition which makes a particular treatment or procedure somewhat inadvisable but does not rule it out. A relative contraindication weighs in against the use of a treatment when assessing its risk versus benefit.
- Dangerous Drug (also known as Legend Drug) – means any drug or device unsafe for self-use in humans or animals, and includes the following legend: "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import. (BUSINESS AND PROFESSIONS CODE SECTION 4022, <http://www.leginfo.ca.gov>)
- Dispense – the furnishing of drugs or devices upon a prescription from a physician, dentist, optometrist, podiatrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7, or upon an order to furnish drugs or transmit a prescription from a certified nurse-midwife, nurse practitioner, physician assistant, naturopathic doctor pursuant to Section 3640.5, or pharmacist acting within the scope of his or her practice. (BUSINESS AND PROFESSIONS CODE SECTION 4022, <http://www.leginfo.ca.gov>)
- Distribution – transfer of custody of packaged and labeled pharmaceuticals from the pharmacy to the FRCAE participant intended for home storage with periodic monitoring for program compliance and quality assurance. For the purposes of this plan, distribution may be carried out by a shipping and logistics vendor (returned receipt requested) or may be shipped directly from the pharmacy to predefined central location(s).
- First Responder and Critical Access Employees (FRCAE) – priority response personnel identified as phase 1 mass prophylaxis groups during public health emergency response. Phase 1 personnel are defined as those who must physically respond to the event no later than 6 to 8 hours. These employees are critical to the continuity of government and provide critical services within any agency, department, division, or jurisdiction at any level of government. FRCAE include, but are not limited to, sworn law enforcement officers, Fire/Emergency Medical Services (EMS), Hazardous Material Response (HAZMAT), Public Health Emergency Response, Regional medical professional and medical ancillary personnel, County Office of Emergency Services (OES), Elected officials, emergency operations centers (EOC) staff and departmental operations centers (DOC) staff for all levels of government and other non-governmental response agencies. FRCAE are identified in more detail in the each respective LJ/RE *Cities Readiness Initiative (CRI) Distribution and Dispensing Plan*. FRCAE are required to respond to a public health emergency no later than 6-8 hours. For specific information, see: *County of San Diego, Health & Human Services Agency (HHSA), Stockpile and Mass Prophylaxis Plan, Alternative Dispensing Methods*.
- Furnishing – to supply by any means, by sale or otherwise. (BUSINESS AND PROFESSIONS CODE SECTION 4026, <http://www.leginfo.ca.gov>)

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- Local Jurisdiction / Response Entity (LJ/RE) – Any regional, county, or city level government agency, department, division, or jurisdiction, or non-governmental response agency participating in this plan.
- ProphyKit – synonym for Home Emergency for Home Emergency Prophylaxis Kit, a sealable tamper evident plastic bag with printed label warnings and instructions containing sealed doxycycline medication regimen bottle(s) for the FRCAE and their immediate household members for initial prophylaxis period of 10 days with a brochure (two copies per kit) explaining instructions for use
- Pre-Exposure Prophylaxis (PrEP) – Long term uses of preventive treatment or vaccinations for a disease prior to exposure so that preventive treatment or protection is in place when exposure to the disease occurs.
- Post Exposure Prophylaxis (PEP) - Is any preventive treatment started immediately after exposure or possible exposure to a disease (such as a disease-causing virus or bacteria), in order to prevent the disease from developing in humans.

## 1. Introduction

### A) Background

In 2004, the United States Department of Homeland Security and the Centers for Disease Control and Prevention (CDC) piloted the Cities Readiness Initiative (CRI). This program was a first step by the federal government to increase and enhance readiness of selected at-risk, vulnerable cities to make full and effective use of the Strategic National Stockpile (SNS) in the event of several possible types of catastrophic terrorist attacks. Of foremost concern was the ability to respond in a timely manner to a bioterrorism attack of weaponized *Bacillus Anthracis* spores aerosolized over a large geographic area. This organism causes anthrax, is highly lethal in an aerosolized form, and is considered the worse case bioterrorism scenario. In this case, antibiotics must reach 100% of the population within 48 hours to have the greatest life-saving effect in the suspected exposed geographic area.

Five dispensing modalities are proposed by the United States Department of Health and Human Services (HHS) for bolstering the nation's capacity to respond to large-scale events by providing the necessary countermeasures to the population within the recommended compressed timeframe:

1. Classical Points of Dispensing (POD) for medicines or vaccines. This is the primary means local governments currently use. The Federal government delivers material to state governments that, in turn, deliver material to local authorities that dispense the material to affected people. This mechanism has been used by many communities over many years, although not on the scope or at the tempo that a major bioterrorism event would require.
2. Direct residential delivery of antibiotics by postal carriers. With this approach, postal workers deliver medicine directly to residences. Discussions are ongoing with the United States Postal Service (USPS) to explore the advantages and limitations of this approach.
3. Pre-deployed community-based caches of pharmaceuticals for emergency use. Locally stored caches of pharmaceuticals could be at the front lines of an emergency very quickly. They would be pre-positioned in selected institutions and agencies.
4. Pre-event dispensing of pharmaceuticals as equipment to traditional and non-traditional first responders. Providing traditional and non-traditional first responders and their households with potentially needed medicines in advance to better equip them to respond to biological emergencies rapidly.
5. Pre-event placement of pharmaceuticals in individual households for use only as directed by public health authorities. Families in the United States would be supplied a medical kit of critical prescription pharmaceuticals needed during an emergency.

While one or more of these modalities will likely be used simultaneously, the combination of strategies may be tailored to fit a community's need. Looking closer at modality number four (4) above, in July 2006, the CDC conducted the Home MedKit Evaluation Study, a one year study conducted in the St. Louis Metropolitan Area in collaboration with the Battelle Centers for Public Health Research and Evaluation and the Institute for Research and

Education in Family Medicine. The evaluation study aim was to determine specific behavioral responses in three different types of households (first responder, healthcare, and public) that had been supplied with a package (aka MedKit) that contained antibiotics to be reserved for emergency use in the event of a potential release of anthrax. The MedKit in this study was a personal cache of antibiotics, along with instructions on proper storage, maintenance and use of the antibiotics during a declared emergency. The results of the study described in the Emergency MedKit Evaluation Study Report (January 2008), indicated that of the 1,535 First Responder households enrolled, the vast majority (98.7%) successfully maintained and stored the MedKit in the home as they were instructed to and refrained from opening and/or using the MedKit for indications other than its primary intent. Moreover, a primary finding of the study determined that a similar majority (95.2%) of the study participants indicated a desire to maintain a MedKit in their home and were willing to purchase one for their personal use. The report demonstrated that the CDC's Home Emergency MedKit for First Responder households is an effective alternative method for dispensing pharmaceutical countermeasures.

Consistent with the dispensing modalities proposed above by the HHSA and in line with the findings from the CDC Home MedKit Evaluation Study, the County of San Diego will develop pre-event dispensing of pharmaceuticals in personal kits as equipment to traditional and non-traditional first responders (Phase I) and their household members prior to any direct bioterrorism attack for use only as directed in a declared public health emergency. Phase 1 mass prophylaxis is defined in the *County of San Diego, HHSA, Stockpile and Mass Prophylaxis Plan, CRI-Alternative Dispensing Section*.

## **B) Planning Considerations and Assumptions**

The assumptions used to develop this plan include:

1. The County of San Diego PHO is the designated prescriber for the antibiotics contained within the ProphyKit for this specific plan.
2. Elements within this plan will be activated with an official order from the County of San Diego PHO or her/his official designee.
3. The EOC is the operations lead for this plan under the direction of the PHO. The Emergency Medical Services (EMS) Department Operations Center(DOC)/Medical Operations Center (MOC) works under the direction of the EOC.
4. The local FRCAE pharmaceutical cache plan is automatically activated when The County of San Diego PHO activates the *CRI Alternative Dispensing Section of The County of San Diego, Health and Human Services Agency (HHSA), Stockpile and Mass Prophylaxis Plan*.
5. Each LJ/RE has developed its own specific CRI Distribution and Dispensing Plan. Each plan identifies the personnel groups that are included in Phase 1 (FRCAE) and the specific total number of regimen bottles required for the FRCAE and their household members. Methods for dispensing medication in an actual emergency may vary by jurisdiction. Conversely, methods for dispensing medication in anticipation of an emergency shall follow this plan as outlined in this document and shall not vary.
6. Each LJ/RE will be notified by the OA EOC via their respective EOC using the local Incident Command System (ICS), when to activate their specific CRI Distribution and Dispensing Plan.
7. Portions of the Local FRCAE Pharmaceutical Cache have been forward placed at various worksite locations throughout the County for rapid access to on-duty FRCAE

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personnel. Details regarding this are described in the *County of San Diego FRCAE Local Pharmaceutical Cache Plan*.

8. Key stakeholders and decision makers will be trained to successfully implement this Plan.
9. Periodic (annual) monitoring and tracking of the ProphyKit will be a cornerstone of this plan. Monitoring will also account for loss of medication and address the return of medications when they expire or when the employee terminates employment.

### C) Authorizations

All pre-event dispensing of medication to employees and their families described in this plan is in anticipation of an actual emergency. Therefore, State of California furnishing and dispensing laws will be followed and involve a licensed California prescriber who furnishes the medication by secure transmission of the prescription to a licensed California pharmacy for dispensing by a licensed California pharmacist.

Authorizations pertinent to the ProphyKit plan include:

- Pharmacy, Scope of Practice and Exemptions  
California Business & Professions Code, Chapter 9, Article 12, 4050-4068  
<http://www.leginfo.ca.gov>; Describes state dispensing requirements by pharmacists for drugs and dangerous devices.
- Requirements for Prescriptions
  - California Business & Professions Code, Chapter 9, Article 12, 4040  
Describes state requirements for prescriptions for drugs and dangerous devices, including who can issue.
  - California Business & Professions Code, Chapter 9, Article 12, 4070-4078  
<http://www.leginfo.ca.gov>  
Describes state requirements for prescriptions for drugs and dangerous devices, including transmission (electronic or otherwise) of a prescription from prescriber to pharmacist as well as medication labeling requirements.

NOTE: This methodology is unlike the *County of San Diego FRCAE Local Pharmaceutical Cache Plan* that describes the forward placing and storing of prescription medication that would be dispensed to employees during an actual emergency. The main difference between these two plans is that during an actual emergency, California state law allows for waiving of many prescription furnishing and labeling requirements in the interest of public safety. The same waivers do not exist for anticipatory prescribing such as described in this plan.

## 2. Anthrax Prophylaxis with Antibiotics

### A) Antibiotic Selection

As shown in Figure 1, "Prophylaxis Antibiotic Screening", both doxycycline and ciprofloxacin are FDA approved for treatment of inhalation exposure to anthrax.<sup>1</sup> Despite this, it must be emphasized that there are limitations to the FDA approvals for both doxycycline and ciprofloxacin with regard to use by children and fetuses. More specifically, ciprofloxacin is known to cause arthropathies and cartilage complications in adults and children. Doxycycline is known to cause mottling and staining of the teeth in children.

The decision for which antibiotic would be made available to FRCAE participants is based on a number of factors including but not limited to past experience with doxycycline, consistency with current stockpiles, cost and shelf life considerations, and consistency with the CDC MedKit Evaluation Program described above. Further more, comparing ciprofloxacin to doxycycline, an article published by Brouillard et al<sup>2</sup> compares the drugs' respective susceptibility patterns and differences in cost, based on available data. Although the article discusses the possibility that ciprofloxacin was more effective than doxycycline in yersinia pestis infections (the causative agent in inhalation plague), it was based on one study done in mice exposed directly with an inoculation into the lungs. With human data lacking on inhalation plague, the decision is not compelling enough to make ciprofloxacin the primary cached antibiotic based on this one study. Moreover, the two fold difference in cost, the comparative side effect profiles, and the fact that one can essentially treat twice the number of people based on cost, substantiates the authors decision that doxycycline is the preferred antibiotic in the management of Category A bioterrorism agents. This recommendation is also consistent with other jurisdictions including neighboring Los Angeles and Orange Counties as well the CDC's Strategic National Stockpile (SNS). For the purposes of this plan, doxycycline is to be the sole antibiotic provided to FRCAE participants.

Consideration that penicillin or penicillin-like (i.e. amoxicillin) medications may be effective against Anthrax is also noted. Inherent in the risk with weaponized anthrax is the possibility that it may be resistant to penicillin-like agents. It follows that all FRCAE should be started on doxycycline or ciprofloxacin. After a minimum of fourteen days, if culture and sensitivity tests confirm sensitivity to penicillin agents, the patient may be switched to amoxicillin if indicated.

### **B) Duration of Prophylaxis**

The ten-day duration amount provided in the PropyKit should NOT be considered a complete course of prophylaxis. It is intended for immediate needs subsequent to an event, while exposure confirmation is being made and while public points of dispensing (POD) sites are being set up. Once exposure to *bacillus anthracis* has been confirmed, taking into account individual parameters, an additional fifty (50) days of prophylaxis/treatment will likely be required (sixty (60) days total). The long duration is based on the inherent "hearty" nature of Anthrax spores<sup>3</sup>. For more information on Anthrax see <http://www.bt.cdc.gov/agent/anthrax/faq/preventive.asp>.

### **C) Doxycycline Drug Interaction**

Doxycycline may interact with some medicines, affecting the way they work in the body. Such examples include the blood thinner warfarin (Coumadin), heart medication digoxin (Lanoxin), and anti-seizure drugs like phenytoin (Dilantin) and carbamazepine (Tegretol). Other medications like certain antacids, dairy products or any supplement containing aluminum, magnesium, calcium or iron will bind to the doxycycline in the gastro-intestinal tract and reduce its absorption into the blood and efficacy. Therefore ingestion of those substances should not occur within four hours of taking doxycycline.

If a prospective FRCAE participant is taking medications, either by prescription or over the counter, s/he should be aware of possibility of an interaction and be educated about the reaction. During the screening and consent process, each FRCAE participant will be given

a patient introduction letter that discusses the specific medications that are known to affect or be affected by doxycycline. If they have any questions, the FRCAE participant shall have ample opportunity to discuss those with the LJ/RE-POC and be directed to call the 24 hour information line (211). If the information line is unable to answer a specific medication related question, referrals will be made to the appropriate health-care provider accordingly.

For more information about drug interactions see the following attachments in the appendix:

- See Training Section 5. Part I. "ProphyKit Brochures"
- See Training Section 5. Part III. "Patient Introduction Letter"

## **D) Risk Considerations**

Note: It will be the responsibility of the FRCAE to inform their household member(s) of the following risks.

### ***D1. Doxycycline Use in Children***

Risks associated with use of doxycycline in children shall be communicated to the FRCAE during the screening and consent phase. These risks are that children less than 9 years old who take doxycycline may have permanent staining and/or dark colored patches on their teeth. Additionally, FRCAE participants whose household member(s) weigh less than 89 pounds are to have their dose of doxycycline reduced according to their weight. Instructions and a dosing table are included in the printed educational instructions in the brochure for Making Emergency Child Doses of Doxycycline. This brochure is available in English and Spanish versions. (See Training Section 5. part I. "ProphyKit Brochures")

### ***D2. Doxycycline Use by Pregnant and Lactating Women***

If the mother of an unborn baby takes doxycycline, permanent staining of the baby's teeth and/or poor bone development may result. In addition, there is a small chance of the development of liver disease in pregnant women. According to the Centers for Disease Control and Prevention (CDC), ciprofloxacin (500 mg, orally, two times a day for 60 days) is the antibiotic of choice for initial prophylactic therapy among asymptomatic pregnant women exposed to *Bacillus anthracis*. Ciprofloxacin should be used for at least two weeks and until susceptibility of the organism to the penicillin drug class can be determined. Once it is determined, conversion to a safer alternative can be made (i.e. amoxicillin 500 mg, orally, three times a day for a total combined duration of 60 days). Doxycycline should be used for prophylaxis only when there are contraindications to the use of other appropriate antibiotics.<sup>4</sup> It's noted that ciprofloxacin, a pregnancy category "C" agent, does not have adequate and well-controlled studies in pregnant women. An expert review of published data on experiences with ciprofloxacin (aka Cipro) use during pregnancy by TERIS – the Teratogen Information System – concluded that therapeutic doses during pregnancy are unlikely to pose a substantial teratogenic risk (quantity and quality of data=fair), but the data are insufficient to state that there is no risk.<sup>5</sup> Nonetheless, it's felt that ciprofloxacin (if available) is safer than doxycycline in pregnant women.

### ***D3. Implications for the LJ/RE***

For the purposes of this plan, it is impossible to predict who will and won't be pregnant if an event occurs and the order to begin prophylaxis is given. It will be an important

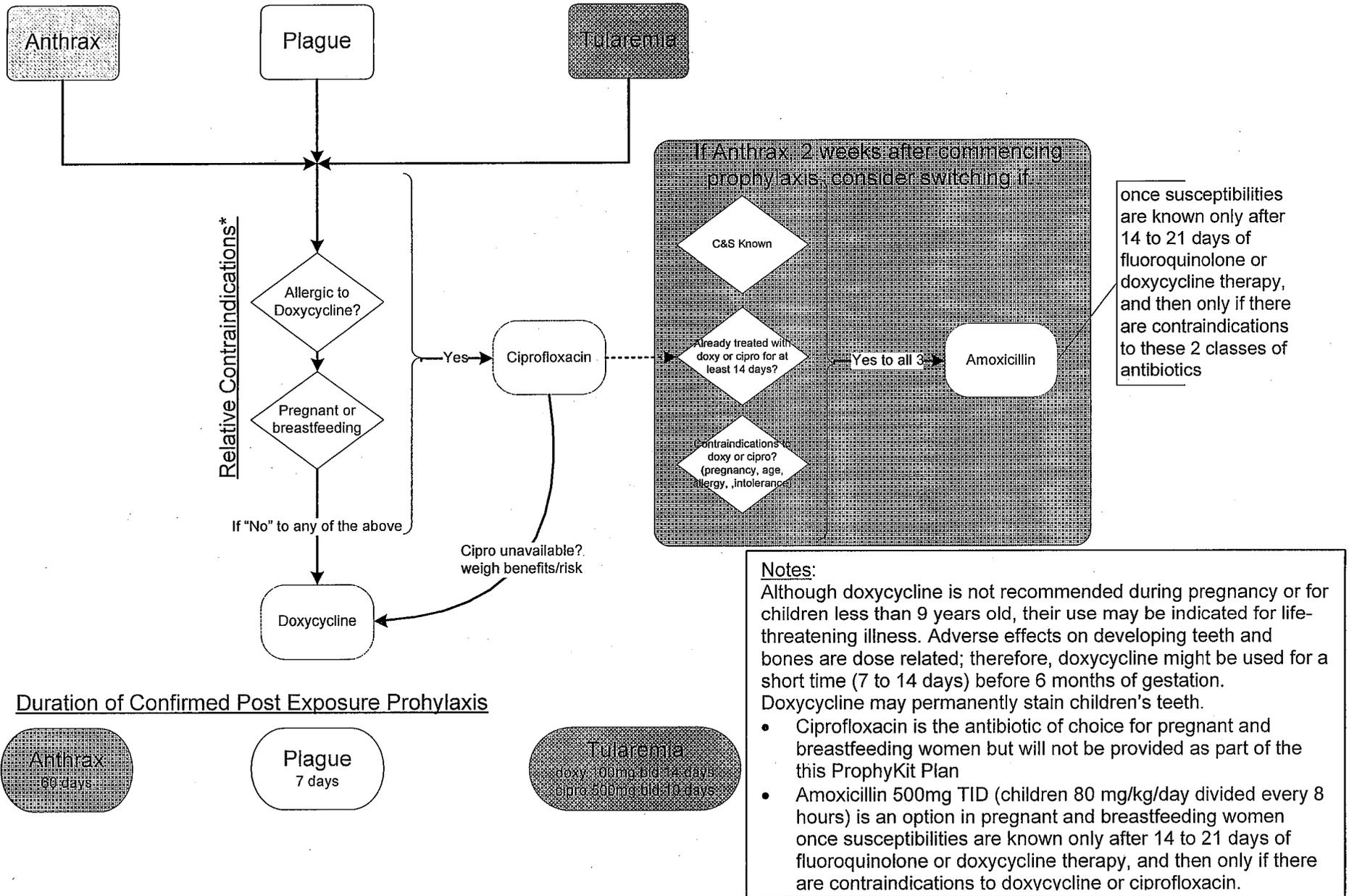
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responsibility of the LJ/RE-POC to ensure the FRCAE participant is educated regarding women of child bearing age who become pregnant during this program. If the order to begin prophylaxis is given they should refrain from taking doxycycline and seek medical advice immediately for an alternative agent from the fluoroquinolone class of antibiotics such as ciprofloxacin or levofloxacin. Likewise, when speaking about the risks with the FRCAE participant, it is important for each LJ/RE-POC to effectively emphasize the risk versus benefit in relation to the bioterrorism emergency situation this program is preparing for. Specifically, if ciprofloxacin or a similar agent from the same class is not available, the risk of anthrax exposure to a pregnant woman far outweighs the risk of doxycycline to the fetus. If any FRCAE participant does not feel comfortable with the risks, they will be given ample opportunity to discuss their concerns in more detail via the 24 hour information line (211), and/or be directed to their primary health care provider. Participation in this program is strictly voluntary and FRCAE participants may decline to be enrolled in this program without any negative consequences.

For more information about risks see the following attachments in the appendix:

- See Training Section 5. Part I. "ProphyKit Brochures"
- See Training Section 5. Part III. "Patient Introduction Letter"

Figure 1: Prophylaxis Antibiotic Screening



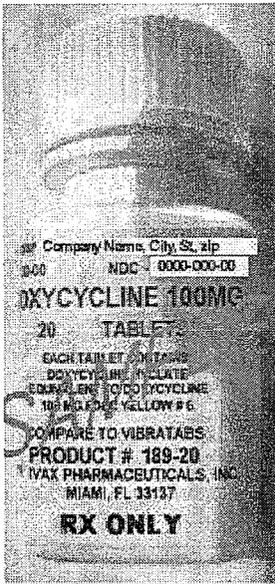
### 3. Emergency Home Prophylaxis Kit

#### A) Regimen Bottle

A ten-day regimen will be packaged in tamper evident, child resistant, 60 ml high-density polyethylene regimen bottles. (See Figure 2). The regimen bottles will be packaged by a contracted licensed re-packager to preserve the original manufacturer expiration dating. Expected shelf-life of the doxycycline in general, can be anticipated between 36 and 42 months from the date of packaging.

Each regimen bottle will contain twenty (20) capsules of doxycycline 100mg. This quantity represents ten (10) days worth of medication in each bottle, based on two (2) capsules per day per person regardless of weight. The bottles will be packaged in five (5) bundles of twenty (20) bottles for a total of one-hundred (100) regimen bottles per box. The boxes will be shipped to a contracted dispensing pharmacy for further packaging into the PropyKit, labeling, and shipping to the LJ/RE.

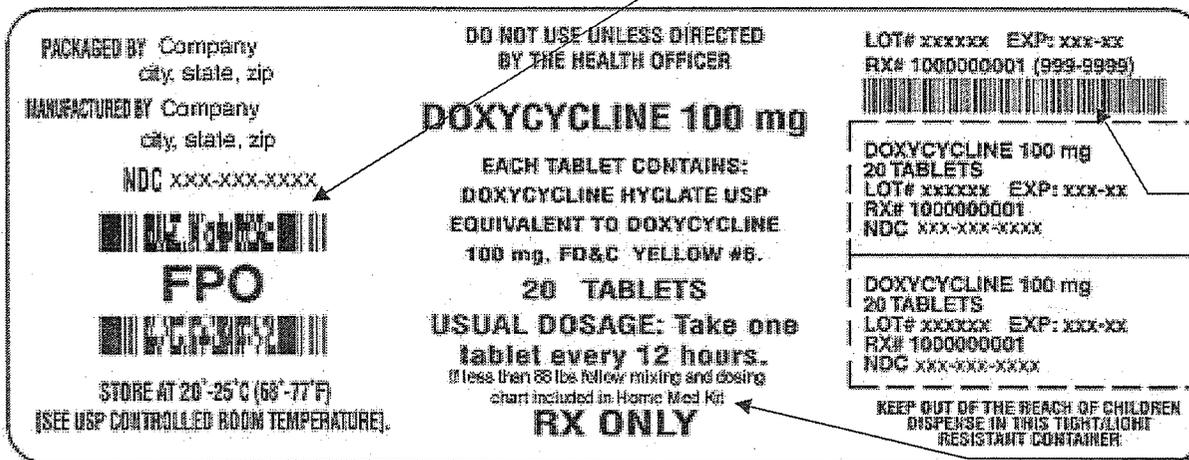
Figure 2: Sample regimen bottle



### B) Regimen Bottle Label

During the repacking process, the licensed re-packer will affix labels to the regimen bottles similar to that shown in Figure 3. The label on the bottle will include barcodes that contain the lot number, expiration date, and NDC number. This label is not to be confused with the ProphyKit bag label that the dispensing pharmacy will affix to the outside of the bag and is described below under the section 3.D. "ProphyKit Bag Prescription Label".

Figure 3: Sample regimen bottle label



The larger barcode on the left side of label is a 2-dimensional pdf4-code which has NDC# and lot # embedded.

The barcode abc the small, perfora tab on the right si of the label is the prescription # embedded in Coc 39

Change Home Me Kit to "ProphyKit"  
Add... "Do not take pregnant and cons your physician."

### C) ProphyKit Bag

Regimen bottle(s) for each FRCAE participant and each corresponding household member are to be placed inside the ProphyKit bag. In general, one bag will be used for each FRCAE and will contain enough medication regimen bottles for the entire household. The number of individual regimen bottles in each kit will depend upon the number of individuals residing in that household. Each bag is large enough to hold up to twelve regimen bottles and in the event that one FRCAE has more immediate household members than one bag can accommodate, additional bags may be used.

As shown in figures four and five, the ProphyKit bag is a sealable tamper-evident transparent plastic bag with a re-sealable outer sleeve pocket. The transparency feature will enable FRCAE participants to verify the contents of the ProphyKit without having to open it and decrease the likelihood that the ProphyKit will be opened prematurely. The bag has exterior surface art and instructions which have been written at a middle school reading level for ease of understanding. Important information related to storage and use, warning statements and around-the-clock phone numbers have been printed on the outside of the bag. Participants may call the Poison Control Center (1-800-222-1222) if, after disregarding warning instructions, they use the kit contents and are concerned about a possible medical problem associated with the contents of the kit. For general questions about the ProphyKit, they may call 211 and be referred to the appropriate public health official.

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The ProphyKit bags re-sealable outer sleeve pocket shall be accessible to the FRCAE participant and will hold a copy of the printed educational materials. A second copy of the printed materials will also be placed inside the main sealed compartment and will be inaccessible without breaking the seal. By placing two copies of the printed material (one on the outside, and one on the inside), easy access to the information is ensured while reducing the likelihood that the participant or household member will open the sealed contents until an actual order is issued to do so.

The exterior surface of the ProphyKit bag on the opposite side of the printing has sufficient space for the dispensing pharmacy to affix the prescription label(s).

The number of bags to purchase for the entire program shall be determined based on estimated number of FRCAE reported in each LJ/RE respective *Mass Prophylaxis Distribution and Dispensing Plan* plus an additional 10% overage to account for households where number of regimen bottles exceed capacity of the bag, misfills, refills, and any unforeseeable situation in which the sealed plastic bag is tampered with during the course of the program.

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Figure 4: PropyKit bag features from the back side ,

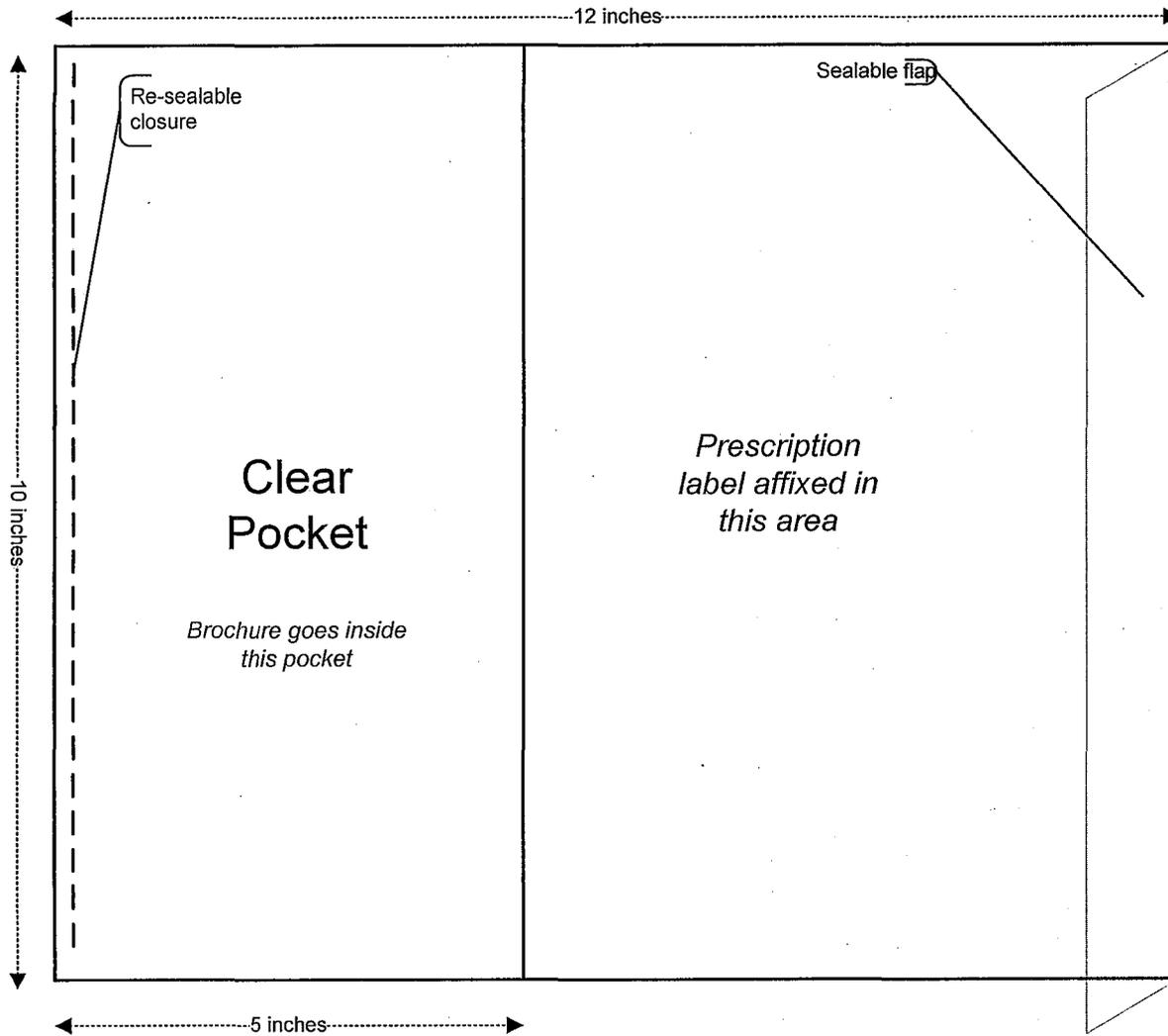


Figure 5: PropyKit bag artwork (front side of bag)

**EMERGENCY PROPHYKIT BAG**  
Home Emergency Prophylaxis Kit

**STOP**

**DO NOT OPEN** this PropyKit unless you have been told to take the medicine by a public official. If you are under 88 pounds, follow the child dosing guidelines contained in the brochure. **DO NOT GIVE AN ADULT DOSE TO A CHILD.**

**What is in this PropyKit Bag?**  
This PropyKit bag contains personal medicine bottles. This bag is called a "PropyKit" (short for Prophylaxis Kit). It is intended for those listed on the prescription label. Each PropyKit bottle has a 10 day supply of medicine for one person to use if there is a public health emergency. SEE ENCLOSED SPECIAL INSTRUCTIONS FOR CHILDREN. The medicine in the PropyKit is an antibiotic that can help keep you from getting sick if you have been exposed to certain germs, such as anthrax.

**When do I use this PropyKit?**  
Public officials will tell you when to start using this PropyKit. Wait for emergency messages from officials in your city or county, like the County Public Health Officer, the County Office of Emergency Services, or your Supervisor. These messages will be by telephone, official email, and on your TV or radio.

**Where do I keep this PropyKit Bag?**  
Keep this PropyKit in a dark and dry place out of reach of children and pets, like your bedroom closet.

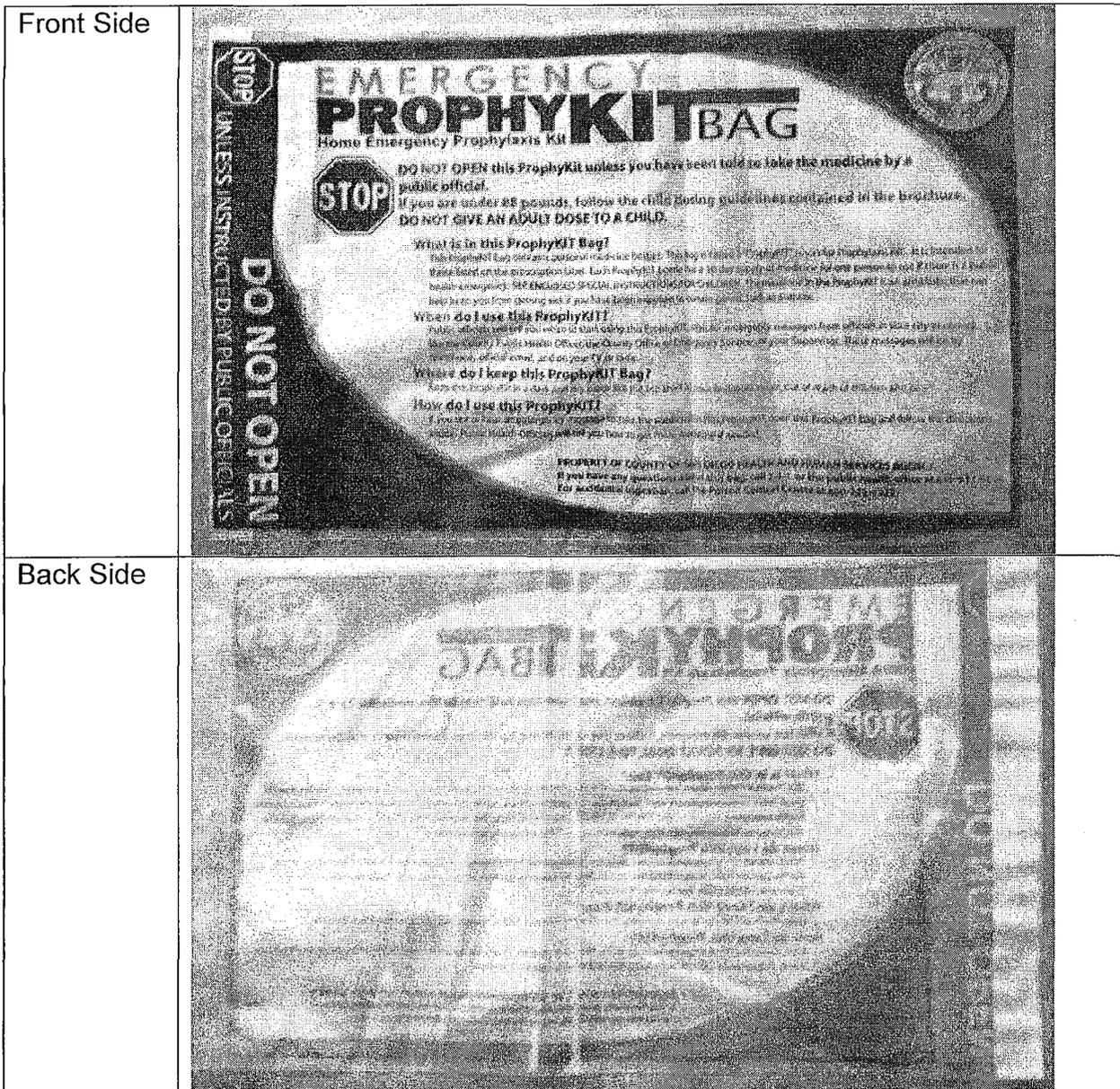
**How do I use this PropyKit?**  
If you see or hear an emergency message to take the medicine in this PropyKit, open this PropyKit bag and follow the directions inside. Public Health Officials will tell you how to get more medicine if needed.

**PROPERTY OF COUNTY OF SAN DIEGO HEALTH AND HUMAN SERVICES AGENCY.**  
If you have any questions about this bag, call 211 or the public health office at 619-531-5800.  
For accidental ingestion, call the Poison Control Center at 800-222-1222.

**UNLESS INSTRUCTED BY PUBLIC OFFICIALS DO NOT OPEN**

**STOP**

Figure 6: Photographs of Actual Bag



### D) ProphyKit Bag Pharmacy Prescription Label

During this phase of the plan, the dispensing pharmacy will affix their prescription label to the outside of the sealed plastic bag on near pocket portion without covering any important printed information. This label will contain the name of the actual FRCAE and each respective household member for which the medication is prescribed. The prescription label will contain all required elements as defined in California Business and Professions Code, Chapter 9, Article 12, Section 4076, "Requirements for Prescriptions Container and Labeling" which specifies that labeling of prescription medication, include at a minimum:

- Directions for the use of the drug.
- Name of the patient or patients
- Name of the prescriber (in this program it will be the County of San Diego PHO)
- Date of issue
- Name and address of the pharmacy, and prescription number or other means of identifying the prescription.
- Strength, quantity, and expiration date of the drug or drugs dispensed

In addition to the above, the pharmacy will assign a unique prescription number (Rx#) for each household. This number is incorporated into the FRCAE Household number and is described in more detail in the FOG under Part 6 – Pharmacy Dispensing.

Figure 7: Sample ProphyKit Bag Pharmacy Prescription Label

Doxy Rx Label (100mg cap)

Pharmacy Name: <insert pharmacy name, address, phone # here>

FRCAE Household Identifier: SM-QTY-LAST-987654 - Rx#: 123456789

Name(s): <put FRCAE + household name(s) here>

Directions: If more than 88 lbs, take 1 capsule by mouth twice daily (approx every 12 hours) for at least 10 days.

If less than 88 lbs follow the mixing and dosing chart in the brochure included in this ProphyKit. If pregnant or breastfeeding do not take doxycycline and consult your physician.

*Listen to the radio or television for further instructions whether or not you should continue this medication beyond the initial 10 days.*

Doxycycline 100mg Capsule, #20; Manuf. \_\_\_\_\_ exp \_\_\_\_\_ Lot: \_\_\_\_\_

Dr. <doctors name here>

## **4. Field Operation Guide (FOG)**

### **Purpose**

The First Responders and Critical Access Employee Home Emergency Prophylaxis Kit (FRCAE PropyKit) plan centers around pre-incident (anticipatory) furnishing, dispensing, and distribution of prescription medication to the FRCAE and their household participants. This Field Operations Guide (FOG) will provide procedures and support documents to be utilized during the implementation, management, and ongoing monitoring of the plan. County of San Diego HHSA will maintain and update this guide as needed based on recommendations and guidance from federal, state and local stakeholders as well as any exercises utilizing this guide. Amendments will be documented and distributed accordingly.

### **FOG Layout**

The layout of the FOG is as follows:

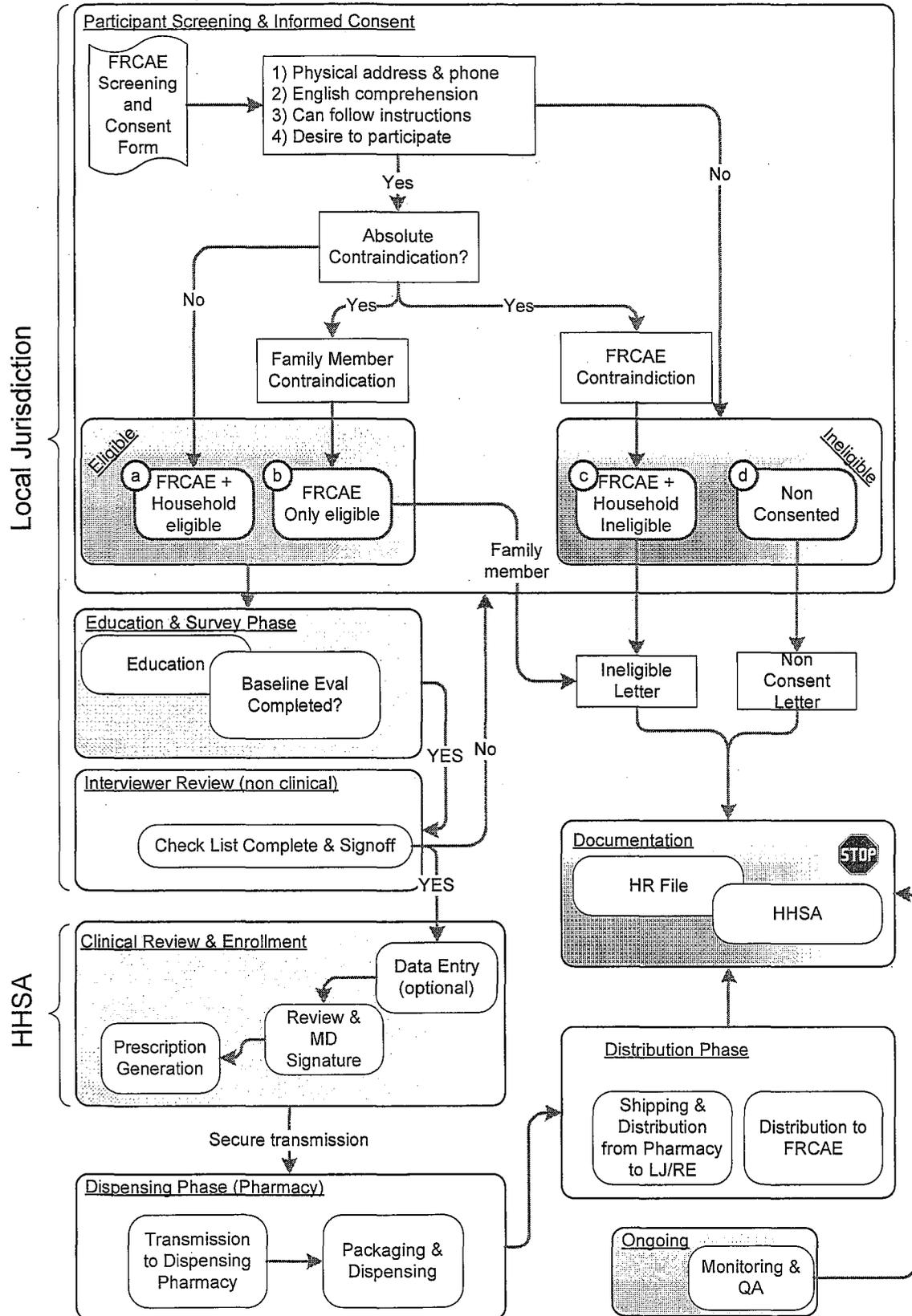
- Dispensing Protocol
- Incident Management & Response
- Post Incident Management
- Educational Support Documents
- FRCAE Screening and Consent Form
- Agency Identifier Key
- FRCAE Participant Evaluation and Questionnaire Tools
- Standard Form Letters / Examples

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A) Dispensing Protocol

Figure 8: FRCAE Plan Algorithm



**Table 1: Overview of Roles and Responsibilities**

As shown above in figure 7 - FRCAE Plan Algorithm, there are specific roles and responsibilities required to implement this plan successfully.

<b>Role</b>	<b>Responsibility</b>
1. FRCAE Screening and Informed Consent	LJ/RE
2. FRCAE Education	LJ/RE
3. Baseline Evaluation and Questionnaire	LJ/RE
4. Interviewer, non clinical review	LJ/RE
5. Clinical Review and Enrollment	HHSA
6. Prescription Transmission and Receipt (secure)	County PHO + Dispensing Pharmacy**
7. Dispensing to the patient via the LJ/RE/Shipping directly to LJ/RE	Dispensing Pharmacy**
8. Distribution (handing out the ProphyKit)	LJ/RE
9. Follow-Up Evaluation and Questionnaire (annually)	LJ/RE

\*\*Dispensing pharmacy will be contracted

### ***Roles and Responsibilities***

#### **County of San Diego HHSA shall:**

- Identify the lead County of San Diego POC for this project who may be the County SNS/CRI Coordinator. This person will oversee all elements of this plan
- Ensure formal contracts and/or memoranda of agreements (MOA) are completed for each participating LJ/RE that has agreed to participate in this County plan.
- Provide guidance, training and oversight of all elements within this plan. Particular focus will be made to ensure each LJ/RE-POC is able and making all efforts to obtain and submit the most complete and accurate screening and consent forms as possible before they are forwarded for clinical review and screening and ultimate PHO review and prescription generation.
- Provide and ensure qualified and trained staff are available to perform the clinical review and method for transferring each FRCAE Screening and Consent Form from the LJ/RE to the clinical reviewer and ultimately to the PHO. Forms must be maintained securely and in compliance with HIPPA guidelines for patient record privacy.
- Provide and ensure a method so that each prescription generated on behalf of the enrolled FRCAE and corresponding household participant(s) is transmitted securely from the PHO to the dispensing pharmacy. Transmission method shall be left up to the preference of the receiving pharmacy and shall include original copies of the prescription delivered via mail, courier or electronic means such as facsimile or secure encrypted email.
- Provide instructions and guidance to the dispensing pharmacy with respect to any dispensing issues or requirements related to this plan.

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- Provide oversight and ensure tracking of the shipping, delivery, and receipt of PropyKits from the dispensing pharmacy to intended LJ/RE destination. This oversight will also include obtaining receipt from the local jurisdiction once the FRCAE has obtained custody of the PropyKit
- Provide a 24 hour information line (211) and/or similar means (i.e. County SNS/CRI Coordinator) for FRCAE participants to request additional information.
- Provide information to and train the 211 phone response agency and also the Public Health Administration (619-531-5800) staff on the key elements pertinent to this plan that they will be asked if FRCAE participants call the numbers printed on the PropyKit bag and also in the brochure. Information and script will include the PropyKit Brochure, the CDC standard doxycycline info sheet, and directions for them to refer to their "Category A" bioterrorism binder (in development as of the writing of this plan) for disease specific information sheets.

### **LJ/RE shall:**

- Obtain jurisdictional authority and approval for participation in this plan via a formal contract or memorandum of agreement.
- Identify at least one key representative who will be the LJ/RE-POC
- Assume custody of the PropyKits from the dispensing pharmacy and distribute (hand-out) the PropyKit to the FRCAE. Transfer of custody will be documented on the LJ/RE copy of the Screening and Consent form, and will be forwarded the County SNS/CRI Coordinator for inclusion in the program database.
- Retain custody of PropyKit medication upon shelf life expiration and/or employee termination, and shall document accordingly on the LJ/RE copy of the screening and consent form, and will be forwarded the County SNS/CRI Coordinator for inclusion in the program database.
- Transfer custody of expired or unwanted medication to County SNS/CRI Coordinator or via mutually agreed upon method. Note that expired medications should be discarded as solid pharmaceutical waste, which generally includes incineration as the required method. Solid pharmaceutical waste should not be placed in the sewer or land-fill.

### **LJ/RE- POC (or designee) shall:**

- Train & educate their associated FRCAE participants and document associated competency with the training.
- Distribute the medical screening and consent forms and oversee completion and accuracy, provide assistance to each FRCAE and their respective household participant(s), and direct additional questions to the appropriate resource.
- Serve as the non-clinical interviewer whose primary role and focus will be to ensure all efforts are made to obtain and submit the most complete and accurate screening and consent forms as possible before they are forwarded for clinical assessment and PHO review. (see checklist on the last page on the Screening and Consent form)
- Maintain secure, confidential custody of each completed FRCAE Screening and Consent Form until they are transferred to the HHS clinical reviewer.
- Maintain a copy of the FRCAE Screening and Consent Form.
- Maintain secure, confidential custody of each completed baseline Evaluation and Questionnaire until they are transferred to the County SNS/CRI Coordinator or designee.
- Inspect each FRCAE's PropyKit during annual employee performance evaluation for signs of tampering, opening or loss of medication in accordance with the plan's protocols and report results to LJ/RE designated POC. LJ/RE POC will forward those findings to the County SNS/CRI Coordinator.

**FRCAE shall:**

- Receive training from the LJ/RE-POC or designee and will demonstrate competency to ensure maintenance of the ProphyKits, storage instructions, child dosing instructions and receive instruction not to open or ingest the ProphyKit contents unless directed to do so by the PHO under specific declared emergency conditions.
- Share the information and educate their associated household accordingly with respect to risks and warnings around pregnancy and dosing considerations in pediatrics.
- Store the ProphyKit as directed.
- Return the ProphyKit to the LJ/RE-POC in the event of shelf-life expiration or employment termination.

**San Diego County PHO (a licensed California prescriber) shall:**

- Receive an approved HHSA briefing for this plan.
- Approve all aspects and oversee the implementation of this plan.
- Review all the completed FRCAE screening and consent forms after the HHSA clinical review has been completed.
- Approve by signing the appropriate section on the Screening and Consent form which in effect generates the prescription. Afterwards, the prescription is transmitted confidentially and securely to the dispensing pharmacy on behalf of the FRCAE and/or their corresponding household participant(s).
- Deny by checking the DENIAL box on the Screening and Consent form and by not signing any prescription where information is incomplete or where the FRCAE or and/or their household participant is medically contraindicated and have been deemed ineligible to participate.

**Dispensing Pharmacy shall:**

- Identify at least one key representative who will be the Dispensing Pharmacy Point of Contact (DP-POC) who will follow the plan as stipulated in their corresponding statement of work (SOW) contract.
- Receive the prescription and label each ProphyKit as prescribed by the County of San Diego PHO who is a licensed physician authorized to prescribe in the State of California.
- Dispense the medication on behalf of the FRCAE participants and transfer custody to the LJ/RE-POC or designee.
- Maintain and follow all existing California laws as described above in the Authorizations section.
- Be available within a reasonable time frame to respond to questions regarding doxycycline use, side effects, and risks.

## **Part 1: FRCAE Screening & Informed Consent**

**TIMELINE:** Anticipate 2-3 months for completion.

See Figure 7 - FRCAE Plan Algorithm

See FOG Section D: FRCAE Screening and Consent Form

**PROCESS:** During the screening and consent phase, each adult (as defined by over 18 years old or emancipated minor) FRCAE participant will be asked to provide information about his/her own medical history and demographic information that may make them ineligible to participate in the ProphyKit program. This information will be recorded on the FRCAE Screening and Consent Form. Prior to completing this form, each FRCAE shall have ample opportunity to ask questions about the program and discuss any safety concerns they may have. The form will be used to determine medical eligibility and enroll FRCAE participants into one of 4 categories; a) eligible consented entire household, b) eligible consented FRCAE only, c) FRCAE + household ineligible, or d) non-consent which are described in more detail below.

Reasons for exclusion in the program (categories C and D) include:

- Lack of a physical residence with a phone (either land line or cell phone)
- Lack of basic English speaking competency or cognitive ability to understand the verbal directions in English to complete the FRCAE Screening and Consent Form
- Choice not to participate.
- Non-English speakers may be screened out during the education and baseline evaluation questionnaire phase if it is determined by the LJ-POC that the FRCAE participant is unlikely to follow the instructions to ensure compliance with the program.

### **Contraindications**

In the rare event it is determined that the FRCAE cannot take doxycycline due to an absolute contraindication such as allergy to tetracycline derivatives like doxycycline, the FRCAE and their entire household will be ineligible to participate in this program for safety reasons. Similarly, if it is determined that one or more household FRCAE participant(s) has an absolute contraindication to doxycycline, the FRCAE may be issued a ProphyKit solely for him/herself (if no absolute contraindication exists) but the entire household would be deemed ineligible. Exclusion of the entire household with one or more members who are allergic to doxycycline will help ensure the safety of households enrolled in the program. These ineligible household members may be referred to their healthcare provider for follow-up. If the FRCAE wishes to contest the ineligibility, they may do so by going through their LJ/RE-POC who shall contact the County SNS/CRI Coordinator on their behalf to discuss this specific situation. The County SNS/CRI Coordinator in consultation with the PHO will ultimately decide the appropriate and safest course of action to take.

### **Household Participation**

The FRCAE (if they are the non-adult/child's legal guardian) or another adult if they are the legal guardian or his/her adult designee will also be asked to provide information about each non-adult/child's (anyone under 18 years of age) medical history. If the FRCAE or the legal guardian or adult designee is uncertain about the answer to any of the medical screening questions for him/herself or any non-adult/child in the household, the household will not be enrolled in the program unless information is clarified within the time period provided. FRCAE participant safety is the County's primary concern and this procedure will be followed strictly for this reason. If consent cannot be obtained from all adult members for themselves and corresponding minors in the

household within thirty (30) days of the issuance of the FRCAE Screening and Consent, the household will be excluded from the initial participation phase. Additional enrollment periods may be determined and allowed at some point in the future but that will be determined after the initial participation phase.

#### **Four Categories of Enrollment**

Category A: Eligible consent entire household – FRCAE participants are eligible to enroll in the program after their concerns and questions have been adequately addressed, no absolute contraindication exists, and have their written consent has been obtained. Once eligibility is determined, the FRCAE will participate and complete an education session on maintenance of the ProphyKits, storage instructions, child dosing instructions and receive instruction not to open or ingest the ProphyKit contents unless directed to do so by the PHO under specific declared emergency conditions. Likewise, each FRCAE will complete a baseline evaluation and Questionnaire for future evaluation of the program (See FOG, Section F, Baseline Evaluation and Questionnaire). The FRCAE Screening and Consent Form shall be initially reviewed by the LJ/RE-POC or their designee who will perform the non clinical review to assess for completeness (see checklist on the form) and accuracy. Afterwards, the form will be forwarded to the HHS where it will undergo clinical review and enrollment as described in Part 5: Clinical Review and Enrollment. Once the clinical review is complete, it will be forwarded to and approved or denied by the PHO. Approval of form effectively generates the prescription which will then be transmitted to the dispensing pharmacy. A copy of the FRCAE Screening and Consent Form documenting their eligibility will be placed in the LJ/RE FRCAE HR file and a copy forwarded to HHS for program monitoring, evaluation and quality assurance purposes.

Optional: Eligible household members may receive a standard form letter (See FOG Section G, Standard Form Letters, Categories A & B) which is written to be given by the FRCAE to their primary care provider to let them know about the medication that was prescribed.

Category B: Eligible Consent FRCAE only – if any one household member, other than the FRCAE, has an absolute contraindication to doxycycline, the entire household will be ineligible but the FRCAE shall remain eligible. Ineligible household members, with allergies to doxycycline or determined ineligible to participate may receive a standard form letter (See FOG Section G, Standard Form Letters, Categories B & C) which details their options and that they may contact their health care provider for follow up and alternative prophylaxis agent if desired. A record of their consent form showing their ineligibility will be placed in the local jurisdiction FRCAE HR file and a copy forwarded to the County SNS/CRI Coordinator or designee for program monitoring, evaluation and quality assurance.

Category C: Ineligible entire household – if the FRCAE is ineligible into the program then the entire household will be considered ineligible. As with category B, category C FRCAE participants may receive a standard form letter (See FOG Section G, Standard Form Letters, Categories B & C) which details their options and that they may contact their health care provider for follow up and alternative prophylaxis agent if desired. A record of their consent form showing their ineligibility will be placed in their local jurisdiction FRCAE HR file and a copy sent to the HHS County SNS/CRI Coordinator or designee for program monitoring, evaluation and quality assurance.

Category D: Individuals who do not wish to participate in this program or wish to opt out at any time after receiving their ProphyKit must return the intact ProphyKit to their LJ/RE-POC or

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designee local who will then return it to the program coordinator. They may receive a standard form letter (See FOG Section G, Standard Form Letters Category D) which describes how they may re-enroll or opt back in at some point in the future. A record of their consent form denoting their declination will be placed in their local jurisdiction FRCAE HR file and a copy sent to HHS County SNS/CRI Coordinator or designee for program monitoring, evaluation and quality assurance.

## **Part 2: FRCAE Education**

**TIMELINE:** Shall coincide with FRCAE Participant Screening & Informed Consent, and occur in coordination with eligibility determination.

**PROCESS:** FRCAE participants shall be instructed verbally and in writing of elements related to the purpose and objective of the ProphyKit and its use. This education session will include a brief reiteration of the directions for use and storage instructions as outlined in the printed brochure.

During the education phase, the LJ/RE-POC or designee educator/trainer will review at a minimum the following elements with each FRCAE participant:

1. Purpose of the project
2. List of contents included in the ProphyKit
3. That they are not to use the contents of the kits unless a public health emergency is declared, and this emergency involves a health threat for which the medicines provide protection
4. Information and emergency numbers; instructions for accidental ingestion
5. Storage and maintenance requirements
6. Frequently asked questions- general (i.e. what is inside, when do I use, where to store, how to use including pediatric instructions)
7. Frequently Asked Questions about Anthrax; Anthrax information, CDC information sheet.
8. Doxycycline facts
9. Pediatric dosing
10. Pregnancy risks and considerations

FRCAE participants will also be provided with an emergency phone number they can call during normal business hours if they have questions about ProphyKit plan. If they use the kit contents and are concerned about a possible medical problem, they will be referred to the California Poison Control Center for assessment and emergency instructions.

In addition to the above, FRCAE participants with children or household participants less than 89 pounds will be instructed to mix the doxycycline with food or drink and take the appropriate amount of that mixture based on the child's weight, so that the entire 100mg capsule is NOT administered. Since doxycycline is known for its extremely bitter taste it is reasonable to assume that the taste alone may make children reluctant to consume the weight adjusted dose preparation unless it is sweetened with a masking food. Instructions for mixing the capsules with fruit jelly, applesauce or apple juice plus sugar to disguise this bitter taste will be included in the printed brochure. The printed brochure will explain how to make the proper dosing adjustment based on the child's weight (if less than 89 pounds). Two copies of the printed brochure will be included with each kit, one inside the sealed plastic ProphyKit bag and the other one in the outer re-sealable sleeve of the ProphyKit bag for use at anytime.

For more information about FRCAE Training, see Section 5, "Training Plan"

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**Part 3: Baseline Evaluation and Questionnaire**

**TIMELINE:** Shall be completed concurrently with the FRCAE Screening and Consent Form once eligibility has been determined and education completed.

See FOG, Section F, Baseline Evaluation and Questionnaire.

**PROCESS:** FRCAE participants shall complete a baseline evaluation and questionnaire involving multiple choice and YES/NO questions. The two main outcome measures include:

1. Perception of Risk –assesses the impact of the PropyKit on perceptions of risk, trust, self-efficacy, and behavioral intentions in a crisis.
2. Comprehension of PropyKit plan addresses education and actual adherence to the instructions for use, storage, and purpose.

Because comprehension of the program is a core requirement for enrollment, the baseline evaluation and questionnaire must be completed prior to enrollment into the PropyKit program.

**Part 4: LJ/RE-POC Non-Clinical Enrollment Review**

**TIMELINE:** Occurs concurrently with the return of the FRCAE Screening and Consent Form, after the completion of education/training and after the evaluation and questionnaire have been completed.

**REVIEWER CRITERIA:** At a minimum, has undergone an approved HHS training program for this project and demonstrated competency.

**PROCESS:** The LJ/RE-POC or their designee will administer the education and training plan to their respective FRCAE employees. This training will assist the FRCAE employee to fill and complete their Screening and Consent Form. Afterwards, the LJ/RE-POC will review it for completeness and accuracy.

The primary role of the LJ/RE-POC is to ensure the following elements are met:

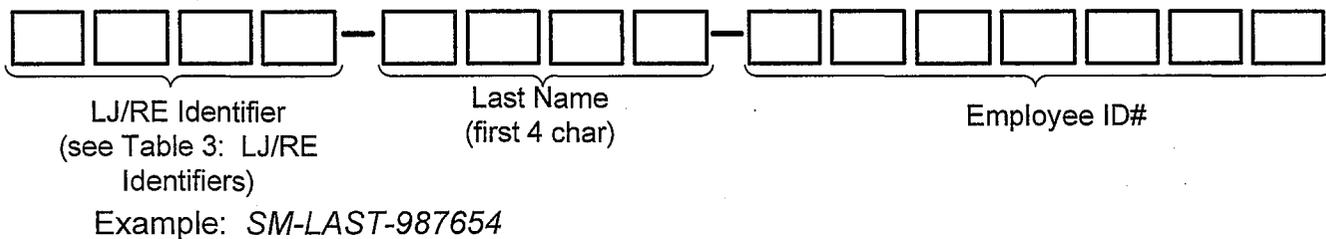
- All elements of the FRCAE Screening and Consent Form are completed
- Education completed
- Baseline Evaluation and Questionnaire completed and comprehension level is satisfied.
- Consent signed (includes counseling waiver)

**FRCAE Household Number Identifier**

On the FRCAE Screening and Consent Form is a section to generate the unique FRCAE household identifier. Unique to each household, this identifier is used for tracking and identification purposes and is a combination of the following 3 elements:

- 1) up to four letter agency identifier (i.e. SM = San Marcos, SDC = san diego city) (See FOG Section E, Table 3, "Agency Identifiers")
- 2) four letter household identifier, first 4 letters of the FRCAE last name
- 3) FRCAE – Employee number (i.e. San Diego County is 6 digits)

**Figure 8: Household Number identifier**



Note: Section 4 of the FRCAE Consent & Screening Form contains an "Interviewer Checklist" that the LJ/RE-POC interviewer will sign off on to ensure completeness. This checklist will also be reviewed by the clinical reviewer and ultimately the dispensing pharmacy to ensure the requirements have been met before they process the form any further.

**Part 5: Clinical Review and Enrollment**

**TIMELINE:** Begins upon receipt of the completed FRCAE Screening and Consent Form with the completion of the Interviewer Checklist in section 4 to ensure completeness; anticipate 1-2 months for completion of this section (depending on number of participants) after the FRCAE Screening and Consent Form is submitted to the HHSA POC for each jurisdiction.

**CLINICAL REVIEWER CRITERIA:** Has successfully completed an approved HHSA training program for this plan, has demonstrated competency, AND is a Registered Nurse or with similar clinical background and experience. Each clinical reviewer shall have met with the County of San Diego PHO if necessary and been given ample opportunity to discuss any issues, concerns, or preferences that either might have.

**PROCESS:** Once the FRCAE Screening and Consent Form has been filled out and the non clinical review completed by the LJ/RE-POC or designee as described above, it will then undergo a clinical review by one of several qualified reviewers who meet the criteria listed above in this section. The clinical review will focus on contraindications for taking doxycycline of the FRCAE and/or their associated household. Once the form is deemed acceptable by the clinical reviewer, the enrollment process may begin whereby critical information (name, no contraindications, weight) from the screening form may be entered into a database. The screening forms and all critical data elements may then be forwarded to the designated prescriber who is authorized to prescribe medication in the State of California. In this plan, the designated prescriber is the San Diego County PHO.

The prescriber will review the screening forms and/or the associated information entered into the database and by way of signature, generates the prescription for Doxycycline 100mg capsules #20, with directions consistent with those defined above in Section 3D, "ProphyKit Bag Label".

## **Part 6: Pharmacy Dispensing**

**TIMELINE:** Begins once the clinical review and enrollment is completed and the prescriptions are transmitted securely to the pharmacy. Estimated timeline depends on desired quantity of prescriptions to be filled in any given batch.

**PROCESS:**

### **Transmission of Prescriptions to Pharmacy**

Prescriptions will be transmitted by the authorized prescriber or designee on behalf of the FRCAE and their immediate household member(s) to a pre-designated contracted dispensing pharmacy in a secure confidential manner. The dispensing pharmacy will be responsible for ensuring secure transmission and handling methods are utilized of all FRCAE patient information. All materials with personal identifiers will be treated as confidential data and will be protected and respected according to HIPAA guidelines<sup>vi</sup>.

### **Dispensing Pharmacy Process (Prescription Processing, Packaging & Assembly)**

**TIMELINE:** Begins after receipt of product and upon receipt of prescription; anticipate 1-2 month(s).

**CRITERIA:** Active California Pharmacy License ([http://www.pharmacy.ca.gov/online/verify\\_lic.shtml](http://www.pharmacy.ca.gov/online/verify_lic.shtml)). (Additional criteria may be defined at a future time)

The pharmacist will review the Screening and Consent form for completeness and shall confirm:

- 1) No material changes (i.e. contraindications) have been communicated to the pharmacy since initial screening form was filled out.
- 2) Consent & Screening form, section 4, non clinical review "Interviewer Checklist" completed

Once the above is complete, the pharmacy will place a quantity sufficient of prepackaged medication regimen bottles for the entire household into the main sealable pocket of the ProphyKit bag. No more than one lot number should be used per household. The pharmacy shall refer to the Screening and Consent form demographics section to determine which version(s) (English or Spanish or Both) shall accompany the ProphyKit. A minimum of two (2) brochures will accompany each ProphyKit, one will be put inside the external re-sealable pocket, and the other will be sealed inside the ProphyKit bags with the medicine. If both languages are denoted as Primary Spoken languages in the household both versions must be included.

The dispensing pharmacy will then generate the ProphyKit Bag Prescription Label as described above in section 3D and label the outside of the bag without covering any important information or artwork on the bag. Included on the label shall be the FRCAE household identifier followed by one unique prescription number for each household. The prescription number, combined with the FRCAE Household identifier (from the screening and consent form) will aid the identification and tracking of the ProphyKit at any point along its lifecycle. The label information shall undergo a final independent verification double check that it matches the information provided on the screening form. After the kit is fully assembled, the bag will be sealed and readied for shipping to the intended destination.

Afterwards, the dispensing pharmacy shall provide (in electronic format) the list of all prescriptions filled with name(s) of each participant and the specific lot number and expiration date of the medication dispensed for each unique prescription number. This information will be provided to the SNS/CRI coordinator, so that it can be tracked accordingly.

**Part 7: Distribution and Shipping**

**TIMELINE:** Begins once assembly of prescription is complete. Anticipate ~4-6 weeks for completion (depends on quantity of prescriptions being transmitted at one time).

**CRITERIA OF DISTRIBUTOR:** ProphylKits will be shipped from the pharmacy to the LR/RE via a method to be determined which includes tracking capabilities.

When shipping the batch of ProphKits, the dispensing pharmacy will send a packing slip that will also serve as a tracking mechanism. The packing slip will include all pertinent information related to shipping and receiving, and include the contents of the package denoted by the household identifier combined with the unique prescription number.

**Sample Packing Slip / Tracking Form**

Date Sent:	_____ / _____ / _____		
Sender	_____ <i>Insert Dispensing pharmacy name &amp; address</i>		
Dispensing Pharmacy	_____		
Point of Contact	_____		
	_____ <i>Signature</i>	_____ <i>Printed Name</i>	_____ <i>Date</i>
Recipient	_____ <i>Insert Local Jurisdiction or Response Entity pharmacy name &amp; address</i>		
Contents	<i>Insert household identifiers + rx numbers</i> <ul style="list-style-type: none"><li>• SM-LAST-987654321-123456789</li><li>• SM-LAST-987654321-123456789</li><li>• SM-LAST-987654321-123456789</li><li>• SM-LAST-987654321-123456789</li><li>• SM-LAST-987654321-123456789</li></ul>		
Shipper (Pickup)	_____ <i>Signature</i>	_____ <i>Printed Name</i>	_____ <i>Date</i>
Shipper (Delivery)	_____ <i>Signature</i>	_____ <i>Printed Name</i>	_____ <i>Date</i>
Recipient	<i>(Local Jurisdiction or Response Entity point of contact)</i>		
	_____ <i>Signature</i>	_____ <i>Printed Name</i>	_____ <i>Date</i>

*LJ/RE-Point of contact to verify contents are received as indicated above. Once verified, please forward all completed packing slips to the SNS/CRI Coordinator.*

**Part 8: Follow-Up Evaluation and Questionnaire (Annual)**

PROCESS: The LJ/RE-POC or designee shall be responsible to ensure at a minimum, annual evaluation and inspection of each FRCAE ProphyKit distributed to their jurisdiction to ensure ongoing monitoring and quality assurance as follows:

See FOG, Section F, Followup Evaluation and Questionnaire.

- Follow-up evaluation and questionnaire is completed and the FRCAE will be assessed for their general knowledge and opinion about the program. The follow-up evaluation will be very similar to baseline version except that it shall also include elements related to ability to locate ProphyKit during the follow-up interview, and appropriateness of ProphyKit storage location.
- Annual Inspection is completed at the same time as the follow-up evaluation is completed, the ProphyKit will be inspected to ensure the FRCAE is still in possession of the ProphyKit and that it's free from any tampering.

Completed follow-up evaluation forms will be kept in the FRCAE HR file, and evidence of completion shall be forwarded to the SNS/CRI Coordinator.

## B) Incident Management & Response

### B1. Authority to Activate

The *CRI Annex of the County of San Diego, HHSA, Stockpile and Mass Prophylaxis Plan* is activated by direct order of the County Public Health Officer (PHO) or official designee. Upon the order of the County PHO, the LJ/RE will activate their CRI Distribution and Dispensing plan for FRCAE (1<sup>st</sup> phase/wave).

### B2. Command, Communication, and Control

See *Command and Control section of the County of San Diego, HHSA, and Stockpile and Mass Prophylaxis Plan* for specific instructions.

Upon activation of the County's *CRI-Alternative Dispensing Section of the County of San Diego, HHSA, Stockpile and Mass Prophylaxis Plan*, the local EOC/DOC will initiate the Critical Access Employee (FRCAE) or 1<sup>st</sup> phase distribution and dispensing process in the following manner:

**Table 2: Incident Management Communication Process**

<b>Communication</b>	<b>Responsibility</b>
Declaration of "Local Emergency"	County of San Diego PHO/CAO
<p>Activation of <i>CRI-Alternative Dispensing Section of the County of San Diego HHSA Stockpile and Mass Prophylaxis Plan</i>:</p> <ul style="list-style-type: none"> <li>FRCAE notified by County of San Diego PHO to open their PropyKits and begin prophylaxis. (see notification messaging section below)</li> <li>Local EOC notified by OA EOC to activate CRI Distribution and Dispensing plan.- 1<sup>st</sup> phase/wave</li> </ul>	County of San Diego PHO via OA EOC Coordinated by EMS DOC (MOC) via County SNS/CRI Coordinator or designee
Notification of elected officials	City Manager's/County Chief Administrative Officer's
<ul style="list-style-type: none"> <li>Local EOC notifies DOC (s) to activate CRI Distribution and Dispensing plan</li> <li>DOC (s) initiate 1<sup>st</sup> phase/wave of FRCAE prophylaxis</li> </ul>	Local Jurisdiction EOC (or City Manager)
<p>Notification of employees*</p> <ul style="list-style-type: none"> <li>Message directed toward those FRCAE with PropyKits to begin taking the medication for themselves and their household participants whose name is on the prescription label.</li> </ul>	Department Heads

### **B3. Notification Messaging for PHO and EOC/DOC Leaders**

Once the decision has been made by the County PHO to begin FRCAE prophylaxis with doxycycline, it should be emphasized that if any medical condition has changed since they initially received the ProphyKit, including a relative or absolute contraindication to doxycycline (see list below) that they should contact a physician or call 211 for more information before taking the medicine.

This new clinical information requires some degree of clinical judgement by a healthcare provider knowledgeable about the antibiotic medication prescribing and the exposure scenario in question. As described above in section two (Anthrax Prophylaxis with Antibiotics) if the patient is pregnant, an alternative medication (any fluoroquinolone like Ciprofloxacin or Levofloxacin) MAY be more advantageous if it is readily available. If a fluoroquinolone is not readily available, they need to exercise clinical judgement and weigh the risk versus benefit of doxycycline with a healthcare provider taking into account the likelihood of exposure.

#### **Absolute Contraindications to Doxycycline**

- Allergy to doxycycline

#### **Relative Contraindications to Doxycycline**

- Pregnant or breastfeeding at the time of the emergency
- On a medication that interferes with doxycycline as shown in the brochure (particularly coumadin or digoxin)

See Section two (Anthrax Prophylaxis with Antibiotics) above for more information about first line alternatives to doxycycline with respect to pregnancy.

#### ***Sample Script***

*".....If you have been or may be exposed to Anthrax, you must begin taking doxycycline. If you have a Home Emergency ProphyKit you may open it now and begin taking the medication as instructed on the label and in the brochure that came with your ProphyKit. If you or your family member is currently pregnant, they should NOT take doxycycline. Call your doctor or if you are a county employee you may contact your employer for an alternative medication.*

*In each ProphyKit is a brochure with detailed instructions on how to take your medication. If you have children under 89 pounds, you must follow the instructions for mixing the capsule with food and giving a portion of this mixture so that the dose is based on the weight of the child.*

*If you are currently taking any prescription or over the counter medications, refer to the information brochure inside the ProphyKit to determine if there is a potential interaction.*

*For more information or if you have any questions about the ProphyKit, you should contact your physician or call the county hotline at 211....."*

### **C) Post Incident Management**

Note: Following an incident requiring use of the ProphyKit, it is assumed that a declaration of emergency has been made. It follows that under these circumstances, certain prescription

requirements will have been waived by the California State Board of Pharmacy in the interest of public safety.

### **C1. Ongoing Prophylaxis**

The antibiotic regimens provided to local jurisdictions by the County of San Diego constitute a ten (10) day course of therapy. In the event of a confirmed anthrax exposure by the County of San Diego PHO, recommendations may be made for an additional 50 days of prophylaxis for a total of 60 days. It is expected that public medical and non-medical POD sites will be established to effectively provide prophylaxis to the entire County for the first 10-day regimen. The health department will decide during the event the method for providing a longer course of antibiotic therapy to FRCAE and their household members if required.

The reason for the limited dosage is that the pre-placement of ProphyKits is intended as a rapid, mass distribution strategy for those response personnel required in the field to set up POD sites for the general public with the 48 hour timeframe for an anthrax event and other critical functions. Within five days of beginning on this post-exposure course of treatment, local health authorities will know the location of the actual dispersion of the biological agent. At that point, health officials will be able to identify those persons who may have actually been exposed to the agent and who require an additional 50 days of antibiotic therapy.

#### **Sample Script**

*".....if it has been confirmed that you were exposed to Anthrax, you must continue receiving prophylaxis medication for an additional fifty days. The entire prophylaxis duration is for a total of sixty days. You may receive the additional supply of medication from < insert appropriate source here, i.e. POD, employer, mail, etc>....."*

*For more information or if you have any questions about the ProphyKit, you should contact your physician or call the county hotline at 211...."*

### **C2. Reporting of Adverse Drug Events**

Participants should be instructed to report adverse effects and suspected allergic reactions to their primary healthcare provider who will use an Adverse Drug Reaction (ADR) form to report to the County Health Department, if applicable. When allergic reactions are reported, sites should continue to employ existing public health policy and procedures for reporting of allergic reactions. At a minimum, the following data elements should be captured.

- Name
- Gender
- Age
- Suspected medication
- Date of Onset
- Brief Description of Event and Resolution
- Life Threatening? YES/NO
- Treatment Required? YES/NO; if yes describe

### ***C3. Post Incident Reporting***

During the event, it is likely that there will be ongoing communication and information dissemination. After the event, the LJ/RE shall continue this communication with County representatives, sharing information regarding all facets of the incident. It will be particularly important that the following information is shared, to best gauge the response effectiveness.

- number of persons provided prophylaxis
- adverse reaction reports
- ending antibiotic inventory
- what worked, what didn't work; lessons learned and opportunities for improvement

### **D) FRCAE Screening and Consent Form**

Purpose: This form is filled out in entirety by the FRCAE participant and is to be reviewed by the LJ/RE-POC or designee who performs the non-clinical review primarily for completeness and accuracy after the participant has completed the education component. Once this is done, the form is forwarded to the clinical reviewer who reviews it for clinical issues (primarily allergy) and forwards to the PHO for prescription generation (this form becomes the physical hardcopy prescription) and will eventually be transmitted to the dispensing pharmacy for prescription preparation, dispensing and shipping to the LJ/RE for eventual distribution to the FRCAE.

# First Responder & Critical Access Employee (FRCAE) Screening and Consent Form

## Section 1: FRCAE Employee Demographics

Last Name \_\_\_\_\_ First Name \_\_\_\_\_ Middle Name \_\_\_\_\_  
 Local Jurisdiction / Response Entity (LJ/RE) \_\_\_\_\_ Employee ID # \_\_\_\_\_  
 Home Address \_\_\_\_\_ City \_\_\_\_\_ State California Zip \_\_\_\_\_ Phone \_\_\_\_\_

Number of Household Members (including yourself)

Brochure Version(s) Desired  English  Spanish  
 (check one or both)

Directions: Read the the following questions and provide your answer in section 3

Question	Instructions
1.) Allergy, have you ever had an allergic reaction to any doxycycline or another tetracycline drug?	If yes, you will be asked to describe the symptoms. Note - Allergic reactions usually DO NOT include symptoms like an upset stomach, diarrhea, or headache. Tetracycline Drugs include Demeclocycline (Declomycin), Doxycycline (Adoxa, Bio-Tab, Doryx, Doxy, Monodox, Periostat, Vibra-Tabs, Vibramycin), Minocycline (Areslin, Dynacin, Minocin, Vectrin), Oxytetracycline (Terak, Terra-Cortril, Terramycin, Urobiotic-250), Tetracycline (Achromycin V, Sumycin, Topicycline, Helidac)
2.) Age & Weight - are any of your household members under 9 years old, or under 89 pounds?	If yes, you must be aware of risks associated with doxycycline in children (teeth staining), and understand how to prepare the special children's dosing doxycycline mixture.
3.) Do you currently take any medications known to interact or be affected by doxycycline?	For specific medications that are known to affect or be affected by doxycycline refer to the ProphyKit brochure. Further information and questions should be shared with your primary health care provider.
4.) Females only, is there any possibility that you might be pregnant, or become pregnant in the near future?	If yes, you must be aware of the risks and understand that pregnant or breastfeeding women should not take doxycycline and should contact your physician for a different medication in an event. Note this only applies if currently pregnant at the time of beginning the medication.

## Section 2: FRCAE Medical and Household Participant\*\* Questionnaire

Directions: Circle one answer to the questions above for each Participant**.	#1. Allergic to Doxycycline?	#2. Age & Weight	#3. Taking Medications that Interact?	#4 Childbearing age? Pregnant, breastfeeding?	For Internal Use Only	Review (initial/ date)	Pharm (initial/ date)	Pharmacy Affix Bottle Sticker
FRCAE Name	YES NO	Under 89 lb's YES NO	YES NO	YES NO	Rx Doxycycline 100 mg PO q12 hrs until gone as directed.			
Participant #1 Name	YES NO	Under 9 yrs old YES NO Under 89 lb's YES NO	YES NO	YES NO	Rx Doxycycline 100 mg PO q12 hrs until gone as directed. (if <89lbs follow dosing guidelines)			
Participant #2 Name	YES NO	Under 89 lb's YES NO	YES NO	YES NO	Rx Doxycycline 100 mg PO q12 hrs until gone as directed. (if <89lbs follow dosing guidelines)			
Participant #3 Name	YES NO	Under 9 yrs old YES NO Under 89 lb's YES NO	YES NO	YES NO	Rx Doxycycline 100 mg PO q12 hrs until gone as directed. (if <89lbs follow dosing guidelines)			
Participant #4 Name	YES NO	Under 89 lb's YES NO	YES NO	YES NO	Rx Doxycycline 100 mg PO q12 hrs until gone as directed. (if <89lbs follow dosing guidelines)			
Participant #5 Name	YES NO	Under 89 lb's YES NO	YES NO	YES NO	Rx Doxycycline 100 mg PO q12 hrs until gone as directed. (if <89lbs follow dosing guidelines)			
<i>If more than 6 in household, use additional form(s) and staple them together.</i>	Absolute contraindication	<i>If yes to any of the above, see notes section below.</i>			FRCAE Household#			

\*\*Participant is defined as a family member or significant other residing in the same household, or a caregiver of a family member or significant other residing in the same household.

LJ/RE Identifier (see table 3) \_\_\_\_\_ Last Name (first 4 char) \_\_\_\_\_ Employee ID# \_\_\_\_\_

Prescriber Signature: \_\_\_\_\_ Date \_\_\_\_\_  
 Prescriber signature effectively validates all prescription(s).

Check here ONLY if prescriptions DENIED. May denote reason on reverse.

Printed in Triplicate: Top (original) = Local Jurisdiction Copy, Middle = SNS/CRI Coordinator, Bottom = Employee

**Section 3: FRCAE & Participant Consent**

All adult participants and emancipated minors (18 and older) must sign the consent form to participate  
YES, as a member of the above household, I am willing to participate in the PropyKit program.

Household Adult Participant #1 Signature: _____	Household Adult Participant #2 Signature: _____
Household Adult Participant #3 Signature: _____	Household Adult Participant #4 Signature: _____
Household Adult Participant #5 Signature: _____	Household Adult Participant #6 Signature: _____

**Household with participants who are minors (under 18 years old) or unable to consent as adults**

Signature of Legal Guardian #1: <small>(required only if non adults participating)</small> _____	For(name of non-adult #1): _____
Signature of Legal Guardian #2: <small>(optional, sign only if legal guardian is different than #1)</small> _____	For(name of non-adult #2): _____
Signature of Legal Guardian #3: <small>(optional, sign only if legal guardian is different than #1)</small> _____	For(name of non-adult #3): _____

~if more than 3 non adult participants in household, may use additional form(s) and staple them together.

YES, I am willing to participate in the Post – Exposure Home Emergency Prophylaxis Kit (PropyKit) program. By signing below, I agree and consent to participate in this program and indicate the following:

**Participants Consent Statement:**

- I understand I am receiving antibiotics to be stored for myself and/or for others residing in my household and will only be used if told to do so by the County of San Diego Public Health officer or his/her designee.
- It has been explained to me that my participation in this program is voluntary and I may quit the program at any time and return my household's PropyKit without affecting my employment status or employee benefits or services. I understand that the decision to take antibiotics is voluntary.
- I understand that I will be asked to keep the PropyKit containing doxycycline in my home for a period of up to the expiration date and agree to bring it in annually during my performance evaluation so that integrity of the medications may be inspected by my supervisor.
- I agree to allow the prescribing physician to transmit my and any other immediate household recipients' prescriptions including name(s), address, and telephone number for the PropyKit to a licensed California pharmacy for dispensing.
- I understand that if the mother of an unborn baby takes doxycycline, permanent staining of the baby's teeth and/or poor bone development may result. In addition, there is a small chance of the development of liver disease in pregnant women. I understand that doxycycline in children under 9 years of age can cause permanent staining and/or dark colored patches on teeth.
- I acknowledge the need to reduce dose in anyone less than 89 pounds. If I or anyone in my household is less than 89 lbs, and will be taking doxycycline, I will ensure they understand and follow the pediatric dosing guidelines provided in the PropyKit brochure.
- I have read the introduction letter and PropyKit brochure (or had them read to me) for information related to doxycycline side effects and drug interactions. I have also had an opportunity to ask questions which have been answered to my satisfaction.
- I do not wish to be counseled by the pharmacist and do not have any questions for the pharmacist. If I wish to receive counseling on the medication or if I have any additional questions about this program, I understand that I may contact my family physician or call the County of San Diego Information Line [211] or the Public Health Department at (619) 531-5800 prior to taking the antibiotics.

**Program Related Injury**

It is important that you follow the instructions. DO NOT take the medicine contained in the PropyKit unless instructed to do so by the County of San Diego Public Health Officer or his/her representative during a declared public health emergency. In the event these instructions are not followed and a member of your household is injured or becomes ill, the cost of treating such injury or illness will be your responsibility to pay or bill to your medical insurance. Your health insurance company may or may not pay for treatment of injuries as a result of your participation in this program.

FRCAE Signature \_\_\_\_\_

Date \_\_\_\_\_

**DECLINE CONSENT**

**NO, I am not willing to participate for myself or entire household in the Post-Exposure Prophylaxis Program at this time. The risk and benefit of antibiotic or vaccine prophylaxis has been explained to me. I am declining participation in the Home Emergency Prophylaxis Kit Program at this time.**

FRCAE initial \_\_\_\_\_  
(if declining to participate)

Comments

**FOR INTERNAL USE ONLY**

FRCAE Household#     -

**Screening & Consent Form – TRACKING & MONITORING TOOL**

**Section 4: Screening Categories**

Each household will end up in 1 of 4 categories:

1. Contraindications Noted?  YES  NO (if no "Eligible Category A" pile) (If yes go to next question)
2. Household Member(s) only with contraindication?  YES  NO (if yes "Eligible Category B" pile) (If no go to next question)
3. FRCAE Contraindicated?  YES (if yes "Ineligible Category C" pile); STOP
4. FRCAE doesn't wish to participate YES? (if yes  "Ineligible Category D" pile); STOP

**Section 5: Interviewer Checklist / Pre-Requisites for Participation**

<input type="checkbox"/> All elements completed (Physical Address & Phone number present)	_____	_____
	Evaluator Initials	Date Completed
<input type="checkbox"/> Education completed	_____	_____
	Evaluator Initials	Date Completed
<input type="checkbox"/> Baseline Evaluation and Questionnaire <small>Section 2, Comprehension Satisfied</small>	_____	_____
	Evaluator Initials	Date Completed
<input type="checkbox"/> Consent signed (includes counseling waiver)	_____	_____
	Evaluator Initials	Date Completed

**Section 6: ProphyKit Transfer of Custody & Inspection LOG (between LJ/RE and the FRCAE)**

<b>Issuance (Yr 0)</b>	_____	_____	_____	_____	_____
	Date Issued	Issuer Name	Issuer Signature	Employee Name	Employee Signature
<b>Inspection (Yr 1)</b>	_____	_____	_____	_____	_____
	Date Issued	Issuer Name	Issuer Signature	Employee Name	Employee Signature
<small>Eval and Inspection Findings (check one):</small>					
<input type="checkbox"/> Satisfactory					
<input type="checkbox"/> Unsatisfactory, describe					
<b>Inspection (Yr 2)</b>	_____	_____	_____	_____	_____
	Date Issued	Issuer Name	Issuer Signature	Employee Name	Employee Signature
<small>Eval and Inspection Findings (check one):</small>					
<input type="checkbox"/> Satisfactory					
<input type="checkbox"/> Unsatisfactory, describe					
<b>Inspection (Yr 3)</b>	_____	_____	_____	_____	_____
	Date Issued	Issuer Name	Issuer Signature	Employee Name	Employee Signature
<small>Eval and Inspection Findings (check one):</small>					
<input type="checkbox"/> Satisfactory					
<input type="checkbox"/> Unsatisfactory, describe					

<b>Re Issue</b>	_____	_____	_____	_____	_____
	Date Issued	Issuer Name	Issuer Signature	Employee Name	Employee Signature
<small>Describe Reason / Circumstance(s)</small>	_____				

<b>Return Custody</b>	_____	_____	_____	_____	_____
	Date Issued	Issuer Name	Issuer Signature	Employee Name	Employee Signature
<small>Describe Reason / Circumstance(s)</small>	_____				

### E) Agency Identifiers

The following key is used as part of the Household prescription number identifier as shown in Section 1 of the FRCAE Screening and Consent Form.

**Table 3: LJ/RE Identifiers**

<b>Local Jurisdiction / Response Entity (LJ/RE)</b>	<b>ABBREV</b>
City of Carlsbad	CBD
City of Coronado	COR
City of Chula Vista	CV
City of Del Mar	DM
City of El Cajon	EC
City of Encinitas	ENC
City of Escondido	ESC
City of Imperial Beach	IB
City of Lemon Grove	LG
City of La Mesa	LM
City of National City	NC
City of Oceanside	OSD
City of Poway - Dept of Safety Services	PWY
City of Santee	SNT
City of San Diego	SDC
City of San Marcos	SM
City of Solana Beach	SB
City of Vista	VST

County of San Diego – Office of Emergency Services	OES
County of San Diego – Department of General Services	GS
County of San Diego- Sheriff's Office	SO
County of San Diego - HHSA	HHSA
Rural and Unincorporated	RUR
County of San Diego - Dept of Environmental Health (DEH)	DEH

## **F) FRCAE Participant Evaluation and Questionnaire Tools**

The following is a description of the two forms on the following pages:

- Baseline Evaluation and Questionnaire is to be used just after the education has been completed and there's a sense from the educator that the participant understands the program. The purpose of this form is to assess baseline understanding to ensure compliance, and determine FRCAE opinions about the program.
- Follow-up Evaluation and Questionnaire is to be used on an annual basis beginning one year after the implementation of the program. The purpose of this form is to assess ongoing compliance and comprehension of the program, and to determine FRCAE opinions about the program.

**Baseline Evaluation and Questionnaire**

First Responder and Critical Access Employee Home Emergency Prophylaxis Kit **Baseline Questionnaire**

**Name** \_\_\_\_\_

**Date** \_\_\_\_\_

FRCAE Household #     -     -

{agency id}                      {last name, first 4 letters}                      {employee id number}

Section 1: Perception of Risk – in this section we’re asking your opinion of what you think might happen if a terrorist attack involving a chemical, radiological, biological, nuclear or explosive weapon occurred.

- 1) How likely do you think it is that a terrorist attack will occur in the United States within the next 12 months
  - Very Likely
  - Likely
  - Undecided
  - Unlikely
  - Very Unlikely
  - Don't know / No Opinion
  
- 2) How likely do you think it is that a terrorist attack will occur in San Diego County within the next 12 months
  - Very Likely
  - Likely
  - Undecided
  - Unlikely
  - Very Unlikely
  - Don't know / No Opinion
  
- 3) How confident are you that you will be able to store the home emergency prophylaxis kit (ProphyKit) out of the reach of children and pets?
  - Very Confident
  - Confident
  - Undecided
  - Not Very Confident
  - Don't know / No Opinion
  
- 4) How confident are you that you will be able to ensure the home emergency prophylaxis kit is not opened unless instructed to do so by the County of San Diego Public Health Officer?
  - Very Confident
  - Confident
  - Undecided
  - Not Very Confident
  - Don't know / No Opinion
  
- 5) Do you have any plans to terminate your employment as a First Responder or Critical Access Employee within the next 12 months?
  - NO     YES

Section 2: Program Comprehension

- 6) Do you have children in your household that are less than 89 pounds?
  - NO     YES if no, skip to question 8

- 7) If yes to question six (6) above, have you reviewed and understood the child dosing instructions? These instructions describe that the medication for your child must be mixed and sweetened with food and that the dose is not an entire capsule but should follow the weight based dosing chart included in the ProphyKit Brochure?  
 NO  YES
- 8) Do you understand how to store the ProphyKit?  
 NO  YES
- 9) Do you know who to call if someone accidentally ingests the doxycycline?  
 NO  YES
- 10) Do you know who to call for general instructions or questions about the program?  
 NO  YES
- 11) Do you know where to access the Instructional brochure?  
 NO  YES
- 12) Do you and your household members know when to open and use the ProphyKit?  
 NO  YES

LJ/RE-Point of Contact to verify acceptable answers to above. Once verified, save in conjunction with the Screening and Consent form and forward copy upon request to the SNS/CRI Coordinator

## Follow-up Evaluation and Questionnaire

First Responder and Critical Access Employee Home Emergency Prophylaxis Kit Follow Up Questionnaire

Name \_\_\_\_\_

Date \_\_\_\_\_

FRCAE Household #     -     -

{agency id} {last name, first 4 letters} {employee id number}

Section 1: Perception of Risk – in this section we're asking your opinion of what you think might happen if a terrorist attack involving a chemical, radiological, biological, nuclear or explosive weapon occurred.

- 1) How likely do you think it is that a terrorist attack will occur in the United States within the next 12 months
  - Very Likely
  - Likely
  - Undecided
  - Unlikely
  - Very Unlikely
  - Don't know / No Opinion
  
- 2) How likely do you think it is that a terrorist attack will occur in San Diego County within the next 12 months
  - Very Likely
  - Likely
  - Undecided
  - Unlikely
  - Very Unlikely
  - Don't know / No Opinion
  
- 3) How confident are you that you will be able to store the home emergency prophylaxis kit out of the reach of children and pets?
  - Very Confident
  - Confident
  - Undecided
  - Not Very Confident
  - Don't know / No Opinion
  
- 4) How confident are you that you will be able to ensure the home emergency prophylaxis kit is not opened unless instructed to do so?
  - Very Confident
  - Confident
  - Undecided
  - Not Very Confident
  - Don't know / No Opinion
  
- 5) Do you have any plans to terminate your employment as a First Responder or Critical Access Employee within the next 12 months?
  - NO  YES

### Section 2: Program Comprehension

- 6.) Do you have children in your household that are less than 89 pounds?
  - NO  YES if no, skip to question 8

- 7.) If yes to question six (6) above, have you reviewed and understood the child dosing instructions? These instructions describe that the medication for your child must be mixed and sweetened with food and that the dose is not an entire capsule but should follow the weight based dosing chart included in the ProphyKit Brochure?  
 NO  YES
- 8.) Do you understand how to store the ProphyKit?  
 NO  YES
- 9.) Do you know who to call if someone accidentally ingests the doxycycline?  
 NO  YES
- 10.) Do you know who to call for general instructions or questions about the program?  
 NO  YES
- 11.) Do you know where to access the Instructional brochure?  
 NO  YES
- 12.) Do you and your household members know when to open and use the ProphyKit?  
 NO  YES
- 13.) Would you be willing to buy a ProphyKit after this one expires to maintain one at home?  
 NO  YES If yes, choose an amount  \$20  \$25  \$30  \$\_\_\_\_ other

=====

**Staff Use Only (to be completed by the Local Jurisdiction / Response Entity Point of Contact (LJ/RE-POC))**

Section 3: Quality Assurance Section

- 14.) Is the FRCAE head of household still employed by same employer?  
 NO  YES if no, please describe \_\_\_\_\_
- 15.) Is the FRCAE still in possession of the home medication kit?  
 NO  YES if no, please describe \_\_\_\_\_
- 16.) Was the plastic bag containing the medication opened or show evidence of tampering?  
 NO  YES if yes, please describe \_\_\_\_\_  
 If contents have been tampered with, the FRCAE shall surrender the kit and the LJ/RE POC shall contact the SNS/CRI coordinator for resolution.

LJ/RE-Point of Contact to verify acceptable answers to above. Once verified, save in conjunction with the Screening and Consent form and forward copy upon request to the SNS/CRI Coordinator.

### **G) Standard Form Letters**

The following form letters are optional and may be used when FRCAE participants fall into one of the four eligibility categories as defined above in the FOG (Section A, Dispensing Protocol, Part 1: FRCAE Screening & Informed Consent, Four Categories of Enrollment).

- Eligibility Letter, Categories A & B – This form may be given to FRCAE for the purpose of notification of their Primary Care Provider that they have a ProphyKit containing doxycycline.
- Ineligibility Letter, Categories B & C – This form may be given to FRCAE for the purpose of notification of their Primary Care Provider that they are ineligible to participate and that they may wish to consider alternatives to doxycycline. A copy may be sent to the LJ/RE HR department and/or supervisor.
- Ineligibility Letter, Category D – This form may be given to FRCAE participants who “Opt Out/Non Consent” and don’t want to participate in program and informs them how to obtain more information in the event they wish to enroll at some point in the future. A copy may be sent to the LJ/RE HR department and/or supervisor.

## Eligibility Letter, Categories A & B

(Optional) - Notification to Patients Primary Care Provider when FRCAE and/or household member is eligible; Category A & B, eligible

When speaking to your doctor, the following information may be provided:

Date: \_\_\_ / \_\_\_ / \_\_\_

Patient name: \_\_\_\_\_

Dear Doctor:

Your patient has been identified as being a "First Responder and Critical Access Employee" (FRCAE). A FRCAE is someone involved in the initial response to a public health emergency and must physically respond to such an event within the first 6 to 8 hours. As such, they are critical to the continuity of government and providing critical services as a part of the agency, department, division, or jurisdiction at any level of government.

San Diego County Health and Human Services Department is preparing its First Responders and Critical Access Employees (FRCAE) and members of their immediate household with a ten day supply of Doxycycline 100mg capsules to be stored in the home. This medication is intended to be used only for post exposure prophylaxis in the event of a public health emergency involving the release of a biological organism like bacillus anthracis, the organism that causes anthrax. The medication is being prescribed and may be initiated under the order of the County Public Health Officer (PHO), Wilma Wooten, MD. The amount provided is intended to protect during the initial phase (10 days) of the emergency only. If additional medication is required beyond the ten days, it will be made available by the Health and Human Services Agency (HHSA).

This notification is being provided to you to inform you that your patient(s) has been enrolled in the program. There is nothing you need to do at this time. You should familiarize yourself with some drug interactions with doxycycline: (partial list of interactions)

- Warfarin (Coumadin® — Blood thinner), effect may be enhanced. Check PT/INR and decrease dose if needed
- Digoxin (Lanoxin) — effect may be enhanced.
- Probenicid (Benemid® — Gout) will increase antibiotic levels; stop until antibiotic regimen is completed
- Antiseizure medications, Phenytoin (Dilantin) & Carbamazepine (Tegretol) — reduce the effect of doxycycline.
- Isotretinoin (Accutane) — slight risk of pseudotumor cerebri, stop if headache develops
- Birth Control Pills — effect may be reduced, use another form of contraception while on doxycycline of that a Following the completion of a brief medical history, a supply of one of the following antibiotics was prescribed and dispensed from the National Pharmaceutical Stockpile. If it is determined that your patient should receive antibiotics for longer than 10 days, we will notify your patient and provide an additional supply of medication.

If you have any questions you may contact:

San Diego County SNS/CRI Coordinator: Jack Walsh  
Strategic National Stockpile Coordinator, Cities Readiness Initiative Coordinator  
County of San Diego, Health and Human Services Agency, Public Health Services  
Disaster Medical & Health Emergency Preparedness  
6255 Mission Gorge Road, Mailstop: S-555, San Diego, CA 92120  
Office: 619-285-6591 Cell: 619-572-4298 Fax: 619-285-6531  
Email: Jack.Walsh@sdcounty.ca.gov

**Ineligibility Letter, Categories B & C**

(Optional) - Notification to Patient and Patients Primary Care Provider if FRCAE or household member is ineligible; Category B or C

Dear \_\_\_\_\_, you or your household member \_\_\_\_\_ is/are ineligible for the San Diego County Home Emergency Prophylaxis Kit program because a contraindication to doxycycline was identified during the medical screening process. At this time, you may wish to contact your doctor for alternative medications for post exposure prophylaxis in the event of a public health emergency involving a release or outbreak of a specific disease causing bacteria like anthrax.

When speaking to your doctor, the following information may be provided:

Dear Doctor,

The San Diego County Health and Human Services Department is preparing its First Responder and Critical Access Employees (FRCAE) and members of their immediate household with a ten day supply of Doxycycline to be stored in the home. This medication is intended to be used **only** for post exposure prophylaxis in the event of a public health emergency involving an intentional release of aerosolized *bacillus anthracis* spores. The medication would be started and continued as directed by the County of San Diego Public Health Officer. The amount provided is intended to protect during the initial phase (10 days) of the emergency only. If additional medication is required beyond the ten days it is anticipated that it will be made available by the public health department.

During the screening process the individual and/or a member of their immediate household identified a contraindication to Doxycycline. (check one)

Allergy to Doxycycline

Other \_\_\_\_\_

Please consider for your patient(s) an alternative agent (i.e. Ciprofloxacin or similar Fluoroquinolone) for post exposure prophylaxis in the event of a public health emergency involving a release or outbreak of a specific disease causing bacteria like anthrax.

If you have any questions you may contact:

San Diego County SNS/CRI Coordinator: Jack Walsh  
Strategic National Stockpile Coordinator, Cities Readiness Initiative Coordinator  
County of San Diego, Health and Human Services Agency, Public Health Services  
Disaster Medical & Health Emergency Preparedness  
6255 Mission Gorge Road, Mailstop: S-555, San Diego, CA 92120  
Office: 619-285-6591 Cell: 619-572-4298 Fax: 619-285-6531  
Email: Jack.Walsh@sdcounty.ca.gov

**Ineligibility Letter, Category D**

*(Optional) - Opt Out/Non Consent; Notification to FRCAE when doesn't want to participate in program; Entire Household falls into Category D; Ineligible Non Consented*

Dear \_\_\_\_\_,

You have been identified as being a "First Responder and Critical Access Employee" (FRCAE). A FRCAE is someone involved in the initial response to a public health emergency and must physically respond to such an event within the first 6 to 8 hours. As such, they are critical to the continuity of government and providing critical services as a part of the agency, department, division, or jurisdiction at any level of government.

San Diego County Health and Human Services Department is preparing its First Responders and Critical Access Employees (FRCAE) and members of their immediate household with a ten day supply of Doxycycline 100mg capsules to be stored in the home. This medication is intended to be used only for post exposure prophylaxis in the event of a public health emergency involving the release of a biological organism like bacillus anthracis, the organism that causes anthrax

**You have elected to not participate at this time in the San Diego County Home Emergency Prophylaxis Kit (ProphyKit) program. If you wish to participate in the future, you may contact your immediate supervisor for instructions on how to enroll.**

If you have any questions you may contact:

San Diego County SNS/CRI Coordinator: Jack Walsh  
Strategic National Stockpile Coordinator, Cities Readiness Initiative Coordinator  
County of San Diego, Health and Human Services Agency, Public Health Services  
Disaster Medical & Health Emergency Preparedness  
6255 Mission Gorge Road, Mailstop: S-555, San Diego, CA 92120  
Office: 619-285-6591 Cell: 619-572-4298 Fax: 619-285-6531  
Email: Jack.Walsh@sdcounty.ca.gov

## 5. Training Plan

This section shall identify training requirements for each trainee role and include all associated training modules to implement the FRCAE Home Emergency Prophylaxis Kit Plan.

The following trainee roles and responsibilities are identified.

**Table 4: Training Curriculum Grid**

Curriculum	Stakeholders					
	FRCAE	LJ/RE POC	Clinical Reviewer	PHO	Call agencies (211 staffed agency, 5800 public health dept)	Disp Pharm
Executive Summary & Introduction	✓	✓		✓	✓	
Definitions		✓		✓		
Doxycycline (risks) (risks)	✓	✓		✓		
Doxycycline (drug interactions)	✓	✓		✓		
Doxycycline (child dosing)	✓	✓		✓		
ProphyKit (description)	✓	✓		✓	✓	
Roles and Responsibilities (HHSA)		✓		✓		
Roles and Responsibilities (LJ/RE )		✓		✓		
Roles and Responsibilities (LJ/RE POC )		✓		✓		
Roles and Responsibilities (PHO )		✓	✓	✓		
Roles and Responsibilities (dispensing pharmacy )		✓				
Plan Implementation (FRCAE Education)		✓	✓	✓		
Plan Implementation (Baseline Eval)		✓	✓	✓		
Plan Implementation (Screening & Informed Consent)		✓	✓	✓		
Plan Implementation (Pharmacy Dispensing)						
Plan Implementation (Shipping, Receiving, Distribution)		✓				✓
Ongoing Plan Monitoring / Evaluation (annual)		✓				✓
<u>Training Method</u>	Direct Instruction	Informational briefing	Informational briefing	Informational briefing	Direct Instruction	Contra
<u>Training Documentation Method</u>	Baseline Evaluation and Questionnaire	Signature Page and Sign In sheet	TBD	n/a	TBD	n/a
<u>Training to be Performed By</u>	LJ/RE-POC	HHSA	HHSA	TBD	HHSA	HHSA

**A) Educational Support Documents**

**i. PropyKit Brochures**

<Insert brochures, English and Spanish>

## **ii. Training Plan Powerpoint**

<Insert PowerPoint slides >

**iii. Patient Introductory Letter**

<Insert Patient Intro Letter on approved County letterhead>

# Attachment 2

## *Professionals Achieving Consumer Trust Summit Agreement*



Professionals Achieving Consumer Trust

Whereas, we, the undersigned, represent the leadership of the professional regulatory programs within the California Department of Consumer Affairs,

Whereas, our mandate is consumer protection and our collective mission is to serve the interests of California consumers by ensuring a standard of professionalism in key industries and promoting informed consumer practices,

Whereas, the greatest form of consumer protection is achieving public trust in the 2.4 million licenses we issue, the diligent enforcement of our standards, and providing the necessary number of qualified professionals licensed to serve in California,

Now, therefore be it resolved, that we do hereby commit ourselves to executing our roles as leaders in consumer protection and education; that we will uphold the value of the licenses issued by the regulatory entities that make up the Department of Consumer Affairs; and that we will regulate in accordance with the following values:

**Accountability** — We will be accountable to the people of California and each other as stakeholders. We will operate transparently and encourage public participation in our decision-making whenever possible.

**Efficiency** — We will diligently identify the best ways to deliver high-quality services with the most efficient use of our resources.

**Effectiveness** — We will make informed decisions that make a difference and have a positive, measurable impact on California consumers.

**Integrity** — We will be honest, fair, and respectful in our treatment of everyone.

**Customer Service** — We will acknowledge all stakeholders as our customers, listen to them, and take their needs into account.

**Employees** — We will be an employer of choice and strategically recruit, train, and retain employees. We value and recognize employee contributions and talent.

**Unity** — We will draw strength from our organizational diversity as well as California's ever-changing cultural and economic diversity.

**Creativity** — We will create productive partnerships with consumers, businesses and other stakeholders, as well as identify new and innovative ways of helping to ensure that California has an adequate supply of licensed, competent professionals.

**Education** — We will strive to educate consumers, so members of the public are capable of making informed decisions in a complex and changing marketplace.

**Action** — We will act aggressively but fairly in cases where violations of the law by our licensees are alleged, thereby upholding the standards that have made California a leader in professional licensing and consumer protection.

Board of Accountancy

Donald R. D. Thomas  
Board President/Chair

Board of Acupuncture

Board President/Chair

California Architects Board

Board President/Chair

California State Athletic Commission

Commission President/Chair

Bureau of Barbering and Cosmetology

Bureau President/Chair

Board of Behavioral Sciences

Board President/Chair

Cemetery and Funeral Bureau

Bureau President/Chair

Contractors State License Board

Board President/Chair

Court Reporters Board

Board President/Chair

Committee on Dental Auxiliaries

Board President/Chair

Dental Bureau of California

Bureau President/Chair

Bureau of Electronic and Appliance Repair Advisory Council

Board President/Chair

Board of Professional Engineers and Land Surveyors

Board President/Chair

Board for Geologists and Geophysicists

Board President/Chair

Board of Guide Dogs for the Blind

Board President/Chair

Hearing Aid Dispensers Bureau

Board President/Chair

Bureau of Home Furnishings and Thermal Insulation Advisory Council

Bureau President/Chair

Inspection Maintenance Review Committee

Bureau President/Chair

Landscape Architects Technical Committee

Board President/Chair

Medical Board of California

Board President/Chair

Bureau of Naturopathic Medicine Advisory Council

Bureau President/Chair

Board of Occupational Therapy

Board President/Chair

Board of Optometry

Board President/Chair

Osteopathic Medical Board

Board President/Chair

Board of Pharmacy

Board President/Chair

Physical Therapy Board of California

Board President/Chair

Physician Assistant Committee

Board President/Chair

Board of Podiatric Medicine

Board President/Chair

Professional Fiduciaries Bureau

Bureau President/Chair

Board of Psychology

Board President/Chair

Board of Registered Nursing

*LaTrancine Tate*

Board President/Chair

Respiratory Care Board

*[Signature]*

Board President/Chair

Bureau of Security and  
Investigative Services Advisory  
Committee

*[Signature]*

Bureau President/Chair

Speech-Language Pathology and  
Audiology Bureau

*Lisa O'Connor*

Bureau President/Chair

Structural Pest Control Board

Board President/Chair

*[Signature]*

Veterinary Medical Board and  
Registered Veterinary Technician  
Examining Committee

Board President/Chair

Vocational Nursing and Psychiatric  
Technicians Bureau

*[Signature]*

Bureau President/Chair

# Attachment 3

## *Automated Delivery Machines*

**§1713. Receipt and Delivery of Prescriptions and Prescription Medications.**

- (a) Except as otherwise provided in this Division, no licensee shall participate in any arrangement or agreement, whereby prescriptions, or prescription medications, may be left at, picked up from, accepted by, or delivered to any place not licensed as a retail pharmacy.
- (b) A licensee may pick up prescriptions at the office or home of the prescriber or pick up or deliver prescriptions or prescription medications at the office of or a residence designated by the patient or at the hospital, institution, medical office or clinic at which the patient receives health care services. In addition, the Board may, in its sole discretion, waive application of subdivision (a) for good cause shown.
- (c) A patient or the patient's agent may deposit a prescription in a secure container that is at the same address as the licensed pharmacy premises. The pharmacy shall be responsible for the security and confidentiality of the prescriptions deposited in the container.
- (d) **A pharmacy may use an automated delivery device to deliver previously dispensed prescription medications provided:**
  - (1) Each patient using the device has chosen to use the device and signed a written consent form demonstrating his or her informed consent to do so.
  - (2) A pharmacist has determined that each patient using the device meets inclusion criteria for use of the device established by the pharmacy prior to delivery of prescription medication to that patient.
  - (3) The device has a means to identify each patient and only release that patient's prescription medications.
  - (4) The pharmacy does not use the device to deliver previously dispensed prescription medications to any patient if a pharmacist determines that such patient requires counseling as set forth in section 1707.2(a)(2).
  - (5) The pharmacy provides an immediate consultation with a pharmacist, either in-person or via telephone, upon the request of a patient.
  - (6) The device is located adjacent to the secure pharmacy area.
  - (7) The device is secure from access and removal by unauthorized individuals.
  - (8) The pharmacy is responsible for the prescription medications stored in the device.
  - (9) Any incident involving the device where a complaint, delivery error, or omission has occurred shall be reviewed as part of the pharmacy's quality assurance program mandated by Business and Professions Code section 4125.
  - (10) The pharmacy maintains written policies and procedures pertaining to the device as described in subdivision (e).
- (e) Any pharmacy making use of an automated delivery device as permitted by subdivision (d) shall maintain, and on an annual basis review, written policies and procedures providing for:
  - (1) Maintaining the security of the automated delivery device and the dangerous drugs within the device.
  - (2) Determining and applying inclusion criteria regarding which medications are appropriate for placement in the device and for which patients, including when consultation is needed.
  - (3) Ensuring that patients are aware that consultation with a pharmacist is available for any prescription medication, including for those delivered via the automated delivery device.
  - (4) Describing the assignment of responsibilities to, and training of, pharmacy personnel regarding the maintenance and filling procedures for the automated delivery device.
  - (5) Orienting participating patients on use of the automated delivery device, notifying patients when expected prescription medications are not available in the device, and ensuring that patient use of the device does not interfere with delivery of prescription medications.
  - (6) Ensuring the delivery of medications to patients in the event the device is disabled or malfunctions.
- (f) Written policies and procedures shall be maintained at least three years beyond the last use of an automated delivery device.

**(g) For the purposes of this section only, "previously-dispensed prescription medications" are those prescription medications that do not trigger a non-discretionary duty to consult under section 1707.2(b)(1), because they have been previously dispensed to the patient by the pharmacy in the same dosage form, strength, and with the same written directions.**

**Patient request for pharmacist counseling and satisfaction: Automated Prescription Delivery**

**System vs. Regular Pick-Up Counter**

Jan D. Hirsch, Austin Oen, Suzie Robertson, Nancy Nguyen, Charles Daniels

**Abstract**

*Objectives:*

1. Assess the rate of patient requested pharmacist counseling for refill prescriptions and satisfaction with pick-up process for patients using an Automated Prescription Delivery System (APDS) vs. those using a regular pick-up counter.
2. Explore patient willingness to utilize an APDS as a tool for pharmacist monitoring of medication therapy outcomes.

*Design:* Uncontrolled study.

*Setting:* Two community pharmacies.

*Participants:* 116 patients using either an APDS or regular counter to pick up their refill prescriptions.

*Intervention:* Cross-sectional survey.

*Main outcome measures:* Number of patients requesting pharmacist counseling for refill prescriptions, satisfaction with pick-up process, and willingness to utilize an APDS to report medication therapy outcomes.

*Results:* None of the regular counter users and only two (3.7%) of the APDS users requested counseling for their refill prescription ( $p=0.126$ ). Almost all patients agreed they were able to talk to a pharmacist about their prescription if they wanted to do so (95.1% regular counter, 92.3% APDS,  $p=0.268$ ). The majority (75%) of patients using the APDS indicated they would be willing to use the APDS to answer questions or perform simple tests to provide information the pharmacist could use to improve medication effectiveness or reduce side effects.

*Conclusion:*

Very few patients (ADPS or regular counter) asked to speak to a pharmacist about their refill medications, although it appeared there were no perceived barriers to pharmacist access. Most APDS patients were willing to use this new technology to provide information about therapy outcomes to the pharmacist. Further exploration and testing of the APDS as a data collection tool to enhance pharmacist access to therapy outcomes is warranted.

# Attachment 4

*Senate Bill 966 and Board Comments  
on Proposed Model Programs*

**Senate Bill No. 966**

**CHAPTER 542**

An act to amend Section 47200 of, and to add and repeal Article 3.4 (commencing with Section 47120) of Chapter 1 of Part 7 of Division 30 of, the Public Resources Code, relating to pharmaceutical waste.

[Approved by Governor October 12, 2007. Filed with  
Secretary of State October 12, 2007.]

**LEGISLATIVE COUNSEL'S DIGEST**

SB 966, Simitian. Pharmaceutical drug waste disposal.

(1) Existing law creates the California Integrated Waste Management Board (board) within the California Environmental Protection Agency.

This bill would, until January 1, 2013, require the board to develop, in consultation with appropriate state, local, and federal agencies, model programs for the collection and proper disposal of pharmaceutical drug waste. The model programs would be required to include, at a minimum, specific actions and informational elements and would be required to be available to eligible participants no sooner than July 1, 2008, but no later than December 1, 2008.

The bill would provide that its provisions shall not apply to a controlled substance, as defined.

(2) Existing law requires the board to expend certain funds, upon appropriation by the Legislature, for the making of grants, as provided, to cities, counties, and other local agencies with responsibilities for solid waste management, and for local programs to prevent the disposal of hazardous wastes at disposal sites, including, but not limited to, initial implementation or expansion of household hazardous waste programs. The total amount of the grants in any one fiscal year may exceed \$3,000,000 but cannot exceed \$5,000,000, if sufficient funds are appropriated from the Integrated Waste Management Account for this purpose.

This bill would increase the limit to \$6,000,000.

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

SECTION 1. Article 3.4 (commencing with Section 47120) is added to Chapter 1 of Part 7 of Division 30 of the Public Resources Code, to read:

**Article 3.4. Drug Waste Management and Disposal**

47120. (a) The Legislature finds and declares all of the following:

(1) The United States Geological Survey conducted a study in 2002 sampling 139 streams across 30 states and found that 80 percent had measurable concentrations of prescription and nonprescription drugs, steroids, and reproductive hormones.

(2) Exposure, even to low levels of drugs, has been shown to have negative effects on fish and other aquatic species and may have negative effects on human health.

(3) In order to reduce the likelihood of improper disposal of drugs, it is the purpose of this article to establish a program through which the public may return and ensure the safe and environmentally sound disposal of drugs and may do so in a way that is convenient for consumers.

(b) It is the intent of the Legislature in enacting this article:

(1) To encourage a cooperative relationship between the board and manufacturers, retailers, and local, state, and federal government agencies in the board's development of model programs to devise a safe, efficient, convenient, cost-effective, sustainable, and environmentally sound solution for the disposal of drugs.

(2) For the programs and systems developed in other local, state, and national jurisdictions to be used as models for the development of pilot programs in California, including, but not limited to, the efforts in Los Angeles, Marin, San Mateo, and Santa Clara Counties, Oregon, Maine, North Carolina, Washington State, British Columbia, and Australia.

(3) To develop a system that recognizes the business practices of manufacturers and retailers and other dispensers and is consistent with and complements their drug management programs.

47121. For the purposes of this article, the following terms have the following meanings, unless the context clearly requires otherwise:

(a) "Consumer" means an individual purchaser or owner of a drug. "Consumer" does not include a business, corporation, limited partnership, or an entity involved in a wholesale transaction between a distributor and retailer.

(b) "Drug" means any of the following:

(1) Articles recognized in the official United States Pharmacopoeia, the official National Formulary, the official Homeopathic Pharmacopoeia of the United States, or any supplement of the formulary or those pharmacopoeias.

(2) Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals.

(3) Articles, excluding food, intended to affect the structure or function of the body of humans or other animals.

(4) Articles intended for use as a component of an article specified in paragraph (1), (2), or (3).

(c) "Participant" means any entity which the board deems appropriate for implementing and evaluating a model program and which chooses to participate, including, but not limited to, governmental entities, pharmacies, veterinarians, clinics, and other medical settings.

(d) "Sale" includes, but is not limited to, transactions conducted through sales outlets, catalogs, or the Internet, or any other similar electronic means, but does not include a sale that is a wholesale transaction with a distributor or retailer.

47122. (a) (1) The board shall, in consultation with appropriate state, local, and federal agencies, including, but not limited to, the Department of Toxic Substances Control, the State Water Resources Control Board, and the California State Board of Pharmacy, develop model programs for the collection and proper disposal of drug waste. Notwithstanding any other provision of law, the board shall establish, for participants, criteria and procedures for the implementation of the model programs.

(2) In developing model programs the board shall evaluate a variety of models used by other state, local, and other governmental entities, and shall consider a variety of potential participants that may be appropriate for the collection and disposal of drug waste.

(3) No sooner than July 1, 2008, but no later than December 1, 2008, the board shall make the model programs available to eligible participants.

(b) The model programs shall at a minimum include all of the following:

(1) A means by which a participant is required to provide, at no additional cost to the consumer, for the safe take back and proper disposal of the type or brand of drugs that the participant sells or previously sold.

(2) A means by which a participant is required to ensure the protection of public health and safety, the environment, and the health and safety of consumers and employees.

(3) A means by which a participant is required to report to the board for purposes of evaluation of the program for safety, efficiency, effectiveness, and funding sustainability.

(4) A means by which a participant shall protect against the potential for the diversion of drug waste for unlawful use or sale.

(c) The model programs shall provide notice and informational materials for consumers that provide information about the potential impacts of improper disposal of drug waste and the return opportunities for the proper disposal of drug waste. Those materials may include, Internet Web site links, a telephone number placed on an invoice or purchase order, or packaged with a drug; information about the opportunities and locations for no-cost drug disposal; signage that is prominently displayed and easily visible to the consumer; written materials provided to the consumer at the time of purchase or delivery; reference to the drug take back opportunity in advertising or other promotional materials; or direct communications with the consumer at the time of purchase.

(d) Model programs deemed in compliance with this article shall be deemed in compliance with state law and regulation concerning the handling, management, and disposal of drug waste for the purposes of implementing the model program.

(e) (1) The board may develop regulations pursuant to Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code that are necessary to implement this article, including

regulations that the department determines are necessary to implement the provisions of this article in a manner that is enforceable.

(2) The board may adopt regulations to implement this article as emergency regulations. The emergency regulations adopted pursuant to this article shall be adopted by the department in accordance with Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, and for the purposes of that chapter, including Section 11349.6 of the Government Code, the adoption of these regulations is hereby deemed an emergency and shall be considered by the Office of Administrative Law as necessary for the immediate preservation of the public peace, health, safety, and general welfare. Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, any emergency regulations adopted by the department pursuant to this section shall be filed with, but not be repealed by, the Office of Administrative Law and shall remain in effect for a period of two years or until revised by the department, whichever occurs sooner.

47123. Notwithstanding Section 7550.5 of the Government Code, no later than December 1, 2010, the board shall report to the Legislature. The report shall include an evaluation of the model programs for efficacy, safety, statewide accessibility, and cost effectiveness. The report shall include the consideration of the incidence of diversion of drugs for unlawful sale and use, if any. The report also shall provide recommendations for the potential implementation of a statewide program and statutory changes.

47124. This article shall not apply to a controlled substance, as defined in Section 11007 of the Health and Safety Code.

47125. Nothing in this article shall limit or affect any other right or remedy under any applicable law.

47126. This article shall remain in effect only until January 1, 2013, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2013, deletes or extends that date.

SEC. 2. Section 47200 of the Public Resources Code is amended to read:

47200. (a) The board shall expend funds from the account, 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, including, but not limited to, programs to expand or initially implement household hazardous waste programs. In making grants pursuant to this section, the board shall give priority to funding programs that provide for the following:

(1) New programs for rural areas, underserved areas, and for small cities.

(2) Expansion of existing programs to provide for the collection of additional waste types, innovative or more cost-effective collection methods, or expanded public education services.

(3) Regional household hazardous waste programs.

(b) (1) The total amount of grants made by the board pursuant to this section shall not exceed, in any one fiscal year, three million dollars (\$3,000,000).

(2) Notwithstanding paragraph (1), the total amount of grants made by the board pursuant to this section may exceed three million dollars (\$3,000,000) but shall not exceed six million dollars (\$6,000,000), in any one fiscal year, if sufficient funds are appropriated from the Integrated Waste Management Account for this purpose.

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

To: California Integrated Waste Management Board

Date: November 10, 2008

Subject: Model Home-Generated Pharmaceutical Waste Comments

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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 CA. We license approximately 6,600 pharmacies in California, 500 of which are hospital pharmacies. We license nearly 110,000 individuals and other businesses involved with prescription drug distribution.

Prescription drugs are tightly regulated down to the consumer level – the manufacturer is 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 legal 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. When they become pharmaceutical or medical waste, and then once again, 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 and prescription drug abuse are two societal issues exist, that make aggregation of unused prescription drugs valuable and attractive to criminals.

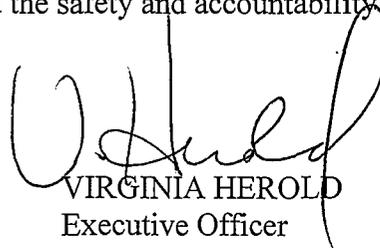
For the last six months, Board of Pharmacy staff has worked with a small working group of other state agencies, including the CIWMB, on the model programs. Recently, we provided comments on the proposed model program guidelines, and many of our recommendations have been incorporated into the draft before the committee.

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

1. California needs to develop a system to aid the public in disposing of their pharmaceuticals in an appropriate, environmentally safe manner.
2. The Board of Pharmacy believes that only the following entities should be authorized to operate take-back programs:
  - California-licensed pharmacies with active, unrestricted licensed from the Board of Pharmacy
  - Government agencies (local, county, state, federal)
  - Police or sheriff's offices

- Licensed medication practitioners who are authorized to prescribe in California under Business and Professions Code section 4170(c), with active, unrestricted licenses.
  - Hazardous waste collection sites
3. The greatest weakness in the model program guidelines are that they are not in regulation form. As such, enforcement of these provisions will be difficult for the regulatory agencies involved. The Board of Pharmacy is likely to correct this via legislation and regulations in 2009. Consequently, the model guidelines will provide entities operating take back programs with direction with respect to operating these programs, but enforcement provisions (currently identified on page 4-3 as new item G) needs augmentation and development.
  4. The board is greatly concerned with diversion of prescription drugs from these sites (whether in pharmacies themselves or in community events) into pharmacies, where they will be re-dispensed to patients. Recently in Washington State, which has allowed pharmacies under a pilot program take back drugs, a pharmacist was arrested who took back drugs, placed them into the current inventory of the pharmacy and then dispensed them to patients. (Attachment 1 to this document.) The risks of prescription drugs being diverted by pharmacies operating such programs, or purchasing drugs from others in the community who operate such take-back programs, are a real concern and threat to our drug supply.
  5. We have concern the assertion that cost-effective collection is possible at pharmacies, if the pharmacy cannot charge for the collection costs (page 4-3, item A).
  6. The drugs should not be reviewed by staff at the collection site before being deposited into the collection device. When patients handle the drugs and deposit the drugs themselves, there should be no reason for labeling describing what the medicine is "in the event of poisoning" (page 4-5, lower list, item 4).
  7. Printed advertisements for community take back events should list who is responsible for operation of the collection location, including the name, address, and phone number of the responsible party.
  8. Every operator of a model program must have written policies and procedures to document their operations and compliance with the guidelines.
  9. Thefts or suspected thefts from any collection site need to be reported within 24 hours at least to the police, the Board of Pharmacy and the CDPH.
  10. On one-day events—we strongly recommend that the pharmaceutical waste must be picked up at the end of the day. It cannot be temporarily stored anywhere, even if the signs on the bins are removed (Pages 4 -3 and 4-14).
  11. There needs correction of an inconsistency: a pharmacy may assist at one-day events (page 4-12) but must assist later in this section (page 4- 17).

Thank you. 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.

  
VIRGINIA HEROLD  
Executive Officer

## **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 doling 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.

# Attachment 5

*California Integrated Waste Management  
Board's Proposed Model Guidelines  
Pursuant to SB 966*

## 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 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;

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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.

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:

1. Provides for the collection of home-generated pharmaceuticals that is convenient for consumers
2. Maintains privacy of all participants;
3. Prevents the illegal collection of controlled substances through displaying signage or legally manages them if they are collected;
4. Ensures that medication information is legible, so that it can be identified in case of a poisoning;
5. Develops 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 to develop permanent collection programs rather than one-day events, so they will be more accessible to the public; and
7. Provides recommendations for implementation of a statewide program; and
8. Recommends 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 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 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 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 be removed and the container shall be stored in a secure intermediate storage area.

Signage should also show how to deposit pharmaceuticals into the secured container, since staff cannot assist the consumers. The 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** - If home-generated pharmaceuticals are kept in the original, labeled container, personal information shall be removed or marked out. The containers and home-generated pharmaceuticals can then be placed in separate collection bins by the consumer for proper management. Staff of the collection site are not to assist consumers in placing home-generated pharmaceuticals in the bins. This is the obligation of the consumer. 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 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 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 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 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, cannot be combined in collection bins with home-generated pharmaceutical waste. If the sharps are not brought in approved container 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 of the pharmaceutical waste and is responsible for assuring that it is stored, 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 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 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 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. A pharmacist, if he or she chooses, to assist consumers with the identification of drugs that are unidentified, shall treat those drugs 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 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 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 shall require two keys-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 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 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 personal data, signage informing the public about what can and shall not be collected.

b. Permanent HHW Collection Facility Equipment – The following equipment and supplies shall be 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.

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

- a. List 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

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-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. If any theft is observed or suspected, the operator shall contact the appropriate law enforcement agency and the Local Enforcement Agency of CDPH.

- a. **Pharmacist** (if a one day event is at a facility other than a pharmacy) - Pharmacists are recommended to be present at the event and must be licensed and in good standing with the California State Board of Pharmacy.
- b. **Dedicated Collection Area** - If the collection site is at an HHW facility, the facility must provide room for additional hazardous waste containers.
- c. **Law Enforcement** - 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. 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 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 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 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 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.

c. 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 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. 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 be removed and the container shall be stored in a secure intermediate storage area.

Signage should also show how to deposit pharmaceuticals into the secured container, since staff cannot assist the consumers. The 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 hours of the event, and who to contact for more information. If home-generated pharmaceuticals are kept in the original, labeled container, personal information shall be removed or marked out. The containers and home-generated pharmaceuticals can then be placed in separate collection bins by the consumer for proper management. Staff of the collection site are not to assist consumers in placing home-generated pharmaceuticals in the bins. This is the obligation of the consumer. 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 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 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 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 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, cannot be combined in collection bins with home-generated pharmaceutical waste. If the sharps are not brought in approved container 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 of the pharmaceutical waste and is responsible for assuring that it is stored, 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 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 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 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, transport controlled substances to evidence storage locker, document the collection of controlled substances, and arrange for and ensure U.S. Drug Enforcement Agency 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, 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 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 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 to collect sharps if the location is also approved by the local enforcement agency or CDPH as a sharps consolidation point.
- 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 facemasks should be considered, especially for the pharmacist who is doing the physical determination 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.

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

- a. List 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.

**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

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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. 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 provide postage-paid envelopes to pharmacies to be provided to consumers that will be utilized 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 shall 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.

December 2008

Comments and Responses - Criteria and Procedures for Model Home-Generated Pharmaceutical Waste Collection and Disposal Programs

Comment	Commenter	Draft Response to Comment in Document
<b>A. Management of Pharmaceuticals</b>		
1. Develop sustainable funding for collection/disposal via EPR framework policies as stated in Board's Strategic Directive 5. Delete grants, ADF and utility funding as sustainable.	CA Product Stewardship Council City of Los Angeles Orange County Tri-TAC <sup>1</sup> Los Angeles County Sanitation Districts ESJPA Pharmaceutical Committee <sup>ii</sup> City of San Jose Waste Management Calaveras County	Page 2 #5 – CIWMB staff suggests that EPR should be included in the document and grants and fees shouldn't be deleted just because they may not be sustainable. Grants and fees could be reclassified as alternative funding.
2. Use a common carrier to reduce costs as many pharmacies and other entities use common carriers to mail new pharmaceuticals or dispose of unsold pharmaceuticals.	City of L.A. Calaveras County Pharmaceutical Committee Tri-TAC	Page 2, # 8 – Statutes enforced by CDPH require 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 includes all statutory requirements for storage and handling, and transportation. Therefore, common carriers cannot be used.
3. Better define consolidation points and collection points.	Tri-TAC	The definition on Page 18, #6 is consistent with the provisions in SB 966.
4. Procedures require that pharm waste be managed according to MWMA.	Tri-TAC L.A. County Sanitation District Pharmaceutical Committee ESJPA	Page 2, #8 – Statutes enforced by CDPH require 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 means that it must be transported as such.
5. Procedures require segregation of pharmaceuticals from other waste streams, which would be difficult, costly, and time consuming.	Tri-Tac L.A. County Sanitation District City of Los Angeles ESJPA	Page 4, #5 – Statutes enforced by CDPH require that 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.
6. HHW generated pharm waste does not need to be managed as HHW in CA. How does this differ from DTSC's statement that collected pharmaceuticals are HHW.	CPSC City of San Jose	Board staff will consult with DTSC staff regarding this comment and amend the procedures as deemed appropriate.
7. Pharmacies should be able to charge for the collection costs.	Board of Pharmacy	PRC 47122 (b), (1) requires that the take back should be at no cost to the consumer. Any collection charges would conflict with existing law.

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Items so marked are statutory requirements and not for modification

**Comments and Responses - Criteria and Procedures for Model Home-Generated Pharmaceutical Waste Collection and Disposal Programs**

<b>Comment</b>	<b>Commenter</b>	<b>Draft Response to Comment in Document</b>
8. Every operator of a model program must have written policies and procedures to document their operations and compliance with the guidelines.	Board of Pharmacy	Page 2, #9 includes the requirement that collection locations have written policies and procedures to document their operations and compliance with this home-generated pharmaceutical waste collection program.
<b>B. How Will Pharmaceuticals Be Collected</b>		
1. Procedures don't show differences between collecting at a pharmacy and at an HHW facility.	City of L.A.	Comment noted.
2. At HHW facilities and mobile events, consumers can't get out of their vehicle to place in bins as required in procedures.	City of L.A. City of San Jose Pharmaceutical Committee	Page 5, #6 – Board of Pharmacy requested that staff of the collection sites not to assist consumers in placing home-generated pharmaceuticals in the bins. This seems unreasonable, so CIWMB staff will recommend revisions to the document allowing collection staff to assist consumers in placing home-generated pharmaceuticals in the bins.
3. Need to develop permanent collection programs to change long term habits.	Orange County	Page 2, #6 - CIWMB is in agreement with this comment.
4. Where home-generated pharmaceuticals are commingled in a plastic bag, staff may place them in the secure bin.	Pharmaceutical Committee	Page 5, #6, a – Board of Pharmacy recommends that collection site staff may assist a consumer in opening a container but shall not otherwise assist consumers in placing pharmaceutical waste into the bins. CIWMB staff recommends that collection site staff may assist consumers in placing pharmaceutical waste into the bins.
5. All pharmaceuticals should stay in their original containers. This should not be a requirement as some residents may consolidate pills into one large plastic bag or container.	City of San Jose Pharmaceutical Committee	Page 8, #11, b and Page 11, #11, b - It may not be possible or practical to have the pharmaceuticals in their original containers, so the reference to the pharmaceuticals staying in their original container will be deleted.
6. The burden of removing personal data should not be on the collection program.	ESJPA	Page 11, #5 –The procedures do not place the burden on the program operator, other than providing that signage advises consumers to remove personal information from the medicine containers. CIWMB staff recommends no change in guidelines.
7. Provide clearer direction on whether or not a pharmacist can assist in the collection.	City of San Jose	Page 6, #7, a – This provision is confusing and CIWMB staff will work with the Board of Pharmacy to clarify this issue.
8. Restricting access to the area may not be possible.	City of San Jose	Page 9, #1 - Collection Site – The intent of this provision is to provide a measure of security to prohibit unauthorized access. This would be consistent with HHW programs where access is restricted to only those authorized areas. CIWMB staff recommends no change in guidelines

**Comments and Responses - Criteria and Procedures for Model Home-Generated Pharmaceutical Waste Collection and Disposal Programs**

Comment	Commenter	Draft Response to Comment in Document
<p>X [ 9. Having law enforcement be able to see the transfer of pharmaceuticals from vehicles is too restrictive.</p>	<p>City of San Jose</p>	<p>Page 9-10, # 1, c - The intent of this provision is to ensure that the controlled substances are indeed placed in a secure collection container and not diverted. CIWMB staff recommends no change in guidelines.</p>
<p><b>C. Types of Collection Locations</b></p>		
<p>1. Door to-door should be a permitted collection method.</p>	<p>CPSC Curbside Inc.</p>	<p>PRC 47121, c, does not specify door-to-door as a type of collection option. However, this could be an option of the One-time or Periodic Collection Events</p>
<p>2. Include those facilities that manufacture, distribute, and sell as part of the solution.</p>	<p>City of San Jose</p>	<p>Page 2-3, #1-1 lists examples of facilities that could be collection locations which include businesses, such as pharmacies that distribute and sell drugs. Mail-back programs are an example of program that could include manufacturers of drugs.</p>
<p>3. How will program hosts implement criteria if existing programs need to revise their activities to comply with model criteria?</p>	<p>City of San Jose</p>	<p>These criteria and procedures are for model programs as described in SB 966. If an existing program want to be considered a model program under SB 966 it will need to analyze which portions of their existing program do not meet these criteria and revise accordingly.</p>
<p>+ [ 4. Delete #1 on Page 3 - Calls out specific facilities for pharm collection but doesn't include places that have historically collected. This should be a recommendation.</p>	<p>Calaveras County Pharmaceutical Committee</p>	<p>Page 2-3, #11 - CIWMB staff disagrees with the recommendation of deleting this paragraph. The facilities listed are examples of the types of facilities that could be collection locations. Feed stores and senior centers may be considered for selection if there is qualified staff to oversee the collection and if they adhere to proper procedures. CIWMB staff recommends no change in guidelines.</p>
<p>5. A list of those facilities that collect home-generated pharmaceutical waste shall be provided to the CIWMB. What is the penalty for not providing the information? Who is required to provide this list?</p>	<p>Pharmaceutical Committee ESJPA</p>	<p>Page 2-3, #1 - There is no penalty given if information is not provided. Page 2-3, #1 - The CIWMB, Board of Pharmacy, and CDPH are requiring that 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.</p>
<p>6. Recommends that only California-licensed pharmacies, government agencies, police or sheriff's offices, and licensed medication practitioners, and hazardous waste collection sites.</p>	<p>State Board of Pharmacy</p>	<p>Page 2-3, #1 - Comment noted.</p>
<p>+ [ 7. Pharmacies should not be required to accept unused medications, because it would ultimately place consumers at risk and compromise the medication safety integrity currently established in both outpatient and inpatient pharmacies.</p>	<p>California Society of Health-System Pharmacists</p>	<p>The Board of Pharmacy recommends that California-licensed pharmacies should be authorized to operate pharm take-back programs; however this law does not require a pharmacy to accept unused medications. PRC 47122 (a) (2) requires an evaluation of a variety of models, such as pharmacies, used by other entities.</p>

**Comments and Responses - Criteria and Procedures for Model Home-Generated Pharmaceutical Waste Collection and Disposal Programs**

Comment	Commenter	Draft Response to Comment in Document
<b>D. Sharps</b>		
1. Delete part about sharps and pharmaceuticals in separate containers, and instead allow sharps and pharmaceuticals to be combined only if transported by med waste hauler for incineration.	Calaveras County Pharmaceutical Committee	<b>Page 5 #6, c and Page 4 #4, b</b> – CIWMB staff agrees with this comment. The sharps and pharmaceuticals could be combined if CDPH’s more stringent requirement of incineration were adhered to.
2. Having consumer reload sharps into an approved sharps container is dangerous.	ESJPA	<b>Page 5, #6, c and Page 12, #6, c</b> – The Board of Pharmacy recommended that if the sharps are not brought in approved containers 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.
<b>E. Government Agency Authorizations</b>		
1. It should be specified as to whom should be notified. Recommend no permit fee and CDPH should provide a permit form in the appendix to be sent to CDPH or LEA. Want a streamlined permit approach.	Tri-TAC Pharmaceutical Committee City of San Jose Waste Management	<b>Page 3, #2</b> - Statutes enforced by CDPH would need to be changed to provide a streamlined permit approach. This information was in general terms, because there are different requirements from one locale to another. Operators should check with their local authorities for specific requirements and fee waivers.
2. Provide generator exemption for collecting pharmaceutical waste.	Calaveras County	<b>Page 3, #2</b> – These are statutes enforced by CDPH and would have to be changed in statute. This may require revising the MWMA which is beyond the scope of these procedures. Simple process is covered in current section via determining requirements for each collection point.
<b>F. Storage Containers</b>		
1. The type of equipment and supplies to use should be left to the discretion of the facility owner/operator.	City of L.A. Pharmaceutical Committee ESJPA	<b>Page 7, #8</b> - Container Security –The Board of Pharmacy requires the entity overseeing the collection location to provide for the security of the collected home-generated pharmaceuticals. The Board of Pharmacy also requires that the home-generated pharmaceutical waste must be deposited into secured containers to limit diversion and theft opportunities and not allow staff or the entity overseeing the program from having access to the contents.
2. Longer storage time is essential in rural areas, since the cost of frequent pickups is prohibitive.	ESJPA	<b>Page 12, #6, b</b> – CIWMB staff believe there is ample storage time allowed. CDPH requires that 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.

**Comments and Responses - Criteria and Procedures for Model Home-Generated Pharmaceutical Waste Collection and Disposal Programs**

Comment	Commenter	Draft Response to Comment in Document
<p>3. The two key bins should be suggestion not a requirement. These access and storage limitations don't allow for a common carrier shipment option, because for a common carrier or mail-back option for collection sites, site staff have to handle, seal, and move collection boxes and get them into the mail.</p>	Pharmaceutical Committee	<p><b>Page 7, #8</b> – The Board of Pharmacy recommended that the bins shall require two keys-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.</p> <p><b>Page 3-4, #3</b> – CDPH requires by statute that 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 MWMA. To utilize common carriers for the transport of pharmaceutical waste would require changes to the MWMA. CIWMB staff recommends no change in guidelines.</p>
<p>4. Once a collection device becomes full, no pharmaceutical waste can be accepted until the waste hauler has removed the pharm waste.</p>	City of San Jose	<p><b>Page 7, #8</b> – The Board of Pharmacy recommended this security measure to ensure that the pharm waste is kept secure.</p>
<p>5. On one-day events, pharmaceutical waste must be picked up at the end of the day. It cannot be temporarily stored anywhere, even if the signs on the bins are removed.</p>	Board of Pharmacy	<p><b>Page 12, #6, b</b> - The Board of Pharmacy would like the pharmaceutical waste to be immediately removed and disposed of by the hazardous or medical waste transporter to prevent the possibility of drug diversion.</p>
<p><b>G. Chain of Custody</b></p>		
<p>1. Delete the words-"becomes the owner of the pharmaceutical waste" and delete the words "in accordance with the MWMA."</p>	Tri-TAC	<p><b>Page 6, #6, d</b> - Chain of Custody- CIWMB cannot suggest procedures that conflict with current statute. In addition, CDPH requires that when the home-generated pharmaceutical waste is collected by the facility, the facility becomes the owner of the pharmaceutical waste and is responsible for assuring that it is stored, transported, and disposed of in accordance with the Medical Waste Management Act by a licensed medical waste or hazardous waste transporter.</p>
<p>2. Having pharmacies assume ownership of the waste would deter them from becoming a collection program due to liability concerns.</p>	Pharmaceutical Committee	<p><b>Page 6, #6, d</b> – CDPH requires that when the home-generated pharmaceutical waste is collected by the facility, the facility becomes the owner of the pharmaceutical waste and is responsible for assuring that it is stored, transported, and disposed of in accordance with the MWMA by a licensed medical waste or hazardous waste transporter. CIWMB staff recommends no change in guidelines.</p>
<p>3. Inventorying what is coming in via collection bins is a large amount of staff time. A weighed and sealed container is sufficient until the controlled substances are incinerated.</p>	Pharmaceutical Committee City of San Jose	<p><b>Page 6, #6, d</b> – Comment noted.</p>

Comments and Responses - Criteria and Procedures for Model Home-Generated Pharmaceutical Waste Collection and Disposal Programs

Comment	Commenter	Draft Response to Comment in Document
4. Any system that results in the aggregation of pharmaceuticals is more susceptible to diversion, loss, or theft than is possible in a mail-back system.	Waste Management	Page 16 – Comment noted.
<b>H. Controlled Substances</b>		
1. Delete requirement for that signed inventory must accompany the pharmaceutical waste and must stay with law enforcement through the point of destruction. Delete requirement that contents must be checked against the inventory.	Tri-TAC	Page 6, #6, d – Deleting this requirement would conflict with U.S. DEA law. The U.S. DEA requires that 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.
2. Is a one-way drop container sufficient for controlled substances? Which law enforcement agent can take possession of controlled substances? Would an open drum qualify if the event is monitored by the police? Locking containers are not available through some local HHW programs. This would also limit ability to remove packing.	City of San Jose	Page 11, #4, d – A one-way drop container would be sufficient for controlled substances. The DEA requires that the person accepting controlled substances must be a sworn law enforcement officer. If a law enforcement officer were onsite, then an open drum would be sufficient.
3. Remove the requirement that if a medication is not identifiable, it shall be assumed to be a controlled substance.	Pharmaceutical Committee ESJPA	Page 11, #4, d – The Board of Pharmacy has stated that if a medication is not identifiable, it shall be assumed to be a controlled substance and handled accordingly.
<b>I. Medical/Hazardous Waste Hauler/Disposal Options</b>		
1. Manifesting presents a barrier by increasing costs. Do RCRA drugs need to be sorted separately?	City of San Jose	Page 3-4, #3 – CDPH regulations require that collected pharmaceuticals shall be handled as hazardous waste or medical waste. Deleting this provision would conflict with existing law.
2. Recommend removing "in accordance with MWMA". This would be a problem for pharmacies due to concerns over liability.	Pharmaceutical Committee	Page 3-4, #3, Page 7, #8 – Statutes enforced by CDPH require that collected pharmaceuticals shall be handled as hazardous waste or medical waste. Deleting this provision would conflict with existing law.

**Comments and Responses - Criteria and Procedures for Model Home-Generated Pharmaceutical Waste Collection and Disposal Programs**

<b>Comment</b>	<b>Commenter</b>	<b>Draft Response to Comment in Document</b>
3. The current language causes problems for sites that collect medications at several sites and consolidate at another site, e.g. San Mateo Sheriff and Palo Alto Medical.	Pharmaceutical Committee	Page 3, #3 – This language was included at the request of CDPH to ensure compliance with the MWMA. Deleting this provision would conflict with existing law.
<b>J. Education and Advertising</b>		
If participation is voluntary, making this a requirement seems to throw up a barrier to collection programs.	Tri-TAC Pharmaceutical Committee	Page 6, #7 – Staff disagrees and believes it is reasonable to require collection location operators to provide educational materials to the community and to consumers dropping off home-generated pharmaceuticals. The Board of Pharmacy requested that this be added and CIWMB believes it is important to educate the public about the proper and improper disposal of pharmaceuticals.
<b>K. Staffing</b>		
1. Suggest the following language: "The following staff are recommended at collection sites, and may be required if controlled substances are to be collected."	Tri-TAC Pharmaceutical Committee	Page 6, # 7. Comment noted.
2. Having a pharmacist on site adds significant cost and complexity to a collection program.	ESJPA	Page 13, #7 c. CIWMB staff agrees that this would add significant costs and could be deleted from the procedures.
3. Having law enforcement on site adds extraordinary costs to the program and is not necessary for programs where the pharmaceuticals are placed directly into secure containers.	ESJPA	Page 13, #7, b - Per DEA laws, only law enforcement officers can accept controlled substances. If a permanent collection program opts to collect controlled substances, a police officer or other law enforcement officer is required to be present to monitor and collect the controlled substances. Deleting this provision would conflict with federal law.
4. How can pharmacists identify drugs if they are not supposed to handle them?	Pharmaceutical Committee	Page 13, #7, c – This provision will be deleted per Board of Pharmacy recommendation thus allowing a pharmacist to handle and identify drugs.
<b>L. Signage</b>		

**Comments and Responses - Criteria and Procedures for Model Home-Generated Pharmaceutical Waste Collection and Disposal Programs**

<b>Comment</b>	<b>Commenter</b>	<b>Draft Response to Comment in Document</b>
1. Delete the section requiring signage that says, "Incineration only", because this is only necessary on containers used to transport the waste for disposal.	Pharmaceutical Committee	Page 4, #5 – Deleting this requirement would conflict with CDPH regulations.
2. Signage indicating pharmaceuticals are collected at this facility might encourage drug theft.	ESJPA	Page 4, #5 – CIWMB staff disagrees with this comment and believes it is important to provide proper instructions at the collection locations.
<b>M. Data Collection</b>		
1. Some facilities may not be able to monitor exact numbers of users.	City of San Jose Pharmaceutical Committee	Page 9, #12 - If the data is not available, the CIWMB would not require the data on the number of residents using the program. Programs would only be required to do the best they can to document this information as is done with the Form 303 for documenting HHW collected.
2. The data collection could be accomplished by providing a copy of the shipment document. Keeping the documents for 3 years is a barrier to becoming a collection site.	Pharmaceutical Committee	Page 15, #12 - CIWMB staff agree with the commenter regarding the data collection strategy but disagree that keeping documentation for 3 years is a barrier.
3. At one time events, does data collection refer to the event host agency or business?	City of San Jose	Page 2, #1- The entities doing the actual collection would be responsible for data collection.
4. Identifying drugs is a difficult task and requires great expertise.	Pharmaceutical Committee	Page 15, #12 - Comment noted.
<b>N. Mail Back</b>		
1. The State needs to review mail back programs with CDPH to assure that it is legal to mail pharmaceuticals through a common carrier.	Pharmaceutical Committee	Page 16 and 17. The Criteria and Procedures were developed in conjunction with CDPH and Board of Pharmacy. As such procedures for mail-back programs were reviewed.
2. Is the only way to get a mail back envelope by going to a pharmacy as suggested by this section?	Pharmaceutical Committee	Page 17, #4 – Yes, because this would be the most logical place to get the mail back envelopes. There may be other options, but pharmacies would be the most logical and convenient location.
3. Waste pharmaceuticals should not be required to be tracked so meticulously.	Pharmaceutical Committee	Page 17, #5 - This provision is required by CDPH and Board of Pharmacy to ensure compliance with their laws and regulations. Any deviation from these requirements would conflict with existing law.

**Comments and Responses - Criteria and Procedures for Model Home-Generated Pharmaceutical Waste Collection and Disposal Programs**

<b>Comment</b>	<b>Commenter</b>	<b>Draft Response to Comment in Document</b>
4. Data should be reported by the facility receiving the mail-back envelopes.	Pharmaceutical Committee	<b>Page 17, #7</b> – The CIWMB is requiring this provision in order to determine the effectiveness of various types of collection programs. This information will be used for the report required by SB 966 that is due in 2010.
5. Mail back programs are good methods to dispose of unwanted and expired pharmaceuticals, because it is convenient. They go directly to destruction repositories, easy to track and keep records on, and it is compliant with HIPA.	Waste Management	<b>Page 16 - first paragraph</b> - Board staff agrees with this comment.
<b>O. Enforcement</b>		
1. The document doesn't address who will perform enforcement actions.	Waste Management City of San Jose	<b>Page 16, #2</b> - These facilities must be DEA-approved and able to accept controlled substances for destruction if controlled substances are mailed directly to the facility. Any enforcement actions would be carried out by the DEA or designated agency.  <b>Page 6, #6, d</b> - These are DEA laws to be enforced by the DEA.
<b>P. Container Security</b>		
1. Thefts should be reported with 24 hours at least to the police, the Board of Pharmacy and the CDPH.	Board of Pharmacy	<b>Page 7, #8</b> - This comment was already incorporated in the procedures.
<b>Q. Additional Comments</b>		
1. Add a section framing the issue of pharmaceuticals collection and disposal to include barriers, existing programs, controlled substances, and EPR funding.	City of San Jose Pharmaceutical Committee	<b>Page 1</b> – CIWMB staff will add brief language to address suggested additions.
2. The proposed model is too restrictive and will discourage jurisdictions from developing model pharmaceutical collection programs. A model should serve as a guide allowing flexibility to adapt to their needs.	ESJPA	These procedures are in response to the requirements of SB 966 and are the culmination of comments from many diverse groups including state agencies, local governments, pharmaceutical manufacturers, and reverse distributors.
3. The document lacks specificity in areas such as the program approval process and is not in regulation and	City of San Jose Board of Pharmacy	This document provides information on what the procedures were attempting to accomplish and are only set up as a model as required in SB 966.

**Comments and Responses - Criteria and Procedures for Model Home-Generated Pharmaceutical Waste Collection and Disposal Programs**

Comment	Commenter	Draft Response to Comment in Document
will be difficult for the agencies involved. The enforcement procedures need augmentation and development.		
4. What is the timing of the effort?	City of San Jose	As stated in SB 966-these procedures were due Dec. 1, 2008 and an evaluation of the different programs is due to the Legislature in 2010.

**Acronyms and Abbreviations Used**

ADF-Advanced Disposal Fee

CDA – California Department of Consumer Affairs

CDPH-California Department of Public Health

CPSC – California Product Stewardship Council

DEA-Drug Enforcement Agency

DTSC-Department of Toxic Substances Control

EPR-Extended Producer Responsibility

ESJPA – Environmental Services Joint Powers Authority

HHW-Household Hazardous Waste

MWMA – Medical Waste Management Act

Pharms- Pharmaceutical Waste

PRC – Public Resources Code

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<sup>i</sup> Tri-TAC is a technical advisory committee on POTW regulatory and policy issues

<sup>ii</sup> The Pharmaceuticals Working Group is an Ad Hoc committee of professionals from local government, non-profit and the pharmaceutical reverse distribution industries working towards pharmaceutical take-back programs.

# Attachment 6

## *DEA Policy on Correcting Controlled Substances Prescriptions*



U. S. Department of Justice  
Drug Enforcement Administration  
8701 Morrisette Drive  
Springfield, Virginia 22152

[www.dea.gov](http://www.dea.gov)

OCT 15 2008

Dear Colleague:

On November 19, 2007, the Drug Enforcement Administration (DEA) published in the Federal Register (FR) the Final Rule entitled *Issuance of Multiple Prescriptions for Schedule II Controlled Substances* (72 FR 64921). In the preamble to that Rule, DEA stated that "the essential elements of the [schedule II] prescription written by the practitioner (such as the name of the controlled substance, strength, dosage form, and quantity prescribed) . . . may not be modified orally."

The instructions contained in the Rule's preamble are in opposition to policy posted on the DEA Diversion website regarding changes a pharmacist may make to a schedule II prescription after oral consultation with the prescriber. In a Question and Answer section, the website instructed that a "pharmacist may change or add the dosage form, drug strength, drug quantity, directions for use, or issue date only after consultation with and agreement of the prescribing practitioner."

DEA recognizes the resultant confusion regarding this conflict and plans to resolve this matter through a future rulemaking. Until that time, pharmacists are instructed to adhere to state regulations or policy regarding those changes that a pharmacist may make to a schedule II prescription after oral consultation with the prescriber.

Questions regarding this correspondence may be directed to the Liaison and Policy Section, Office of Diversion Control, DEA at (202) 307-7297.

Sincerely,

A handwritten signature in black ink, appearing to read "Joe Rannazzisi".

Joseph T. Rannazzisi  
Deputy Assistant Administrator/  
Deputy Chief of Operations  
Office of Diversion Control

# Attachment 7

## *Theft of Dangerous Drugs from the Supply Chain*

## Licensees can be held accountable for drug delivery thefts

Medication drugs stolen from drug transportation companies are a serious problem nationwide. These stolen drugs are sold on the street, on the Internet, or introduced into the medication supply chain by being sold at heavily discounted prices to pharmacies or wholesalers. When the stolen drugs enter the medication supply chain, unsuspecting consumers face potential health and safety risks from legitimate products, which may have been mishandled by the criminal enterprises. Improper storage or adulteration of the stolen drugs can pose a significant health hazard to consumers when reintroduced into the retail market.

Apart from the more sensational instances where more than 16 million doses of hydrocodone combination products were

stolen from a tractor-trailer parked at a truck stop or a courier van containing 2,000 tablets of hydrocodone and approximately 200 tablets of oxycodone was stolen while the driver was inside delivering the freight, there are smaller but significant thefts that occur in-transit. Licensees must be aware that the Board and DEA hold registrants accountable for failing to take actions to prevent, discover, and report in-transit thefts as required by law.

For example, a pharmacist-in-charge was cited and fined by the Board because she signed for a delivery and did not open the container until later. Upon opening the container, the PIC discovered that the box contained objects other than the controlled substances listed in the shipment. The PIC was cited

*See Licensees, Page 3*

## Licenseses

*Continued from Page 2*

for violation of Business & Professions Code section 4059.5 for signing for the shipment and failing to immediately examine the shipment contents. Wholesalers and the receiving pharmacies have also been cited and fined for allowing non-pharmacists (pharmacy technicians) to accept and sign for drug deliveries.

Wholesalers and pharmacies are equally responsible for the careful review of all pharmaceutical shipments and must report any short shipments to the DEA and the police, and the loss of any controlled substance must be reported to the Board of Pharmacy within 30 days of discovery (Title 16, California Code of Regulations section 1715.6).

Preventing and discovering in-transit thefts include strict monitoring and review of drug shipments at every point from the manufacturer to the pharmacy. The manufacturer is responsible for checking the shipment amounts before the shipment leaves the facility, and the receiving wholesaler must then review the shipment for correct amounts before delivering or passing the shipment on to a contracted carrier. The wholesaler carrier is then responsible for the shipment until the receiving pharmacist signs for it. Consequently, the receiving pharmacist must immediately open and inspect the shipment to ensure that the boxes contain the correct products and amounts, because once the pharmacist signs off on the shipment, the responsibility for the shipment's contents becomes his or hers.

Other ways of preventing in-transit theft are for manufacturers to refrain from including the drug's name on the outside of the shipping container and for wholesalers to investigate the backgrounds of any carriers with whom they contract. A licensed wholesaler may be operating within the law, but many wholesalers use ground couriers who might then subcontract other couriers of varying sizes and standards of professionalism.

At its November 2007 meeting, the National Association of Boards of Pharmacy created the NABP Task Force on Prescription Drug Diversion from Common Carriers. The task force was created as a result of a resolution passed at their annual meeting in May 2007 that noted:

- (1) The diversion of prescription medication from common carriers presents a threat to the public health; and
- (2) Regulations regarding the distribution and delivery of prescription drugs vary by state and often do not include accountability provisions for common carriers that distribute and deliver prescription drugs.

The charge of the task force is to study issues surrounding the diversion of prescription drugs from common carriers or their agents during interstate and intrastate distribution and delivery to wholesalers, pharmacies, patients, and patients' agents and to recommend possible solutions.

January 31, 2008

2008 FEB -6 AM 10:55

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

Dear Board Members:

Kaiser Permanente is asking for your assistance in educating and gaining compliance from the top common carriers UPS, FedEx, and DHL etc regarding Business and Professions Code 4059.5 That law requires dangerous drugs (as defined) to be delivered by common carriers directly to each licensed pharmacy, except for hospital pharmacies.

The common couriers are generally compliant with this code for hospital pharmacies which allows delivery by the common carrier to the hospital loading, receiving dock. They are not generally compliant regarding pharmacies that are located outside a hospital i.e. pharmacies operating as community pharmacies with a "PHY" license prefix due to the carriers refusing to deliver directly to the pharmacy. We have on many occasions contacted these companies at local and national levels and have been unsuccessful at obtaining substantial compliance.

We would like the Board to formally notify these companies to educate and warn them on their lack of legal compliance with California law. Their lack of compliance does not only affect Kaiser Permanente but many other pharmacies which receive dangerous drugs from these common carriers. I have listed the addresses of the top three common carriers corporate offices. If you should need any further information please feel free to contact me.

Thank you,

Steve W. Gray

FedEx Corporate Contributions  
3610 Hacks Cross Road  
Building A, First Floor  
Memphis, TN 38125  
Phone: 901-369-3600

UPS Corporate Headquarters  
55 Glenlake Parkway, NE  
Atlanta, GA 20214  
Phone: 404-828-6000

DHL Express  
1200 South Pine Island Road Suite  
600  
Plantation, FL 33324

Steve.W.Gray



Steve.W.Gray@kp.org

11/06/2008 12:01 PM

Several years ago, after receiving a "Correction Notice", we committed to the Board of Pharmacy to try our best to get the Rx Drug deliveries to be delivered DIRECTLY to the licensed pharmacies (as required by statute B&P 4059.5) in our medical facilities, vs. being "dropped off" at the "loading dock" and be handled by our non-pharmacy, materials Management (MM) personnel. It has been frustrating and not very successful. Several months ago, I believe at an Enforcement Committee meeting, I ask if the BoP would officially contact the main carriers, e.g. UPS and FedEx with some kind of "encouragement" to follow the law. I simply cannot remember what the BoP decided to do or if it already acted?

Do you need more from us? Is anything planned? Is this still an important issue, relative to other issues "we" face?

Frankly, when I check with other organizations, they virtually all say they have the same problem but they are making no effort to change the delivery practices. We have repeatedly contacted the carriers' National leadership and we get statements that things will change. I believe that the UPS change described below is an effort but as you can see we are still having trouble. I believe that if it is important to the BoP, we need its help.

Steven W Gray, PharmD, JD

Kaiser Permanente, California Pharmacy Regulatory Compliance and Professional Affairs Leader

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----- Forwarded by Steve W Gray/CA/KAIPERM on 11/06/2008 11:48 AM -----

# Attachment 8

*Minutes of the Enforcement Committee  
Meeting of December 9, 2008*



**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  
MINUTES**

**DATE:** December 9, 2008

**LOCATION:** Department of Consumer Affairs  
Hearing Room, First Floor  
1625 N. Market Blvd.  
Sacramento, CA 95834

**BOARD MEMBERS  
PRESENT:** Robert Swart, PharmD, Chairperson  
Stanley C. Weisser, RPh  
James Burgard, Public Member

**STAFF PRESENT:** Virginia Herold, Executive Officer  
Anne Sodergren, Assistant Executive Officer  
Kristy Schieldge, Senior Staff Counsel

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Chairperson Swart called the meeting to order at 9:36 a.m.

**1. Update on the Implementation of Drug Take Back Programs from Patients (SB 966 Chapter 542, Statutes of 2007)**

Chairperson Swart provided an overview and background of the bill and highlighted the comments submitted by Executive Officer Herold to the California Integrated Waste Management Board (CIWMB). Many of the board's comments were not incorporated into the new guidelines. However, because many comments were received from other agencies as well, CIWMB will consider all comments at its meeting on December 19, 2008.

The committee discussed additional concerns including the diversion of the returned products and how to keep the pharmacy clean. Ms. Herold also advised the committee about the introduction of SB 26 (Simitian, 2009) which requires the board to work with other agencies to develop regulations for the drug-take back programs.

Ms. Herold introduced Jim Cropper (CIWMB) and requested process clarification on the CIWMB process for changing the adopted guidelines.

Jim Cropper stated that board comments were not received and therefore were not incorporated into the final draft model programs. He stated that the comments which were received were placed in a metrics to allow for quick review. Mr. Cropper indicated that the metrics will be released at the end of the week. Three or four primary comments will be reviewed during the December 19, 2008 meeting and recommendations will be made. The CIWMB will consider the revised requirements at its February 2009 Board Meeting.

Mr. Cropper indicated that about 10 different organizations submitted comments representing the public, cities that have collection programs, etc. Chairperson Swart expressed concern that the board's comments will not be included, especially given that the board is responsible for enforcement of some of the provisions.

Stan Weisser expressed concern also that some of the issues raised by the board were not included and highlighted. He noted one in particular, that being the inability of a pharmacy to recoup the costs for collection and disposal.

Jim Cropper responded that the legal mandate was that the program needed to be at no cost to consumers. The document does include possible ways to recover some of the costs such as applying for grants, clean water programs funding, etc.

John Cronin stated that he was involved in this issue when the original bill, SB 966, was being passed. The impression at that time was that these programs are being rushed. Dr. Cronin stated concern that, based on the current program specifications, there will not be wide adoption. Dr. Cronin suggested that everyone take a step back and review the whole program rather than just throwing together these model programs.

Executive Officer Herold provided an overview of SB 26 (Simitian, 2009) which puts the board squarely in the middle of the implementation of the drug-take program. Ms. Herold read section 4001.1 from the bill, which requires the board to coordinate with other state agencies, local governments, drug manufacturers and pharmacies to develop sustainable, efficient policies and programs to properly manage pharmaceutical wastes and the disposal of these wastes. Board staff will need to speak with Senator Simitian's staff as well as complete a full bill analysis. This will be provided at the January 2009 Board Meeting.

## **2. Discussion of Sharps Take Back by Pharmacies**

Chairperson Swart discussed the board's policy with respect to pharmacies accepting the return of used needles in sharps containers. The policy statement will be included in the January 2009 *Script* newsletter.

The board agreed, at its October 2008 Board meeting, to pursue a statutory change to authorize the pharmacy to take back used syringes. A similar provision is contained in SB 26.

Committee discussion included the question of the cost. While some counties are providing grants to cover the costs, typically 1-2 years of grant money is required to establish the program. At that point, however, the grant money is gone.

Members of industry indicated that they are complying with local ordinances in conformance with sharps take back requirements. Longs, specifically, indicated that they are receiving not only returned needles, but also drugs. In addition, needles are being returned in unauthorized containers. While Longs Drugs have sharps containers available for sale, many consumers are not returning the used needles in sharps containers. San Luis Obispo (SLO) is providing Longs with containers to place the sharps units directly into the container. Longs keeps them behind the pharmacy counter, theoretically, when the pharmacy is closed, should someone could come back and try to access the container. Consumers do put other items in the containers. SLO is also arranging for the disposal of the needles and is paying for it with a two year grant. Marin County has a similar program and also pays for the disposal. In Marin County, the county also pays for the sharps container so the disposal is not the same issue as in SLO.

#### **Board Comments:**

Stan Weisser asked if similar problems are occurring for entities using mail back containers.

In response, Mr. Weisser was advised that patients appear resistant to purchase mail back containers, which cost over \$20.00. Also, there is a company that is promoting the ability of pharmacies to melt sharps units. To do this, a specific sharps container is used, that when returned by the customer, can be melted at the pharmacy. The cost of each unit is about \$1800 and the pharmacy would be left with the cost to implement.

Longs provided some "lessons learned" from their efforts in various parts of the California and stated that the costs for these solutions make the programs cost prohibitive.

Clarification was provided on the containers provided from SLO. They are round containers without a lid, similar to a garbage can. The public has become very familiar with the process in Marin County. Longs indicated that public education is a key component to ensure that needles are returned in sharps containers. Longs suggested that there be a uniform public education and outreach.

John Cronin reiterated the importance of dealing with the costs of this program. He added that CIWMB may not be aware of some of the hidden costs and all of the different laws that cover such disposal.

The committee asked for clarification of disposal options of these returned products. Jim Cropper (CIWMB), Kelvin Yamada (Department of Public Health (DPH)) and Steve Kubo (DPH) described the three methods: Household Hazard Waste collection facilities, use of mail back container or collection at consolidations centers (including pharmacies).

DPH advised the committee that individual agencies can have the products sent to an incineration facility. DPH also highlighted some problems during transportation of the products, including occasional cases where returned product has fallen off the truck. There are also investigations resulting from stolen containers and sharps showing up at recycling centers because people put them in bottles that are turned in to the recycling center. DPH anticipates seeing more problems now that the ban has been implemented.

DPH is aware that SLO is providing the sharps containers to consumers, however they are unclear on the continued funding. Some counties are offering sharps containers at no cost, however there is no widespread advertising.

Lynn Rolston (CPhA) informed the board that CPhA has made waste the highest priority and will be meeting with all stakeholders. Ms. Rolston requested to meet with Ms. Herold to put forward a coordinated effort to address all concerns and find a true solution that also manages the cost, especially given the current economy.

### **3. E-Prescribing Discussion**

Chairperson Swart highlighted the two forums, a board-sponsored forum as well as one sponsored by the California Healthcare Foundation that both occurred on November 20, 2008 to discuss E-prescribing. The forums were very similar in structure and both allowed for public input. Dr. Swart stated that E-prescribing is a priority of the administration.

Dr. Swart discussed the DEA proposed changes to allow for E-prescribing of scheduled drugs and the issues were raised specific to the proposed rules for E-prescribing. The DEA has not responded to the board's comments. It is unclear when or how the DEA will proceed with the proposed rule and stated that there is considerable momentum to push for E-prescribing. He noted, however that the inability to e-prescribe scheduled drugs is a large barrier to full implementation.

The California Healthcare Foundation and Ms. Herold will share results from both forums. Ms. Herold will provide the board with an update at the January 2009 Board Meeting.

John Cronin stated that one outcome pharmacists are reporting is that medication errors are not necessarily being reduced, rather that the type of errors that occur is changing. Dr. Cronin recommended that the board track this information and move slowly. Dr. Cronin highlighted issues with privacy and the interface with medical records and advised the committee that there are some government agencies looking at these issues.

No committee action was taken.

#### **4. Fingerprinting Initiative of the Department of Consumer Affairs for Health-Related Boards**

Chairperson Swart discussed recent changes to fingerprinting and provided a summary. For a number of years the board has fingerprinted all applicants to secure criminal background information before issuing a license. On November 4, 2008, Director Carrie Lopez issued a memo to all Executive Officers and Bureau Chiefs under the department's purview, setting out expectations for enforcement and public disclosures. One of the specific requirements detailed by the Director is that all health boards within the Department implement a plan for securing fingerprints from all licensees regardless of when they were first licensed.

When researching the possible impact to board operations to implement such a change, staff learned that the board was fingerprinting pharmacist applicants as early as September 1949, and we estimate that approximately 150 currently licensed before this date were not fingerprint cleared with the Department of Justice. It is unclear when the board began requiring fingerprints for business owners.

In 2001, the Department of Justice began transitioning to electronic submission of fingerprints (LiveScan). Fingerprint background information collected since that time is stored electronically. However, pre-existing fingerprint information was not converted into this electronic format. Given that full conversion of previous records is unlikely to occur, the committee should consider a recommendation to require licensees to resubmit fingerprints as a condition of renewal. Ms. Herold highlighted that the majority of the board's licensees are currently not in the automated system because they were fingerprinted before the implementation of LiveScan.

Ms. Herold also discussed the creation of the Criminal Conviction Unit to address current workloads and centralize the functions of background check review and investigations. Ms. Herold recommended that the Public Education Committee develop informational brochures to educate licensees on the process should the board move forward. Also, Ms. Herold advised the committee that renewal notices will now require the licensee to indicate whether or not they have been convicted or disciplined during the last renewal cycle.

## **Public Comments:**

John Cronin expressed concern about the requirement to post all pending accusations on the board's Web site as detailed in the director's memo.

Ms. Herold clarified that the board will be posting the accusation after it becomes a public document.

Dr. Cronin also expressed concern over the administrative process in general and that regulatory agencies may be misusing this.

Staff counsel advised that the Department of Consumer Affairs legal office is drafting language that explains what an accusation is and what it means.

There were no additional public comments and no committee action.

## **5. Citation and Fine Program Overview 2007-2008**

Bob Ratcliff, Supervising Inspector, provided a power point presentation on citation and fines issued and provided a comparison by fiscal year. The presentation included a breakdown of citations issued by sites as well as the top five violations charged to licensed sites, pharmacists-in-charge, and individual pharmacists. Supervising Inspector Ratcliff also provided a breakdown of the range of fines issued for the license category.

## **Public Comments:**

Dr. Cronin wanted to ensure that the board understands how the program is perceived and provided his historical perspective on why the board implemented the program. Dr. Cronin stated that he believes the program was never intended to be used as a first line of action by the board, rather as an opportunity to allow a licensee to correct a problem and if the licensee failed to do so, then board could pursue a citation and fine. Dr. Cronin also stated that the most common complaint that he receives in his role is surrounding the citation and fine program. He expressed concern over citations being issued for multiple violations and that the totals are beginning to be very substantial. He encouraged the board to reconsider that the administrative process is to gain compliance and is not designed to be punitive. He encouraged the board to look at the roots of the program.

Dr. Cronin expressed concern over medication errors and the investigations that result from a consumer alleging such an error.

Chairperson Swart agreed with some of the statements made by Dr. Cronin including the issue of medication errors.

Ms. Herold responded to these concerns, highlighting that it is not unusual for the board to close a case due to insufficient evidence. The board does not issue a citation and fine if we are unable to substantiate the error. Ms. Herold also underscored the value of the office conference appeal, which many times allows the licensee the opportunity to provide additional information, as well as establishes an educational opportunity.

Chairperson Swart recommended that the board should take into consideration whether the licensee's history can be factored into whether the citation is issued.

Ms. Herold made distinction that the board is a consumer protection agency and does not have a provision to allow for a "free pass" for a first offense. A medication error is very relevant to the consumer that it happens to. Inspectors are trained to look at the QA program to see how serious the program is being used and whether changes were made to prevent future errors.

Lynn Rolston, CPhA, acknowledged the board's consumer protection role. Pharmacists are concerned about public trust and keeping people safe. Ms. Rolston stated that she believes most behavior change takes place because someone has been sensitized to the information and shared that this issue was brought to President Schell. Ms. Rolston stated that education will help pharmacists avoid the mistakes and would appreciate the opportunity.

Ms. Herold highlighted the presentation given at the July 2008 Board Meeting, focusing on medication errors. She shared that the January 2009 issue of *The Script* will include some investigation results but reiterated that the Institute of Safe Medication Practices and others may have better resources to help educate licensees to prevent future errors. The board does try to provide education outreach.

Ms. Rolston restated her previous request for a new effort be put forth to better educate licensees. Ms. Rolston expressed concern that *The Script* is only provided to facilities and may not be passed on to individual licensees.

Supervising Inspector Ratcliff indicated that inspectors have a lot of enforcement discretion when it comes to routine inspections and that these inspections present a good educational opportunity. He also stated that the board has historically used its enforcement discretion when a new mandate goes into effect to allow for industry to implement. However, after a period of time, the board must begin to enforce against it. We do not have a lot of enforcement discretion when the investigation/inspection is a result of a consumer complaint. If the board substantiates findings, they must take action.

There was no further committee discussion or action on this item.

## **6. DEA Policy on Correcting Schedule II Prescriptions**

Chairperson Swart provided background on this topic. In October 2008, the board received clarification from the Drug Enforcement Administration on the final rule, entitled *Issuance of Multiple Prescriptions for Schedule II Controlled Substances* (72 FR 64921) as it relates to the changes that can be made by a pharmacist.

As highlighted by the DEA, the preamble to the final rule is in conflict with information posted on the DEA's website regarding changes a pharmacist may make to a Schedule II prescription after oral consultation with the prescriber.

In light of this confusion, the DEA is instructing pharmacists to adhere to state regulations or policy until this matter is resolved through a future rulemaking.

### **Public Comments:**

John Cronin stated that when the triplicate law change occurred, the board developed Frequently Asked Questions (FAQs) that do not appear to be updated. He requested that the FAQs be updated. Also, he stated that he recently received a call on a Q&A from CPhA regarding the use of the tamper resistant forms satisfying the requirement.

### **7. Theft of Dangerous Drugs from the Pharmaceutical Supply Chain**

Chairperson Swart provided an overview of the topic. California Pharmacy Law requires that all deliveries of dangerous drugs and devices may only be received by and signed for by a pharmacist or designated representative. Further, the law specifies that delivery of such products to a hospital's central receiving area must be subsequently delivered to the hospital pharmacy within one working day, and the pharmacist on duty must immediately inventory the products. (Business and Professions Code Section 4059.5(a) and (c))

Board staff received correspondence from Kaiser Permanente, requesting the board's assistance in communicating the delivery requirements for dangerous drugs and devices to pharmacies. According to information received from Kaiser, despite numerous attempts to address this issue with common carriers like Fed Ex and UPS, deliveries are still made to unauthorized locations.

The board does not regulate common carriers, nor is there any requirement in pharmacy law requiring such licensure to handle dangerous drugs and devices. However, board licensees are responsible for ensuring the appropriate delivery, receipt and handling of such products.

This is an issue for many pharmacies that use common carriers. It is easy to identify the problem, however the solution is difficult.

Ron Bone, McKesson Corporation discussed this issue last week. Healthcare Distribution Management Association, the trade association and McKesson are all very concerned with this issue. They are educating the driver community as well as addressing other security issues that cannot be shared publicly.

John Cronin stated that UPS and other common carriers probably do not know the law requiring that the products be delivered directly to the pharmacy. He stated that this may be a good topic for the board to provide direction to licensees. He complained that *The Script* article did not provide any realistic solutions. Dr. Cronin expressed the need for some clarity and that pharmacists look to the board for clarity and stated that drugs get diverted from other sources, such as mail carriers and common carriers as well as from a licensed person or site.

Chairperson Swart requested guidance from counsel on how to proceed.

According to counsel, it is incumbent upon the wholesaler to ensure the appropriate delivery of the product. It appears that this could be a contractual issue between the wholesaler and the common carrier. Legally, the board does not have any authority over the common carrier. Business and Professions Code section 4166 imposes a legal obligation on the wholesaler to ensure the appropriate delivery of the products. Counsel advised that the board could consider convening a subcommittee to further explore if any additional changes need to be made in our law.

Stan Weisser stated that an organization that maintains a contract with the common carrier holds the hammer and can make results happen.

Jim Burgard shared a similar scenario which occurred with hazardous materials when establishing the chain of custody and stated that when parameters were established, it became a straight forward process.

Chairperson Swart also indicated that the store could send the delivery back if it is not delivered appropriately. Chairperson Swart requested that this item be brought to the full board for consideration and to gain input on what can be done.

#### **8. Public Comment for items Not on the Agenda**

No additional public comment was provided.

The meeting was adjourned at 12:23 p.m.

# Attachment 9

*Second 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						
	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						
	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><u>N</u></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><u>N</u></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><u>N</u></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					
<b>Qtr 4</b>	<b><u>N</u></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:	<b>1. Administer the Pharmacists Recovery Program.</b> <table border="1" data-bbox="365 252 1510 525"> <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></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Qtr 4</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					Qtr 4																												
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	Qtr 4																																																							
	<b>2. Administer the Probation Monitoring Program.</b> <table border="1" data-bbox="365 598 1234 903"> <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></td> <td></td> </tr> <tr> <td>Sites</td> <td>3</td> <td>6</td> <td></td> <td></td> </tr> <tr> <td>Tolled</td> <td>18</td> <td>14</td> <td></td> <td></td> </tr> <tr> <td>Inspections Conducted</td> <td>41</td> <td>26</td> <td></td> <td></td> </tr> <tr> <td>Successfully Completed</td> <td>9</td> <td>1</td> <td></td> <td></td> </tr> <tr> <td>Petitions to Revoke Filed</td> <td>1</td> <td>0</td> <td></td> <td></td> </tr> </tbody> </table>								Qtr 1	Qtr 2	Qtr 3	Qtr 4	Individuals	108	117			Sites	3	6			Tolled	18	14			Inspections Conducted	41	26			Successfully Completed	9	1			Petitions to Revoke Filed	1	0																
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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			
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				
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 30.77%	2 15.38%	5 38.46%	0 0%	2 15.38%	553
Qtr 2	16	2 12.50%	8 50%	2 12.50%	3 18.75%	1 6.25%	680
Qtr 3							
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:	<p>1. Inspect licensed premises to educate licensees proactively about legal requirements and practice standards to prevent serious violations that could harm the public.</p> <table border="1" data-bbox="367 289 1479 506"> <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></td> <td></td> <td></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				Qtr 4			
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	Qtr 3																				
	Qtr 4																				
	* Decrease due to new licenses issued for CVS/Long's buyout.																				
	<p>2. Inspect sterile compounding pharmacies initially before licensure and annually before renewal.</p>																				
	<table border="1" data-bbox="367 653 1162 873"> <thead> <tr> <th></th> <th>Number of Inspections</th> <th>Number Inspected Late</th> </tr> </thead> <tbody> <tr> <td>Qtr 1</td> <td>59</td> <td>0</td> </tr> <tr> <td>Qtr 2</td> <td>67</td> <td>0</td> </tr> <tr> <td>Qtr 3</td> <td></td> <td></td> </tr> <tr> <td>Qtr 4</td> <td></td> <td></td> </tr> </tbody> </table>		Number of Inspections	Number Inspected Late	Qtr 1	59	0	Qtr 2	67	0	Qtr 3			Qtr 4							
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Qtr 2	67	0																			
Qtr 3																					
Qtr 4																					
<p>3. Initiate investigations based upon violations discovered during routine inspections.</p>																					
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Qtr 2	373	13	4%																		
Qtr 3																					
Qtr 4																					

Objective 1.5	Initiate policy review of 25 emerging enforcement issues by June 30, 2011.
Measure:	The number of issues.
Tasks:	<p>1. <b>Monitor the implementation of e-pedigree on all prescription medications sold in California.</b></p> <p><b>Sept. 28, 2006:</b> Board convenes third Workgroup on Implementation of E-Pedigree Meeting. Presentations provided by EPCglobal, McKesson, Supervising Inspector Nurse and Johnson and Johnson.</p> <p><b>Sept. 30, 2006:</b> 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.</p> <p><b>Oct. 6, 2006:</b> FDA provides presentation on federal pedigree requirements at board-hosted NABP District 7 &amp; 8 Meeting.</p> <p><b>Dec. 2006:</b> 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.</p> <p><b>Jan. 2007:</b> EPCglobal finalizes electronic messaging standards for electronic pedigrees.</p> <p><b>Feb. 2007:</b> 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.</p> <p><b>March 2007:</b> 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.</p> <p><b>May 2007:</b> Board convenes fifth Workgroup on Implementation of E-pedigree Meeting. Presentations are made by EPCglobal, AmerisourceBergen and SupplyScape. 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.</p> <p><b>June 2007:</b> 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.</p> <p><b>Dec. 2007:</b> 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.</p> <p><b>Jan. 2008:</b> Board reviews requests for delay until 2011 from members of the pharmaceutical supply chain.</p> <p><b>Feb. 2008:</b> Questions and Answers released. Specialized area of the Board's Website is created to consolidate e-pedigree information.</p> <p><b>March 2008:</b> Board delays implementation date for e-pedigree requirements from January 1, 2009 until January 1, 2011.</p>

- 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.

**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.
- July 2007:* Board hears presentations on EPCglobal standards.
- Sept. 2007:* Enforcement Meeting has large audience (200 people). Presentations by PhRMA, GSK, Bracco, CPhA, EPCglobal, Walgreens, Rite Aid, CVS, rfXcel, and HDMA. 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.
- 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.

**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.*
- 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 gave 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 and presents status of California's e-pedigree efforts.*
- June 2008: Executive staff and supervising inspector provides 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.*

- 6. Provide information about legal requirements involving e-prescribing to support the Governor's Health Care Initiative and its promotion of e-prescribing.**
- Sept. 2007: Provided comments on proposed statutory requirements.*
- Dec. 2007: Sought DCA's support for involvement in e-prescribing by the Administration. Provided comments on proposed e-prescribing initiatives.*
- Oct. 2008: Executive Officer Herold joins a task force to achieve e-prescribing coordinated by the California HealthCare Foundation.*
- 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.*
- Jan. 2009: Executive Officer Herold works with California HealthCare Foundation and Medical Board to plan joint activities with licensees to facilitate e-prescribing.*
- 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.**
- 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.*
- Dec. 2007: Meeting with Department of Health Care Services on issues involving security forms for MediCal prescriptions.*
- 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.*
- April 2008: Subscriber alert released with information for contact resources from the California Department of Health Care Services about security forms for MediCal prescriptions.*
- Oct. 2008: Requirements for security forms in place.*
- 8. Liaison with other state and federal agencies to achieve consumer protection.**
- 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.*
- 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.*
- 3rd Qtr 07/08: Bimonthly meeting with the Department of Health Care Services continue. Board works with the Drug Enforcement Administration on joint investigations and received specialized training.*
- 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.*

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.
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.
- 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.
- 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.
- 3rd Qtr 08/09:* First stakeholder meeting scheduled to discuss drug distribution within hospitals.

# Attachment 10

*Enforcement Statistics 2008-09*

# 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			69
Pleadings Filed	29	28			57
<b>Pending</b>					
Pre-accusation	73	76			76
Post Accusation	76	84			84
<b>Total</b>	<b>153</b>	<b>160</b>			<b>160</b>
<b>Closed**</b>					
<b>Revocation</b>					
Pharmacist	0	1			1
Pharmacy	1	2			3
Other	3	5			8
<b>Revocation, stayed; suspension/probation</b>					
Pharmacist	3	3			6
Pharmacy	0	0			0
Other	0	0			0
<b>Revocation, stayed; probation</b>					
Pharmacist	0	2			2
Pharmacy	0	0			0
Other	1	2			3
<b>Suspension, stayed; probation</b>					
Pharmacist	0	0			0
Pharmacy	0	0			0
Other	0	0			0
<b>Surrender/Voluntary Surrender</b>					
Pharmacist	2	0			2
Pharmacy	0	0			0
Other	1	2			3
<b>Public Reproval/Reprimand</b>					
Pharmacist	0	0			0
Pharmacy	0	0			0
Other	0	0			0
Cost Recovery Requested	\$46,643.50	\$62,140.50			\$108,784.00
Cost Recovery Collected	\$25,856.54	\$45,622.15			\$71,478.69

\* 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			95
Pharmacy	2	4			4
Other	13	16			16
Probation Office Conferences	10	8			18
Probation Site Inspections	41	26			67
Probationers Referred to AG for non-compliance	3	0			3

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 12/31/08)**

Program Statistics

In lieu of discipline	1	2			3
In addition to probation	3	2			5
Closed, successful	5	7			12
Closed, non-compliant	0	1			1
Closed, other	1	1			2
Total Board mandated Participants	59	59			59
Total Self-Referred Participants*	20	20			20
Treatment Contracts Reviewed	56	51			107

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 December 31, 2008

# 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	504	302			806
Closed	705	284			989
Pending (at the end of quarter)	1813	1831			1831

#### Cases Assigned & Pending (by Team)

Compliance Team	224	270			270
Drug Diversion/Fraud	160	182			182
Probation/PRP	12	125			125
Mediation/Enforcement	145	170			170

#### Application Investigations

Initiated	81	120			201
Closed					
Approved	46	32			78
Denied	10	11			21
Total*	70	64			134
Pending (at the end of quarter)	257	323			323

#### Citation & Fine

Issued	424	87			511
Citations Closed	258	178			436
Total Fines Collected	\$418,500.00	\$240,975.00			\$659,475.00

\* This figure includes withdrawn applications.

\*\* Fines collected and reports in previous fiscal year.

# California State Board of Pharmacy Citation and Fine Statistics July 1, 2008 – December 31, 2008

**511 Citations were issued this fiscal year**

Total dollar amount of fines issued this fiscal year  
\$ 947,525.00

Total dollar amount of fines collected  
\$659,475.00\*

\*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 164

Average number of days from date case is routed to Citation Unit to date citation is issued 15.75

223 citations are closed. The average number of days from date citation is issued to date citation is closed is 53

## 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
511	74	5	65	47	156	7	19	0

## Citation Breakdown by Miscellaneous license type

Wholesalers	Exemptee's	Clinics	Drug room	Exempt Hosp.	Hosp. pharmacy	Misc.	Unlicensed Premises	Unlicensed person
13	11	1	7	18	72	7	9	0

\*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	19%	1716 - Variation from prescription	25%	4301(j)/111295/351- Adulterated Heparin Held at Pharmacy	37%
1732.5(a)- Renewal requirements for pharmacist - 30 hours of continuing education	15%	1714(b)- Operational standards and security; pharmacy responsible for pharmacy security	6%	4169(a)(2) - Prohibited Acts; Purchase, trade, sell, or transfer dangerous drugs to that the person knew or reasonably should have known were adulterated...	8%
1732.5(b)- Renewal requirements for pharmacist - Retain certificates of completion for four years	10%	4301(j)/111295/351- Adulterated Heparin Held at Pharmacy	3%	1716-Variation from prescription	7%
1732.5 - Renewal requirements for pharmacist	6%	4104-Procedures to take action when licensed individual is impaired or known to have diverted or used drugs; Written policies; Report; Immunity	3%	4104-Procedures to take action when licensed individual is impaired or known to have diverted or used drugs; Written policies; Report; Immunity	3%
4301(j)/111295/351- Adulterated Heparin Held at Pharmacy	5%	1716/1761(a) – Variation from prescription/No pharmacist shall compound or dispense any prescription, which contains any significant error or omission...	2%	1714(d)- Operational standards and security; pharmacist responsible for pharmacy security	3%
1761(a)- No pharmacist shall compound or dispense any prescription, which contains any significant error or omission...	4%	1707.2 – Duty to consult	2%	1715-Self-assessment of a pharmacy by the pharmacist in charge	2%
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	2%	1715-Self-assessment of a pharmacy by the pharmacist in charge	2%	1716/1761(a) – Variation from prescription/No pharmacist shall compound or dispense any prescription, which contains any significant error or omission...	2%
1716/1761(a) – Variation from prescription/No pharmacist shall compound or dispense any prescription, which contains any significant error or omission...	2%	1716/1761(a) – Variation from prescription/No pharmacist shall compound or dispense any prescription, which contains any significant error or omission...	2%	4169(a)(1) - Prohibited Acts; Purchase, trade, sell, or transfer dangerous drugs to unlicensed person or entity	1%
1707.2 – Duty to consult	2%	1304.11-Inventory requirements	2%	1304.11-Inventory requirements	1%
1711-Quality assurance program	1%	1709.1- Designation of pharmacist in charge	2%	1707.2 – Duty to consult	1%

# Contested Citations Office Conference

(These statistics also include contested Letters of Admonishment)

There were fifteen office conferences held so far this fiscal year

Number of requests	288
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Number scheduled	288
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Number appeared	226
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Number Postponed	58**
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\*\*Please note these are added back into the number of requests and scheduled case totals above.

Total number of requests withdrawn	13
Failed to appear	4

## Office Conference between July 1, 2008 and December 31, 2008

Total number of citations affirmed	126
------------------------------------	-----

Decision	Total citations	Total dollar amount reduced
Modified	31	\$2,500.00
Dismissed	29	\$27,000.00
Reduced to Letter of Admonishment	0	\$0.00

Please note thirteen cases are pending decisions due to additional investigation being required.