



Secretary Carol Aichele

PENNSYLVANIA STATE BOARD OF PHARMACY



www.dos.state.pa.us

June 2014

Disciplinary Actions

Pharmacy Diversion Awareness Conference

The Drug Enforcement Administration will be hosting a Pharmacy Diversion Awareness Conference (PDAC) in Philadelphia, PA on Saturday, July 12 and Sunday, July 13, 2014.

It's actually a one-day conference that is offered on two days for the convenience of potential conference attendees. The Philadelphia PDAC will be held at the Sheraton Philadelphia Downtown Hotel, 201 North 17th Street, Philadelphia, PA 19103. The Philadelphia PDAC announcement, which provides detailed information about the PDAC including a tentative agenda, is currently on the DEA's Diversion website (link below).

http://www.deadiversion.usdoj.gov/mtgs/pharm_awareness/index.html

The Philadelphia PDAC is open to pharmacists, pharmacy technicians, and pharmacy loss prevention personnel in the state of Pennsylvania. Attendees are eligible to receive CE credits.

Drug Enforcement Administration, Office of Diversion Control Proposed Rulemaking - Disposal of Controlled Substances Federal Register Volume 77, Number 246 (December 21, 2012)

By Board Member Janet Getzey Hart

On October 12, 2010 the Secure and Responsible Drug Disposal Act of 2010 (Disposal Act) was enacted.

Before the Disposal Act, ultimate users who wanted to dispose of unused, unwanted or expired controlled substances had limited disposal options. The federal Controlled Substance Act (CSA) only permitted ultimate users to destroy the substances themselves. The Disposal Act amended the CSA to authorize ultimate users to deliver their controlled substances to another person for the purpose of disposal in accordance with regulations promulgated by the U.S. Attorney General. The U.S. Attorney General delegated responsibility for promulgating the Disposal Act to the Drug Enforcement Administration (DEA). As a result, the DEA issued proposed rulemaking in December 2012. The proposed rulemaking is not final.

The goal of the proposed new section on disposal is to set controlled substance diversion prevention parameters that will encourage public and private entities to develop a variety of methods for collecting and destroying controlled and non-controlled substances in a secure, convenient and responsible manner.

The primary focus of the proposed rule addresses ultimate user disposal. The rule proposes three voluntary options for ultimate user disposal: (1) take-back events, (2) mail-back programs and (3) collection receptacles. The DEA proposes specific language that will authorize federal, state, tribal and local law enforcement agencies to voluntarily hold take-back events and administer mail-back programs. All mail-back programs must provide specific mail-back packages to the public, either at no cost or for a fee and collectors that conduct mail-back programs must have and utilize an on-site method of destruction.

[Contact Us](#)

[Report Unethical Activity](#)

[Renew Your License](#)

[Meet the Board](#)

[PHMP](#)

State Board of Pharmacy

P.O. Box 2649, Harrisburg, PA 17105-2649

(717) 783-7156

The DEA proposes to authorize certain registrants (manufacturers, distributors, reverse distributors and retail pharmacies) to be “collectors”, to conduct mail-back programs and/or to maintain collection receptacles at long term care facilities. The retail pharmacy as a collector will be the focus of this article.

Retail Pharmacies Collection Sites

In order to be a collector, a retail pharmacy must apply for a modification to their DEA registration. Upon DEA approval of their registration modification, the pharmacy’s DEA Certification of Registration will specify their status of “collector” and the location(s) approved for collection. The option for renewal of collector status will be available at the time of renewal. The pharmacy must contact DEA to modify their registration if they cease activity as a collector.

The DEA proposes that pharmacies have a designated employee or agent with access to or influence over controlled substances acquired as a collector to be responsible. This employee or agent could be only those persons who have never been convicted of any felony offense related to controlled substances and have never had a DEA registration denied, revoked or suspended or surrendered a DEA registration for cause.

Pharmacies may maintain collection receptacles at their registered location or at authorized Long Term Care Facilities (LTCF).

The only persons that may transfer controlled substances to the receptacles are the ultimate user, persons lawfully entitled to dispose of a deceased ultimate users property and a LTCF on behalf of the ultimate user that resides or has resided at the LTCF when the collection receptacle is located at the LTCF.

Collection receptacles must have a permanent outer container with a removable inner liner.

The outer container must have an opening big enough to allow contents to be added to the inner liner but small enough to prevent removal of the inner liner contents. The opening must have the capability of being locked at times when an authorized employee is not present, unless the receptacle is located in a secured area of a LTCF which is regularly monitored by LTCF personnel.

The collection receptacle must be securely fastened to a permanent structure such as a wall, floor or immovable countertop. The collection receptacle must be located within immediate proximity of a designated area where controlled substances are stored and where an authorized employee is present. Access to the inner liner is restricted to authorized employees of the pharmacy.

The outer container must prominently display a sign indicating that only non-controlled drugs and Schedule II, III, IV and V substances are acceptable for collection.

The inner liner must be waterproof, tamper-evident and tear resistant. The inner liner must be removable and sealable immediately upon removal without emptying or touching the contents and the content of the inner liner shall not be viewable from the outside when sealed. The size of the inner liner must be clearly marked on the outside of liner (such as “5 gallon”). The inner liner must bear a permanent, unique identification number that enables the liner to be tracked. The DEA is proposing that collectors take an inventory of all inner liners and maintain records on the use and destruction of such liners for two years. Pharmacies must be able to track the unique identification number located on each inner liner from collection to destruction.

Once sealed, inner liners may not be opened or otherwise penetrated and the substances within may not be individually handled, counted, inventoried or otherwise discerned.

Removal of the inner liner shall be performed by or under the supervision of at least two authorized employees of the collector.

Pharmacies must store the sealed inner liners following the same security utilized for Schedule II controlled substances; however, they may not be dispersed through the stock of controlled substances.

DEA proposes to allow pharmacies to dispose of their controlled substances in one of four ways:

(1) Promptly destroy the substances using onsite method destruction in accordance with applicable federal, state and local laws. Two authorized employees of the collector shall load controlled substances for destruction, transport controlled substances for destruction, accompany the controlled substances for destruction and finally handle and observe controlled substances until the substances are rendered non-retrievable.

(2) Promptly deliver the substance to a reverse distributor at its registered location or by common or contract carriers, or by reverse distributor pick-up.

(3) For the purpose of return or recall, promptly deliver the substance to the registered person from whom it was obtained, the registered manufacturer or another registrant authorized by the manufacturer to accept returns or recalls (not applicable for inner liners).

(4) Request assistance from the local DEA office. In circumstances in which a pharmacy regularly destroys controlled substances, it may do so on a regular basis upon instructions from the relevant Special Agent in Charge.

The comment period on the proposed DEA rule ended February 19, 2013. The DEA considered all comments and is promulgating a final rule on the Disposal of Controlled Substances. The final rule is expected to be published in 2014.

Commissioner Travis Gery, Esq.

On November 8, 2013, Governor Corbett nominated Travis Gery to be the Commissioner of Professional and Occupational Affairs and appointed him Acting Commissioner. He was unanimously confirmed by the Senate on January 28, 2014. As Commissioner, he carries out the statutory duties set forth in the Administrative Code and is responsible for directing the staff of the Bureau of Professional and Occupational Affairs charged with providing administrative support and services to the 29 Licensing Boards and Commissions within the Bureau's jurisdiction. He also serves as a full, voting member on 27 of the Boards.

Immediately prior to assuming the duties and responsibilities of Commissioner, Travis served as Executive Deputy Chief Counsel to the Department of State. In that role he provided legal advice to the Commissioner on all matters relating to the 29 Boards and Commissions administered by the Bureau. He was also the head of the Bureau's Legal Office comprised of 38 attorneys assigned to the Prosecution Division, 15 attorneys assigned to the Counsel Division and 41 support staff. As such, he supervised and directed the investigations and prosecutions of licensees for violations of the applicable practice acts and regulations and the provision of legal advice and counsel to the 29 Boards and Commissions.

Prior to his appointment as Executive Deputy Chief Counsel, Travis was a member of a Philadelphia law firm where he litigated civil matters in State and Federal courts. He also has significant experience as a criminal prosecutor at Federal, State and County level. He was an Assistant United States Attorney for the Southern District of West Virginia, a Pennsylvania Deputy Attorney General, an Assistant District Attorney in Cumberland County, PA, rising to the position of Chief Deputy District Attorney, and an Assistant District Attorney in Dauphin County.

From 1990 to 1993, while on active duty in the United States Navy, Judge Advocate General's Corps, he served as Senior Trial Counsel, Senior Defense Counsel, and Head of Civil Law at the Naval Legal Service Office, New London, CT. He is currently a Commander in the United States Navy Reserve. He has been awarded the Navy and Marine Corps Achievement Medal twice, the Navy Commendation Medal twice, and the Meritorious Service Medal twice. He has also been awarded the Naval War College Diploma in National Security and Strategy.

Travis received his J.D. from Widener University School of Law in 1989, graduating with honors. He received his B.A. from Dickinson College in 1986.

He lives in Pottstown, PA with his wife and four children. He has no free time because when not at the office he and his wife are always either at, going to or coming from some gymnastics arena, ball field or other sporting event.