

VIA Electronic Submission to <http://www.regulations.gov>

January 12, 2011

Mark W. Caverly
Chief, Liaison and Policy Section
Office of Diversion Control
Drug Enforcement Administration
8701 Morrisette Drive
Springfield, VA 22152

Re: Drug Enforcement Administration [Docket No. DEA-316N] Procedures for the Surrender of Unwanted Controlled Substances by Ultimate Users; Notice of Meeting

Dear Mr. Caverly:

The National Community Pharmacists Association (NCPA) respectfully submits the following comments regarding the Drug Enforcement Administration Docket No. DEA-316N. NCPA represents the interests of America's community pharmacists, including the owners of more than 23,000 independent community pharmacies, pharmacy franchises, and chains. Together these represent a \$93 billion health care marketplace, have more than 315,000 employees including 62,400 pharmacists, and dispense over 41% of all retail prescriptions.

NCPA members are the primary providers of drugs and pharmaceutical supplies to millions of Americans. Policies relating to the surrender of unwanted controlled substances are critical to our membership, as pharmacists are active members in their communities and are in a prime position to ensure the safe and proper handling of medications, from dispensing to disposal.

We appreciate the opportunity to provide information to the DEA in response to this solicitation. NCPA supported the *Secure and Responsible Drug Disposal Act of 2010* and we look forward to working with the Agency as you draft regulations that will allow for the disposal of unwanted controlled substances by those not registered with DEA.

From dispensing to disposal, pharmacists & pharmacies are a valuable resource

NCPA has long supported efforts to properly dispose of unused, unwanted or expired medication through safe, secure and environmentally responsible take-back programs. Such programs assist in deterring abuse and diversion of medications, reduce accidental poisonings, and foster public involvement in protecting our environment.

We understand that proper disposal has become an important public health issue in the United States. For many Americans this issue has also become painfully personal. That is why NCPA began participating in the national effort to find sensible solutions to meet various stakeholder needs, while working within existing laws and regulations, by creating a prescription drug disposal program for our members. Consumers want ongoing, convenient and clear disposal options, as evidenced by surveys showing that local pharmacies are the most convenient locations to which consumers say they would return unused or expired medicines. NCPA's Prescription Disposal Program, *Dispose My Meds*, helps participating independent pharmacies do just that.

Also important to NCPA's decision to offer assistance to our members in creating take-back programs is the fact that prescription drug abuse, particularly among younger adults, is drastically rising. Results from SAMSA's 2009 National Survey on Drug Use and Health show that there were seven million persons (2.8 percent of the population) who used prescription-type psychotherapeutic drugs non-medically in the past month—more than cocaine, hallucinogens, and methamphetamine combined and second only to marijuana.¹ We recognize the importance in keeping these prescriptions off the street and taking unused medications out of the medicine cabinet for proper disposal, even though there have been significant roadblocks to disposal of controlled substances.

As active members in the community, pharmacists are in a prime position to ensure the safe and proper handling of medications, from dispensing to disposal. The NCPA medication take-back program demonstrates how community pharmacists continue to lead the way in pharmaceutical waste disposal by highlighting their role as a respected and knowledgeable resource on medications. Additionally, involving pharmacists in medication disposal allows for the identification of adherence problems during direct patient counseling and provides a way to address the enormous issue of waste in the health care system from medications not appropriately taken as prescribed.

NCPA's Prescription Disposal Program utilizes a comprehensive, turn-key medication returns system

NCPA's Prescription Disposal Program, launched in 2009, offers information and resources for pharmacies to create medication disposal programs to help their patients safely dispose of unused and expired medicines that may be dangerous to them and to the environment. After a successful start, our program expanded in 2010 to include a low-cost, turn-key program as well as a consumer outreach website.

¹ Substance Abuse and Mental Health Services Administration. (2010). *Results from the 2009 National Survey on Drug Use and Health: Volume I. Summary of National Findings* (Office of Applied Studies, NSDUH Series H-38A, HHS Publication No. SMA 10-4586Findings). Rockville, MD.

The NCPA Prescription Disposal Program was recognized as an official activity of the 2010 Earth Week Observance in the United States, coinciding with the 40th Anniversary of Earth Day. Through our comprehensive, turn-key program, community pharmacists utilize the Sharps TAKEAWAY Environmental Return System, which allows the return of unused medications in postage pre-paid envelopes for patients to mail on their own as well as 10- or 20-gallon pharmacy collection boxes at participating community pharmacies.

As part of a consumer outreach effort, NCPA also launched [DisposeMyMeds.org](http://www.disposemymeds.org) (www.disposemymeds.org), an online resource to help consumers learn more about medication disposal programs at local independent community pharmacies. This online resource contains information on proper disposal of medications, the environmental and health impact of improperly handled and disposed medications, and links to articles and videos with news and tips on drug disposal. It also has a pharmacy locator for consumers to find local pharmacists who are participating in drug disposal programs.

To date, the program includes over 1,100 community pharmacy locations across 47 states and has collected more than 20,000 lbs. of unused prescription and over-the-counter medications from consumers. This amount is only a conservative estimate of the potential need for a take-back program considering there is \$290 billion per year lost to medications not taken as prescribed (13% of the United State's health care expenditures).²

The medications that are being returned by the take-back program of participating pharmacies were originally dispensed from many other locations, including retail pharmacies and especially mail-order facilities. Consumers are encouraged to talk to their pharmacist to ensure that they are taking their medications correctly, and to understand everything they need to know about their medications, including how to store, use and dispose of them properly. It is important to note that NCPA's Prescription Disposal Program strictly prohibits the return of any controlled substance prescriptions.

To help ensure compliance with all applicable laws and regulations, the following recommendations are provided and reinforced in communications with all pharmacies participating in the Prescription Disposal Program:

- Determine that your participation complies with state pharmacy regulations
- Do not allow the return of controlled substances
- The pharmacist should be directly involved to ensure that controlled substances are not being placed into the return boxes
- The medication take back boxes should not be freely accessible to the public

² New England Healthcare Institute Research Brief. *Thinking Outside the Pillbox: A System-wide Approach to Improving Patient Medication Adherence for Chronic Disease*, August 2009.

State and local support of NCPA's Prescription Disposal Program

NCPA has shared its Prescription Disposal Program and objectives with dozens of boards of pharmacy and the National Alliance of State Pharmacy Associations (NASPA), among others. There is broad support for the NCPA program because officials recognize the logic and value of using community pharmacies for programs that enable pharmacists to directly counsel patients about their unused medications. Most state pharmacy practice acts governing the practice of pharmacy do not specifically address prescription medication take-back programs. However, NCPA continues to facilitate the ability of its members to work with various local and state agencies, the DEA, and the EPA, among others, to address the disposal of controlled substances.

Community pharmacies who wish to participate should be considered collection sites for controlled substance disposal

The intent of the *Secure and Responsible Drug Disposal Act of 2010* is to encourage the Attorney General to establish regulations which prevent the diversion of controlled substances, but still “allow public and private entities to develop a variety of methods of collection and disposal of controlled substances, including some pharmaceuticals, in a secure, convenient, and responsible manner.”

NCPA contends that community pharmacies, as both state and DEA licensed entities, provide a safe and viable manner by which consumers can dispose of unwanted controlled substances. Community pharmacies are well equipped to handle controlled substances and are held accountable on a daily basis for ensuring these substances are not diverted. Therefore, those pharmacies who volunteer to participate in take-back programs should be considered by the DEA as appropriate locations to receive unwanted controlled substances. There should be no requirements to keep controlled substances separate from other prescription medications being returned, as take-back receptacles should not be accessible to the public.

NCPA's current disposal program allows for either the United States Postal Service or United Parcel Service to transport unused pharmaceuticals from take-back programs to their ultimate destruction site. These same carriers currently transport millions of doses of mail order prescriptions, including controlled substances, so any concerns regarding diversion via these carriers should be unwarranted.

In addition, DEA should consult with the EPA to ensure the regulations are consistent with that Agency's goals and requirements. Lastly, regarding regulations impacting the take-back of controlled substances by long-term care facilities, NCPA requests that no requirements be placed on pharmacies to take back unwanted controlled substances for disposal from long-term care facilities with which they contract to provide pharmacy services. Long-term care facilities should have mechanisms by which they currently document and keep records of waste, which could be utilized for the disposal of controlled substances.

Obstacles to the disposal of controlled substances in community pharmacies

Despite the success of the NCPA Prescription Disposal Program, significant challenges remain, making it difficult to increase the program's scope. With passage of the *Secure and Responsible Drug Disposal Act of 2010*, NCPA asks that DEA address the following issues during the regulatory process:

- **Convenience for the consumer** - Patients need viable, convenient solutions when seeking to dispose of their unused medications. Programs that allow for drop off of unwanted controlled substances at multiple public locations under the supervision of a licensed pharmacist as well as programs that allow for patients to utilize pre-paid mailers to dispose of medications should be allowed.
- **Legal and Regulatory Feasibility** - In addition to current laws in place that prevent take-back programs from accepting controlled medications, those that may prohibit postal carriers from handling mailers containing controlled substances are also impediments the DEA must address in order for programs to succeed. Also, there should be liability protections in place for pharmacies that choose to operate these programs.
- **Program Financing** - Adequate funding is necessary for any drug disposal program to succeed, whether it is through states or grant programs.
- **Effective Outreach and Education** - Thorough education for all involved stakeholders is necessary for understanding of a drug disposal program and to ensure that all applicable laws are recognized and respected. Education programs on the proper handling and disposal of unwanted medications should be designed to allow for maximum participation by all.

Conclusion

NCPA supports efforts to encourage disposal of expired and unwanted medications through appropriately designed drug take-back programs. NCPA also advocates for funding sources at the local, state and federal levels to assure that pharmacists and/or pharmacies are appropriately compensated for drug disposal programs. Such programs will assist in deterring abuse and diversion of medications and will foster public involvement in protecting our environment and in poison prevention efforts. Additionally, involving pharmacists in medication disposal allows for the identification of adherence problems during direct patient counseling and provides a way to address the waste in the health care system from medications not taken as prescribed. NCPA appreciates the opportunity to comment and looks forward to working with the DEA and other stakeholders during the regulatory process to ensure workable options that will lead to an increase in the proper disposal of drug waste, including controlled substances.

We would welcome the opportunity to discuss our comments regarding this important matter with you further. Please do not hesitate to contact Ronna Hauser, Vice President of Policy and Regulatory Affairs at ronna.hauser@ncpanet.org, (703) 838-2691, if you have any questions. Thank you.

Sincerely,

A handwritten signature in black ink that reads "Ronna B. Hauser". The signature is written in a cursive style with a long horizontal flourish at the end.

Ronna B. Hauser, PharmD
VP Policy and Regulatory Affairs