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February 19, 2013

John W. Partridge
Drug Enforcement Administration
Attention: DEA Office of Diversion Control (OD/DX)
8701 Morrissette Drive
Springfield, VA 22152

Re: Drug Enforcement Administration [Docket No. DEA–316] Disposal of Controlled Substances; Notice of Proposed Rulemaking

Dear Mr. Partridge,

Thank you for the opportunity to share community pharmacy’s perspective as the Drug Enforcement Administration (DEA) proposes rulemaking for the disposal of controlled substances. The National Community Pharmacists Association (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 they represent an $88.5 billion health-care marketplace, have more than 300,000 employees including 62,000 pharmacists, and dispense over 40% of all retail prescriptions. NCPA members are the primary providers of medications and pharmaceutical supplies for millions of Americans. In addition, 28% of our members serve one or more long-term care (LTC) facilities and 52% serve one or more assisted living facilities. In total, approximately 40% of the long-term care market is serviced by an independent community pharmacy.

Independent community pharmacists support safe and responsible medication disposal

NCPA and its members fully support efforts to dispose properly of unused, unwanted or expired medications through safe, secure and environmentally responsible voluntary disposal programs, including controlled substances. Community pharmacists understand the challenge consumers face in properly disposing of unused or expired medication. Patients want a solution to the problems associated with unused medications.

In April 2010, NCPA launched a prescription disposal program, Dispose My Meds, for community pharmacies to create voluntary non-controlled medication disposal programs. The response from pharmacists has been tremendous, and, so far, over 1,600 pharmacies nationwide have disposed of more than 100,000 pounds of unused prescription (non-controlled) and over-the-counter medications from consumers. Pharmacists who choose to participate provide a much-needed service in their communities, and often find that there are no easy answers to the questions they receive on a daily basis from patients about the proper disposal of controlled substances.
NCPA was pleased finally to see the DEA’s proposed rule on controlled substance disposal that will expand the options available to consumers safely to discard unused or expired medications. However, we do have serious concerns with several specific proposals within the rule and offer several recommendations below.

**Challenges remain for effective disposal programs in community pharmacies and long-term care facilities**

NCPA has been closely following the disposal of controlled substances issue, starting with our support for the passage of *The Secure and Responsible Drug Disposal Act*, which offers consumers more options for safe, secure, and environmentally responsible medication disposal programs. In addition, NCPA provided comments when DEA first contemplated these rules, met with DEA officials to discuss, and presented at the January 2011 public meeting for DEA to gather feedback as it was drafting the proposed rules.

NCPA understands the various factors that need to be contemplated, most of all the safety and security measures that need to be in place to protect public health and prevent diversion. However, we have concerns that certain provisions in the rule will serve as barriers to greater adoption and voluntary participation by authorized collectors and ultimately deter from the shared goal of reducing misuse and abuse of controlled substances. This is especially true for logistical and liability concerns associated with retail pharmacies authorized to maintain collection receptacles at long-term care facilities (LTCF). After careful review of the proposed rule, we wish to take this opportunity to provide our thoughts on the challenges for community pharmacies to implement such programs should they choose, and seek clarification on several aspects of the rule.

- **Modification in registration**: NCPA seeks to clarify DEA’s intent that the retail pharmacy registrant category also includes closed-door long-term care pharmacies. Closed-door long-term care pharmacies also serve many LTCFs. With regard to registration modifications for retail pharmacies that choose to maintain a collection receptacle at an LTCF, DEA states that such registrants shall include the physical location of each LTCF at which the registered pharmacy intends to operate a collection receptacle. NCPA would like to confirm that the inclusion of these LTCF locations on a retail pharmacy’s registration is considered the registrant’s “registered location.” DEA is proposing that reverse distributors may acquire controlled substances from other registrants by pick-up from a registrant at the registrant’s registered location. If LTCFs are registered locations by way of a retail pharmacy’s registration, NCPA asks that DEA clearly allow reverse distributors to pick-up the contents of collection receptacles directly from registered LTCF locations for disposal.

- **Collection receptacle and inner liner requirements**: NCPA’s community retail pharmacist members have been offering convenient, safe, and environmentally responsible disposal programs for non-controlled substances for several years and we can share our experiences with how the programs have operated thus far, and potential challenges with the proposed requirements for the collection receptacles and inner liners.
NCPA’s Dispose My Meds program has been operating collaboratively with a DEA-registered reverse distributor responsible for the disposal and handling of medications being returned. We have made it clear to our participating retail members and their patients that controlled substances are prohibited from collection and disposal at retail pharmacy locations. As an added precaution, both NCPA and the reverse distributor handle the collection boxes and envelopes as if controlled substances were placed inside. The program’s current functions and capabilities could provide a framework that would satisfy DEA’s proposed security measures. If the DEA is permitting the co-mingling of non-controlled and controlled substances, community pharmacies are prepared to treat all medications placed into the receptacle with the storage security requirements of a Schedule II controlled substance, as this is what is similarly carried out today.

The disposal method utilized in the Dispose My Meds program is a comprehensive system with security checks in place throughout the disposal process. The program offers 10 or 20-gallon collection boxes for pharmacy use or convenient postage pre-paid envelopes for patients to mail directly. When the box is full, the pharmacist seals the contents and prepares it for pick up by a common carrier. All collection boxes and envelopes have bar codes for tracking, and are sent to an incineration facility operated by a registered reverse distributor. Upon receipt, the unused medications are stored in a secure storage area and processed by a licensed law enforcement officer for witnessed and assured destruction.

In addition, the tracking mechanism for the Dispose My Meds program includes the following elements for both tracking of the collection receptacles to the pharmacy and upon receipt from the pharmacy for ultimate destruction: date shipped out, date received, weight, package condition, and date of treatment. The collection boxes and envelopes are uniquely tracked throughout the disposal process, and pharmacists receive manifest reports. There have not been any incidents of diversion in the Dispose My Meds program to date.

To help ensure compliance with all applicable laws and regulations, the following recommendations are provided and reinforced in NCPA communications with all retail pharmacies currently participating in the Dispose My Meds program:

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

NCPA requests that the DEA strongly reconsider the requirements for the collection receptacles and inner liners, both in terms of security and placement. Based on experience with the Dispose My Meds containers, the requirement for permanent outer shells for the collection receptacles would be an unnecessary burden and not practical. The installation and securing of such permanent fixtures would necessitate significant changes to the current layout of the pharmacy area to comply with the proposed requirements. The removal of the inner liners, which requires supervision of two authorized employees, could be disruptive to pharmacy workflow if the authorized personnel are not available. In addition, the recommended storage of the inner liners in accordance with Schedule II security requirements until prompt destruction occurs, could lead to accumulation of these substances in the locked areas normally reserved for Schedule II substances still to be dispensed.
Currently the Dispose My Meds program containers include attached inner liners that are waterproof and tear-resistant. We suggest that DEA consider revising the specifications for the collection receptacles so long as they are constructed in a way that is tamper-evident, and only allow for one-way entry and irretrievability. For example, the collection receptacles and liners could be assembled as one unit to reduce the chance of diversion compared with separate liners. Therefore, NCPA asks that DEA consider greater flexibility in terms of the collection receptacles, and believes that the practice of sealing up the collection box, part and parcel with the inner liner, with a traceable identifier on the tamper-evident receptacle would be a more amenable system while maintaining the utmost security.

Furthermore, we do not recommend prominent display on the outer container specifying that only non-controlled drugs and Schedules II – V controlled substances are acceptable for collection. The public generally cannot discern the differences between the scheduling of these substances and having a symbol on the receptacle could draw unwarranted attention from drug seekers and others looking to divert these products.

Regarding placement of the collection receptacles, NCPA advocates that collection receptacles should not be located in an open space that is freely accessible to the public. We caution against securely fastening the receptacle to a permanent structure, and remain unclear on DEA’s intent in designating that the receptacle be located within the immediate proximity of a designated area where controlled substances are stored and where an authorized employee is present. If this refers to an area outside the pharmacy dispensing premises (i.e. over the pharmacy counter), this could potentially leave controlled substances sitting in a public space outside of a secure area that cannot be monitored by pharmacy staff. Without direct supervision of the receptacles, pharmacists cannot be assured of the products being inserted for disposal, posing potential hazards. Although the ultimate user cannot transfer the controlled substances directly to pharmacy staff to place into the collection receptacle, NCPA recommends that the receptacles should be kept behind the pharmacy counter and only made available to the patient when disposal services are requested. We strongly believe that a pharmacist should supervise the drop-off process to monitor what is placed inside the collection receptacle.

- **Long-term care facility (LTCF) considerations:** Per the law, the DEA proposed rules make clear that the program is voluntary from a retail take-back perspective. However, concerning the regulations affecting the disposal of controlled substances by long-term care facilities, NCPA contends it is not clear that this is a voluntary program and recommends several changes to the proposed rule. LTCFs currently have mechanisms in place by which they handle unused or expired medications on behalf of residents, which vary by state, and could actually be thwarted by this rule.

In the proposed rule, DEA indicated that it is “not requiring a particular method of destruction, so long as the desired result is achieved.” NCPA would like to clarify that with the introduction of the proposed rule, DEA does not intend to supplant existing methods LTCFs currently utilize to dispose of controlled substances in their facilities. A potential consequence for LTCFs, which are not registered with the DEA, is that their disposal options will be further limited, and could result in greater stockpiling of unused or expired controlled substances.
If the proposed rule eliminates existing disposal arrangements, LTCFs will be left with only two disposal options. One that is incumbent upon a retail pharmacy’s willingness to install an on-site receptacle potentially at their own expense and the other that would be to return the controlled substances to the resident upon discharge, if permitted by state regulations. NCPA believes this would ultimately impose a de facto mandate for our members to provide collection receptacles for LTCFs in this voluntary program. We recommend that DEA allow for flexible disposal systems for controlled substances in LTCFs that still render the product non-retrievable, as the facility sees fit, and in accordance with any applicable state and federal regulations.

In the rule, DEA states that LTCFs would be permitted to dispose of controlled substances on behalf of an ultimate user who currently resides or has resided at the facility. NCPA finds the concept of “has resided” to be ambiguous, and requests clarification on what DEA intended. Is there a particular period after the patient has been discharged when this would be applicable, or is this in reference to residents who expired while residing in the facility?

The proposed disposal procedures for the collection receptacles placed at LTCFs pose several logistical challenges. First, the removal of the inner liner of the collection receptacle requires two authorized employees of the retail pharmacy, which would necessitate the pharmacy sending two team members to the facility on a frequent basis. Not all LTCFs have retail or closed-door pharmacy on the premises or near the facility to service residents; therefore, this requirement would present considerable commuting and staffing challenges on behalf of the retail pharmacy to be present for the supervision and removal of inner liners. The travel and staffing time away from the pharmacy location to supervise and document the disposals would be cost prohibitive and likely dissuade pharmacies from installing a receptacle.

In long-term care, some facilities may be serviced by multiple pharmacies when residents are permitted to select their pharmacy provider. There could be scenarios where controlled substances from various servicing pharmacies are disposed of in a single receptacle that one pharmacy collector installed. Furthermore, NCPA believes there are liability concerns to consider when the LTCF is in possession of the receptacle while the retail pharmacy is fully responsible for it. Such a scenario could become difficult and impractical for a retail pharmacy, as an authorized collector, to be responsible for installing, managing, and maintaining a collection receptacle, which the pharmacy does not have constant, direct supervision over. Also, if the inner liners must be removed by authorized pharmacy personnel and returned to the registered retail pharmacy location to await disposal, this raises concerns for potential diversion if there is additional transport between the facility back to the retail pharmacy establishment for disposal arrangements.

NCPA is concerned about the potential for stockpiling at LTCFs. The proposed rule states that a LTCF may dispose of controlled substances on behalf of an ultimate user immediately, but no longer than three business days after discontinuation. With the frequency and volume of controlled and non-controlled substances distributed in LTCFs and the inconvenience of requiring two authorized pharmacy representatives to be present for the removal of the liners for disposal, the result could be piles of discarded controlled substances awaiting disposal from authorized retail pharmacy collectors.
Along these same lines, the facility itself may not have the security controls in place to store properly the liners as a Schedule II substance, leaving the liners vulnerable to diversion. As other options, NCPA is recommending that DEA consider authorizing one pharmacy representative and one LTCF representative, such as the nursing supervisor, to fulfill the requirement that two staff members are present for the removal of the inner liner. LTCFs typically have licensed health professionals who are available to maintain controlled substances; DEA may even consider allowing a consultant pharmacist to fulfill the requirement of authorized pharmacy staff member. In addition, we are again asking for clarity on what constitutes a registered location. If the LTCF is considered a registered location when the retail pharmacy applies for a modification in registration to become an authorized collector, reverse distributors should be allowed to pick-up the contents of collection receptacles directly from registered LTCF locations for disposal.

NCPA understands DEA’s rationale for authorizing certain registrant categories to be deemed collectors due to their experience with security controls to handle controlled substances. However, the proposed arrangement between a retail pharmacy and LTCF in order to operate a collection receptacle poses challenges and liability concerns which will serve to deter retail pharmacies from participating, and further limit the ability of the LTCF to properly dispose of controlled substances if this is the only on-site option for the facility. We recommend that DEA work with the long-term care community to develop disposal standards that would enable more LTCFs to operate disposal systems.

**Conclusion**

As one of the most accessible and trusted health care providers, community pharmacists recognize the importance of addressing the serious and growing problem of prescription drug diversion and abuse. NCPA and its members have long supported efforts to dispose properly of unused, unwanted or expired medication through safe, secure and environmentally responsible take-back programs, as part of the broader aims of the Office of National Drug Control Policy’s *Prescription Drug Abuse Prevention Plan*. Such programs assist in deterring abuse and diversion of medications, reduce accidental poisonings, and foster public involvement in protecting our environment. NCPA would like to offer some final points for consideration as the DEA finalizes the proposed rule:

*Security balanced with flexibility:* NCPA asks that DEA consider greater flexibility in terms of the collection receptacles, and believes that the practice of sealing up the collection box, part and parcel with the inner liner, with a traceable identifier on the tamper-evident receptacle would be a more amenable system while maintaining the utmost security.

*Legal and regulatory feasibility:* In addition to current laws in place that prevent take-back programs from accepting controlled medications, those that may prohibit the transit of controlled substances or the handling of hazardous waste are also impediments the DEA must continue to address in order for programs to succeed. We urge DEA to harmonize the proposed rules with the rules of other federal agencies including EPA and DOT, as well as with state requirements, to the extent possible.

*Effective outreach, education and harmonization:* Thorough education for all involved stakeholders is necessary to understand any drug disposal program and to ensure that all applicable laws are recognized and followed. NCPA encourages DEA work closely with other federal agencies in order to align disposal requirements, such as, what constitutes acceptable methods of disposal for controlled substances.
NCPA stands ready to work with the Agency as you finalize regulations that will allow for the disposal of unwanted controlled substances by those not currently registered with DEA. We welcome the opportunity to discuss our comments regarding this critical public health matter with you further.

Sincerely,

Ronna B. Hauser, PharmD  
VP Policy and Regulatory Affairs