

the proposal, that “the Commission believes DCMs benefit from endeavoring to recruit their public directors from a broad and culturally diverse pool of qualified candidates.” The purpose of the acceptable practices is to “ensure that there is adequate independence within [exchange] board[s] to insulate [their] regulatory functions from the interests of the exchange’s management, members and other business interests of the market itself.” 71 FR 38740 (July 7, 2006). It is not clear to me how recruiting directors from a culturally diverse pool of candidates advances that goal, nor is it a given that seating a well-qualified board that is culturally diverse is something that may be practicably accomplished. My primary objection, however, is based on the fact that we have no legal authority to issue pronouncements on the subject. We are not a commission of general jurisdiction. Our authority and oversight responsibilities are specifically limited by statute and do not include the promotion of equal employment opportunity. Moreover, to the extent the Commission may be suggesting that exchanges consider factors such as race, gender, national origin, or religion in selecting public directors, we may be encouraging activity that could potentially violate Title VII of the Civil Rights Act of 1964.

Concurring Statement of Commissioner Bart Chilton Regarding the Withdrawal of Previously Proposed Amendments to the Acceptable Practices for Core Principle 15 and Solicitation of Public Comments on New Proposed Amendments

I concur in the Commission’s issuance of the above-referenced action. I write separately, however, to comment on certain aspects of the proposal of particular interest to me.

First, I am gratified to see language in the proposal relating to my longstanding request that we note to designated contract markets the benefits of diversity in recruiting public directors. While this is, as stated, not a requirement under the acceptable practices, it is quite obviously a laudable and attainable goal, and one that should be encouraged.

Second, I would ask commenters to respond specifically as to whether the Commission has included within the proposal all appropriate decision-making bodies at designated contract markets, or whether the class should be broadened to include entities other than boards of directors, executive committees or similarly empowered bodies, regulatory oversight committees, and disciplinary panels.

Lastly, I note with some concern the timeline of this proposal. In November 2007, the Commission stayed the “final” acceptable practices that had been issued in February 2007. This was a necessary action, although unfortunate in that it created further delay in an already protracted and flawed process. Even more unfortunate, swift action was promised on this proposal in December 2007, yet it has taken more than a full year to see any progress. As public servants, we can and should do better to serve American consumers and businesses.

[FR Doc. E9–891 Filed 1–16–09; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1300, 1301, 1304, 1305, and 1307

[Docket No. DEA–316A]

RIN 1117–AB18

Disposal of Controlled Substances by Persons Not Registered With the Drug Enforcement Administration

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: In response to concerns raised by individuals, public and private organizations, the healthcare industry, and the law enforcement community, the Drug Enforcement Administration (DEA) is soliciting information on the disposal of controlled substances dispensed to individual patients, also defined as ultimate users, as well as long term care facilities. DEA is seeking options for the safe and responsible disposal of dispensed controlled substances in a manner consistent with the Controlled Substances Act and its implementing regulations.

DATES: Written comments must be postmarked on or before March 23, 2009, and electronic comments must be sent on or before midnight Eastern time March 23, 2009.

ADDRESSES: To ensure proper handling of comments, please reference “Docket No. DEA–316” on all written and electronic correspondence. Written comments being sent via regular or express mail should be sent to the Drug Enforcement Administration, *Attention:* DEA Federal Register Representative/ODL, 8701 Morrissette Drive, Springfield, VA 22152. Comments may

be sent to DEA by sending an electronic message to dea.diversion.policy@usdoj.gov. Comments may also be sent electronically through <http://www.regulations.gov> using the electronic comment form provided on that site. An electronic copy of this document is also available at the <http://www.regulations.gov> Web site. DEA will accept attachments to electronic comments in Microsoft Word, WordPerfect, Adobe PDF, or Excel file formats only. DEA will not accept any file formats other than those specifically listed here.

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

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

SUPPLEMENTARY INFORMATION:

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

If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase “PERSONAL IDENTIFYING INFORMATION” in the first paragraph of your comment. You must also place all the personal identifying information you do not want posted online or made available in the public docket in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be posted online or made available in the

public docket, you must include the phrase "CONFIDENTIAL BUSINESS INFORMATION" in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be posted online or made available in the public docket.

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

Legal Authority

The Drug Enforcement Administration (DEA) enforces the Comprehensive Drug Abuse Prevention and Control Act of 1970, often referred to as the Controlled Substances Act (CSA) and the Controlled Substances Import and Export Act (21 U.S.C. 801–971) as amended. DEA regulations implementing these statutes are published in Title 21 of the Code of Federal Regulations (CFR), Parts 1300 to 1399. These regulations are designed to establish a framework for the legal distribution of controlled substances to deter their diversion to illegal purposes and to ensure that there is a sufficient supply of these drugs for legitimate medical, scientific, research, industrial, and other purposes. Controlled substances are those substances listed in the schedules of the CSA and 21 CFR 1308.11–1308.15, and generally include narcotics, stimulants, depressants, and hallucinogens that have a potential for abuse and physical and psychological dependence, as well as anabolic steroids.

The CSA and DEA's regulations require that persons involved in the manufacture, distribution, research, dispensing, import, and export of controlled substances register with DEA (unless exempt), keep track of all stocks of controlled substances, and maintain records to account for all controlled substances received, distributed, or otherwise disposed of.

Background

Under the CSA, Congress established a "closed system" of distribution designed to prevent the diversion of

controlled substances.¹ As part of this closed system, all persons who lawfully handle controlled substances must be registered with DEA or exempt from registration by the CSA or DEA regulations. Another central element of this closed system is that DEA registrants must maintain strict records of all transactions in controlled substances. Consistent with the CSA requirements, current DEA regulations employ a system to account for all controlled substances received, stored, distributed, dispensed, or otherwise disposed of. Under this system, all controlled substances used in legitimate commerce may be transferred only between persons or entities who are DEA registrants or who are exempted from the requirement of registration, until they are dispensed to the ultimate user. Thus, for example, a controlled substance, after being manufactured by a DEA-registered manufacturer, may be transferred to a DEA-registered distributor for subsequent distribution to a DEA-registered retail pharmacy. After a DEA-registered practitioner, such as a physician or a dentist, issues a prescription for a controlled substance to a patient (i.e., the ultimate user), that patient can fill that prescription at a retail pharmacy to obtain that controlled substance. In this system, the manufacturer, the distributor, the practitioner, and the retail pharmacy are all required to be DEA registrants, or to be exempted from the requirement of registration, to participate in the process.

As set forth in the CSA, an ultimate user is exempt from the requirement of registration—but only to the extent the ultimate user possesses a controlled substance that has been lawfully obtained for his own use or the use of a member of his household or for an animal owned by him or by a member of his household (21 U.S.C. 822(c)(3), 802(27)). Beyond such circumstances, the CSA and its implementing regulations do not currently contemplate a situation in which an ultimate user would distribute a controlled substance. Thus, such distribution, regardless of the purpose, is illegal.

Under the Controlled Substances Act, specifically 21 U.S.C. 802(27), the term "ultimate user" means a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or by a member of his household. Ultimate users are not required to

register with DEA to possess controlled substances.

Every person who manufactures or distributes any controlled substance or List I chemical, or who proposes to engage in the manufacture or distribution of any controlled substance or List I chemical, shall obtain annually a registration issued by the Attorney General in accordance with the rules and regulations promulgated by him (21 U.S.C. 822(a)). "The term 'distribute' means to deliver (other than by administering or dispensing) a controlled substance or a listed chemical" (21 U.S.C. 802(11)). "The terms 'deliver' or 'delivery' mean the actual, constructive, or attempted transfer of a controlled substance or a listed chemical, whether or not there exists an agency relationship." (21 U.S.C. 802(8)). Thus, because the terms deliver and distribute, as defined in the CSA, encompass all methods of delivery and distribution of controlled substances, and because the CSA allows ultimate users to obtain and possess controlled substances solely for purposes of use, under current law, an ultimate user may not deliver or distribute controlled substances for purposes of disposal (unless the ultimate user is also a DEA registrant).

DEA issues registrations to certain business firms, called reverse distributors, to authorize them to take controlled substances that are expired or otherwise unwanted from other DEA registrants for subsequent disposal or distribution back to the manufacturer. Reverse distributors are the only DEA registrants permitted to receive controlled substances from other registrants expressly for the purpose of disposal; other registrants, e.g., pharmacies, may dispose of controlled substances already in their possession that have expired, been damaged, or contaminated, but may not accept controlled substances from another person solely for the purpose of disposal. Under 21 CFR 1300.01(b)(41):

The term "reverse distributor" means a registrant who receives controlled substances acquired from another DEA registrant for the purpose of—

- (i) Returning unwanted, unusable, or outdated controlled substances to the manufacturer or the manufacturer's agent; or
- (ii) Where necessary, processing such substances or arranging for processing such substances for disposal.

DEA issues these firms registrations as reverse distributors and they must adhere to certain security and recordkeeping requirements to ensure that unwanted controlled substances are accounted for and disposed of in accordance with all relevant State and

¹H.R. Rep. No. 91–1444 at 3 (1970).

Federal laws and regulations. In addition, reverse distributors must adhere to any local, county, State, and/or Federal environmental regulations when they dispose of the unwanted controlled substances. While a reverse distributor is registered by DEA at a specific location and is permitted to store controlled substances at that location, it is important to note that the reverse distributor is not required to dispose of the controlled substances at its registered location. Opportunities for large scale disposal (including by reverse distributors) of unused or expired controlled substances have been complicated by existing statutory requirements under the Controlled Substances Act and Federal and State waste disposal laws.

By regulation, a reverse distributor cannot take unwanted controlled substances from non-DEA registrants. For example, as stated previously, once a controlled substance has been dispensed to a patient as the ultimate user, either by prescription or through other means, the ultimate user cannot give the controlled substance to a reverse distributor. Such furnishing of a controlled substance by the ultimate user would be a distribution, which an ultimate user is not permitted to make without being registered. Further, the reverse distributor cannot currently take custody of the controlled substance because reverse distributors are only permitted to receive controlled substances from other DEA registrants. Members of the public have told DEA that the inability to use a reverse distributor in the disposal process is one of the reasons that ultimate users have difficulty safely disposing of unwanted medications, especially controlled substances.

Aside from ultimate users not being permitted to distribute controlled substances for purposes of disposal without being separately registered and reverse distributors not being permitted to receive controlled substances from non-registered ultimate users, recordkeeping requirements also apply to the disposal of controlled substances. The CSA requires every registrant who manufactures, distributes, or dispenses a controlled substance or substances to maintain, on a current basis, a complete and accurate record of each such substance manufactured, received, sold, delivered, or otherwise disposed of by the registrant (21 U.S.C. 827(a)(3)). Records must contain such information as the Attorney General requires to be kept by regulation (21 U.S.C. 827(b)(1)). For reverse distributors, these records include, for each controlled substance in finished form, the following:

- (i) The name of the substance.
- (ii) Each finished form (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial).
- (iii) The number of commercial containers of each such finished form received from other persons, including the date of and number of containers in each receipt and the name, address, and registration number of the person from whom the containers were received.
- (iv) The number of commercial containers of each such finished form distributed back to the original manufacturer of the substance or manufacturer's agent, including the date of and number of containers in each such distribution and the name, address, and registration number of the manufacturer or manufacturer's agent to whom the containers were distributed.
- (v) The number of units or volume of finished forms and/or commercial containers disposed of including the date and manner of disposal, the quantity of the substance in finished form disposed, and the signatures of two responsible employees of the registrant who witnessed the disposal.

(21 CFR 1304.22(e)(2))

Based on current law and DEA regulations, if ultimate users were otherwise permitted to provide their unwanted controlled substances to reverse distributors then the above recordkeeping requirements would continue to apply to the reverse distributors, unless an exemption is granted by regulation pursuant to 21 U.S.C. 827(c)(3).

Redistribution or Reuse

As discussed below, nonregistrants may dispose of controlled substances upon instruction by DEA Special Agents in Charge. However, no provisions in the CSA or DEA regulations allow a DEA registrant to routinely acquire controlled substances from a non-registrant (i.e. individual patient). Hence, patients are currently prohibited from furnishing controlled substances to reverse distributors for disposal and from returning controlled substances to a registrant for the purpose of redistribution or reuse. According to the National Conference of State Legislatures, in 2007, 10 States passed laws allowing or encouraging the donation of unused pharmaceutical drugs. Many of these programs involve health care facilities, nursing homes or other pharmacies. However, the CSA and current DEA regulations prohibit ultimate users from delivering or distributing controlled substances—even if such distribution takes the form of a donation to a DEA registrant participating in one of these State authorized programs—and prohibit

registrants from accepting such donations from ultimate users. Consequently, these State laws do not provide a mechanism consistent with Federal law for donation, return, or reuse of controlled substances.

The Food and Drug Administration (FDA) does not generally permit the redistribution of medications, except under limited circumstances. The FDA Compliance Policy Guides Manual, Chapter 4, Human Drugs, Section 460.300 reads as follows:

Sec. 460.300 Return of Unused Prescription Drugs to Pharmacy Stock (CPG 7132.09)

POLICY:

A pharmacist should not return drugs [sic] products to his stock once they have been out of his possession. It could be a dangerous practice for pharmacists to accept and return to stock the unused portions of prescriptions that are returned by patrons, because he would no longer have any assurance of the strength, quality, purity or identity of the articles.

Many state boards of pharmacy have issued regulations specifically forbidding the practice. We endorse the actions of these State boards as being in the interest of public health.

The pharmacist or doctor dispensing a drug is legally responsible for all hazards of contamination or adulteration that may arise, should he mix returned portions of drugs to his shelf stocks. Some of our investigations in the past have shown that drugs returned by patrons and subsequently resold by the pharmacist were responsible for injuries.²

DEA shares similar concerns regarding the redistribution of controlled substances. This practice is not addressed by the CSA or its implementing regulations.

Disposal of Unused or Unwanted Medications by Ultimate Users

As stated previously, the CSA and its implementing regulations do not contemplate a situation in which an ultimate user would distribute controlled substances. However, 21 CFR 1307.21 provides the procedure for disposing of controlled substances by persons who are not registrants. This procedure involves the nonregistrant submitting a letter to the local DEA Special Agent in Charge. The letter must include the name and address of the person; the name and quantity of each controlled substance to be disposed of; how the applicant obtained the controlled substance, if known; and the name, address, and registration number, if known, of the person who possessed

² Food and Drug Administration, *Compliance Guides Policy Manual* Section 460.300, Return of Unused Prescription Drugs to Pharmacy Stock (CPG 7132.09). October 1, 1980. http://www.fda.gov/ora/compliance_ref/cpg/cpgdrg/cpg460-300.html.

the controlled substances prior to the applicant, if known (21 CFR 1307.21(a)(2)). Provided such disposal is permissible under the CSA, the Special Agent in Charge shall authorize and instruct the applicant to dispose of the controlled substance through any of the following methods: Transfer of the substance to a person registered under the CSA and authorized to possess the substance; delivery to an agent of the Administration or to the nearest office of the Administration; by destruction in the presence of an agent of the Administration or other authorized person; or, by such other means as the Special Agent in Charge may determine to ensure that the substance does not become available to unauthorized persons (21 CFR 1307.21(b)). Though this is an option currently available to ultimate users, it is used in extremely limited circumstances.

Another option available for the disposal of unwanted controlled substances dispensed to ultimate users is through take-back programs that comply with applicable Federal and state law. Take-back programs are organized collection events designed to reduce the amount of unwanted or unused pharmaceuticals that may pose a risk to public health and safety, may be accessible to diversion, or that otherwise may be disposed of in a manner that does not comply with State or Federal laws or regulations. As previously stated, the distribution of a controlled substance by an ultimate user for the purpose of disposal is a scenario not contemplated by the CSA and its closed system of distribution. However, as indicated above, ultimate users, and other DEA nonregistrants, in possession of controlled substances may dispose of those substances by receiving permission from the local DEA Special Agent in Charge, provided such disposal takes place in a manner consistent with the structure of the CSA.

In the absence of regulations expressly addressing the disposal of controlled substances dispensed to ultimate users, DEA has recently granted temporary permission to law enforcement agencies who have requested authorization to accept for disposal controlled substances that have been dispensed to ultimate users. In granting such temporary authorization, DEA has imposed certain conditions to ensure that the controlled substances do not become available to unauthorized persons, consistent with 21 CFR 1307.21, and to promote consistency with the structure of the CSA. Thus, the only take-back programs for which DEA has recently granted temporary allowances are those in which law

enforcement officials directly receive the controlled substances from the ultimate users. Recognizing that there might be additional appropriate methods of allowing for the disposal of controlled substances dispensed to ultimate users, DEA is seeking information to provide more accessible ways to safely and responsibly dispose of dispensed controlled substances in a manner consistent with the CSA.

Disposal of Unused Medications by Long Term Care Facilities (LTCFs)

The term "long term care facility" (LTCF) is defined to mean "a nursing home, retirement care, mental care, or other facility or institution which provides extended health care to resident patients." (21 CFR 1300.01(b)(25)). Most LTCFs are not DEA registered entities.

When patients residing at LTCFs require controlled substances their practitioner issues a prescription which is usually dispensed for the full amount by a registered pharmacy. The LTCF holds the prescribed drugs in a custodial manner for the patient and dispenses the medications on the schedule the practitioner orders. As a result of these dispensing practices, when patients die, leave the facility, or their medication is discontinued or changed, the LTCF may be left with excess controlled substances that must be disposed of to avoid diversion.

DEA has been acutely aware of the problems surrounding the disposal of dispensed controlled substances at LTCFs for some time, and has worked to reduce the accumulation of controlled substances at LTCFs through a number of regulatory actions. Prescribing practitioners are required by regulation to specify the quantity prescribed on the prescriptions. However, DEA recognized that LTCF patients are a unique part of society, and may often need the Schedule II controlled substances medications they are prescribed changed on short notice based on their rapidly changing health conditions. Consequently, patients might not need the full quantity of the Schedule II controlled substance that the practitioner had initially prescribed. To reduce the potential excess amounts of dispensed controlled substances, practitioners prescribing Schedule II controlled substances for LTCF patients needed the ability to prescribe smaller quantities of those substances more frequently than would be necessary for other patients. Practitioners are required to manually sign prescriptions for Schedule II controlled substances for the prescription to be valid (21 CFR 1306.05(a)), and the dispensing

pharmacy is unable to dispense the needed controlled substance until it receives a valid prescription (21 CFR 1306.11(a)). It became evident that this requirement made it more difficult for prescribing practitioners to be responsive to the immediate and changing needs of LTCF patients. To address this circumstance, DEA promulgated regulations that permit the facsimile transmission of written, manually signed Schedule II prescriptions for residents of LTCFs by the practitioner or the practitioner's agent to the dispensing pharmacy (21 CFR 1306.11(f)). The facsimile serves as the original prescription for the dispensing pharmacy's records. DEA has also permitted the facsimile transmission of written, manually signed Schedule II controlled substance prescriptions for patients enrolled in hospice care programs certified and/or paid for by Medicare under Title XVIII of the United States Code, or hospice programs licensed by the State (21 CFR 1306.11(g)).

DEA has also established partial dispensing provisions for Schedules II–V prescriptions (including unit-dose dispensing, if desired), to limit the quantity of controlled substances dispensed at one time and avoid waste if the treatment was changed or discontinued. These regulations include specific provisions for residents of LTCFs or patients with medical diagnoses documenting a terminal illness (21 CFR 1306.13(b), 1306.23). According to the pharmacy industry, however, dispensing fees, reimbursement practices, and difficulties in educating practitioners regarding the need to prescribe controlled substances in anticipation of a patient's actual need for the controlled substance have, for the most part, precluded using that approach.

To further prevent the accumulation of controlled substances at LTCFs, DEA has permitted retail pharmacies to install and operate automated dispensing systems (ADS) at LTCFs (21 CFR 1301.27). ADS are conceptually similar to a vending machine. A pharmacy stores bulk controlled substances in the ADS in separate bins or containers and programs and controls the ADS remotely. Only authorized staff at the LTCF has access to the ADS's contents, which are dispensed on a single-dose basis at the time of administration pursuant to a prescription. The ADS electronically records each dispensing, thus maintaining dispensing records for the pharmacy. Because the controlled substances are not considered dispensed until the system provides them,

controlled substances in the ADS are pharmacy stock, not waste.

Despite DEA's efforts to reduce the accumulation of dispensed controlled substances at LTCFs, accumulation continues to be a concern. LTCFs that are not DEA registrants may not transfer the controlled substances to either the pharmacy that supplied them or to a reverse distributor for disposal.

Purpose of Advance Notice of Proposed Rulemaking

On February 20, 2007, in recognition of the advice being provided by environmental organizations to the public to dispose of medications in household trash (as opposed to flushing them into the waste-water system), the U.S. Office of National Drug Control Policy (ONDCP) announced guidelines for the disposal of ultimate user medications, including dispensed controlled substances. The guidelines were published by ONDCP in conjunction with the Department of Health and Human Services (HHS), and the EPA.³ The guidelines advise the public to flush medications only if the prescription label or accompanying patient information specifically states to do so. Instead of flushing, ONDCP recommends that, after performing a minimal deactivation procedure, the medications be disposed of in common household trash or at community pharmaceutical "take-back" programs. The press release announcing the guidelines stated:

The new Federal guidelines are a balance between public health concerns and potential environmental concerns. "While EPA continues to research the effects of pharmaceuticals in water sources, one thing is clear: Improper drug disposal is a prescription for environmental and societal concern," said EPA Administrator Stephen L. Johnson. "Following these new guidelines will protect our Nation's waterways and keep pharmaceuticals out of the hands of potential abusers."

In addition to environmental concerns, there are safety concerns that medications, especially controlled substances, could be either intentionally or unintentionally abused. Children may retrieve a medication from the trash and ingest it without the specific intention of abusing it. For these reasons, some medications include flushing disposal instructions to make them less available and to mitigate safety risks.

The illicit use of prescription medication is a growing problem among young adults. According to the 2007 National Survey on Drug Use and Health, more persons age 12 and above are engaged in the non-medical use of psychotherapeutic drugs than those abusing cocaine, heroin, and methamphetamine combined. Prescription drug abuse is second only to marijuana use.⁴ The 2005 Partnership Attitude Tracking Study (PATS) reported that 62 percent of teens say prescription pain relievers are easy to get from parents' medicine cabinets.⁵

DEA is seeking options for the disposal of controlled substances dispensed to DEA nonregistrants that protect public health and safety, minimize the possibility of diversion, are consistent with the CSA and DEA regulations, and provide sound environmental solutions.

Request for Information

DEA seeks comments regarding the promulgation of regulations to permit the disposal of controlled substances by ultimate users and long term care facilities consistent with the Controlled Substances Act and its implementing regulations. DEA seeks comments regarding how various entities would address the issue of the disposal of dispensed controlled substances held by DEA nonregistrants in light of the current restrictions that are in place. Commenters are encouraged to include the question number enumerated below in their response. Although all comments are welcome, DEA is particularly interested in comments regarding the questions listed below. These questions are separated into groups by area of interest. The groups are:

- Ultimate Users
- State and Local Law Enforcement Agencies & Publicly Owned Treatment Works
- Concerned Interest Groups
- Long Term Care Facilities
- Hospices and In-Home Care Groups
- Pharmacies
- Narcotic Treatment Programs
- Reverse Distributors
- State Regulatory Agencies
- All Interested Parties

⁴ Office of National Drug Control Policy, Executive Office of the President, Prescription for Danger, A Report on the Troubling Trend of Prescription and Over-the-Counter Drug Abuse Among the Nation's Teens, January 2008.

⁵ Partnership for a Drug-Free America, The Partnership Attitude Tracking Study (PATS): Teens in grades 7 through 12 (2005). May 16, 2006.

For Ultimate Users (Patients or Family Members of Patients Who Possess Controlled Substances Which Have Been Legally Dispensed)

1. Can you distinguish a controlled substance from a non-controlled substance?
2. Why do you have unwanted or outdated controlled substances in your possession?
3. What method, if any, do you currently use to dispose of your unwanted or outdated pharmaceuticals, including controlled substances?
4. Are you willing to seek locations outside of your home to dispose of unwanted pharmaceuticals?
5. Does your community, county, or State have laws, regulations, or policies in place that prohibit medications, including controlled substances, from being flushed or placed in the garbage?
6. Does your community have take-back programs during which you can provide pharmaceuticals to an entity for disposal? If so, do you know whether these programs accept controlled substances?
7. If your community has take-back programs, who sponsors the program?
8. If you participated in a take-back program, please describe how the program worked.
9. If you participated in a take-back program, was a law enforcement agency involved?
10. If you participated in a take-back program, did you encounter any problems? Please explain.
11. What do you believe is the best method of disposing of unwanted or outdated pharmaceuticals, including controlled substances dispensed to ultimate users?
12. Would you be willing to pay a fee to have your medication disposed of in a manner that minimizes the possibility of the diversion of legally obtained controlled substance medications for illegal purposes and is environmentally safe? If so, how much would you be willing to pay?
13. Would you consider using a postage paid mailing container to dispose of unwanted medications?
14. Where would you be willing to go to obtain such a postage paid mailing container (e.g., local pharmacy, police department, take-back event)?
15. Would you be willing to pay the postage on a mailing container used to ship controlled substances and other pharmaceuticals to another location for disposal? If so, how much would you be willing to pay?
16. Would you consider the use of a mailing container more convenient or less convenient than taking unwanted

³ Office of National Drug Control Policy, Executive Office of the President, Proper Disposal of Prescription Drugs, February 2007. http://www.whitehousedrugpolicy.gov/publications/pdf/prescrip_disposal.pdf.

controlled substances to a pharmacy or to a take-back event?

17. What other means of disposal would you consider convenient?

For State and Local Law Enforcement Agencies and Publicly Owned Treatment Works

18. Is the disposal of unwanted or outdated pharmaceuticals a problem in your area?

19. Do individuals bring their unwanted or outdated pharmaceuticals, including controlled substances which have been legally obtained, to your department for disposal?

20. Does your department encourage or discourage such activity? Please explain.

21. If individuals bring their unwanted or outdated pharmaceuticals, including controlled substances which have been legally obtained, to your department for your department to dispose of, how does that process work? Do individuals drop the pharmaceuticals in a container, hand them to a department employee, or hand them to a law enforcement officer?

22. Have you ever had any challenges or difficulties with taking individuals' unwanted or outdated pharmaceuticals, including controlled substances, for disposal? If so, please explain.

23. Does your department/facility participate in take-back programs?

24. If your department/facility participates in take-back programs, what is the nature of your participation?

25. Have you ever encountered any challenges or difficulties when participating in such programs? Please explain.

26. If your department/facility does not participate in take-back programs, what, if anything, prevents such participation?

27. Does your department/facility have the staffing and resources to participate in take-back programs?

28. Is your department aware of any cases of diversion involving take-back programs? If so, did the diversion result in the arrest or prosecution of any individuals?

29. Regardless of how you receive the medications (e.g., take-back program, individual drop off) for disposal, do you differentiate between controlled substances and noncontrolled substances? If so, how?

30. Regardless of how you receive the medications for disposal, what would you estimate to be the percentage, quantity, or other measurable unit of controlled substances as compared to noncontrolled substances?

31. Regardless of how you receive the medications for disposal, prior to

disposal, where do you store these pharmaceuticals and under what security?

32. How do you dispose of the controlled substances that you receive?

33. What records do you generate regarding what you receive and what you dispose of?

34. How far must you travel to dispose of pharmaceuticals, including controlled substances?

35. What do you do if the landfill or incinerator you plan to use is closed, nonoperational, or otherwise unavailable?

36. How much money has your participation in pharmaceutical disposal cost your department/facility in the previous year?

37. How many man-hours has your participation in drug disposal cost your department/facility in the previous year?

38. If you are receiving unwanted or outdated pharmaceuticals for disposal, are you doing so as a result of local or State policy, law, or regulation?

39. If your department does not currently receive pharmaceuticals for disposal, would it be interested in receiving them?

40. Would your department/facility be willing to make available postage paid envelopes to be used by the public to mail pharmaceuticals to a reverse distributor or a law enforcement agency for disposal?

41. What do you believe is the best method of safely disposing of unwanted or outdated controlled substances held by DEA nonregistrants?

For Concerned Interest Groups

42. What prompted you to get involved in the issue of drug disposal?

43. What is your group doing to address this issue?

44. What have been your successes?

45. What challenges or difficulties have you encountered?

46. If you accept medications for disposal, what records do you maintain, if any?

47. If you accept medications for disposal, how do you store and secure these medications prior to disposal?

48. If you accept medications for disposal, do you differentiate between controlled substances and noncontrolled substances? If so, how?

49. What has been law enforcement's involvement in the disposal of these medications, if any?

50. What would you estimate to be the percentage, quantity, or other measurable unit of controlled substances as compared to noncontrolled substances that your disposal programs received?

51. If you have a pharmaceutical disposal program in place, how is it funded?

52. There is concern that residue from pharmaceuticals is being found in drinking water. What is your understanding of the percentage of this problem that is due to ultimate users flushing their unused or unwanted medications?

For Long Term Care Facilities

53. Is the issue of unwanted or unused pharmaceuticals, including controlled substances, a concern at your facility?

54. What are the reasons why your facility is in possession of unwanted or outdated pharmaceuticals, including controlled substances?

55. At the end of each month is your facility in possession of a significant amount of unwanted or outdated pharmaceuticals? How much? Of those pharmaceuticals, what would you estimate the percentage of controlled substances to be?

56. How do you normally dispose of these pharmaceuticals, including controlled substances?

57. Does law enforcement, or some other State agency, assist you in disposing of controlled substances?

58. Are you mandated by any local or State law or regulation to dispose of these medications, including controlled substances, in a specific manner? If so, how?

59. Does your facility take unwanted or outdated pharmaceuticals to local take-back programs?

60. Are you aware of automated dispensing systems? If so, does your facility use them? Have they reduced the amount of excess medications at the facility?

61. Has the ability of a pharmacy to receive faxed schedule II prescriptions for patients in long term care facilities helped to reduce the amount of excess medications at your facility?

62. How do you believe the accumulation of unwanted or outdated pharmaceuticals at long term care facilities can be better addressed?

63. What do you believe is the best method for disposing of these pharmaceuticals?

For Hospices and In-Home Care Groups

64. Is the accumulation of unwanted or outdated controlled substances a problem for your business?

65. If you dispose of unwanted or outdated pharmaceuticals, what methods do you currently use to dispose of such pharmaceuticals, including controlled substances?

66. If you dispose of pharmaceuticals, including controlled substances, what have been your successes?

67. If you dispose of pharmaceuticals, including controlled substances, what challenges or difficulties have you encountered?

68. What do you believe is the best method of disposing of these unwanted or outdated pharmaceuticals, including controlled substances?

69. Has the ability of a pharmacy to receive faxed schedule II prescriptions for patients enrolled in hospice programs helped to reduce the amount of excess medications?

70. How do you believe the accumulation of unwanted or outdated pharmaceuticals by patients enrolled in hospice programs can be better addressed?

For Pharmacies

71. Is the disposal of unwanted or outdated pharmaceuticals by ultimate users a problem in your area?

72. Does your State permit your pharmacy to take unwanted or outdated pharmaceuticals, including dispensed controlled substances, from ultimate users?

73. Does your State permit your pharmacy to place unwanted or outdated pharmaceuticals obtained from ultimate users, including dispensed controlled substances, back into stock?

74. If you provide pharmaceuticals, including controlled substances, to long term care facilities, does your State permit your pharmacy to take back unwanted, unused, or outdated medications from those facilities?

75. Does your State permit your pharmacy to place unwanted or outdated pharmaceuticals obtained from long term care facilities, including dispensed controlled substances, back into stock?

76. Does your pharmacy participate in any pharmaceutical take-back programs? If so, please describe.

77. If your pharmacy participates in pharmaceutical take-back programs, what have been the successes?

78. If your pharmacy participates in pharmaceutical take-back programs, what challenges or difficulties have you encountered?

79. Would your pharmacy be willing to make available postage paid envelopes to be used by the public to mail unwanted or outdated pharmaceuticals to a reverse distributor or law enforcement agency for disposal? Would your pharmacy consider paying for any costs associated with this activity? If so, how much would your pharmacy be willing to pay?

80. Would your individual pharmacy or chain consider contributing financially to offset the expense of a pharmaceutical disposal program? If so, what type of program is your pharmacy interested in?

81. What do you believe is the best method to dispose of unwanted or outdated pharmaceuticals obtained from ultimate users, including dispensed controlled substances?

82. Has the ability of a pharmacy to receive faxed schedule II prescriptions for patients enrolled in hospice programs or residing at long term care facilities helped to reduce the amount of excess medications?

83. How can the accumulation of unwanted or outdated pharmaceuticals, including controlled substances, at long term care facilities and hospice programs be better addressed?

For Narcotic Treatment Programs

84. What are the concerns of narcotic treatment programs regarding the disposal of controlled substances used in maintenance or detoxification treatment?

85. Would your narcotic treatment program consider contributing financially to offset the expense of a pharmaceutical disposal program? If so, what type of program would best meet your needs?

86. What do you believe is the best method to dispose of unwanted or outdated dispensed controlled substances?

87. What are the reasons why NTPs are in possession of controlled substances that require disposal?

88. Have controlled substances awaiting disposal been a source of diversion for your NTP?

For Reverse Distributors

89. Have you been approached by any group or any law enforcement agency requesting that you participate in the disposal of pharmaceuticals, including controlled substances dispensed to ultimate users?

90. Do you currently accept pharmaceuticals, including dispensed controlled substances, from ultimate users for disposal? If so, how?

91. Are your competitors accepting pharmaceuticals, including dispensed controlled substances, from ultimate users for disposal?

92. If you accept pharmaceuticals, including dispensed controlled substances, from ultimate users for disposal, what have your successes been?

93. If you accept pharmaceuticals, including dispensed controlled substances, from ultimate users for

disposal, what challenges or difficulties have you encountered?

94. If you were able to accept pharmaceuticals, including dispensed controlled substances, from ultimate users for disposal, would your facility be able to handle this added volume?

95. What does it cost to dispose of controlled substances?

96. What do you estimate it would cost to dispose of controlled substances dispensed to ultimate users? On what basis are costs calculated (e.g., per pound disposed of)?

97. Do you currently accept pharmaceuticals from long term care facilities (LTCFs) for disposal? If so, how?

98. Are your competitors accepting pharmaceuticals from LTCFs for disposal?

99. If you accept pharmaceuticals from long term care facilities for disposal, what have your successes been?

100. If you accept pharmaceuticals from long term care facilities for disposal, what challenges or difficulties have you encountered?

101. If you were able to accept pharmaceuticals, including dispensed controlled substances, from long term care facilities for disposal, would your facility be able to handle this added volume?

102. What do you estimate it would cost to dispose of dispensed controlled substances obtained from long term care facilities? On what basis are costs calculated (e.g., per pound disposed of)?

103. What do you believe is the best method of disposing of unwanted or outdated pharmaceuticals, including controlled substances dispensed to DEA nonregistrants?

104. Would you accept for disposal controlled substances that have been dispensed to ultimate users directly from ultimate users by means of individual mailing containers?

105. Do you perceive any problems with reverse distributors accepting dispensed controlled substances directly from ultimate users by means of individual mailing containers?

106. Would your company be interested in contributing financially to offset the expense of a disposal program for ultimate users that would be instituted at your company?

107. If reverse distributors were permitted to accept controlled substances dispensed to ultimate users for disposal, how do you believe the unwanted or outdated controlled substances should be provided by the ultimate user to the reverse distributor?

For State Regulatory Agencies

108. What current laws or regulations does your State have regarding the disposal of dispensed controlled substances and noncontrolled substances by ultimate users?

109. What laws or regulations, if any, is your State considering regarding the disposal of dispensed controlled or noncontrolled substances by ultimate users?

110. Does your State agency participate in any initiatives (e.g., take-back or mail-back programs) regarding the disposal of dispensed controlled and noncontrolled substances by ultimate users at this time? If so, please describe.

111. Is your State agency aware of any cases of diversion regarding take-back programs? If so, did the diversion result in the arrest or prosecution of any individuals?

112. If your State agency does not participate in any initiatives regarding the disposal of dispensed controlled or noncontrolled substances by ultimate users, why not?

113. If your State agency participates in any initiatives regarding the disposal of dispensed controlled and noncontrolled substances by ultimate users, what would you estimate to be the percentage, quantity, or other measurable unit of controlled substances as compared to noncontrolled substances received?

114. If your State agency participates in any initiatives regarding the disposal of dispensed controlled and noncontrolled substances by ultimate users, does your agency fund all or part of the initiative? If other funding is received, who provides the other funding?

115. If your State agency participates in any initiatives regarding the disposal of dispensed controlled and noncontrolled substances by ultimate users, what successes have you seen regarding these initiatives?

116. If your State agency participates in any initiatives regarding the disposal of dispensed controlled and noncontrolled substances by ultimate users, what challenges or difficulties have you encountered?

For All Interested Parties

117. DEA also seeks comment from all interested parties regarding the funding of the disposal of unwanted or outdated controlled substances held by DEA nonregistrants.

Regulatory Certifications

This action is an Advance Notice of Proposed Rulemaking (ANPRM). Accordingly, the requirement of

Executive Order 12866 to assess the costs and benefits of this action does not apply. Rather, among the purposes DEA has in publishing this ANPRM is to seek information from the public on the costs, benefits, and other impacts pertaining to the disposal of controlled substances dispensed to ultimate users and long term care facilities. Similarly, the requirements of section 603 of the Regulatory Flexibility Act do not apply to this action since, at this stage, it is an ANPRM and not a "rule" as defined in section 601 of the Regulatory Flexibility Act. Following review of the comments received to this ANPRM, if DEA promulgates a Notice or Notices of Proposed Rulemaking regarding this issue, DEA will conduct all analyses required by the Regulatory Flexibility Act, Executive Order 12866, and any other statutes or Executive Orders relevant to those rules and in effect at the time of promulgation.

Dated: January 13, 2009.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control.

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DEPARTMENT OF TRANSPORTATION**Federal Highway Administration****23 CFR Part 180****Office of the Secretary****49 CFR Part 80****Federal Railroad Administration****49 CFR Part 261****Federal Transit Administration****49 CFR Part 640****Maritime Administration****49 CFR Part 1700**

[Docket No. DOT-OST-2009-0004]

RIN 2105-AD70

Credit Assistance for Surface Transportation Projects

AGENCIES: Federal Highway Administration (FHWA), Federal Railroad Administration (FRA), Federal Transit Administration (FTA), Maritime Administration (MARAD), Office of the Secretary of Transportation (OST), Department of Transportation (DOT).

ACTION: Notice of proposed rulemaking (NPRM); request for comments.

SUMMARY: Recent changes to the Transportation Infrastructure Finance and Innovation Act (TIFIA) statute require changes in the TIFIA rule. In addition, the DOT has gained substantial administrative experience since the TIFIA rule was last amended in 2000. The DOT proposes to amend the TIFIA rule to implement the recent statutory changes and to incorporate certain other changes to the rule that it considers will improve the efficiency of the program and its usefulness to borrowers. In addition, the DOT seeks comment on policy issues with potentially significant impact on the TIFIA project selection process.

DATES: Comments must be received on or before March 23, 2009.

ADDRESSES: Mail or hand deliver comments to the U.S. Department of Transportation, Dockets Management Facility, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590, or submit comments electronically at <http://www.regulations.gov>, or fax comments to (202) 493-2251. Alternatively, comments may be submitted via the Federal eRulemaking Portal at <http://www.regulations.gov> (follow the on-line instructions for submitting comments). All comments should include the docket number that appears in the heading of this document. All comments received will be available for examination and copying at the above address from 9 a.m. to 5 p.m., e.t., Monday through Friday, except Federal holidays. Those desiring notification of receipt of comments must include a self-addressed, stamped postcard or you may print the acknowledgment page that appears after submitting comments electronically. All comments received into any docket may be searched in electronic format by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). Persons making comments may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70, Pages 19477-78), or you may view the statement at <http://dms.dot.gov>.

FOR FURTHER INFORMATION CONTACT: Mr. Mark Sullivan, TIFIA Joint Program Office (202) 366-5785, or Mr. Steven Rochlis, Office of the Chief Counsel (202) 366-1395, Federal Highway Administration; Mr. Michael Bouril, Office of Budget (202) 366-4587, Mr. Jacob Falk, Office of Policy (202) 366-