February 14, 2013

Via Electronic Transmittal: www.regulations.gov
Docket No. DEA-316
Mr. John W. Partridge
Executive Assistant
Office of Diversion Control (OD/DX)
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, VA 22152

Re: Proposed Rulemaking Disposal of Controlled Substances Federal Register, Vol. 77 No. 246, Docket No. DEA-316

Dear Mr. Partridge:

WM Healthcare Solutions, Inc., a Waste Management company, (WMHS) appreciates the opportunity to comment on the Drug Enforcement Administration's (DEA) proposed rule to govern secure disposal of controlled substances. We support DEA's and other interested parties' goals of implementing the Safe and Responsible Drug Disposal Act of 2010 by expanding the options available to collect controlled substances from ultimate users for disposal. We also appreciate the efforts made by DEA to address the continuing concerns about management and disposal of controlled substances within the healthcare community.

WMHS provides integrated sustainability, environmental and compliance services for the healthcare industry including the protective management, treatment and disposal of hazardous and non-hazardous pharmaceuticals and controlled substances. Our comments highlight the potential impacts of the proposed regulation on the various types of healthcare customers we serve. We offer comments based on the healthcare sector affected, e.g. reverse distribution, hospital providers, etc. and/or the process, e.g. consumer mail back options, etc. and we offer our recommended revisions to the proposed regulatory language.

Ultimate User Collection

Page 75785, Collectors that conduct mail-back programs must have on-site destruction.

WMHS is very concerned that this proposed provision will have the unintended consequence of significantly restricting the number of facilities that can operate a mail-back program. We are aware of only five or six registrants with on-site destruction capability at their facility. While WMHS supports the DEA's goal of providing a regulatory framework for secure and well-controlled disposal of ultimate user's pharmaceuticals including controlled substances, we do not believe the DEA has provided sufficient data or explanation to demonstrate the need for proposing such a severe limitation.

Reverse distributors, registered by DEA, serve the primary function of evaluating outdated drugs for their credit worthiness, either for their pharmacy/distributor clients or for pharmaceutical manufacturers. Reverse distributors normally contract for the disposal of outdated, non-creditable drugs, but do not conduct actual disposal/destruction themselves. From a security perspective, they are fully equipped to receive, document, and securely store packages of pharmaceuticals including controlled substances received from manufacturers, healthcare facilities, and pharmacies and with promulgation of DEA's rule, ultimate users as well.

Destruction could be performed in the same manner and level of security as expected for other controlled substances received either from registrants or from law enforcement. To restrict mail-back programs to only those facilities with on-site incinerators will significantly limit the availability, competitiveness and affordability of such programs.

It would be helpful if DEA would clarify whether the term "mail-back" is generic and can UPS and FedEx also be used in addition to the USPS.

Page 75785, column 2: "Controlled substances collected by collectors may not be individually counted or inventoried."

WMHS agrees that to protect against diversion of controlled substances that may be present in pharmaceuticals collected from ultimate users, containers should not be required to be opened for inventory purposes. Nonetheless, we do see value in organizations being able to apply for an exemption to this prohibition to collect data to conduct research.

The prohibition on opening containers to inventory the contents does present possible conflicts for reverse distributors who also handle drug returns from registrants. State boards of pharmacy require reverse distributors to inventory all drugs received. Since law enforcement is able to deliver undocumented containers of both controlled substances and other medications to a reverse distributor, a reverse distributor will not be able to comply with the FDA and state boards of pharmacy inventory requirements. We suggest DEA conduct dialogs with the FDA

and NABP (National Association of Boards of Pharmacy) to enable an exemption for the receipt of these packages.

Page 75791 column 1: "DEA recommends that law enforcement agencies also keep a record of any transfer of controlled substances to reverse distributors for destruction."

It appears from this statement that law enforcement may transfer controlled substances to a reverse distributor for destruction by actually transporting and delivering the materials in person. Given the relatively small number of reverse distributors in the country, can law enforcement ship the waste drugs via common carrier? What DEA has not made clear in the proposal is how law enforcement is to manage DOT requirements related to the transfer of drugs that may contain hazardous materials. Additionally, DEA has not clarified what records need to be kept by the reverse distributor when receiving controlled substances from law enforcement, either in person or via common carrier.

Page 75791 Column 3: We understand that retail pharmacies within hospitals can be collectors but hospitals may not.

DEA should clarify whether hospitals may still conduct take-back programs in cooperation with law enforcement. Furthermore, DEA should address circumstances in which hospitals will be in possession of controlled substances from ultimate users. Hospitals need a solution for patients' personal controlled substances brought into the hospital and left with no return possible, due to death or the absence of any relatives or other responsible parties to take possession of the discarded medicine.

Page 75792, column 2: "authorized collectors may conduct the following activities: (1) Receive mail-back packages from ultimate users and persons lawfully entitled to dispose of an ultimate user decedent's property if the collector has and utilizes an on-site method of destruction."

We believe the requirement for on-site destruction is too restrictive and severely limits this important activity to a very small number of possible vendors. This will restrict competition, raise costs and deter safe management and disposal of unused controlled substances. Reverse distributors receive controlled substances through the mail and by common carrier such as FedEx and UPS on a daily basis, including from consumers during a recall event. They have sufficient security in place to manage mail-back packages through final destruction at their normal off-site incineration facility. DEA has failed to show that existing management by reverse distributors presents risks warranting these new, proposed restrictions.

Page 75793, column 3: The requirement that reverse distributors must destroy controlled substances no later than 14 calendar days from receipt is unworkable.

Very few reverse distributors have on-site destruction units or incinerators. Available incinerators that are permitted to burn non-hazardous pharmaceuticals may be thousands of miles away requiring substantial logistics. Some states do not recognize the household exemption for consumer drug waste thereby requiring hazardous waste incineration for collected medications from ultimate users. Only six hazardous waste incinerators are commercially available in the US. Transport of controlled substances may require a lock box on the truck and considerable support from trained personnel. It is not economically viable to ship the small amounts of pharmaceuticals that reverse distributors will likely be receiving from ultimate users. It is also not reasonable to require two employees of the reverse distributor to accompany the load and witness the destruction. We have outlined alternative methods currently in use and approved by DEA SACs below, beginning at the end of page 7.

Page 75793, column 3: "Any storage of such substances at the registered location of the reverse distributor or distributor must be in a manner consistent with the security requirements for Schedule II controlled substances."

Controlled substances make up a small percentage (approximately 10%) of pharmaceuticals prescribed to patients, and they will comprise an even smaller percentage of the unused pharmaceuticals collected from ultimate users. Schedule II controlled substances comprise an even smaller percentage (about 2%) of prescribed pharmaceuticals. Schedule II substances are often delivered to patients in hospital settings, and thus are not likely to be found, except very rarely, in unused pharmaceuticals collected through take-back programs. The requirement that reverse distributors store ultimate user pharmaceuticals in the same manner as Schedule II controlled substances is unwarranted and will serve as a deterrent to establishing take-back programs. For these registrants, a vault is required for Schedule II storage. These vaults are very expensive to construct and typically quite small. The size constraints will be problematic in storing potentially large shipments of consolidated ultimate user discarded pharmaceuticals from take-back programs, and the additional expense may deter reverse distributors from accepting ultimate user medicines. Furthermore, reverse distributors typically limit employee access to Schedule II vaults to a very small number of authorized personnel as a security measure. Requiring that potentially large shipments or frequent small shipments of ultimate user pharmaceuticals be stored in these vaults will increase employee traffic in the secure area and undermine registrant security protocols. We urge DEA to reconsider imposing this requirement. A standard controlled substance cage or a distinctive locked area within the controlled substance cage will provide adequate security, particularly as non- controlled substances will make up the bulk of the packaged materials.

Page 75793 Column 2: "DEA is proposing...that registered reverse distributors and registered distributors that choose to acquire such collected controlled substances from authorized collectors do so in the manner prescribed for acquiring registrants' controlled substances inventory for purposes of disposal."

This statement seems to imply that use of the Form 222 and detailed inventories are required for return purposes; however, such requirements will not be workable for collected

ultimate users' controlled substances since there will be no inventory of the materials. We recommend DEA revise this language to correspond to an inventory of the inner liners. We again strongly recommend that mail-back programs be allowed to ship to reverse distributors who are fully capable of secure receipt of materials and secure arrangement for their destruction. This modification would also be consistent with the ability of law enforcement agencies who conduct mail-back programs to use reverse distributors.

Page 75794, Column 2: "DEA proposes...that each take-back event should have at least one receptacle for the collection of permitted substances." We recommend defining "permitted substance" - presumably controlled substances in schedules II, III, IV and V.

Page 75794, Column 2: "DEA also proposes ...that only an ultimate user or person lawfully entitled to dispose of an ultimate user decedent's property may transfer controlled substances..."

In many cases, an ultimate user may be incapable for health reasons of disposing of the controlled substances personally. We recommend that in addition to addressing the circumstance where an ultimate user is deceased and a responsible person is then authorized to dispose of their unused controlled substances, DEA should address the circumstance of an "incapacitated ultimate user" to enable a lawfully entitled person to represent and properly manage an ultimate user's unused pharmaceuticals. We also recommend addition of language pertinent to the parent or guardian of a minor who may be the ultimate user.

Page 75795, Column 2: "No other person, such as a take-back event volunteer, may handle or touch the controlled substances at any time."

It is likely that controlled substances will be mixed in with the other medications when delivered to take-back events. We recommend that registered pharmacists be allowed to receive and sort the controlled substances from other medications. This would enable the waste vendor to remove immediately the non-controlled substances for destruction at the end of the event. Without sorting, law enforcement will have huge amounts of medications to store in their evidence rooms and either transport to a destruction facility or send to a reverse distributor for destruction. Such a requirement could make take-back events financially non-viable, removing an important alternative. In some states, the household exemption from the Resource Conservation and Recovery Act hazardous waste regulations does not apply to take-back events. In such states, all drugs that become a hazardous waste under RCRA would need to be managed by a hazardous waste vendor at the collection site and could not be transferred to law enforcement. Very few controlled substances become hazardous waste when disposed so by segregating at the site, the event could operate within the state environmental regulations.

Page 75796, Column 2: "DEA is also proposing that the outer container prominently display a sign indicating that only non-controlled drugs and Schedule II, III, IV, or V controlled substances are acceptable for collection."

The notification that DEA proposes to require will be meaningless to the lay public as most are unaware of which prescription drugs are controlled substances and are not familiar with distinguishing among the scheduled categories. We recommend the notice to the public on the outer container should state that only prescription (Rx) and Over-the Counter drugs (OTC) should be placed into collectors. There is no uniformly recognized symbol to distinguish controlled substances on prescription containers and the public does not generally know what controlled substances are.

Ultimate User Long Term Care Facilities (LTCF)

Page 75797 column 2 & 3: "...employees of the long term care facility will not have access to the inner liner of the collection receptacle..."

In the proposed regulations, LTCF employees do not have access to the inner liners of receptacles. This does not account for the likelihood that collection boxes will reach capacity between scheduled delivery times for destruction DEA should provide some type of failsafe mechanism to authorize responsible LTCF personnel, such as the Director of Nursing and Assistant Director of Nursing, to remove, store, and replace the inner liner. We also strongly recommend that only controlled substances be placed into the collectors to minimize the need for this intervention. It not reasonable to require non-controlled substances to be transferred to the retail pharmacy, stored in a secure environment, and then transported for destruction, when the LTCF can easily sort non-controlled substances into appropriate pharmaceutical waste containers for more efficient transport and disposal.

DEA should seek comment specifically from LTCF provider pharmacies to determine if it is feasible to have two employees pick up the liners. Currently only one employee delivers the controlled substances to the LTCF. Consideration must also be given to the time between the adoption of the regulations and the implementation of collection programs by provider pharmacies to provide this service. LTCFs need an alternative, such as flushing, in both in the short –term and possibly longer term, based on their market area and service providers. The clause about the ultimate user or relative disposing of medications is not realistic and should be removed.

Page 75797 column 3: The statement that LTCFS do not have in place physical security controls to minimize risk of diversion is inaccurate.

Current LTCF regulations require secure storage and tight control of controlled substances.

Page 75798 column 1: The statement that LTCF residents may use any other disposal method is unrealistic, especially in a skilled nursing facility.

The proposed regulation should also address assisted living situations, where medication control may reside with the resident or with the facility, depending on the needs of the resident.

Page 75797, column 2: The commingling of controlled and non-controlled substances will also be problematic in states, which consider LTCFs to be businesses and all wastes generated subject to the EPA Resource Conservation and Recovery Act hazardous waste regulations.

LTCFs should be actively encouraged to consider these requirements before deciding to commingle ultimate users' discarded pharmaceuticals. Transferring pharmaceutical waste that meets the definition of a hazardous waste to the registered pharmacy collector would be a violation of the EPA RCRA regulations for both parties. Very few controlled substances are RCRA hazardous wastes, so continuing to separate these wastes would enable the LTCF to manage the RCRA hazardous waste in a compliant manner.

Hospitals and other Healthcare Facilities

Page 75791 column 1: "In contrast, a controlled substance dispensed for immediate administration pursuant to an order for medication in an institutional setting remains in the possession of that registered institution even if the substance is not fully exhausted."

We recommend that clarification be provided by DEA as to the status of used fentanyl and testosterone patches. While there will be drug remaining in the used patch, the amount is unknown and variable. Storage of these patches, which are "used" from DEA's perspective and out of the hospital's inventory, is not realistic and could lead to additional diversion. Typically, hospitals dispose of these used patches down the drain or in the red sharps containers. Hospices and LTCFs also have these issues.

Page 75799, Column 3: "DEA therefore proposes ....to allow non-practitioners to deliver (i.e., transfer) controlled substances themselves for the purpose of disposal provided that such substances are transported directly to the destruction location and accompanied by two authorized employees."

As noted above, the destruction facility may be hundreds or thousands of miles from the non-practitioner. Currently, some reverse distributors have received permission from the DEA SAC to send the controlled substances via common carrier with witnessed inventories both upon departure and upon receipt at the destruction facility. The SAC's have also authorized the hiring of off-duty law enforcement officers or other security personnel to witness the receipt, unloading, and actual destruction by incineration of the controlled substances. The contracted security personnel then sign the Form 41. Common carriers do not normally allow employees

of other companies to ride on their trucks and many reverse distributors do not operate their own trucking fleets.

Page 75800, column 2: "Under the proposed definition ..., an "authorized employee" is a person directly employed by the registrant full time etc."

This definition is problematic with respect to both pharmacists and nurses, either of whom may be part-time employees. In some pharmacy departments, pharmacy staff may be employees of an outside consulting firm. With respect to nurses, many are now part-time or may be contract labor from a nursing pool. We suggest DEA include regulatory language that would encompass all of these situations to the effect that an "authorized employee" would be one who has been hired or contracted to perform the duties normally performed by a full-time employee of the registrant and who is duly licensed to do so.

Page 75800, column 3 (and Page 78795, column 3) : "Additionally, DEA proposes ...that a registrant that destroys controlled substances or causes the destruction of controlled substances is required to maintain a record of the destruction in a form to be issued by DEA. This form will be DEA Form 41."

We have previously expressed concerns to OMB through DEA[1] regarding the requirement to use a paper Form 41, especially in hospitals where automated dispensing machines (ADMs), or cabinets (ADCs) are in use and disposal documentation of controlled substances is done electronically by two health care professionals as witnesses. In addition to the information expressed in the January 21, 2013 letter, we have sought additional information from manufacturers of automated dispensing machines. The standard electronic data captured by automatic dispensing machines includes the patient's name for whom the dose was removed from the machine, the name and strength of the drug, the amount of controlled substance administered, the amount of controlled substance "wasted," the means of wasting (device, flushing, or returned to pharmacy for additional management), and the identity of the two healthcare professionals who witnessed the disposal. The programming usually also provide prompts for nurses who have not completed the wasting process, notifications to nursing supervisors of any discrepancies, and notifications to the pharmacy department of unresolved discrepancies. These records are readily available for at least two years and are archived indefinitely. The records are exportable into Excel and can be customized through a report writer function. Returning to a paper Form 41 would not only be cumbersome, but also provide much less functionality with respect to identifying diversion. In a large full service hospital, typically as many as 10,000 doses of controlled substances will be

[1] Letter dated January 21, 2013 from Kerry Kelly, Director, Federal Public and Regulatory Affairs, to Mr. John W. Partridge, Executive Assistant, Office of Diversion Control (OD/DX), Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152 entitled **Comments for the Office of Management and Budget (OMB) regarding Collection of Information Requirements and proposed changes to DEA Form 41 pursuant to Federal Register notice published Friday, December 21, 2012, Vol. 77 No. 246 Part V pp. 75784 to 75817.**

delivered daily, again illustrating the inappropriateness of a manual paper system. We encourage DEA to seek additional information from the major manufacturers of automated dispensing machines, including CareFusion, Omnicell, and McKesson, to develop appropriate alternative language.

Page 75803, column 3: The proposed standard of destruction – non-retrievable- is too broad and not well defined enough to be practical.

"The proposed definition of 'non-retrievable' means to permanently alter any controlled substance's physical and/or chemical state through irreversible means in order to render that controlled substance unavailable and unusable for all ***practical purposes***." Because incineration is not practical in most facilities for small amounts of controlled substances and neither is reverse distribution, LTCFs will need an authorized disposal mechanism, such as flushing, during an interim period while the retail pharmacy providers establish and implement collection programs and install collectors. Without authorized interim methods, DEA's rule will leave the industry in a state of limbo, without acceptable disposal methods. DEA should also provide clarifying performance standards to define "non-retrievable." Such standards could encourage entrepreneurs and capital investment companies to develop innovative and cost-effective solutions. Once controlled substances are rendered non-retrievable at the healthcare facility by methods acceptable to DEA, the rule should definitively state that the resulting waste may then be shipped as solid waste without additional documentation or monitoring with respect to the controlled substances that once existed. This would seem to be implied but should be clarified.

Page 757806, column 1: Methods of Destruction: "DEA proposes a standard of destruction – non-retrievable- for persons that intend to destroy controlled substances. DEA is not requiring a particular method of destruction, so long as the desired result is achieved."

While this statement is well intentioned, as noted above, it leaves the marketplace insecure about what destruction methods DEA considers non-retrievable. For example, do the following technologies render the controlled substances "non-retrievable": the new Contra-Patch for sequestering leftover drug in fentanyl patches; the Cactus SmartSink system, etc.? While it is laudable that DEA does not want to limit innovation, non-specific language actually inhibits innovation by creating uncertainty and making it difficult for innovators to obtain funding in the marketplace. WMHS recommends DEA consider inclusion of performance standards that would better define non-retrievable and allow innovators to develop cost-effective disposal solutions.

On page 75803, column 3, the proposed rules state that "flushing" does not render the drugs non-retrievable.

In many settings, including long-term care facilities and small practices including physician, veterinary, and dental, flushing may remain the only option in the short term to comply with the controlled substances regulations and prevent diversion. The industry in general agrees flushing is not an advisable environmental solution. In fact, WMHS works

closely with its customers to assist them in finding alternative solutions that are more environmentally protective. Nonetheless, until DEA provides guidance and approval of additional methods for rendering controlled substances non-retrievable, and the market provides cost-effective collection and disposal alternatives to implement this rule when finalized, flushing should remain a temporary option. DEA should consider a time limit of 3 to 5 years that would enable the industry to develop destruction options, which could be examined and approved by DEA.

Reverse Distributors

28. Page 75785, column 3: DEA states "...the same recordkeeping safeguards that exist when controlled substances are distributed between registrants are not present" in the reverse distribution process.

This is an inaccurate statement. To the contrary, most reverse distributors also document the lot number and expiration date along with NDC, product description, quantity, etc. Those reverse distributors that operate only as destruction facilities may not capture the lot number and expiration date, but should be documenting all other data fields. Reverse distributors report to ARCOS and in every other way conform to the same recordkeeping requirements of forward distribution registrants.

Page 75801, Columns 2 and 3: Fourteen-day destruction requirement.

As we stated above, WMHS believes the requirement for destruction within a maximum of 14 days is unworkable given the added requirement for witnessed destruction. It is often not possible within the crediting timeframe needed by some manufacturers to process the return authorization for either shipment or destruction. If the drug is a RCRA hazardous waste, the reverse distributor must be able to accumulate a significant amount to make shipment for destruction affordable. Of the four possible actions, immediately returning the controlled substance to the manufacturer or manufacturer's agent may also not be possible based on credit application and processing times. Since reverse distributors have been receiving, storing and arranging for destruction over the past 20 years with few instances of diversion at well-run facilities, these unrealistic timeframes should not be imposed. We recommend DEA institute a requirement allowing up to 90 days as a maximum amount of time for consolidation and shipment.

Page 75802, column 3: The requirement to keep records of receipt and destruction "together" are not workable.

The majority of reverse distributors will be documenting both processes electronically and should be able to generate reports that enable matching records of receipt with records of destruction. Upon receipt, records will normally be kept based on the entity transferring the controlled substance to the reverse distributor. When destroyed, the primary record will be a record of destruction of a batch of controlled substances. Registrants should be allowed to pull

records from systems to match up this information but storing paper documents together is not realistic.

Recordkeeping

Page 75803, column 2: DEA should clarify whether registrants need to report receipt of recalled controlled substances to DEA or if reporting to FDA is sufficient.

Page 75806, column 2: New recordkeeping requirements will require extensive re-programming.

DEA's estimate of the universe of potential respondents is limited to distributors, reverse distributors, manufacturers, and retail pharmacies. No mention is made of hospitals, surgery centers, dental clinics, veterinary practices, or physicians' offices.

Proposed Regulations: Suggested alternate language is italicized

1317.02 Definitions.

An authorized employee should not be required to be full-time and should not be required to be employees of the registrant, especially with respect to retail pharmacies and hospitals, where pharmacists and nurses are often part-time, or contracted.

The definition of an "ultimate user" should be included and should include the instance of "incapacitated ultimate user" to enable a lawfully entitled person to represent the ultimate user in this instance. Provision should also be made for parents or guardians of minors who are ultimate users.

1317.05 Registrant disposal.

(a)Give examples of who are "practitioners", e.g. retail pharmacies, hospitals, physicians, dentists, veterinarians, and their healthcare employees who are healthcare professionals, such as nurses, etc.

(a)(4)(iii) In the event that a practitioner is required regularly to dispose of controlled substances, the Special Agent in Charge may authorize the practitioner to dispose of such substances, in accordance with subparagraph (a)(2) of this section, without prior application in each instance, on the condition that the practitioner keep records of such disposal and file periodic reports with the Special Agent in Charge summarizing the disposals.
NOTE: Subparagraph (a)(2) Promptly deliver that controlled substance to a reverse distributor's registered location by common or contract carrier or by reverse distributor pick-up at the registrant's registered location.

It would appear from this language that a blanket authorization to destroy requires the use of reverse distributors. This is not practical for the following reasons. The language limits routine destruction by nurses, pharmacists, dentists, veterinarians, etc. to reverse distributors. Only retail and hospital pharmacies currently use reverse distributors, and then primarily for outdated, unused stock. It is not economically viable for others to do so. In addition, small amounts of controlled substances, such as that left over in a vial, syringe, or IV bag, are not conducive to collecting, inventorying, and shipping. These should be destroyed on-site, by flushing or an alternative method as described by DEA. If the restriction to using reverse distributors was not the intent of the regulations, DEA should modify the language to remove any ambiguity.

1317.05 Registrant disposal.

(c) Collected Controlled Substances. (1)Mail-Back Program (i) Destroy the package in accordance with Subpart C of this part using an on-site method of destruction etc.

It is not necessary to require on-site destruction. Reverse distributors are capable of managing mail-back programs and have done so in the past e.g. Capital Returns, Inc,.now Genco Pharmaceutical, participated in the DEA pilot several years ago in the State of Wisconsin. The ongoing return program for Actiq and Fentora includes return to a reverse distributor without on-site destruction.

(c) (2) Collection Receptacles. (ii) Store the inner liner and its contents at the collector's registered location in a manner consistent with the security requirements for Schedule II controlled substances until prompt destruction can occur.

This requirement is problematic because it requires either a safe or vault. Most retailers will not have a vault or safe large enough to accommodate collected waste pharmaceuticals with controlled substance returns from registrants. Mixing ultimate user waste pharmaceuticals with other inventory would violate regulatory prohibitions on combining viable inventory with waste. We recommend that DEA provide a more general statement requiring security that insures diversion does not occur. Perhaps the statement used for law enforcement could be modified as follows: 1317.35 Collection by law enforcement agencies. (c) (Modified) *Any controlled substances collected by a "collector" should be stored in a manner that prevents diversion of controlled substances and is equivalent to that registrant's standard procedures for security of controlled substances.*

1317.15 Reverse Distributor registration requirements and authorized activities.

(d) A registered reverse distributor shall destroy or cause the destruction of any controlled substance received for the purpose of destruction as soon as practicable but no later than fourteen calendar days of receipt.

As noted above, this timeframe is too short to be economically or procedurally workable for the following reasons: distance to incinerator; need to send two employees (should be

changed to arrange for witnessed incineration by law enforcement or other); and possible RCRA hazardous waste disposal which is even more problematic. If the controlled substances are returned for credit and then destruction, there is not enough time for the manufacturer to issue credit and authorization to destroy.

1317.25 Reverse distributor inventory, recordkeeping, reporting, and order form requirements. (c) Record requirements. (4) For all records, the record of receipt shall be maintained together with the corresponding record of return or destruction.

If maintained electronically, the reverse distributor should be able to access these records based on an identification number, but the records should not need to be stored together. The data is stored in different categories and matching physically would not be possible in many cases.

(d) Reports to ARCOS. Registered reverse distributors shall report acquisition/distribution transactions pursuant to 1304.33 of this chapter.

We suggest DEA reconsider this requirement to report records of destruction to ARCOS. We question whether DEA can show that these reports over the past 20 years have provided useful diversion information. The drugs that are NOT reported would be the ones being diverted.

SUBPART B – DISPOSAL OF CONTROLLED SUBSTANCES BY ULTIMATE USERS AND OTHER NON-REGISTRANTS

1317.30 Authorization to collect from non-registrants. (b) The following non-registrant persons in lawful possession of a controlled substance in Schedules II, III, IV, or V may transfer that substance to the authorized persons listed in paragraph (a) of this section, and in a manner authorized by this part, for the purpose of disposal: (2) Any person lawfully entitled to dispose of a decedent's property if that decent was an ultimate user that died while in lawful possession of a controlled substance, *any parent or guardian of a minor in lawful possession of a controlled substance, any person lawfully entitled to dispose of property for a person incapacitated and unable to dispose of their lawfully obtained controlled substance; (suggested revision)*

1317.40 Registrants authorized to collect and authorized collection activities. (c) Authorized collectors may conduct the following activities: (1) Receive mail-back packages at a registered location that has an on-site method of destruction pursuant to 1317.70 of this chapter:

As state above, this requirement will restrict the mail-back option to the very few reverse distributors that have incinerators. Given the amount of recordkeeping to be required of reverse distributors, there should be no reason why reverse distributors should not be able

to participate in mail-back programs, just as they participate in recall and return efforts without on-site destruction units.

1317.50 Collector inventory, recordkeeping, reporting, and order from requirements. (b) Continuing record requirements. (1) For registrants authorized to collect through a mail-back program, the record shall include the following: (ii) For those unused packages provided to a third party to make available to ultimate users and other authorized non-registrants....the name of the third party and physical address of the location receiving the unused packages, date sent, and the number of unused packages sent with the corresponding unique identification numbers.

DEA should clarify whether the numbers on the packages need to be reconciled with the initial inventory, and whether there a time limit on the viability of the packaging.

1317.55 Registered reverse distributor and distributor acquisition of controlled substances from law enforcement agencies or authorized collectors. (c) A registered reverse distributor or a registered distributor that acquires controlled substances in accordance with paragraphs (a) or (b) of this section shall: (2) Dispose of the controlled substances in the following manner: (iii) Destroy, or cause the controlled substances to be destroyed, as soon as practicable but no later than *within ninety calendar days* of receipt. Fourteen days is unworkable.

1317.65 Take-back events. (c) Each take-back event should have at least one receptacle for the collection of permitted substances.

Controlled substances will be mixed with other drugs. Trying to use the same receptacle that is required in a retail pharmacy, etc. will not work.

(e) Only ultimate users and persons entitled to dispose of an ultimate user decedent's property in lawful possession of a controlled substances in Schedule II, III, IV or V may transfer such substances to the law enforcement agency during the take-back event. No other person may handle the controlled substances at any time.

This procedure eliminates the option of having pharmacists on hand to sort the controlled substances from non-controlled substances. Not only will this cause any collection bins to fill up extremely fast, it requires law enforcement to take possession of all discarded drugs, rather than the waste vendor who could immediately transport the non-controlled substances to an appropriate incinerator. Many law enforcement agencies will not have the facilities to store the larger amount of unsegregated drugs until they can be shipped to a reverse distributor.

1317.75 Collection receptacles. (e) For authorized collectors, a controlled substance collection receptacle shall: (3) meet the following design specifications: (iii) The outer

container shall prominently display a sign indicating that only non-controlled drugs and Schedule II, III, IV , or V controlled substances are acceptable.

This language is meaningless to the general public. A better alternative would be to require the following language in some form: *ONLY prescription and over-the-counter drugs can be accepted in this container. NO illegal drugs. NO syringes/needles, NO cosmetics, toothpaste, deodorant or other self-care materials.*

(iv) Access to the inner liner shall be restricted to authorized employees of the authorized collector.

This will be problematic in long-term care facilities when the collector fills up after hours and/or after the daily delivery of medications. There must be designated LTCF staff, such as the Director of Nursing, Assistant Director of Nursing, and Nursing Supervisor, who can move the inner liner to a secure location and replace it with a new one.

1317.85 Ultimate user delivery for the purpose of recall or investigational use of drugs. (a) (3) Report to ARCOS.

DEA should clarify the following questions: What code should a registrant use to designate the entity from which the registrant received the recalled controlled substance? Since this information is already being captured for FDA under a recall, what additional value does ARCOS reporting offer? Does it apply only to Schedule II drugs and Schedule III Narcotics?

1317.95 Destruction procedures. (a) If the controlled substances are transferred to a person registered under the Act and authorized to accept the controlled substances for purposes of disposal, two authorized employees of the transferring registrant shall load and unload or observe the loading and unloading of any controlled substances until transfer is complete.

The site of destruction may be thousands of miles away and shipments must be made very frequently (14 days is the longest amount of time proposed by DEA). It will be cost prohibitive to fly employees to and from destruction sites this often. The receiving registrant should be responsible for documenting the accurate receipt of the transferred controlled substances as is now the case for all forward-bound controlled substances. There should be no need for the transferring registrant to have employees present for the unloading.

(b) If the controlled substances are transported by a registrant to the location of destruction, the following procedures shall be followed: (2) Two authorized employees of the transporting registrant shall accompany the controlled substances to the destruction location; (3) Two authorized employees of the transporting registrant shall load and unload or observe the loading and unloading of the controlled substances; (4) Two authorized employees of the transporting registrant shall handle or observe the handling of any controlled substance until the substance is rendered non-retrievable; and (5) Two authorized

employees of the transporting registrant shall personally witness the destruction of the controlled substances until it is rendered non-retrievable.

The registrant will need to use a common carrier, or in the case of a RCRA hazardous waste, a hazardous waste transporter, neither of which will allow a non-employee to accompany them. As stated above, it is also cost prohibitive to fly employees to and from destruction sites this often. DEA should continue to enable the hiring of responsible contractors, such as off-duty law enforcement personnel, at the site of the destruction facility to witness the unloading and destruction of the controlled substances, as occurs currently. DEA should examine the successful current practices that have been in use for the past 20 years to determine if any significant diversion has occurred and, assuming they have worked effectively, continue to utilize them.

1317.100 Recordkeeping requirements.

In addition to any other recordkeeping requirements, any registered person (why this term – why not registrant?) **that destroys or causes the destruction of a controlled substance shall maintain a record of destruction on a form issued by DEA that includes the following information:**

As noted above, a revised DEA Form 41 will not work well for the automated systems currently in used in hospitals and some other medical facilities. DEA should enable the use of the current electronic reporting systems utilized by nurses in the automated dispensing machines, which are much more effective at identifying potential diversion.

WMHS appreciates the opportunity to comment on this important proposal. If you have any questions, please contact Charlotte Smith at 713-725-6363 or csmith32@wm.com.

Sincerely,

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