Controlled Substance Disposal Program Frequently Asked Questions

| Can you combine Controlled and Non-Controlled Substances? | • | YES | All 3 options allow for co-mingling of controlled and non-controlled substances |
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| Can I use this program in an institutional setting for unused dosages? | • | NO o | These programs are not the same as a controlled substance being dispensed for immediate administration in an institutional setting in a situation where the entire substance is not used These must still be properly recorded, stored, and destroyed according to current regulations This also applies to most hospice settings |
| Will Law Enforcement procedures have to change in how they handle, store, transfer, and dispose of controlled substances? | • | NO o | Law enforcement agencies will be able to continue with current procedures regarding handling, storage, transfer, and destruction of controlled substances |
| If I partner with a Law Enforcement Agency to operate a mail-back program am I also exempt from these regulations? | • | NO o | Partnering with a law enforcement agency does not allow you to circumvent the regulations The entity that partners with law enforcement to implement an ultimate user disposal program must comply with all laws and regulations |
| Who can be an "Authorized Collector?" | | 0 0 0 0 0 | Manufacturer Distributor Reverse Distributor Retail Pharmacy Narcotic Treatment Program Hospital/Clinic with an on-site pharmacy be registered with DEA for Schedule II controlled |

| Do I have to become an authorized collector if I am one of the above entities? | NO No one is required to become an authorized collector The entities listed above MAY obtain authorization for the DEA to collect | |
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| Is there a separate class of registration solely for authorized collectors? | NO Authorized collectors will be limited to those with DEA registrations noted above to allow the DEA to conduct inspections and implement other security measures The DEA does NOT have the authority to specifically register persons for the purpose of collecting and disposing controlled substances from ultimate users | |
| How do I become an authorized collector? | Modification of registration must be completed This can be completed online at www.DEAdiversion.usdoj.gov (or click HERE) to modify registration If collection is discontinued the registration must be updated to reflect this change in activity No fee for modification of registration | |
| Can a distributor or a reverse distributor manage and maintain a collection receptacle at a retail pharmacy or LTCF? | ■ NO | |
| Who can operate a collection receptacle at a LTCF? | A hospital/clinic with an on-site pharmacy, or a retail pharmacy | |
| Reverse Distributor: How can they acquire controlled substances? | Pick-up the controlled substance from a registrant at the registrant's registered location, OR Receive the controlled substance from a registrant at the reverse distributor's registered location delivered directly by non-practitioner or by common or contract carrier May never be re-routed once on route | |
| Reverse Distributor: What must be done once the controlled substance has been received? | Immediately store or transfer the controlled substance to the reverse distributor's registered location for secure storage until timely destruction or return to the registered manufacturer can occur Immediately deliver the controlled substance to the manufacturer or manufacturer's agent Timely destroy the controlled substance | |

| | Immediately deliver the controlled substance to the place of destruction |
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| Reverse Distributor: When does the controlled substance have to be destroyed? | Within 30 days of receipt Day 1 is the day the controlled substance is physically acquiring through pick-up or delivery |
| Do destruction facilities have to be registered with the DEA? | ■ NO |
| Can Non-Registrants still collect non-controlled substances? | YES Non-registrants may collect non-controlled substance pursuant to all federal, state, tribal, and local laws and regulations |
| Can Schedule I controlled substances be collected? | NO Schedule I controlled substances are illegally possessed and may not be collected |
| Does the controlled substance have to be in a specific packaging? | NO The DEA has not mandated whether a substance must be disposed with or without packaging Collectors may have procedures that prevent collecting certain packaging |
| Is there a minimum/maximum capacity for collection receptacles? | ■ NO |
| Is there a maximum duration an inner liner may be kept in a collection receptacle? | NO However, the DEA notes that it is the authorized collector's responsibility to provide effective controls and procedures to protect against theft and diversion |
| If an authorized collector sells mail-back program packages do they have to track packages that were sold but never returned? | ■ NO |

Source:

 $http://www.deadiversion.usdoj.gov/drug_disposal/fact_sheets/disposal_registrant.pdf$