Reverse Distribution and your MDS System

Overview and Summary

DJF 4/21/16

"Reverse distributor" has a regulatory definition. The Drug Enforcement Administration (DEA) regulatory definition of reverse distributor refers only to management of controlled substances. In practice, reverse distributors also accept drugs that are not controlled substances, so use of the term is actually broader than the regulatory reference.

"Returns industry" refers to companies that return drugs to the manufacturer for credit. While some "reverse distributors" return drugs to the manufacturer for credit, others simply destroy the drugs.

Reverse distributors are defined by the DEA at 21 CFR 1300.01 (b)(41) as follows: (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controlled substances acquired from another DEA registrant for the purpose of— (i) Returning unwanted, unusable, or outdated controlled substances to the manufacturer or the manufacturer's agent; or (ii) Where necessary, processing such substances or arranging for processing such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.

A brief summary of the industry is provided in the Mission Statement:

The pharmaceutical returns industry is an integral element of the U.S. healthcare system. Reverse distributors handle a large percentage of those pharmaceutical products that become outdated before use. They assist pharmacies and drug wholesalers in returning these items for credit or assuring environmentally responsible disposal.

They assist pharmaceutical manufacturers by providing an economical outsourcing alternative to return goods processing. And, by providing efficient reverse supply chain management, they reduce total cost in the healthcare system.

A returns company fee is often based on a percentage of the credits received from drug manufacturers. By accepting drugs as product and making the decision about whether the drug is waste, reverse distributors are in the position of designating drug waste, and thus become the waste generator. If some drug wastes designate as hazardous under Federal or state hazardous waste regulations, the reverse distributor can separate them from other drugs for proper disposal at permitted hazardous waste facilities. Federal and state guidance provide the foundation for reverse distributor operations under hazardous waste regulations.

Summary of the Pharmaceutical industry rules as of 4/1/16

(Source HDMA Website)

Summary: Return of Saleable Products(By Agency)

DEA: Traditional transfer between registrants; schedule II drugs require a Form 222; no CSOS between pharmacies and wholesalers

EPA: Not relevant as no waste is involved

FDA: DSCSA applies (Track and Trace is required to be updated), CSOS between ARCOS-reporting trading partners, e.g. drug wholesaler and reverse distributor

DOT: Current Hazardous Material regulations; possible relief when new reverse logistics regulations finalized and published

Summary: Return of Unsaleable Products (Agencies that are involved)

• Unsaleable, outdated products being processed for potential credit and eventual destruction DOT, DEA, EPA

• Recalls/Withdrawals FDA, DOT, DEA, EPA

• Consumer drug take-back options DEA, EPA (consumer exemption applies federally)

Types of Permits Reverse distributors need various permits to operate.

All permits are based upon local state law, no real federal standard exists. This is really to educate you so that you are aware of the local laws regarding your reverse distributor.

• Drug Enforcement Administration controlled substance registration.

Most were permitted to handle schedule II through V drugs; only two were registered for schedule I drugs. One reverse distributor was registered to handle schedule III-V drugs only and subcontracted schedule II drug management to another registered reverse distributor.

• State Board of Pharmacy license. Licensing requirements vary by state. Many reverse distributors were licensed in multiple states.

• Environmental Protection Agency hazardous waste identification number. Reverse distributors are generally fully regulated large quantity generators or hazardous waste transporters.

• Local solid waste management permit.

• Local medical waste management permit.

Reverse Distribution Models

Based on current business practices we have outlines two modes of operation for reverse distributors.

1. No Credit Processing/ Destruction-Only Service: Licensed reverse distributors who do not manage credit processing through drug manufacturers. (A "zero credit invoice" may be issued for every pickup or clients are encouraged to process manufacturer credits themselves.) Some companies clearly market themselves as providing destruction service only. Some may specialize in witnessed destruction of controlled substances only and others may pick up drugs and transport them directly to the incinerator, without stopping at a reverse distributor location, in this instance the MDS system allows you to track the destruction and disposition as well as generate a claim to the manufacturer.

2. Pre-shipment Screening Companies: many companies ask clients to submit drug lists prior to shipment and use a screening criteria to determine acceptance. If drugs not meeting the screening criteria are shipped anyway, they are returned to the client. Screening criteria, with the number of companies using the criteria, include:
   Whether the drug designates as a federally regulated hazardous waste
   Whether the drug has credit value.
   Whether the drug is made by specified manufacturers .
   Client type (example one company doesn't accept drugs from veterinarians because they lacked a National Drug Code.), These are handled slightly differently but the MDS system still allows for the full cycle.

MDS Processes by Business Model (Suggested best practices)

Overview and Setup

Depending on the Reverse distributor your deal with it may be both a customer and a vendor in the MDS system. We recommend setting them up as both so that you can handle all types of transactions.

1. No Credit Processing/Destruction-Only Service:
2. MDS Sales Order/Pick/Pack Ship.
   To record the transfer of the goods from your warehouse to the RD (Reverse distributor) enter an MDS Sales Order, pick/pack and ship the goods to the RD. Assuming you will not be getting any credit from the RD directly you can enter the products at 0.00 price however depending on how you and your accountant wish to record the item cost you can override the costs manually. By default we recommend selling it at 0.00 price but having the cost come out using your standard costing method (whatever parameter you normally use) – this allows you to record the goods coming out of inventory at the proper cost. Note: you can write off or depreciate these goods later based upon the invoice costs and sales history to the RD.
3. Recording the Receipt/Destruction
   Once the Order has shipped you should get a confirmation of destruction, some provde actual picture,s but for the most part is a letter or form. Using the MDS Document management system you can attached this to either the Invoice – we recommend using the MDS Invoice as the reference point and using the Detailed release inquiry to add the image to MDS.
4. Making a Claim to the Manufacturer/Vendor
   At this point in most cases you wll then be able to claim a credit with the manufacturer based upon the invoice Cost of the good that were destroyed, this is why we recommend using real costs on the invoice. To record the Claim for this credit enter an A/P Debit memo against a speciifc GL Code for the amount you are claiming.
   To generate a detailed Claim you can use the MDS Sales tracing Export to create a detailed spreadsheet with costs and prices if need be. Once the claim is approved by the vendor/manufacturer if they send you a check you can record it as miscelaneous cash against the same GL used on the Debit memo to wipe it out. Or if no check is sent you can take that credit on your next invoice from the vendor/ manafacturer.
5. To complete the transaction you can then wipe out the zero dollar invoice on the customers (RD) account using MDS Cash Application

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   Email/Fax/Print an MDS Order Confirmation to the RD and request that they review and advise the total amount of credit by item or line.
   Once you are advised of the credit amount you can then update the Sales Order to Reflect the amount of the invoice. In the Event you do no want the total amount to show in the Sales GL you can record a journal entry after the fact to move the sales for the customer (RD) to another GL or update sales by customer type and create a new customer type of RD
   Once the Credit is verified you will then ship the goods and invoice the RD for the amount due.
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   If your RD has already performed this service for you in step one you can skip this , however in many cases you may make an additional claim for credit.
   . To record the Claim for this credit enter an A/P Debit memo against a speciifc GL Code for the amount you are claiming.
   To generate a detailed Claim you can use the MDS Sales tracing Export to create a detailed spreadsheet with costs and prices if need be. Once the claim is approved by the vendor/manufacturer if they send you a check you can record it as miscelaneous cash against the same GL used on the Debit memo to wipe it out. Or if no check is sent you can take that credit on your next invoice from the vendor/ manafacturer.
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