Reevaluating Your Reverse-Distribution Program

By Charlotte A. Smith, RPh, MS, HEM

OVER THE PAST 15 YEARS, MOST HOSPITAL PHARMACIES HAVE OUTSOURCED their reverse-distribution function for managing expired medications. There are several excellent reasons for this decision. Reverse distributors have developed the following core competencies:

- maintaining manufacturers' return policies
- developing efficient software to receive and manage outdated drug inventory
- expediting the return and crediting process, although this area still has room for improvement

One of the most interesting advantages of using a reverse distributor (RD) has been the ability to maintain an outdated drug as a product rather than a waste, thereby reducing the amount of both hazardous and non-hazardous waste generated by the facility. As the industry continues to evolve, it is important to periodically revisit your choice of vendors to be sure you are maximizing your value on a number of parameters.

Vendor-Selection Criteria

While pricing is always an important factor, it should not be the principle driver in your vendor decision. The regulatory factors involved in reverse distribution are significant, involving the DEA, the FDA, state boards of pharmacy, state health departments, the EPA, and state environmental regulatory agencies. Several national reverse distributors have had serious violations of both EPA and DEA regulations in the past, so merely having the appropriate registrations, licenses, and permits does not insure a compliant operation. For example, if you ask a reverse distributor how they identify and manage P-listed hazardous waste, such as epinephrine, and you are met with stunned silence, this is not a good sign. While the primary regulatory liability rests with the reverse distributor, your organization is responsible for doing "due diligence." For your reverse-distribution program, "out of sight, out of mind" should not be your motto.

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For assistance in selecting a vendor, refer to the checklist on page 25. This list barely scratches the surface, but it will give you a reasonable feel for the reverse distributor's knowledge of the multitude of regulations that affect them. The optimum situation is to actually visit the company and see first-hand how the operation is run. Since this is often cost-prohibitive, encourage your GPO to make this a priority for their contracting agents when a new request for proposal (RFP) is issued. They will learn a great deal from the experience and make better-informed decisions to your benefit.

Second, in selecting a vendor, consider the service level that best fits your time constraints and comfort level. If you have the necessary staff to box and inventory your controlled substances, along with your other outdated inventory, you will achieve the highest level of internal control and usually incur the lowest fees. If you need your RD to come on-site to inventory the controlled substances and prepare the remainder of the outdates for shipment, be sure to carefully check the controlled substance quantities against the inventory. You are liable for any discrepancies. Finally, if you want a complete inventory of all items, expect to pay considerably more for the time involved. Two states, Ohio and Florida, require an inventory prior to shipping, but it is optional in the rest of the country. Regardless of the service level you select, be sure that return policy information is not applied to the outdates prior to shipment. If you determine an item is not returnable at your facility, it becomes waste at that moment, and cannot be sent through reverse distribution.

Reverse Distribution Vs. Waste Management

The EPA has issued two letters to the industry, to Merck Sharpe & Dohme in 1981 and to BFI Pharmaceutical in 1991, expressly forbidding using reverse distribution as a waste-management system. Do not send waste-like items, such as unused IVs, opened vials, and so on, through reverse distribution, regardless of the claims of some reverse distributors that they are "permitted" to handle your waste. The one exception is controlled substance waste, if the reverse distributor has a solid waste permit and can complete the complex ARCOS reporting requirements for non-standard drugs required by the DEA. Some of the EPA regions and states are tightening up this restriction even further, especially in New York, New Jersey, and Minnesota. This situation is in flux, so it is wise to check with the state and federal authorities in these and other states from time to time.

Maximizing Your Credit Value

To insure maximum credit value, plan to ship your outdated drugs at least quarterly, so you can benefit from even three-month return policies. If you are shipping high-value in-dated items, first evaluate your reasons for no longer wanting them in stock and determine if they can be returned to your drug wholesaler. If they are very short-dated, be sure to find out how the reverse distributor will manage these. Often they are not eligible for return until they outdate and may be destroyed by the reverse distributor if they do not have an in-date holding program.

Fee Structures

Once you are comfortable with the regulatory and service-level issues, look carefully at the various fee structures available. Since most hospital reverse-distribution pricing is based on a percentage of value, be sure to determine how the estimated value of either the returnable products or the total inventory is being determined. The reverse distributor may use either the group-purchasing price, which is ideal since it is closest to the credit value you will receive, or they may use AWP, WAC, or some other pricing scheme. The lowest percentage charged may not be the lowest in dollars paid, if the estimated value is overly inflated.

Reports

The industry is mature enough now that all reverse distributors should be providing a minimum number of reports to you upon completing your process. These should include an itemized list of all drugs by name, strength, dosage form, manufacturer, quantity, and ERV (estimated return

value) that were returned for credit or sent for destruction by the reverse distributor. This report is especially important for destroyed items, and should note if the drug was managed as hazardous waste. If you are not receiving this level of detail, insist that it be provided or change vendors. You may need to present these documents to a state or EPA inspector or JCAHO to document that hazardous waste was, in fact, managed properly by your vendor. Controlled substances that are returned or destroyed should also be segregated into a separate report for DEA reporting, if needed. You should also receive summary reports by manufacturer for credit reconciliation. Some reverse distributors also provide management reports to assist you in maximizing your return and minimizing your outdate generation in the future.

Credit Reconciliation

The final step is credit reconciliation, and it has always been problematic. Some reverse distributors offer a flat-percentage return on the ERV after a certain period of time, such as two months after processing. Some reverse distributors claim to provide credit more quickly, often when the reverse distributor is also the returned-goods processor for major manufacturers,

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since the items can go through both processes at the same physical location. If you have the time to reconcile credits the "old-fashioned" way, document credit memos as you receive them from your drug wholesaler against the ERV summary provided by the reverse distributor. This is also an excellent way to evaluate the accuracy of their ERV for future processes.

The Case for Careful Consideration

With the very tight budgets that most hospital pharmacies have, preventing drugs from becoming outdated is the most effective way to save dollars. Benchmarking the percentage of dollars sent through reverse distribution against total inventory would be an innovative way to document improvement. Choosing a vendor that provides the regulatory compliance, service levels, fee structure, and customer service that best suits your needs has become an essential pharmacy-management skill. Spending a little extra time up front to make the best choice will pay back large rewards for years to come.

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Reverse Distributor Evaluation Criteria

Fee Schedule:

☐ How are fees assessed? If a percentage of either the estimated return value (ERV) or the actual value of the total inventory is used, does the reverse distributor use the contracted GPO values, AWP, WAC, or some other basis for assessment? A low percentage based on a high ERV is not a good value. Also, is the RD commingling your facility's returns with other non-related facilities? Such batching systems may make credit reconciliation almost impossible.

On-site Versus Off-site Processing:

☐ Does the RD provide on-site processing, and what does that entail? Inventories may be done, but there should be no evaluation of the creditability done on-site, to avoid additional waste generation at the hospital.

Compliance with DEA Regulations:

☐ Obtain a copy of the DEA registration, and check to insure schedules II through V can be accepted.

☐ Are tamper-proof pouches or other security measures provided to the pharmacy for shipping of controlled substances?

☐ Does the firm have a routing form or procedure for tracking controlled substances through the process?

☐ Does the RD provide witnessed incineration of non-returnable controlled substances? Ask for the name and address of the incineration firm. If not, how are these items disposed? Does the RD incinerate or landfill other non-returnable items?

☐ How does the RD dispose of controlled substances that are also hazardous waste, such as chloral hydrate?

☐ Has the firm ever been audited by the DEA? If so, when, and what was the outcome of the audit?

Compliance with EPA Resource Conservation and Recovery Act Regulations (RCRA)

☐ What is the hazardous-waste-generation status of the RD? Have they notified the EPA of their generation status, and what is their EPA Identification Number? The RD should be a large-quantity generator.

☐ If the RD is a large-quantity generator, have they completed an environmental contingency plan?

☐ If the RD offers to accept pharmaceutical waste, are they permitted as a treatment, storage, and disposal facility (TSDF) under RCRA, and what is their permit number? (To date, only specialty firms that specialize in transportation and disposal are TSDFs; none of the full-line RDs are TSDFs.)

☐ How does the RD identify which non-returnable pharmaceuticals become hazardous waste under RCRA?

☐ Does the RD provide complete documentation of all non-returnable items, including which items are disposed as hazardous waste under RCRA?

☐ Obtain the names, addresses, permit numbers, and contact information for any non-hazardous and hazardous incineration firms used by the RD.

☐ Has the firm ever been investigated by a state environmental protection agency? If so, what was the outcome?

Insurance and Indemnification

☐ Does the RD have a pollution endorsement in addition to their general liability policy? Do they have errors-and-omissions insurance? Does the RD indemnify its customers against any EPA violations incurred in the disposal of their products?

☐ Is the RD in compliance with DOT Regulations?

☐ Does the RD provide ORM-D Consumer Commodity labels to insure department of transportation compliance when the outdated drugs are shipped from the hospital to the RD?