Hospitals Can Collect Leftover Narcotics
But Restrictions Imposed by the DEA Are a Disincentive

Stephen Barlas

The Drug Enforcement Administration (DEA) has given some hospitals freedom to voluntarily collect controlled substances on their premises from people who visit the hospital for outpatient treatment or to use the on-site pharmacy. The final rule the DEA issued in September is meant to help reduce deaths from drug abuse centered on narcotics, which when left at home can end up in the wrong hands.

Hospitals and clinics can become collection sites only if they have an on-site pharmacy. The rule also allows hospitals to conduct “mail-back” programs, but those that do must use an on-site method to destroy returned packages so they are “nonretrievable.” The DEA declined to define that term further.

The DEA is trying to address the problem of drug diversion, which is partly the result of consumers having limited avenues for disposal—because of federal restrictions—of narcotics that they no longer use. The DEA said in the final rule: “These restrictions resulted in the accumulation of pharmaceutical controlled substances in household medicine cabinets that were available for abuse, misuse, diversion, and accidental ingestion.” Hospital pharmacists would generally be responsible for collecting unused narcotics from receptacles placed in the hospital and would have to follow regulations regarding that collection. The same requirements apply to retail pharmacies, which may take advantage of this provision more frequently than hospitals.

Whether hospitals decide to join the collection effort is another question entirely. There does not appear to be much of a business case for doing so. Certainly a “good citizen” case can be made. But the final rule is hazy on some issues, and hospitals will be very cautious about signing on.

“While this might be a nice thing to do, it is fraught with difficulties in the way that the rule was written,” states one pharmacy manager for a Western hospital chain. “We are not going to participate at our hospitals, since the logistical challenges are a nightmare. We support the take-back programs at police facilities and others that occur twice a year. We will continue in that vein. The DEA should have been less restrictive in the way that they wrote this regulation.”

Hospitals that introduce collection receptacles may have trouble finding reverse distributors to take those controlled substances off site. “We will not be supporting the service due to conflicts with EPA [Environmental Protection Agency] regulations as well as the requirement for all receptacles to be handled presumptively as Schedule II controlled substances, which requires concrete-and-steel vault security,” says Victor F. Vercammen, PharmD, RPh, Vice President of Quality Assurance & Regulatory Affairs at Genco, a major reverse logistics provider.

Aside from allowing some hospitals to collect unused controlled substances, the final rule apparently dictates a change in the way hospital pharmacies handle controlled substances that remain in their inventories but cannot be used, for whatever reason. In the past, pharmacies sometimes “sewered” unusable inventory leftovers. The final rule prohibits that practice, as it does for controlled substances collected in receptacles. Moreover, according to Dr. Vercammen, the DEA has made it clear that unwanted hospital inventory cannot be dumped into the receptacles a hospital may provide at its location.

So a hospital would have two potential waste streams. One would be its self-generated controlled-substance waste from inventory; at current rates, disposal may cost in the vicinity of $8 per pound, based on hazardous-waste transport and incineration requirements, which would not go to a reverse distributor. The other waste stream would be for the hosted receptacles, which Dr. Vercammen’s company, for one, will not service.

Here is where things get more confusing. The unused portions of controlled substances left in vials when administered at bedsides can still be severed, as long as state and local laws permit that.

The DEA believes that limiting authorized collection activities to hospitals and clinics with on-site pharmacies is necessary to help protect against diversion. These hospitals and clinics routinely handle a large volume of controlled substances that are dispensed to inpatients as well as to the public, and as a result they are more experienced with security; theft- and loss-prevention procedures; and inventory, recordkeeping, and reporting requirements than hospitals and clinics without on-site pharmacies.

The collection receptacles are subject to several requirements. They must have a “small” opening, a locked entry, and a liner. They can be placed anywhere in the hospital in the immediate proximity of a designated area where controlled substances are stored (probably the pharmacy) and where an employee is present. The receptacles cannot be placed where emergency or urgent care is provided. Wherever they are installed, they must be “securely fastened to a permanent structure.” Noncontrolled substances can also be tossed in, but they cannot at any later point be separated from the narcotics.

Hospitals are not going to rush to embrace voluntary collection efforts. Their first order of business is probably going to be figuring out what to do with their own unused controlled substances from their pharmacy inventory. That will be time-consuming enough.

REFERENCE