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New, Final DEA Drug Disposal Rules Are Shady On Details

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On Sept. 9, the Drug Enforcement Administration published its final rule implementing the Secure and Responsible Drug Disposal Act. The rule contains several amendments to the Code of Federal Regulations relating to the collection and disposal of controlled substances. The stated purpose of the rule is to facilitate the destruction of controlled substances in the hands of consumers in the U.S., whom the code collectively refers to as "ultimate users," defined to include individuals that have controlled substances dispensed by a pharmacy, nurse or physician.

The salutary purpose of the rule is clear: To rid our communities of hundreds of thousands of pills sitting in medicine cabinets in homes, which, for whatever reason, have not been consumed or are at long-term care facilities where a patient has died without consuming the drugs, or the drug regimen of the patient has changed and there are still drugs outstanding. It is believed that having the drugs remain in circulation in this way presents opportunities for drug diversion and abuse.

Up until now, there have been no measures to address this problem, other than periodic national takeback days offered by the DEA, potential drop offs at an authorized police department or causing environmental damage by flushing the drugs into our wastewater stream. All of these measures are widely regarded as woefully inadequate to address this problem.

The Disposal Act, and its implementing rule that became effective on Sept. 9, seeks to finally address this issue. Under the new rule, DEA-registered manufacturers, distributors, reverse distributors, hospitals and clinics with onsite pharmacies and retail pharmacies may apply to the DEA to modify their current department registrations so they may become "authorized collectors," authorized to "receive a controlled substance for the purpose of destruction." As "authorized collectors," they are empowered to collect and receive back controlled substances in Schedules II-V from "ultimate users." This takeback can occur in one of two permitted manners:

Mail Back Programs

The registrant may operate a mail back program to receive and destroy controlled substances. The way

this works is that the registrant, a pharmacy for example, would send an envelope to the patient in which the patient would then deposit their drugs, seal the envelope and mail it back to the pharmacy. Once received from the patient, the pharmacy is to destroy the envelope on site. Oddly, however, the pharmacy registrant is not to open the envelope and inventory the contents. They are simply to destroy the envelope and whatever may be inside, sight unseen. When it comes to recordkeeping, which are generally painstaking requirements imposed by the DEA, the pharmacy is required to keep track of how many envelopes were in their inventory, and how many were returned and destroyed. However, no record is kept whatsoever of what drugs were actually received and what was supposedly destroyed.

Collection Receptacles

In lieu of mail backs, the registrant may install, manage and maintain a collection receptacle for Schedule II-V controlled substances at the business premises for ultimate users to drop off their unused drugs. Controlled substances collected in this manner may be destroyed onsite at the pharmacy or they may be sent to a DEA-registered reverse distributor trained in the destruction of such substances. However, whether destroyed onsite or via a standard reverse distributor, their contents are not inventoried in any way, instead they are removed from the receptacles in large sealed liners and destroyed in that condition. No one knows what was received or what was destroyed.

In the case of pharmacies servicing long-term care facilities, the pharmacies are allowed to install collection receptacles at the long-term care facility, where patients, family members and nursing staff acting on a patient's behalf, are permitted to dispose of drugs by placing them in the receptacle. Still, there is no effort to inventory contents. So, unless the long term-care facility is electing to keep its own records of its own volition, no one knows whether a drug ever finds its way into the receptacle and no one knows what drugs were inserted. It is a blind process.

Conclusion

It is strange that we would create a system to prevent diversion, which is not seeking to track itself or create any meaningful metric by which we can gauge success. We have a huge problem in this country relating to the diversion of pharmaceuticals. Is the new program effective? Are drugs of abuse being turned in? How will we know? Hydrocodone, now a Schedule II controlled substance, is the most legitimately prescribed, yet widely abused pharmaceutical in this country. Is any coming back through the program? We simply will not know. How is this rational or helpful?

Moreover, precisely because no one is counting, we have new opportunities presented for diversion because no one really knows what is supposed to be there — in the mail back envelope or in the receptacle. Anyone who has ever participated in the battle against diversion knows that accountability among the many players is key. The principal reason the DEA itself has resisted the current rule for a considerable period of time is because they are dedicated to the concept of the "closed system" of distribution, whereby once a drug is distributed and dispensed there is perfect accountability in recordkeeping from the manufacturer to the end user. Everyone must keep detailed records, but now we are altering that. We are permitting the flowback from the end user to the registrant, be it a pharmacy, hospital, distributor or even manufacturer. Yet there is no system or recordkeeping track of what is being transferred and what is being destroyed. As a result, opportunities for diversion from the home, from the long-term care facility, from the collecting registrant and from any collection receptacle or envelope are presented.

Further, this lack of accountability runs counter to the current regulations relating to existing “reverse distributors,” that is, those who for some time have been specifically authorized to receive controlled substances from other DEA registrants and to destroy those substances. These reverse distributors are required by regulation to maintain very detailed records regarding all of the drugs that they receive, down to the number of pills and to account on a DEA Form 41 a listing of all drugs being destroyed, down to the pill, and present evidence of their actual destruction.

All of this accountability was stepped over in the final rule affecting the implementation of the Disposal Act. It was disregarded. Whether there will be increased diversion as a result will be hard to know. Whether the new system is effective will be equally hard to know, for the simple reason that no one will know what was collected and what was destroyed. The system’s blindness — created with eyes wide shut — has ensured that result.

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