U. S. Department of Justice
Drug Enforcement Administration

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Dear Practitioner:

The Drug Enforcement Administration (DEA) recently learned that some practitioners misunderstand how pharmaceutical wastage should be disposed of in conformance with the Disposal of Controlled Substances final rule (79 Fed. Reg. 53,520, Sept. 9, 2014). This letter seeks to clarify the DEA position regarding a practitioner's disposal of pharmaceutical wastage.

In the disposal final rule, the DEA stated that a "controlled substance dispensed for immediate administration pursuant to an order for medication in an institutional setting remains under the custody and control of that registered institution even if the substance is not fully exhausted (*e.g.*, some of the substance remains in a vial, tube, transdermal patch, or syringe after administration but cannot or may not be further utilized, commonly referred to as 'drug wastage' and 'pharmaceutical wastage'). Such remaining substance must be properly recorded, stored, and destroyed in accordance with DEA regulations (*e.g.*, § 1304.22(c)), and all applicable Federal, State, tribal, and local laws and regulations, although the destruction need not be recorded on a DEA Form 41." 79 Fed. Reg. 53,521. The DEA further stated that "pharmaceutical controlled substances remain under the custody and control of the DEA registrant if they are dispensed by a practitioner for immediate administration at the practitioner's registered location (such as a hospital) pursuant to an order for medication. If that substance is not fully exhausted (*e.g.*, some of the substance remains in a vial, tube, or syringe after administration but cannot or may not be further utilized), then the DEA registrant is obligated to destroy the remaining, unusable controlled substances, and record the destruction in accordance with § 1304.22(c). The DEA registrant shall not place such remaining, unusable controlled substance in a collection receptacle as a means of disposal. Hospital/clinic staff ***must also*** not dispose of any controlled substances ***in inventory or stock*** in a collection receptacle." 79 Fed. Reg. 53,523 (emphasis added).

The DEA intended the above excerpts to emphasize that practitioners shall continue to record the destruction of pharmaceutical wastage in accordance with 21 C.F.R. § 1304.22(c), and that the new disposal regulations contained in Part 1317 do not alter a practitioner's existing obligations to destroy pharmaceutical wastage in accordance with applicable Federal, State, tribal, and local laws and regulations (e.g., environmental, hazardous/biohazard, and other safety-related laws and regulations).

Further, the above excerpts were intended to emphasize that the disposal of practitioner ***inventory*** (as opposed to pharmaceutical wastage) shall be accomplished in accordance with the new disposal requirements of Part 1317. For example, controlled substances contained within multi-dose vials remain part of the practitioner's inventory.

In contrast, once a controlled substance has been dispensed to a patient by an institutional practitioner on the basis of an order for immediate administration to a patient at the registrant's registered location, the substance is no longer in the practitioner's inventory. For example, after a pre-filled syringe or a single-dose vial or syringe is administered to a patient, any remaining substance in the syringe or vial is not required to be destroyed in accordance with new Part 1317. However, the remaining substance should be destroyed in accordance with applicable Federal, State, tribal, and local laws and regulations.

Although Part 1317 does not apply to pharmaceutical wastage, the DEA strongly encourages all practitioners to continue to adhere to security controls and procedures that ensure pharmaceutical wastage is not diverted. For example, most institutional practitioners have implemented policies that require two persons to witness and record destruction of pharmaceutical wastage.

Should you have any questions pertaining to this matter, please contact your local DEA field office, or you may contact the DEA Office of Diversion Control, Liaison and Policy Section, at (202) 307-7297.

Sincerely,

Joseph T. Rannazzisi
Deputy Assistant Administrator