Constructive Transfer of Controlled Substances by Pharmacists

The International Academy of Compounding Pharmacists (IACP) supports statutory or regulatory language changes to the Controlled Substances Act to clarify that “constructive transfer” of a dispensed controlled substance by a DEA registrant pharmacy to a DEA registrant prescriber for the purpose of administering the medication to the ultimate patient is a legal and permitted act.

IACP also supports statutory or regulatory language changes to the Controlled Substances Act which permits “constructive transfer” of specific types of medications and routes of administration (e.g., veterinary medicines, medications intended for intrathecal administration) provided that such changes do not limit, restrict or prohibit “constructive transfer” of other types of medications or routes of administration.

Background

In October 2010, the International Academy of Compounding Pharmacists and seven other national pharmacy and patient organizations wrote to the DEA for clarification on their position and enforcement policy related to “constructive transfer.”

The Drug Enforcement Agency (DEA) appears to believe that it is illegal to transfer controlled substances from pharmacies to treating physicians and veterinarians and other home healthcare providers on behalf of their patients for professional safekeeping and prior to administration of the medication. This position contradicts statutory language providing for this transfer, as affirmed by the 2007 decision of the U.S. Court of Appeals for the D.C. Circuit in Wedgewood v. DEA, 509 F. 3d 541 (D.C. Cir. 2007).

DEA’s position is also inconsistent with the generally accepted practice in human and veterinary medicine that relies upon constructive transfer of controlled substances to properly treat human and animal patients and prevent diversion. The existing statute appears to clearly permit a registered practitioner, such as a pharmacist, to dispense a controlled substance through a constructive transfer, such as to the treating physician, veterinarian or licensed practitioner on behalf of the patient.

The existing statutory provisions authorize “constructive . . . transfer” – within and even without “an agency relationship” – as a mode of “delivery” from the pharmacy (as “practitioner”) to the patient as (“ultimate user”) that constitutes an authorized “dispensing.” 21 U.S.C. § 802 (8)(10)(21)&(27). The D.C. Circuit affirmed this interpretation in rejecting DEA’s position in Wedgewood.

DEA’s imposed delivery process introduces an unacceptable increase and risk in the potential for contamination and stability issues that would result in an adverse health outcome when the medication in question is for administered to the patient via intravenous, intramuscular, or intrathecal routes. In addition, this delivery process increases the chances of diversion and abuse of the controlled substance.
Intrathecal drugs are but one subset of sterile, injectable controlled substances that require great care and expertise to be handled and administered safely and effectively.

Similar considerations and practices hold for all sterile, injectable controlled substances. Nonetheless, DEA’s position would appear to prohibit injectable and other controlled substances from being properly transferred to physicians and other licensed healthcare professionals for proper, safe storage and administration.

It is wholly within DEA’s power to address its stated concerns about drug diversion under the existing statute as interpreted in Wedgewood. To address its concerns, DEA could easily promulgate rules specifying the circumstances and constraints under which constructive transfer may proceed. Among other factors, DEA could impose appropriate record-keeping requirements commensurate with the goal of guarding against diversion.

Promulgating such rules would be in keeping with the DEA’s desire to maintain a “closed system” whereby transfer of controlled substances between registrants is regulated and recorded. Indeed, DEA has already undertaken much the same rulemaking exercise in creating an entire “central fill” regime permitting transfers between pharmacies, complete with safeguards specially crafted to address potential diversion concerns. DEA should institute a similar policy with respect to “constructive transfers” from pharmacies to physicians and licensed healthcare professionals.

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