Clarify DEA Position on Dispensing of Medicines to Prescribers

IACP seeks a clarification and change to the DEA policy that prohibits dispensing a controlled substance to a prescriber for the purposes of administering that medicine to a patient.

Background
The Drug Enforcement Agency has a policy that a pharmacy is acting illegally when it dispenses a patient’s prescription directly to the patient’s doctor. This policy – which contends that a pharmacist may only dispense controlled substances to the patient or a patient’s household member – has an unintended impact on quality medical care. Certain medications administered in physician offices, hospices, nursing homes, clinics and veterinary practices are particularly sensitive to light and temperature. Keeping the integrity and safety of these products intact prior to administration through the process of “constructive transfer” is critical. This is especially important when the medicines are administered through pain pumps, via intrathecal (spinal) injection, and other means.

The DEA’s position appears to contradict 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). 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.

The DEA has informed organized pharmacy that constructive transfer is illegal, that the only acceptable way to deliver a controlled substance to a prescriber is through a “sale” appropriately recorded on a DEA Form 222. In constructive transfer, a pharmacist is dispensing a legal, patient specific prescription to a DEA registered prescriber to provide patient care – that act is not a sales transaction.

Key Points
- The DEA does not permit a pharmacist to dispense a controlled substance to the patient’s doctor.
- There are medicines which should only be handled and managed by health care professionals to assure stability and product integrity.
- The DEA has statutory authority to change its position but has not done so.
- The DEA has informed organized pharmacy that it is not willing to change its position despite a court opinion to the contrary...

Supporting This Will
- Require the DEA to be accountable to Congress for its position and why that position is contradictory to court findings.
- Protect quality patient care by clarifying that “constructive transfer” is a permitted act.
- Prevent action against physicians, veterinarians, and pharmacists who are appropriately handling controlled substances.
- Help assure the integrity of the drug dispensing and administration process by letting doctors and pharmacists make the best medical decisions.