AMERICAN SOCIETY OF PLASTIC SURGEONS ®
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In-Office Compounding

Safely reconstituting agents in office settings

Background

In 2012, an outbreak of fungal meningitis linked to contaminated compound drugs sourced from the New England Compounding Center sparked a national crisis. These tragic events triggered a national response to ensure that patient safety was better protected in the manufacturing and distribution of compound drugs.

In November 2015, the United States Pharmacopeia (USP) – which works with the FDA to set standards of identity, strength, quality and purity of medicines – published revisions to General Chapter 797 Pharmaceutical Compounding – Sterile Preparations. While well intentioned, these revisions would over regulate physician practices by holding them to the same set of standards as pharmacies. Almost 8,000 comments – mostly from providers – were submitted in response to the USP revisions. The vast majority expressed concern that the proposal was an overly-restrictive, one-size fits all approach developed without sufficient supporting scientific evidence. In recognition of the many issues raised, the USP announced in July 2016 that it was tabling any updates until it had an opportunity to meet with stakeholders to further discuss the unintended consequences the proposal will have on both physicians and patients.

Some state pharmacy boards began updating state regulations on this issue to reflect the revisions proposed by the USP. In Ohio, for example, the State Board of Pharmacy proposed changes that would require all prescribers who order and store compounded drugs or compound drugs to obtain licensure as a terminal distributor of dangerous drugs (TDDD). While accreditation requirements have addressed many facility design issues, not all private-practice physician offices are equipped with the requirements to obtain licensure as a TDDD. Requiring that these small businesses also register as a TDDD is both unnecessary and would deal a crushing blow to solo and small practice physicians in Ohio.

The Solution

Physician's offices that reconstitute sterile drugs should follow the existing U.S. Pharmacopeia Chapter 797 standards to ensure that drugs are safely compounded in these settings. While it is of the utmost importance that patients receive the safest and most effective drugs, state regulations that extend beyond the existing USP law may over-regulate and unnecessarily increase the cost of care. This will, in turn, reduce access to care. State pharmacy boards should refrain from updating local compounding laws until the U.S. Pharmacopeia meets with stakeholders and produces a final rule.

Request

Urge the state pharmacy board to hold all revisions to state compounding laws until U.S. Pharmacopeia Chapter 797 is formally revised and adopted.