FDA Proposes Ban on Office Use Compounding

The Food and Drug Administration (FDA) recently released three draft guidance documents for drug compounders, including one that would prohibit compounding for office use by traditional pharmacies. The documents, which are open for public comment for 90 days, describe FDA’s proposed policies on prescription requirements for compounds under section 503A; how FDA intends to apply section 503A to drugs compounded in state-licensed hospital or health system pharmacies; and how 503B outsourcing facilities are to operate.

Many pharmacy associations at the state and national levels, including TPA, continue to advocate that office use compounding should be overseen by state boards of pharmacy. According to the National Community Pharmacists Association (NCPA), prior to the passage of the Drug Quality and Security Act (DQSA) in 2013, FDA circulated a draft Compliance Policy Guide to Congress that recognized office use as legitimate and permissible and explained how compounding pharmacists can engage in office use compounding before the receipt of a patient-specific prescription consistent with the provisions of 503A.

TPA will continue to work with key state and national pharmacy stakeholders to engage federal legislators and the FDA regarding these draft guidance documents and to advocate for changes which would permit office use compounding under the oversight of state boards of pharmacy. TPA, along with NCPA and other pharmacy associations, plans to submit comments to FDA on the guidance documents.

FDA Draft Guidance Documents:
- Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act
- Hospital and Health System Compounding Under the Federal Food, Drug, and Cosmetic Act
- Facility Definition Under Section 503B of the Federal Food, Drug, and Cosmetic Act

TPA encourages all members whose practices may potentially be affected by these proposed guidance documents to review them and submit comments to FDA. (The deadline to submit comments is July 18, 2016, at 11:59 pm ET.)

To view these documents and provide comments, please visit:

www.tnpharm.org/fda-proposes-ban-on-office-use-compounding

Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with its docket number, shown above. Comments and suggestions regarding this draft document should be submitted within 90 days of publication in the Federal Register of the notice announcing the availability of the draft guidance.

TPA also requests that members communicate specific comments and concerns to our staff (micah@tnpharm.org) so they can be communicated to our federal legislators and key pharmacy organizations.