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Broad Provider and Pharmacy Coalition Encourages State Boards of Pharmacy and Medicine to Join Effort Ensuring DQSA is Implemented as Congress Intended

WASHINGTON - A broad cross-section of organizations representing varied health care providers, state pharmacy associations and the pharmacy community has sent a letter to State Pharmacy and Medicine Boards expressing serious concerns with the federal government's implementation of the Drug Quality and Security Act (DQSA), enacted in November 2013. The coalition is asking these state Boards to delay consideration of any pending regulatory or policy decisions on the ability of practitioners to obtain and use office-use compounded preparations until such time as the Food & Drug Administration (FDA) issues its guidance in a manner that is consistent with DQSA as Congress intended.

"Specifically, we are deeply concerned about the implementation of the DQSA in regards to both compounded and repackaged medications for office-use," says Gary McCrory, RPh, CCN, International Academy of Compounding Pharmacists (IACP) President, and lead DQSA Coalition organization. "Recent implementation actions by the FDA and the information being provided by the Agency to States have caused confusion amongst State boards of Medicine and Pharmacy and have adversely impacted practitioner and patient access to vital medications."

The FDA's current interpretation of the DQSA essentially eliminates all repackaging of medicines and creates barriers to office-use by requiring a prescription in advance of a compounded medication's preparation. This runs counter to the intent of office-use, which is the method by which physicians and other prescribers obtain medications from pharmacists to administer and treat patients.

"The letter to these state Boards of Pharmacy and Medicine is designed to send a very clear message that the law Congress wrote and intended is not being carried out," says McCrory. "This is troubling to practitioners and pharmacists alike, but it is most worrisome for patients, who often have an immediate need for a medication that they cannot get because of the way this law has been incorrectly interpreted and applied. People are suffering as a result."

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Office-use enables many physicians to order compounded prescription preparations in their practices to care for patients when manufactured drug products are either unavailable or do not provide the necessary strengths, dosage forms, or combinations of medicines they need. Repackaging of manufactured drug products for office-use is also done by pharmacists so that medications can be made available in the necessary dosages and strengths for physicians to administer in the office.

Office-use is often used to meet an urgent patient need and these medications are administered to treat viral infections, vitamin deficiencies, and macular degeneration (which if left untreated can cause immediate blindness). They are also used as anesthetic agents for outpatient surgical procedures, and for many other purposes by doctors.

When drafting and enacting the DQSA, Congress made six statements in the Congressional Record expressing that office-use compounding should remain governed by state laws.

“While the pharmaceutical industry has praised the FDA for its implementation of DQSA, the people who take care of patients each and every day – physicians, nurses, and pharmacists – are seeing accessibility to vital compounded medications hindered,” says McCrory. “Much of that impact is due to the FDA's attempt to define more broadly the instructions it was given by Congress, putting health care providers in the 'no man's land' of complying with their state law or the federal law, which are not in agreement.”

[Click here](#) to view a copy of the letter.

About the International Academy of Compounding Pharmacists

The International Academy of Compounding Pharmacists (IACP) is an association representing nearly 4,000 pharmacists, technicians, students, and members of the compounding community who focus upon the specialty practice of pharmacy compounding. Compounding pharmacists work directly with prescribers including physicians, nurse practitioners and veterinarians to create customized medication solutions for patients and animals whose health care needs cannot be met by manufactured medications.