ADVOCACY COUNCIL
of the American College of Allergy, Asthma & Immunology

March 11, 2016

The Advocacy Council of the American College of Allergy, Asthma & Immunology is contacting you today to make you aware of an issue that is affecting many physicians. We are asking for your help in monitoring and identifying proposed legislation in your state, which is generally brought about through the Boards of Pharmacy, which will seriously restrict patients' access to treatments. Please read the attached information.

We ask that you share this communication with your lobbyist and if this type of legislation is identified in your state, please contact Susan Grupe at SueGrupe@ACAAI.org or 847-427-1200.

Thank you for your consideration.

Sincerely,

J. Allen Meadows, MD
Chair
Advocacy Council of ACAAI

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Inappropriate Restrictions on Practice of Medicine

Issue

We want to make you aware of efforts by national and state-based pharmacy organizations to modify state laws and regulations on drug compounding in a way that could severely limit the ability of physicians to provide a wide range of office-based treatments and procedures. We believe these efforts, which are generally implemented through state Boards of Pharmacy, may be an inappropriate restriction on the practice of medicine. We ask for your help in monitoring activity in your state, alerting us if such efforts appear, and taking appropriate action should it be necessary.

Background

We have recently become aware of efforts in a number of states to apply pharmacy compounding regulations previously only applicable to pharmacies to include physician offices. These efforts can take a number of forms such as, for example, requiring special permits or licensure for physician offices that engage in compounding or the imposition of new standards such as expensive and unnecessary engineering and environmental controls These efforts generally go beyond what is required by the United States Pharmacopeia's sterile compounding rules and impact not only our specialty of allergy and immunology but potentially other specialties as well including pediatrics, dermatology, ophthalmology, neurology.
Although these efforts are often presented to legislators and regulators as part of an initiative to make "compounding" more sterile and safer for patients, these efforts are misplaced. The patient specific in-office preparation of therapies by the treating physician is quite different than the drug compounding that occurs in a pharmacy. Physicians have been preparing and providing patient-specific therapies in their office for decades and in the case of our specialty, allergists and immunologists have been preparing allergen extracts for their patients for over one hundred years with no reported sterility problems.

Discussion

Improperly crafted state laws, rules, or regulations on compounding could prevent physicians from preparing and providing effective and necessary in-office treatment for their patients and will reduce patient access to care with little or no countervailing improvement in patient safety. Moreover, these types of state initiatives reclassify services that have historically been part of the practice of medicine regulated by state Board of Medicine as the "practice of pharmacy."

Such initiatives also undermine recent amendments to the Federal Food Drug and Cosmetic Act adopted by Congress in 2013. Congress specifically decided to exclude physician offices from the new restrictions applicable to "outsourcing facilities" and sought to preserve traditional physician office-based compounding provided certain conditions were met.

These state initiatives fail to consider that preparation of therapies in the physician's office for his or her own patients is quite different from pharmacy compounding. Unlike the physician, the pharmacist may not see the patient at all, is rarely involved in the ongoing care of the patient, and is unlikely to be in a position to quickly learn of problems associated with compounded products.

In the case of allergen extracts, both the FDA's Draft Industry Guidance and current USP Ch. 797 sterile compounding rules permit compounding in the office provided basic rules of aspetic technique, beyond use dating, labeling and storage are met. Yet these rules have generally been ignored by state legislators and regulators as they adopt a "one size fits all approach." Fortunately, when we have had adequate notice, we have been successful in reversing or modifying some of these efforts before they could take effect.

We believe states must consider the unique aspects of the doctor/patient relationship in the development of any new state laws or regulations that would adversely impact physician compounding and patient access. We also believe that standards and enforcement related to physician office compounding should be under the authority of the state Board of Medicine and not the Board of Pharmacy.

Request

We ask for your help in identifying compounding initiatives in your state that could impact physicians and bringing them to our attention. We are more than willing to work with you to try and prevent inappropriate legislation or regulations from becoming the law in your state. Please contact Susan Grupe, Director of Advocacy Administration at SueGrupe@ACAAI.org or 847-427-1200 for further information.