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April 10, 2017

Kerry Maloney, Board Counsel
State Board of Pharmacy
RA-STRegulatoryCounsel@pa.gov

Re: State Board of Pharmacy
Proposed Regulations: Compounding
IRRC #3163

Dear Mr. Maloney:

As representatives of Pennsylvania Academy of Otolaryngology – Head and Neck Surgery (PAO-HNS), we are writing to share the concerns of our members regarding Regulation #16A-5419: Compounding, which could impact the potentially lifesaving care otolaryngologists provide to their patients.

The PAO-HNS represents 300 otolaryngologists in Pennsylvania, many of whom practice otolaryngic allergy.

We respectfully ask the board to clarify that the new regulations are designed for compounding commercial pharmacists and does not include physician offices.

We recognize that the proposed regulations are warranted for compounding pharmacies mass producing therapeutic compounds, especially after the 2012 incident where steroid injections were manufactured under unsafe conditions by a compounding pharmacy in Framingham, Massachusetts and caused many fatalities and illnesses. However, if compounding that occurs in physician offices must conform to these regulations, there may be an unintended and overreaching effect on clinical practitioners who engage in allergy immunotherapy.

If physicians who engage in practice of allergy/immunology must follow same criteria as commercial compounding pharmacies that manufacture products, many of them will have to stop providing allergen immunotherapy to the patients who are currently on active treatment plans. These practices would have to invest thousands of dollars in order to meet commercial pharmacy compounding standards and to do so would disrupt patient care. Disruption of immunologic treatment can have a devastating rebound effect on allergy and asthma patients and can significantly increase the cost of treatment.

We would like to point out the following reasons why such stringent regulations are unnecessary and impractical in case of allergy immunotherapy:

1. Allergy serum preparation involves making individualized mixtures for specific patients. It is not a massive compounding process. The process of making serum for allergies does not alter the nature of a given compound nor does it produce a totally new compound. It is simply a dilution process, much like the dilution of medications that nurses perform at the patient's bedside for injections.

2. Allergens used in an injection mixture are typically standardized allergens. Manufacturers follow FDA guidelines for standardization. This eliminates discrepancies in dosing outcomes after dilution.
3. The solution media where these antigens are stores typically contain Phenol (0.4%) which is a bacteriostatic agent. In fact, the allergy industry has been able to get longer shelf life approval for antigens because of presence of phenol as opposed to other preparations that expire every 28 days according to the United States Pharmacopeia (USP).
4. Skin allergy testing panels are also made and refreshed in the office. This often requires on-the-spot modification of mixture and dose selection appropriate for patient needs. This flexibility of individualized care would be compromised if the ability to mix and prepare solutions was taken away from facilities that provide these tests.
5. Allergy testing and immunotherapy has been around for 100 years. It is a well-established and safe practice that has not been associated with infectious side effects. This immunomodulation is one of the most effective remedies for patients with severe allergies and asthma. It is particularly effective when mixtures are individualized for each patient. The sterile techniques followed by health care personnel are the same as what is required of them in every facet of health care. In fact, to the best of our knowledge, infectious dissemination has not been an issue in decades.

In addition to immunotherapy, otolaryngology offices may encounter on a given day acute scenarios where mixing solutions and injections are required. For instance, injections to the middle ear, temporomandibular joint space, or intramuscular trigger points may be required to alleviate incapacitating symptoms such as dizziness, tinnitus, and pain. Analgesics, steroids, and antibiotics such as gentamicin are typical injections that may be mixed or diluted prior to injection.

Otolaryngology is not the only specialty potentially impacted if these regulations include practitioners' offices, but we are sharing these specific examples to highlight the potential threat to patient safety, access to care, and physicians' ability to deliver the life improving services that we all are committed to provide.

Thank you for the opportunity to comment on this very important issue. If you have any questions, please contact our executive offices at otopa@pamedsoc.org or call (717) 558-7750 ext. 1519.

Sincerely,

Jeffery Simmons, MD, FACS
President

Mahmoud Max Ghaderi, DO, FAOCO
Chair, Allergy Committee

cc: Independent Regulatory Review Commission
via email, irrc@irrc.state.pa.us