

3163

RECEIVED
IRRC

2017 APR -6 AM 10: 54



Pennsylvania MEDICAL SOCIETY®

April 10, 2017

Charles Cutler, MD, MACP
President

Theodore A. Christopher, MD, FACEP
President Elect

Danae M. Powers, MD
Vice President

David A. Talenti, MD
Chair

Frick J. Bergquist, MD, PhD
Secretary

Martin P. Raniowski, M.A
Executive Vice President

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 President of the Pennsylvania Medical Society (PAMED), I would like to comment on the proposed regulations for the State Board of Pharmacy (Board) regarding compounding pharmacies. PAMED appreciates the opportunity to comment on this draft regulation.

PAMED supports safeguards to ensure that drugs made in compounding pharmacies are dispensed at consistent and appropriate dosage levels for patients. We applaud the Board for taking steps in furtherance of these safeguards.

PAMED has comments specific to §§ 27.604 and 27.605 (relating to dispensing compounded drugs; and resale of compounded drug products).

In its responses to questions 15 and 16 of the Regulatory Analysis Form, the Board indicates that all pharmacies and pharmacists who compound drugs will be required to comply with this rulemaking. What is not specified is to what effect these regulations will have on health care practitioners, i.e. to what extent do these regulations apply to practitioners.

In § 27.604, a compounded drug may be dispensed pursuant to a prescription or drug order by the prescriber for a specific patient. Pharmacists may also compound drugs in anticipation of receiving a valid prescription based on the practitioner/patient/pharmacist relationship. Based solely on this section, this language suggests that pharmacists may compound a drug in anticipation of receiving a prescription but may not dispense or send a drug to the prescribing practitioner until they receive the patient-specific prescription. In other words, pharmacies may not dispense compounded drugs "for office use."

However, § 27.605 allows for the wholesale distribution of compounded drug products to medical practitioners to administer to an individual patient if the practitioner has an administrative system whereby the product can be tracked through the medical practitioner to the individual patient.

777 East Park Drive
PO Box 8820
Harrisburg, PA 17105-8820

Membership Inquiries
855-PAMED4U
(855-726-3348)

Tel: (717) 558-7750
Fax: (717)-558-7840
Email: KnowledgeCenter@pamedsoc.org
www.pamedsoc.org

This language suggests pharmacies may be able to send a batch of a compounded drug to physicians with whom they have a relationship so that the physicians can directly administer individual dosages to their patients.

Physicians who administer compounded medications in an office setting should be allowed to order and purchase those medications from the compounding pharmacy for the purposes of storing them in the office for future use, and administer those medications according to the physician/patient/pharmacy practice relationship. Regulations that prohibit physicians from purchasing drugs made in compounding pharmacies for the purpose of in-office use can delay patient treatment, require inconvenient multiple appointments for the patient, and increase health care costs. We believe these products should be made available in quantities to meet the anticipated needs of patients to assure continuity and access for medications as identified by the health care provider. By doing so, it will not require traditional prescription labeling or patient-specific information, but shall be able to be validated within the pharmacy or practitioner's record keeping system.

Based upon the above, PAMED is asking the Board to clarify the following:

1. Whether pharmacists may compound a drug in anticipation of receiving a prescription but may not dispense or send a drug to the prescribing practitioner until they receive the patient-specific prescription, i.e. that these regulations prohibit dispensing compounded drugs "for office use"? In addition, do the proposed regulations limit a physician's ability to order and purchase compounded drugs from the compounding pharmacy for the purposes of storing them in the office for future use?
2. Does § 27.605 require a patient-specific prescription in order for a pharmacy to be able to send a batch of a compound drug directly to a physician for administration to that patient?
3. To what extent, if any, do the Board's regulations prohibit or otherwise limit a physician from compounding drugs on their own in-office for administration to the physician's own patients?

On behalf of PAMED, I appreciate the opportunity to provide comments on this important set of regulations.

Sincerely,

Charles Cutler MD MACP

Charles Cutler, MD, MACP
President

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