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American Society of Clinical Oncology

*Making a world of difference in cancer care*

April 10, 2017

Kerry Maloney  
Board Counsel  
State Board of Pharmacy  
P.O. Box 69523  
Harrisburg, PA 17106-9523

[RA-STRegulatoryCounsel@pa.gov](mailto:RA-STRegulatoryCounsel@pa.gov)

RE: No. 16A-5419 (Compounding)

Dear Mr. Maloney,

The Pennsylvania Society of Hematology and Oncology (PSOH) and the American Society of Clinical Oncology (ASCO) are pleased to provide comments on the Pennsylvania State Board of Pharmacy proposed rulemaking on compounding (Reference No. 16A-5419).

PSOH represents physicians and other health care professionals in the Commonwealth who are dedicated to the care of patients with cancer and blood disorders. ASCO is the national organization representing over 40,000 physicians and other healthcare professionals specializing in cancer treatment, diagnosis and prevention. ASCO members are dedicated to conducting research that leads to improved patient outcomes, and to ensuring that evidence-based practices for the prevention, diagnosis and treatment of cancer are available to all Americans.

PSOH and ASCO are deeply committed to safeguarding all patients and professionals who are treated with or exposed to chemotherapy drugs. In 2014, ASCO appointed a panel of experts to review the existing scientific evidence and to develop updated recommendations for the safe handling of hazardous drugs in the context of oncology care. Independent oncology practices in Pennsylvania provide critically important community-based points of access to high-quality, high-value cancer care services for individuals with cancer.

PSOH and ASCO would appreciate seeing clarification that the proposed compounding regulations do not apply to the routine reconstitution and mixture of cancer drugs in medical oncology practices in Pennsylvania. The Food and Drug Administration (FDA) definition of compounding excludes the activities of diluting and reconstituting in accordance with the manufacturer's labeling (or associated instructions).

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PSOH and ASCO welcome the opportunity to be a resource for you. If you have questions or would like assistance on any issue involving the care of patients with cancer, please do not hesitate to contact Robbi-Ann Cook at PSOH 717.909.2688 [rcook@pamedsoc.org](mailto:rcook@pamedsoc.org) or Jennifer Brunelle at ASCO at [jennifer.brunelle@asco.org](mailto:jennifer.brunelle@asco.org).

Sincerely,



John Lister, MD  
President

Pennsylvania Society of Oncology and Hematology



Daniel F. Hayes, MD, FACP, FASCO  
President

American Society of Clinical Oncology