January 26, 2018

Committee on Ethics and Professionalism  
Claudette E. Dalton, Chair  
Federation of State Medical Boards (FSMB)  
400 Fuller Wiser Road  
Euless, Texas 76039

Re: Comments on Draft Policy on Compounding of Medications by Physicians

Dear Dr. Dalton and Members of Ethics and Professionalism Committee:

I am writing on behalf of the American Society of Clinical Oncology (ASCO) to provide comments on the proposed position statement entitled “Compounding of Medications by Physicians” under consideration by the Federation of State Medical Boards (FSMB). ASCO is the national organization representing over 42,000 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 ensuring that evidenced-based practices for the prevention, diagnosis, and treatment of cancer are available to all Americans.

ASCO is deeply committed to safeguarding patients and professionals in the context of compounding medications and handling hazardous drugs. We appreciate FSMB’s efforts to ensure the safety of compounded medications. ASCO commented on the previous draft compounding statement, and was pleased to meet with FSMB leaders and staff last year to discuss these important issues. While we appreciate the work the committee put into this updated draft, ASCO believes that if finalized in its current form, the proposed position statement will lead to confusion and barriers to providing care for cancer patients requiring medical oncology services. We urge FSMB in the strongest possible terms to make the clarifications and other edits described below, or alternatively, to delay final approval of this position statement pending further study and review.

The current draft makes recommendations about the regulation of compounding without clarifying that the activities typically performed in oncology practices do not fall within the scope of compounding as used by
Congress, the U.S. Food and Drug Administration (FDA), and as proposed for the next version of USP 797. We urge you to edit the document to clarify that the reconstitution and other acts performed in accordance with the manufacturer’s instructions do not fit within the scope of compounding.

As an example, the federal definition of compounding expressly excludes the activities that outpatient oncology providers typically perform when preparing to administer anticancer drugs. Specifically, section 503A of the Federal Food, Drug, and Cosmetics Act excludes the following activities from the definition of compounding:

...mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with that labeling.

We urge FSMB to add a clarification regarding medical oncology, and we note that the current draft position statement includes an exception endorsing compounding activities performed by allergy and immunology physicians. Consistent with the spirit and context of footnote 1 in the FSMB draft, we urge FSMB to add the following language to the position statement to avoid confusion or adverse consequences:

Accepted practice in medical oncology practices regularly includes the mixing and reconstitution of drugs for administration to the practices’ patients. This is consistent with the definition used by the FDA, which expressly excludes from compounding the mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with that labeling.

This clarification should be discussed in the text of the position statement in a manner that is exceedingly clear. If finalized as currently written, one can anticipate that the position statement will adversely impact patient access to medically necessary oncology services without any meaningful improvement in safety.

In addition, we urge FSMB to strike the language on lines 66 and 67 of the draft position statement requiring that physicians comply with USP 797 and USP 800. USP 797 is undergoing revisions at this time, and it is confusing and premature for FSMB to opine on what aspects of USP 797 warrant support.

Further, there are significant flaws in USP 800, including requirements that lack adequate scientific support and that threaten the safety of individuals in the oncology workforce. FSMB should be particularly sensitive to the problems arising from policies developed by USP without meaningful involvement by practicing physicians. By endorsing USP 800 for use by state boards
of medicine, FSMB will perpetuate the significant flaws in the substance of this chapter. We would be pleased to meet with you in the near future to review these specific concerns, but given that USP 797 is undergoing revisions and that USP 800 may also undergo further revisions, we question why FSMB would rush to endorse these chapters at this point in time.

Thank you for considering ASCO’s comments. If you have questions or would like assistance on any issue involving the care of individuals with cancer, please do not hesitate to contact Jennifer Brunelle at ASCO at jennifer.brunelle@asco.org.

Sincerely,

[Signature]

Bruce E. Johnson, MD, FASCO
President, American Society of Clinical Oncology