

1 **Position of the Federation of State Medical Boards**

2
3 **Compounding of Medications by Physicians**

4
5 Compounding is a non-specific term that may encompass a variety of actions ranging from the
6 simple dilution of a prescribed medication for a specific patient in a physician’s office to the
7 production of a drug from bulk drug substance(s) and other ingredients by a licensed
8 pharmaceutical manufacturer. The definition of compounding in these many settings may vary
9 depending on the source of the definition. Before writing any regulations on compounding, state
10 medical boards are encouraged to ensure they use the definition of compounding that aligns with
11 the situation they intend to regulate.

12
13 Safety concerns have been raised around compounding after a series of serious incidents
14 involving harm to patients using medications compounded in “outsourcing” facilities. Congress,
15 the Food and Drug Administration and U.S. Pharmacopeia responded to these incidents by
16 proposing new guidelines and standards that exceeded the remedial need to license outsourcing
17 facilities and included physician office-based compounding. The USP and the FDA continue to
18 try and reconcile their definitions and the revised USP standards are still being considered and
19 are not final. The need for careful and sterile manipulation of medications is not debatable.
20 Further, there are documented incidents where either the ingredients or the final product have
21 been kept beyond their designated “By Use Date” (BUD), thus again risking contamination and
22 potential injury to patients. Correct storage of medications is also important. It is therefore
23 critical that compounding occur in accordance with conditions and practices designed to prevent
24 contamination and according to protocols to ensure that ingredients are added in the appropriate
25 proportions.

26
27 In any setting, the decision to compound or prescribe a compounded medication should be in the
28 best interests of the patient. The prescription of a compound and the act of compounding should
29 be triggered by a specific medical need in an individual patient. In the office setting, physicians
30 should only compound medications for their own patients and not for patients of other physicians
31 or healthcare practitioners. Clear guidelines and training should be available for any staff who
32 assist with manipulating the medications. Medications should not be compounded in large
33 quantities in anticipation of patients who exhibit a particular set of symptoms or for retail sale.
34 This could fall under the definition of conventional medication manufacturing, a practice that
35 presents greater safety risks to patients and is therefore restricted to entities that are registered
36 with the U.S. Food and Drug Administration (FDA) and abide by a more stringent set of
37 safeguards for the preparation of medications. However, section 503A of the Federal Food,
38 Drug, and Cosmetic Act (FD&C Act) provides for “anticipatory compounding” by a licensed
39 pharmacist or a licensed physician in limited quantities before receiving a prescription for an
40 identified individual patient. To remain in compliance with federal legislation regarding drug
41 compounding, physicians should not engage in anticipatory compounding beyond such limited
42 quantities.

43
44 Physicians must ensure that active ingredients included in a compound are necessary for treating
45 a medical condition in an individual patient. The medical condition and rationale for prescribing
46 a compounded medication should be reflected in the patient’s medical record. Physicians should
47 not add or request the addition of unnecessary substances in order to ensure a higher rate of
48 reimbursement, as this would unnecessarily put patients at risk. Physicians should also refrain

49 from exploiting patients by charging unreasonable or excessive fees for compounded
50 medications.

51
52 In instances where patients require medications in forms that are different from those
53 commercially available, physicians are encouraged to establish relationships with pharmacies or
54 other entities that have registered as outsourcing facilities with the FDA. These facilities are
55 required to compound according to “good manufacturing practices” and are subject to risk-based
56 inspections by the FDA and additional standards that reduce the risk that contamination or other
57 product quality problems might occur during the compounding process. As a rule, the physician
58 should not compound any medication for which there is an FDA approved drug that could be
59 obtained from a licensed and inspected facility.

60
61 If physicians choose to compound medications themselves, they are encouraged, where possible,
62 to limit compounding activity to non-sterile preparations¹ and they must comply with Federal
63 and state laws regarding compounding and dispensing drugs. If sterile medications are
64 compounded by physicians, there is a responsibility for the physician and the staff to know,
65 understand and employ aseptic techniques. While state laws on compounding vary across the
66 U.S., physicians should comply with the standards set out in the United States Pharmacopeia-
67 National Formulary (USP-NF), particularly Chapters 795, 797, and 800. Chapters 795 and 797
68 provide guidance on the preparation of non-sterile and sterile compounds and describe conditions
69 and practices that can prevent patient harm. Chapter 800 addresses the compounding and
70 handling of hazardous drugs in healthcare settings. These Chapters of the USP-NF also describe
71 the responsibilities of supervisors of compounding practices, which may be relevant for
72 physicians who oversee compounding activities of employed staff.²

73
74 Legislation and practices regarding the oversight of in-office compounding vary by state. Some
75 state boards of pharmacy grant compounding licenses to individual providers and may perform
76 inspections of facilities where medications are compounded. Inspections are also performed by
77 state Departments of Health and through facilities accreditation processes for those clinics
78 affiliated with a hospital or health system. While in-office compounding may occur in some
79 states in the absence of regulatory oversight, it is unlikely that state medical boards have the
80 resources or established protocols to provide this function. It is therefore recommended that clear
81 lines of communication be established between state medical boards and state boards of
82 pharmacy to ensure that any existing regulatory gaps are closed.

83

¹ Exceptions exist in some medical professions such as Allergy and Immunology where accepted practice regularly includes the preparation of sterile compounds by or under the supervision of a specially trained physician for their individual patients. In such instances physicians should follow aseptic technique, as well as the protocols developed by their specialty and set forth in applicable published practice parameters.

² Please note that at the time of drafting this position statement, the USP-NF is undergoing significant revision. Confusion exists regarding the current USP-NF Chapter 797 definition of “immediate use” which is intended only to apply in emergency code circumstances. It is recommended that until the revised USP-NF 797 is completed, physicians and state medical boards interpret “immediate use” to apply to rare circumstances when a compounded medication is needed urgently (e.g., cardiopulmonary resuscitation) for a single patient, and preparation of the compounded medication under the conditions currently specified in USP-NF 797 would subject the patient to additional risk due to delays in therapy.

84 **FSMB COMMITTEE ON ETHICS AND PROFESSIONALISM**

85

86 Claudette E. Dalton, MD, Chair
87 FSMB Director-at-Large
88 Former President, Virginia Board of Medicine

89

90 Jeffrey D. Carter, MD
91 FSMB Director-at-Large
92 Former President, Missouri Board of Registration For the Healing Arts

93

94 Rebecca J. Hafner-Fogarty, MD, MBA
95 Former President, Minnesota Board of Medical Practice, Chief Medical Officer of Zipnosis

96

97 Katie Templeton, JD
98 Board Member, Oklahoma State Board of Osteopathic Examiners

99

100 Sarvam P. TerKonda, MD
101 Board Member Florida Board of Medicine

102

103

104 **SUBJECT MATTER EXPERT**

105

106 Bruce D. White, DO, JD
107 Director, Alden March Bioethics Institute

108

109

110 **EX OFFICIOS**

111

112 Gregory B. Snyder, MD, DABR
113 Chair, FSMB

114

115 Patricia A. King, MD, PhD, FACP
116 Chair-elect, FSMB

117

118 Humayun J. Chaudhry, DO, MS, MACP, MACOI
119 President and CEO, FSMB

120

STAFF SUPPORT

Mark L. Staz, MA
Director, Continuing Professional Development