The practice of medicine includes compounding of prescription medications. Compounding is the process of “combining, admixing, mixing, diluting, pooling, reconstituting, or otherwise altering of a drug or bulk drug substances to create a drug.” 21 U.S. Code § 353b(d)(1). Compounding can include seemingly simple actions such as watering down an elixir, crushing and combining prescription drugs, or adding flavoring to a medicine. It can also involve complex combinations of medicines to create unique substances which are not commercially available. However, compounding does not include mixing, or any other such acts, if the physician is following manufacturer instructions.

The U.S. Food and Drug Administration (FDA), to an extent, regulates compounding of prescription medications. The FDA approves all new drug formulas, reviews all drug labels, product inserts, and marketing materials, and audits drug manufacturing and storage facilities. Licensed physicians, as well as licensed pharmacists, are exempted from these FDA regulations as long as they meet certain requirements. Some, but not all, of these requirements are discussed in this Position Statement.

Compounding by physicians must be done for an individual identified patient. The patient should have a prescription order or notation that the compound is medically necessary. This compound may be used for immediate or subsequent use. The North Carolina Medical Board expects the patient’s medical record to properly document need for the compounded drug. Physicians are also expected to follow informed consent standards. Patients should be notified that they are receiving a compounded drug and made aware of any risk of using the particular compound. Also note that North Carolina pharmacy dispensing laws require a physician to register with the North Carolina Board of Pharmacy when dispensing for a fee or charge. This would mean a physician who sends a patient home with a compound and charges the patient a fee for the compound would need a dispensing permit.

When compounding, physicians should follow United States Pharmacopoeia or National Formulary (USP-NF). USP-NF standards are a set of uniform regulations for compounding practices. These regulations include, but are not limited to, instructions on sterile and non-sterile preparations of compounds, calculations, storage, labeling, and proper equipment for weighing and measuring. All drugs and ingredients used in

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1 This Position Statement only applies to compounding by physicians. Under the Medical Practice Act, physician assistants and nurse practitioners are not allowed to compound without supervision of a licensed pharmacist.

2 Exempted status does not apply to the compounding of radiopharmaceuticals or positron emission tomography (PET) drugs. Radiopharmaceuticals are regulated by the Nuclear Regulatory Commission. PET drugs are subject to FDA manufacturing, distributing, and packaging regulations. Licenses and permits with the NRC or FDA are required for compounding these drugs.
compounding should comply with USP-NF standards. If a USP-NF monograph, or
formula, for a compound exists, the monograph should be followed.

These standards exist to ensure the safety and effectiveness of all compounded
substances. Improper preparation, packaging, or storage of a compound can have
detrimental effects on a patient. The compound could be too weak and ineffective,
leaving a patient unimproved. The compound could be too strong and have negative
side effects. The compound could be contaminated and subject a patient to other
ailments. All physicians who compound must be competent in the practice of
compounding; this includes proper education, training, and understanding of these USP-
NF compounding standards.

The FDA also prohibits physicians from making certain compounds. Physicians may not
compound drugs that have been removed from the market because such drugs have
been found to be unsafe or ineffective. In addition, physicians cannot compound drugs
that are copies of commercially available drugs. This does not include changing a
commercially available drug where the change will produce a significant difference for an
individual patient.

If a physician fails to comply with these FDA requirements, a physician will lose the
exempted status and be subjected to the stricter FDA standards that are applied to drug
manufacturers and subject to penalty. This can include a warning letter, seizure of any
compounded product, an injunction to stop a physician from further compounding, or
criminal prosecution.

In addition, if a physician fails to subscribe to the FDA requirements, the North Carolina
Medical Board has grounds for discipline whether or not the FDA prosecutes the
violation. The Medical Practice Act requires physicians to follow all laws involving the
practice of medicine. This would include meeting the FDA requirements for
compounding by physicians. (See N.C. Gen. Stat. § 90-14(a)(7) for “violation of a law
involving the practice of medicine.”) The Medical Board may also find a physician
lacking in professional competence or to have committed unprofessional conduct if they
fail to have the proper training and education on compounding practices or to meet the
standards of medical practice in connection with treating a patient with compounds. (See
N.C. Gen. Stat. Section 90-14(a)(6), (11)).

This Position Statement discusses some of the federal requirements. It does not set out
all the requirements for compounding by physicians. The silence of this Position
Statement on any legal requirements should not be construed as the lack of an
enforceable standard for discipline. For additional information, please see the following:

FDA 503A Exemption Requirements for Physicians:
http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompo
unding/ucm376733.htm
FDA 503A Amendment:
https://www.congress.gov/113/bills/hr3204/BILLS-113hr3204enr.pdf

FDA Guidance on Pharmacy Compounding of Human Drug Products under 503A: