



nabp

## National Association of Boards of Pharmacy

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October 28, 2002

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
Room 1061  
5630 Fishers Lane  
Rockville, MD 20852

**Re: Docket No. 02D-0242: Compliance Policy Guides Manual Section 460.200,  
"Pharmacy Compounding"**

To Whom It May Concern:

The National Association of Boards of Pharmacy (NABP) is the professional organization whose membership consists of all state boards of pharmacy in the United States, the District of Columbia, Guam, Puerto Rico, the Virgin Islands, eight provinces of Canada, four states in Australia, New Zealand, and South Africa. NABP was established in 1904 to develop uniform standards and procedures for pharmacist licensure and for the transfer of licensure. Over the past 98 years, NABP has been repeatedly called upon to develop programs and services to assist the state boards in their charge to protect the public health, safety, and welfare. It is in this capacity that we comment on the Food and Drug Administration's (FDA) Compliance Policy Guide (CPG) Manual Section 460.200, entitled "Pharmacy Compounding."

NABP clearly recognizes and supports the authority of the FDA to regulate manufacturers and the manufacturing of prescription drugs. However, NABP maintains that the regulation of pharmacy compounding is the constitutional purview of the states boards of pharmacy and an activity that must continue in order for patients' needs to be best served. Past and recent incidences of the inappropriate preparation of compounded medications and the manufacture of medications under the guise of compounding are dangerous events that should evoke the attention and concern of the FDA. However, that attention and concern must be appropriately directed toward cooperative efforts with the states, establishing a clear distinction between compounding and manufacturing, and assisting the states to eliminate the inappropriate manufacturing of medications. The state boards of pharmacy also have the responsibility to appropriately regulate the compounding of medications and to act quickly and responsibly when improper transgressions are occurring. Most importantly, when disagreements arise between the states and the FDA about whether a practice activity constitutes compounding or manufacturing, a cooperative dialogue that recognizes, not seeks to supersede, the authority of both the FDA and state boards should be implemented.

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We thank the FDA for releasing CPG 460.200, and providing the pharmacy community with an opportunity to submit comments in response. NABP notes that one of the most important declarations within the CPG is *that the focus of the CPG will be establishments with retail pharmacy licenses ... engaged in manufacturing and distributing unapproved new drugs for human use and not pharmacists and pharmacies engaged in the traditional practice of compounding human drugs ... upon the receipt of a valid prescription for an individually identified patient from a licensed practitioner*. NABP strongly maintains that this focus and recognition should be reflective in the individual components of the CPG and that the primary purpose of the CPG should be to help regulators and practitioners definitively distinguish between compounding and manufacturing. In that regard we offer the following specific comments about the CPG as released.

COMMENTS:

*The overall premise and focus of the CPG should be on distinguishing manufacturing from compounding.*

The overall premise and focus of the CPG should be on defining manufacturing and distinguishing this activity from legitimate, traditional, and legal compounding. Repeated references to how the FDA intends to regulate pharmacy compounding confuse this focus and seem to suggest that the FDA is disregarding the authority of the states with the intent to regulate pharmacy compounding. NABP requests that the FDA remove these references or clarify its recognition of state authority over pharmacy compounding.

Factor 2:

Compounding drugs that were withdrawn or removed from the market for safety reasons.

Comment:

NABP agrees that the manufacture of medications, which were withdrawn from the market for safety reasons, could compromise the medication distribution system and pose a risk for patient safety. The wide scale introduction of such products is the activity that NABP considers manufacturing and which compromises the medication distribution system. NABP believes that if a pharmacist or pharmacy is involved in such activities, those pharmacists and pharmacies are engaged in manufacturing not pharmacy compounding. However, the CPG must recognize and allow for the compounding of products withdrawn from the market for safety reasons for individual patients pursuant to a bonafide prescriber-patient-pharmacist relationship. In such instances, it is the responsibility of the prescriber and pharmacist to ensure that the prescribing and preparation of the medication does not harm the patient and is in the patient's best interest. A recent example of the introduction of a medication previously withdrawn from the market for safety reasons that is serving a select population of patients is Lotronex®.

Factor 3:

Compounding finished drugs from bulk active ingredients that are not components of FDA-approved drugs without an FDA-sanctioned investigational new drug application (IND) in accordance with 21 USC Section 355(i) and 21 CFR 312.

Comment:

It appears to NABP that Factor 3 of the CPG is included to prohibit the widespread introduction of products not sanctioned through the present FDA approval and oversight system. NABP agrees that the widespread introduction of unapproved drugs could be problematic and dangerous. NABP requests consideration to allow for the compounding medications from bulk active ingredients that are not components of FDA-approved drugs without an FDA-sanctioned investigational new drug application (IND) for individual patients pursuant to a bonafide prescriber-patient-pharmacist relationship. NABP's request acknowledges that pharmacists and prescribers involved in the compounding of these products must understand the effects of using such bulk active ingredients. Our request notes that there are a number of bulk active ingredients currently available on the market to treat patients that are not components of FDA approved drugs, such as grandfathered drugs and OTC monographed drugs.

Factor 4:

Receiving, storing, or using drug substances without first obtaining written assurance from the supplier that each lot of the drug substance has been made in an FDA-registered facility.

Comment:

Obtaining written assurance from the supplier that each lot of the bulk substances used in traditional, legal pharmacy compounding has been made in an FDA-registered facility should be considered a standard of practice and a necessary component of risk management and quality improvement programs in place in pharmacies. In this context, such compounding activities should be monitored and regulated by the state boards of pharmacy. NABP and several state boards of pharmacy have taken the position that if a supplier's written assurance cannot be obtained, then pharmacists shall use their professional judgment in procuring alternative components. NABP supports the FDA's position in the CPG that manufacturing products, under the guise of compounding, cannot and should not be used to avoid the necessity to obtain the written assurances noted. The failure to obtain such required written assurances when involved in the manufacturing of products would constitute a practice subject to regulation by the FDA. We request that the CPG clarify this distinction.

Factor 5:

Receiving, storing, or using drug components not guaranteed or otherwise determined to meet official compendia requirements.

Comment:

Once again, NABP's position is that the receiving, storing, or use of drug components not guaranteed or otherwise determined to meet official compendia requirements does not, in and of itself, constitute manufacturing and could instead constitute a practice regulated by the state boards of pharmacy. NABP and some state boards of pharmacy have taken the position that if obtaining a guarantee is not possible for legal pharmacy compounding, then pharmacists shall use their professional judgment to procure alternative components. This position is based upon the pharmacist and prescriber collaborating to ensure that the patient receives the safest and best available treatment and contingent upon individual patient interactions not the wide scale preparation and introduction of products into the medication distribution system.

Factor 6:

Using commercial scale manufacturing or testing equipment for compounding drug products.

Comment:

NABP fully understands that distinguishing between compounding and manufacturing is a difficult task. We agree that the presence of commercial scale equipment is often an indicator that the pharmacist/pharmacy is engaged in the manufacturing of products and not the compounding of medications. However, this is not always the case. Currently, only one state board of pharmacy prohibits the use of commercial scale manufacturing or testing equipment in compounding pharmacies while two states, Arkansas and Oklahoma, specifically allow it. We ask the FDA to define in greater detail the phrase "commercial scale equipment."

Factor 7:

Compounding drugs for third parties who resell to individual patients or offering compounded drugs at wholesale to other state licensed persons or commercial entities for resale.

Comment:

NABP agrees that selling compounded drugs at wholesale would indicate a compounding pharmacy is likely acting as a manufacturer. However, NABP is aware of the accepted practice whereby pharmacies that compound drugs sell them to prescribing practitioners who then administer them to individual patients. We ask that FDA clarify whether this practice is exempt from Factor 7.

Factor 9:

Failing to operate in conformance with applicable state law regulating the practice of pharmacy.

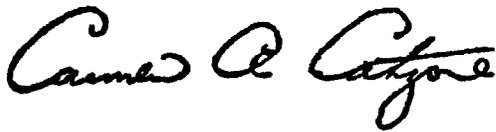
Comment:

NABP believes that this factor may contradict the FDA's recognition of state authority to regulate the practice of pharmacy. We ask that it be removed or rephrased to recognize the separation of authority and cooperative enforcement actions of the states and the FDA.

In conclusion, NABP supports FDA's efforts to identify and regulate the manufacture of drug products. However, we emphasize that these efforts should not be extended to curtail legitimate pharmacy compounding. Such an extension would fail to recognize the jurisdiction of the state boards of pharmacy. We appreciate the opportunity to comment on this CPG and look forward to working with the FDA to harmonize efforts with those of the state boards of pharmacy.

Sincerely,

NATIONAL ASSOCIATION OF  
BOARDS OF PHARMACY

A handwritten signature in black ink that reads "Carmen A. Catizone". The signature is written in a cursive, flowing style.

Carmen A. Catizone, MS, RPh, DPh  
Executive Director/Secretary

cc: NABP Executive Committee  
Executive Officers – State Boards of Pharmacy