National Business Group on Health®

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Creative Health Benefits Solutions for Today, Strong Policy for Tomorrow

July 14, 2016

The Honorable Dr. Robert M. Califf, MD
Commissioner, Food and Drug Administration
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Rm. 1061
Rockville, MD 20852

RE: Docket No. FDA-2016-D-0271 for "Hospital and Health System Compounding Under the Federal Food, Drug, and Cosmetic Act; Draft Guidance for Industry; Availability"

Dear Dr. Califf:

Consistent with our comments on Docket No. FDA-2016-D-0269 for "Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act," the National Business Group on Health (the Business Group) is also pleased to comment on the current docket, which seeks to more clearly distinguish hospital pharmacies, which may compound drugs under section 503A(a)(2) of the Food, Drug & Cosmetics (FD&C) Act, from outsourcing facilities, which are regulated by section 503B of the FD&C Act. Once again, we appreciate the efforts of the agency, the Congress (through the Drug Quality and Security Act), and the Pharmacy Compounding Advisory Committee (PCAC) within the Center for Drug Evaluation and Research (CDER), to ensure safe and appropriate pathways by which compounded drugs are regulated.

We strongly support the clear articulation that section 503A(a)(2) of the FD&C Act applies to hospital pharmacies, just as it applies to stand-alone pharmacies that are not registered as outsourcing facilities under section 503B.

Consistent with our companion comments on anticipatory compounding, specifically, we support limiting the use of anticipatory compounding under section 503A(a)(2) of the Food, Drug & Cosmetics (FD&C) Act, and clarifying that these limits apply to hospital pharmacies by:

1. Requiring that, absent exemption qualifiers, drug products be compounded after the licensed pharmacist or licensed physician receives a valid prescription order for an individual patient;
2. Establishing specific conditions under which anticipatory compounding may take place under section 503A(a)(2) of the FD&C Act; and
3. Specifying that compounded drugs may only be distributed under section 503A(a)(2) of the FD&C Act when they are "for an identified patient based on the receipt of a valid prescription order" either "on the receipt of a prescription order for such individual patient" or, under certain conditions, "before the receipt of a valid prescription order for such individual patient."

Additionally, we support the important clarification that anticipatory compounding at a hospital 1) may only take place for drugs which will be distributed only to healthcare facilities that are owned and controlled by the same entity that owns and controls the hospital pharmacy and that are located within a 1 mile radius of the compounding pharmacy, and 2) that the drugs are only administered within the healthcare facility, to patients within the healthcare facility – i.e., that compounded drug products produced at a hospital facility may not be sent home with a patient, or picked up by a patient to take home.

We feel this is a very important distinction that will reduce the misuse of hospital exemptions for anticipatory compounding, to compound mass quantities of drugs, which may then be shipped to various other facility locations. Not only is this an important safe guard for payers, in terms of reducing unnecessary expenditures, it is also an important risk mitigation effort for patients. By closing this loophole, FDA can ensure that a hospital pharmacy is not functioning by default as a large manufacturing operation, but without the necessary safeguards to assure drug quality. Additionally, we agree with FDA's position that hospitals that intend to manufacture large quantities of compounded agents, for broader facility distribution, should be required to register as an outsourcing facility under section 503B.

As stated in our companion comments on this issue, while we appreciate that there are legitimate, important and necessary uses for compounded medications, and that most medications are compounded honestly and at the request of a physician, profit potential associated with compounding continues to lure some pharmacists and physicians into inappropriate compounding behaviors and adds to unnecessary expenses for employers. Taking this into consideration, we appreciate the agency's continued effort to ensure that compounded medications are reserved for appropriate use and that such usage is triggered by medical necessity. We believe the proposed rule on anticipatory compounding creates important consistencies for patients and payers, which, in turn, creates a stabilizing opportunity for the compounding industry. Additionally, we feel this is an important step toward ensuring patient safety, as stricter limits on anticipatory compounding, particularly that which is conducted at stand-alone entities, ensures limited distribution of products which may become contaminated during the compounding process.

The National Business Group on Health represents approximately 425 primarily large employers, including 72 of the Fortune 100, who voluntarily provide group health plan coverage and other health programs to over 55 million American employees, retirees and their families.

We look forward to continuing to work with you on important health policy issues affecting large employers. Again, thank you for the opportunity to comment. Please contact me or Steven Wojcik, the National Business Group on Health's Vice President of Public Policy, at (202) 558-3012, if you want to discuss our comments in further detail.

Sincerely,

Brian Marcotte
President and CEO