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-0269 for "Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act."

Dear Dr. Califf:

The National Business Group on Health (the Business Group) is pleased to comment on the proposal put forth by the Food and Drug Administration (FDA), which more clearly defines instances in which compounded medications may be dispensed with and/or without a patient-specific prescription. 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.

Specifically, we support limiting the use of anticipatory compounding under section 503A(a)(2) of the Food, Drug & Cosmetics (FD&C) Act 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."

We recognize the legitimate value that compounded medications have the potential to bring to the overall patient care ecosystem, in niche categories. In hospitals, there are uses for intravenous antibiotic solutions, total parenteral nutrition units, and special pediatric formulations. In community pharmacies, concentrations, dosage forms or combinations of medications that are unavailable or not readily available can be manufactured. And, when urgency dictates, compounding can be used to prepare products that are hard to acquire or are temporarily unavailable from their manufacturer. Finally, products that are free of dyes or preservatives may be required for patient use, albeit rarely.

While compounding may be medically appropriate in certain circumstances, as outlined above, the healthcare industry has seen a recent, dramatic increase in the use of compounded drugs and the number of compounding pharmacies entering the marketplace, which is disproportionate to the need for these products, and financial considerations are likely to play an important part in this rapid growth, due to the potential for massive profits.

Thus, 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