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May 21, 2013

The Honorable Joe Pitts
House Committee on Energy and Commerce
Health Subcommittee
420 Cannon House Office Building
Washington, DC 20515

Re: "Examining Drug Compounding"

Dear Chairman Pitts,

On behalf of Central Admixture Pharmacy Services, Inc. (CAPS), I am writing to provide comments and insights that are relevant to current discussions regarding pharmacy compounding. CAPS appreciates the opportunity to work with the House Committee on Energy and Commerce to ensure that compounding pharmacies produce safe compounded sterile preparations.

Compounding pharmacy has a storied history in the provision of pharmaceutical care, from a time when essentially all prescriptions were compounded (estimated at 80% in the 1920's) to a period in which only a very small percentage are compounded (estimated at <1% in the 1970's). Today, the definition of pharmacy compounding is unclear and encompasses a host of practices ranging from adding simple flavorings to commercially available oral pharmaceuticals to the preparation of sterile injectables from approved pharmaceutical ingredient (API) powders.

In recent years pharmaceutical compounding has grown rapidly in the acute care setting. The hospital segment of the health care industry is facing extraordinary pressure to provide better patient care, improved patient outcomes and cost reductions. Hospital pharmacies have adapted their practices to be harmonized with these priorities and in doing so have appropriately focused on the provision of pharmaceutical care models to optimize outcomes. One such strategy is to contract sterile injectable compounding to outsourcing partners thus allowing scarce pharmacy resources to be focused on direct patient care activities. Over the last several years severe drug shortages have forced physicians and hospitals to seek compounded alternatives to otherwise commercially available products. The pharmacy compounding community continues to adapt their practices to meet the growing demands and needs of the market.

CAPS was founded in 1991 with seven original pharmacies to serve as an intravenous (IV) outsourcing partner to hospital and health system pharmacies. We work closely with our clients to identify compounded sterile preparations (CSPs) and services that add value to their pharmaceutical care model. Our activities and the CSPs we provide are an extension of the activities routinely performed onsite at the host hospital pharmacy. Centralization of these compounding activities allows CAPS to focus on associated quality systems, compounding processes, facilities, environmental controls, qualification practices and validation activities not commonly associated with traditional pharmacy practice.

- Today we have grown into a network of 25 pharmacies serving more than 1500 hospital pharmacies with clients and patients in all 50 states.
- In 1994 CAPS voluntarily registered all of our pharmacies with the FDA.
- Today our pharmacies that perform compounding activities beyond fulfilling patient specific prescriptions remain registered with FDA.
- Our business model focuses on both acute care and out patient care market segments.
- Our core business is comprised of patient specific parenteral nutrition formulations for those patients unable to meet nutritional needs orally.
- Other business components consist of non-patient specific compounded CSPs prepared in anticipation of a prescription in limited quantities based on historic ordering patterns. These formulations range from complex multi-ingredient admixtures such as cardioplegic solutions to single component admixtures such as standard antibiotic doses.

Recent discussions within the pharmacy community have sought to better define pharmacy compounding, clarify regulatory authority over the variations in practice, identify the appropriate rules and regulations to govern the practice, and establish minimum standards for all stakeholders who wish to engage in the practice. CAPS is of the belief that there are several key concepts that should be adopted when considering governance of compounding manufacturing.

- Language in the Federal Food, Drug, and Cosmetic Act should be revised to remove loopholes that permits pharmacies to “manufacture” under the guise of “Anticipatory Compounding”:
 - Define traditional pharmacy compounding as a compounding activity resulting in a CSP specifically made for an identified individual patient and dispensed only upon receipt of said patient specific prescription. Defining the practice in this way does not prohibit compounding in anticipation of a prescription in limited quantities and based on historic ordering patterns. It does however impose a requirement that all CSPs be dispensed only upon receipt of the patient specific prescription.
- State Boards of Pharmacy should be responsible for governing the practice of traditional pharmacy compounding.
- Define compounding manufacturing as a compounding activity resulting in CSPs that are sold and distributed to identifiable clients without patient specificity. Such activities should be construed as compounding manufacturing regardless of distribution in interstate or intrastate commerce. Third party distribution or reselling should not be permissible.
- The FDA should be responsible for governing the practice of compounding manufacturing and has such authority within the existing framework.
- The FDA should be required to clearly define the applicable standards on which compounding manufacturers will be evaluated for compliance.
- An exemption for hospital pharmacies should be considered that will allow them to compound and distribute CSPs within their institution without patient specificity, at the time of distribution, to meet the needs of the patients within their institution.
- Such hospital pharmacy exemption should not extend beyond the care of patients within that specific institution. If a hospital or health system wishes to distribute non-patient specific CSPs to other entities under common ownership or otherwise, they should be required to register and meet the requirements of a compounding manufacturer.

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- To this end, compounding manufacturers should be permitted to hold a pharmacy permit in addition to registration with FDA. Such hybrid practices should meet all requirements for a compounding manufacturer and the standards set for pharmacies within the states in which they are registered. The FDA and Boards of Pharmacy have demonstrated the ability to conduct joint inspections and focus on the component of business within their respective enforcement areas.
- Any CSP designated for office use that is compounded and distributed in advance of a patient specific prescription should be considered compounding manufacturing and the pharmacy engaged in such a practice held to that standard.
- A provision for intracompany transfer of compounded sterile preparations produced by a compounding manufacturer and designed to be used as components of finished doses (e.g. parenteral nutrition electrolytes) should be a permissible act. This is especially true during this period of significant drug shortages.

CAPS appreciates the opportunity to comment on this issue that is a vitally important to public health today. We look forward to supporting your efforts and are most willing to be available and serve as a resource to you during this process.

Sincerely,

A handwritten signature in black ink, appearing to read 'Thomas Wilverding', with a long horizontal flourish extending to the right.

Thomas Wilverding
President
Central Admixture Pharmacy Services, Inc