



American Hospital
Association

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August 1, 2013

The Honorable Tom Harkin
United States Senator
428 Dirksen Senate Office Building
Washington, DC 20510

Dear Chairman Harkin:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our nearly 43,000 individual members, the American Hospital Association (AHA) is pleased to express our support for the *Pharmaceutical Quality, Security, and Accountability Act* (S. 959), legislation to improve safety for patients receiving compounded drugs.

Having safe compounded medications available is essential for patient care in hospitals and other settings. This legislation has emerged out of the tragic fungal meningitis outbreak caused by contaminated compounded products prepared by the New England Compounding Center (NECC). However, out of that tragedy there is now an opportunity to create a new framework that will provide better and more comprehensive oversight of drug compounding. We believe that S. 959 is a step in the right direction and would go a long way toward addressing the current gaps in regulatory oversight of organizations that engage in compounding.

Hospital and health system pharmacies routinely compound medications for dispensing to patients. Doing so is critical to high-quality and safe patient care. It is for this reason that we strongly support the included exception in the legislation which states that hospital and health system pharmacies that compound and ship drugs for dispensing to patients within facilities that are part of their organization, even if it involves interstate shipment, be regulated as traditional compounders under state oversight. We believe this exception will allow hospitals and health systems to continue to centralize, standardize and operationalize compounding sterile product preparation.

Centralized compounding activities of health and hospital systems utilize pharmacists and technicians that are highly trained in appropriate compounding practices that employ standardized and consistent processes that make errors much less likely to occur. In addition, it provides a ready source of compounded products to a health system's other facilities that may not have the infrastructure and environment to engage in sterile compounding themselves, such as critical access hospitals, ambulatory surgery centers and satellite emergency departments.



We understand that questions have been raised as to why hospitals and health systems should receive an exception from federal oversight as compounding manufacturers. The AHA believes hospital and health system pharmacies are clearly different from compounding manufacturers, primarily because there are many safeguards in place to ensure medications are safely prepared and dispensed to their system patients. Unlike compounding manufacturers, which introduce product for sale into interstate commerce, hospitals and health systems prepare compounded sterile drugs for dispensing to their own patients in response to a prescription or physician order or in limited anticipatory amounts based on established relationships with their medical staff.

Hospital and health system pharmacies are not only regulated by the state in which they operate, but must also comply with accreditation standards established by The Joint Commission (or other accrediting body) and are routinely inspected and held to the applicable standards contained within USP <797>, <795> and other USP chapters. Furthermore, unlike compounding manufacturers, hospitals and health systems have comprehensive legal responsibility for their patients that extends far beyond the pharmacy, encompassing the entire continuum of care. For instance, hospitals must comply with comprehensive Centers for Medicare & Medicaid Services conditions of participation that ensure accountability for the safety and quality of all the care that they furnish to patients.

The bill allows the compounding of Food and Drug Administration- (FDA) approved, marketed drugs as long as the drug is included on the FDA's drug shortage list and the compounder "submits notice to the Secretary not later than three calendar days after beginning the compounding of such drug." This is improved language from the previous draft. It is now clear this is to be a notification and not a request for approval. This instance is one of many examples where we appreciate your taking providers' concerns into consideration and making changes to improve the bill. The process followed by the Health, Education, Labor and Pensions Committee on this legislation has been transparent, bipartisan and responsive. You and your staff are to be commended, and we are very appreciative.

We would like to raise three issues with the legislation. The exception that defines "health system" states that a health system includes "...facilities wholly owned and operated by such entity..." The AHA is concerned that this definition could be interpreted narrowly so as to exclude from the exception arrangements between system entities such as joint ventures, where majority or some partial ownership occurs. We would hope to see this issue addressed as the bill moves forward.

The definition of "health system" includes a requirement that each facility be accredited by a national accrediting organization. Many hospitals are accredited by a national organization, such as The Joint Commission, but health systems often have hospitals or parts of their systems that are not nationally accredited, instead these mostly small, rural facilities are certified by the state survey agency. We recommend this issue be addressed by adding on page 15 lines 11-12 after "(II) includes only the inpatient, outpatient, and ambulatory facilities..." language similar to the following: "... accredited by a national accreditation body, approved by the Secretary for purposes of this section or certified to meet Medicare conditions of participation by an entity recognized by the Secretary...."

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Another potential concern is the compounding of drugs that are variations of FDA-approved, marketed drugs that need to be prepared in batches in advance of a prescription. We agree that when an FDA-approved drug is available, that should be used; and the bill also allows for variations to be compounded as long as there is a prescription for an individual patient available prior to the drug being compounded. But there may be instances of drugs that are variations of FDA-approved, marketed drugs, that need to be made in batches prior to a prescription being in possession of the compounder. We will continue discussions with staff on this issue and welcome continued clarification of this point.

Thank you again for the work you have done on this legislation, the open, bipartisan process and the attention to detail displayed. The AHA looks forward to working cooperatively as the legislation moves through the Senate and House to ensure that the current gaps in regulatory oversight are addressed and the availability of safe compounded medications ensured.

Sincerely,

Rick Pollack
Executive Vice President