



7272 Wisconsin Avenue
Bethesda, Maryland 20814
301-657-3000
Fax: 301-664-8892
www.ashp.org

March 13, 2009

Virginia Herold
Executive Officer
California State Board of Pharmacy
1625 North Market Blvd, Suite N219
Sacramento, CA 95834

RE: Proposed Modifications to Title 16, Section 1735.3(a) of the California Code of Regulations

Dear Ms. Herold:

The American Society of Health-System Pharmacists (ASHP) has received notification of the proposed modifications to section 1735.3(a)6 of Title 16 of the California Code of Regulations and is pleased to submit the following comments. We appreciate the Board's efforts to modify the current regulatory language, as we all seek to preserve patient safety and ensure that pharmacy practice continues to evolve and develop. Having reviewed the modified language, we do believe that the proposed exemption is in the best interest of all parties and support the adoption of such language. However, we are concerned that there is an overall focus on documentation that is impractical for inpatient situations, leading to a reduction in patient care and the effective and timely delivery of medication.

As the national professional association representing over 35,000 pharmacists who practice in hospitals and health systems, ASHP offers unique and vital feedback on this important health-care issue. Pharmacists in hospitals and health systems are experts in medication use who serve on interdisciplinary patient-care teams. They work with physicians, nurses, and other health-care professionals to ensure that medicines are used safely, effectively, and in a cost-conscious manner. As an essential duty of the pharmacist, the issue of compounding and its impact on patient safety is one that we consider to be of paramount concern.

The proposed exemption in section 1735.3(a)6, is one that we, along with our affiliate, the California Society of Health-System Pharmacists, support. By exempting "sterile products compounded on a one-time basis for administration within two hours to an inpatient in a health care facility," we believe that the potential delay to patients with

urgent medication needs will be avoided. This is in the best interest of our patients and we applaud the Board's decision to modify the language.

We would urge the Board to continue to be mindful of the potential implications of other proposed modifications to the regulations. While it is imperative to provide appropriate and necessary parameters around the practice of compounding, it is equally vital that the pharmacist continues to be empowered and retains the necessary flexibility to decide what is best for each individual patient. As the medication expert in the health care environment, we need to balance the value of documentation with a recognition that onerous requirements may lead to delay in care and have a negligible impact on patient safety. Especially in hospital settings, compliance with labeling requirements that are more akin to manufacturing best practices would be, at best, time consuming and, at worst, have a direct negative impact on patient care. Such an expectation of documentation could be onerous on any size hospital. When you consider the impact of such regulation on the workforce in smaller and rural hospitals, the ramifications could be not only unreasonable but unmanageable.

Documentation is clearly an important step in the delivery of any medication. Lot numbers are recorded for large batches, a practice that is reasonable. However, recording lot numbers for small or individual compounds that are administered immediately or within 24-hours is a requirement that removes the focus of the pharmacy from patient care and effective delivery to documentation. We would question the value of such language, from both a workforce perspective as well as that of patient safety and delivery of care.

There also continues to be confusion as to whether the documentation requirement applies to every product that is prepared, including those for an individual patient, or if the new requirement will apply solely to those products that are prepared in batch for a yet-to-be determined patient. As pharmacies typically do not record such detailed information for patient-specific items, such a proposed regulation could create an extraordinary burden for pharmacies. Not only could this new requirement exist for emergency drugs, it could impact all products prepared for routine care. This added documentation requirement has the potential to delay the preparation and delivery of one-time and immediate-use medications. We would urge the Board to consider the potential implications of such a regulatory change.

Again, we applaud the Board's intent to modernize the regulations and its recognition to exempt the sterile compounds for immediate use. In principle, documentation is a good thing. We would recommend that the Board continue to assess how documentation is being currently achieved and to seriously consider the consequences of requiring hospitals to rapidly divert scarce resources into documentation, rather than critical patient care services. It may be worthwhile, as this process continues to move forward, to consider a phased-in approach, with defined milestones and deadlines, should you continue to proceed with the current proposed language.

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We appreciate the opportunity to provide these comments and would be happy to work with you as you continue to develop appropriate guidelines and requirements that affect the pharmacy profession. If you have any questions or comments, please do not hesitate to contact me at 301-664-8687 or gtrujillo@ashp.org.

Sincerely,



Geralyn M. Trujillo, MPP
Director, State Government Affairs

cc: Dawn Benton, California Society of Health-System Pharmacists