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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
COMPOUNDING REGULATION SUBCOMMITTEE MEETING
MINUTES

DATE: August 22, 2011

LOCATION: Department of Consumer Affairs
El Dorado Room, 2nd Floor, N-220
1625 N. Market Boulevard
Sacramento, CA 95834

SUBCOMMITTEE MEMBERS PRESENT: Stan Weisser, RPh
Randy Kajioka, PharmD
Neil Badlani, RPh

STAFF PRESENT: Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Janice Dang, Supervising Inspector
William Young, Supervising Inspector
Carolyn Klein, Legislation and Regulation Manager
Tessa Miller, Staff Analyst

Call to Order

Board President Stan Weisser appointed himself to the Subcommittee.

Chair Randy Kajioka called the meeting to order at 10:07 a.m.

Discussion Including Questions and Answers from Hospital Pharmacies and the Public on the Board's Implementation of 16 California Code of Regulations Sections 1735-1735.8, Pharmacies That Compound, and Sections 1751-1751.8, Pharmacies That Compound Sterile Injectable Medications

Chair Kajioka provided that the board has received questions regarding the new compounding regulations that took effect in July 2010. He stated that the answers to these questions have been compiled into a document and are available on the board's

Web site. Chair Kajioka discussed that the Subcommittee has convened in order to provide additional clarification on the implementation of the compounding regulations.

Presentation

Rita Shane, representing Cedars-Sinai Hospital, provided a presentation on sterile compounding to ensure patient safety. A copy of the presentation is attached, following this meeting summary.

Dr. Shane provided an overview of sterile compounding and an analysis of current requirements in this area. She reviewed U.S. reported events and recalls associated with sterile compounding from 1991 to present and indicated that 65 percent of these events were caused by contamination.

Katherine Palmer, representing Cedars-Sinai Hospital, reviewed epidural medication components and the 38 elements of documentation required to compound this medication. She discussed the balance between meeting compounding requirements while also providing timely patient care.

MJ Ziadeuin, representing Cedars-Sinai Hospital, reviewed a patient example of a Vancomycin order for five days of therapy as well as specific considerations for compounded medications for hospital patients.

Dr. Shane provided an overview on the comprehensive guidelines for sterile compounding and dating of such products pursuant to US Pharmacopeia Chapter 797 (USP 797).

Dr. Shane reviewed results from a survey on hospital compounding practices in California regarding USP 797 guidelines, safety strategies, training, drugs shortages, error prevention, and hospital pharmacy computer systems. She stated that survey responses indicated that most commercial systems do not have the ability to support documentation of lot number and manufacturer information.

Dr. Shane discussed dating for sterile compounded medications. She indicated that 24-hour dating of these products and change in patient condition or medication dose contributes to product waste, including waste of medications that are part of a drug shortage. Dr. Shane stated that the medication cannot be reused if recording requirements are not met due to time limitations for immediate use medications.

Discussion

Katy Marconi provided an overview on DoseEdge, a pharmacy workflow system that has been implemented at Doctors Hospital of Manteca. (DoseEdge performs the selecting, compounding, inspecting, tracking, and reporting of IV or oral doses and records the entire dose preparation and dispensing process including photo imaging.) Dr. Marconi reviewed the time required to operate the system for photo imaging as well as the cost to operate the system including an expense per label. She indicated that this system is not used for immediate use medications due to the cumbersome process.

Executive Officer Virginia Herold provided comment on AB 377 (Solorio). She stated that the bill would allow for anticipatory unit-dose packaging to ensure patient care.

Lynn Paulsen, representing UCSF, provided comment on "just-in-time" compounding. She stated that this process is becoming more common in hospitals across the country. Dr. Paulsen reviewed processes that have been implemented at UCSF in this area.

Supervising Inspector Robert Ratcliff advised that documentation of all recording requirements is required in order to reuse a compounded product. He stated that sterile products compounded on a one-time basis for administration within 24-hours to an in-patient in a health care facility are exempt from recording of the manufacturer and lot number of each component.

Steve Gray, representing Kaiser Permanente, suggested that the board clarify its intent for implementing the records requirements. He also suggested that clear definitions be provided for "components" and "equipment."

Public comment was provided regarding the definition of "equipment." It was recommended that the board revisit its interpretation of this term in the regulation.

Dr. Shane reviewed challenges associated with quantitative and labeled strength analysis such as overfills. She also discussed that cytotoxic medications are being inappropriately labeled as chemotherapy.

A member of the public discussed that appropriate labeling is critical as chemotherapy and cytotoxic medications are to be administered by specially trained staff.

Dr. Shane summarized her presentation and reiterated the importance of quality assurance and training programs to prevent errors and harmful events. She also reiterated the need for clarity regarding the definitions for "quantitative analysis," "cytotoxic," "equipment," and "non-sterile products."

Steve Gray, representing Kaiser Permanente, provided comment on quality assurance programs. He discussed that the regulations require that pharmacies develop their own policies and procedures for quality assurance and record and verify the accuracy of the compounded products.

Dr. Gray discussed that there has also been a lot of discussion on the definition of a "batch." He stated that this term should be clarified, possibly through a regulatory revision process.

A representative from the UCSF School of Pharmacy suggested that the discussion focus on the available evidence regarding compounding errors to identify possible problems and to identify goals to alleviate these issues.

Chair Kajioka discussed that the board should look at whether the regulations are enhancing healthcare for patients or imposing unnecessary, labor intensive requirements.

Board Member Anil Badlani asked whether there is any other compounding software currently being used.

A representative from Kaiser Permanente provided that Kaiser has developed its own software, similar to the DoseEdge system, in response to the regulations to record the actual ingredients of a compounded sterile product. He discussed that the system is easy to use and can be searched to identify patients who have received a compounded drug with specific ingredients, manufacturer, and lot number. The system does not interface with the existing electronic medical record system. He stated that the system is currently being piloted and should be fully implemented by the end of the year.

A member of the public provided comment regarding PK software, a system that is proprietary for compounding pharmacies that tracks active and inactive ingredients, lot number, manufacturer, etc. He advised that this software cannot track what syringe was used but can track at the patient level and can track ingredients that have been recalled.

There was discussion on § 1751.3 regarding sterile injectable policies and procedures for cleanups and spills in conformity with local health jurisdiction standards. Input received indicated that hospital pharmacies have policies and procedures in place to address this requirement.

Chair Kajioka discussed that under § 1735.3, sterile products compounded on a one-time basis for administration within 24-hours to an in-patient in a health care facility are exempt from the specific records requirements. He suggested that the record requirement be clarified.

Dr. Shane provided that 24-hour dating is used for these products.

Dr. Fujimoto discussed that the board has previously discussed and clarified that a “batch” is made for more than one patient.

A member of the public suggested that the group look at the definition of a “batch” versus a “product” that is compounded for a specific patient to provide clarification in this area. He indicated that he interprets a “batch” to be a large quantity of a product created to be used and designated to a specific patient in the future.

Dan Wills spoke in opposition to the proposed definition. He stated that USP has interpreted that a “product” that is compounded for 10 or more patients constitutes a “batch.”

Ms. Herold asked if the number of patients is known in advance of the preparation of the medication.

Ms. Sherpa clarified the difference between USP 795 and 797 regarding sterile and non-sterile products.

Dr. Paulsen discussed that irrespective of the regulations, it has been typical practice to record the lot number and expiration date of the drug when preparing a batch.

Chair Kajioka encouraged pharmacists to use their professional judgment in this area. He discussed that rather than being overly prescriptive, “gray area” is beneficial as it allows pharmacists to best serve their patients. Chair Kajioka stated that guidelines have been established to provide direction and to ensure the safety of the public.

Ms. Herold indicated that the minutes of this meeting will be brought to the full board. She advised that any action on this issue will come from the board itself and not from today’s discussion. Ms. Herold discussed that this meeting is an opportunity to provide comments to the board, to explore and discuss the topic to better understand the comments of industry, and to provide some consideration regarding problems that have developed. She discussed that regulations must be clear and consistent and where such clarity does not exist, the pharmacy must be in a position to explain how or why a decision or action was made.

A member of the public suggested that the discussion focus on the risk of the product. He stated that low and medium risk products should have a different quality plan than high risk products. He suggested that the board provide each pharmacy with some latitude on what quality and quantitative analysis is necessary.

Mr. Badlani suggested that the board define the terms “equipment” and “supplies” and provide clarification on what documentation is to be maintained. He stated that a master formula could include the equipment as well as the supplies being used for a particular compounded drug product. Mr. Badlani suggested that some items currently required, may not need to fall under the definition of equipment and provided an example of the IV syringe.

A member of the public sought clarification regarding the board’s goal in requiring the recording of this information and how this goal can be best achieved.

A member or the public provided comment on the outsourcing of compounded drug products and another approach to risk assessment.

Dr. Gray spoke to the limitations on the data provided and the challenges that could be presented if an internal recall was necessary and provided some historical perspective on this.

Dr. Shane spoke in support of the need for internal processes and indicated that patients are kept safe by the quality of the people performing the work.

A member of the public discussed that hospital pharmacies have spent several years focusing on USP 797 compliance and risk assessment. He stated that as reconsideration of the regulation is being sought, harmonization with USP 797 would be beneficial as hospital administration has already bought off on this compliance as important. He spoke in support of leveraging USP 797 as the foundation of the regulations.

Dr. Marconi requested that the board look at USP 797 as the best practice. She suggested that the board allow industry to demonstrate how they can achieve patient safety with their 797 policies and procedures. Dr. Marconi discussed approaches to tracking and reacting to a recall.

Dr. Fujimoto sought clarification regarding whether the master formula should include the supplies being used.

Dr. Kajioka responded that the terms “supplies” and “equipment” will need to be discussed and brought to the full board. He discussed that documenting the equipment used is beneficial when conducting a root cause analysis.

A member of the public comment spoke in opposition to the documentation of supplies being used and provided an example of two different staff using different syringe sizes while performing the same task.

Dr. Shane discussed that hospitals use prep labels and indicated that the amount that is being added to a solution is known prior to preparation. She stated that the focus should be on the amount of the solution and spoke in support of the previous public comment.

Dr. Gray provided that “supplies” is only mentioned in § 1751 and clarified that the regulation does not state that the master formula needs to include the supplies being used. Dr. Gray did indicate that Kaiser found benefit in recording such information and indicated that such documentation should be determined by each institution. He underscored that as long as the policies and procedures are appropriate, patient safety will be met because risk assessment considerations can be a determining factor in the level of documentation for each type of product.

A public comment was received indicating that there are very specific policies and procedures for pediatric compounds. She spoke in support of flexibility and professional judgment in this area.

Dr. Shane clarified that the group’s request of the board is to relax some of the recording requirements for patient specific medicine.

Mr. Wills reviewed the recording requirements that are clarified in the Q&A document for each compounded drug product pursuant to § 1735.3.

Dr. Ratcliff explained how the definition of “equipment” was arrived upon as well as the definition of a “batch,” as both are not defined in statute or by regulation. He indicated that both of these definitions may be action items by the board.

Dr. Gray suggested that the board look at the definition of “supply” versus “equipment” and determine whether these terms have been defined under the Good Manufacturing Practice Regulations (GMP) by the U.S. Food and Drug Administration (FDA). Dr. Gray also specified that the regulations require the recording of the equipment, but not the lot number. He recommended that the current interpretation of the regulation in this area be revisited.

Dr. Fujimoto reviewed a section of USP 797 which appears to define equipment as related to compounding. She suggested that USP 797 can be cross-referenced.

Discussion continued regarding the requirements under USP 797.

Dr. Shane provided an example of the master formula versus a chart order.

Dr. Young suggested that the group look at § 1735.3 in terms of components that are helpful and components that are not necessary in the interest of patient safety.

Ms. Sherpa suggested that the discussion focus on batches that are non-patient specific for anticipatory needs versus onetime patient specific doses for immediate use. She confirmed that the group agrees that anticipatory batches require all necessary recording. Ms. Sherpa suggested that immediate use doses should be exempt from all recording requirements.

Dr. Marconi reviewed the recording requirements under § 1735.3 and indicated that recording the manufacturer and lot number and the equipment, as required in subdivision (a), paragraphs (6) and (7), poses the greatest challenge and difficulty.

Ms. Sherpa provided that these items are currently being recorded in prescription records, and not in a separate documentation log.

Ms. Herold advised that USP is a guideline. She reviewed possible implications of referring to USP via regulation.

Dr. Paulsen indicated that hospital pharmacies are required to meet both the requirements of the board and the USP guidelines as required by the California Department of Public Health.

Discussion continued regarding the required documentation with regards to patient safety and necessity when trying to meet patient care demands. Public comment

suggested that the recording requirements may not be addressed if the drugs are dispensed via a Pyxis machine. Possible consequences to recalls were also evaluated.

Dr. Shane discussed the challenges and time limitations when adding additional recording requirements given all of the other processes that must occur as part of the compounding process.

Dr. Paulsen suggested that policies and procedures should allow for the development of a process to address a recall versus recording the lot number for recall purposes and provided an example of a recent alcohol wipe recall. She indicated that it is easier and faster to re-compound then to try to identify and recall impacted IV bags.

Ms. Herold clarified that the group is requesting an exemption to the recording requirements under § 1735.3 (a) (6) and (7) for patient-specific compounded medications for immediate use.

Public comment requested that the exemption be granted for settings other than hospitals including outpatient oncology infusion practices.

Dr. Shane provided comment on pharmacists' dedication to patient safety and reiterated that adding additional recording requirements will complicate the process and the ability of pharmacists to provide patient care.

Mr. Wills requested that the definition of "equipment" be re-evaluated for all settings, not just the inpatient setting, and questioned how a problem can be fixed if good records are not maintained.

Dr. Kajioka summarized the issue and indicated that the information will be presented to the board. He discussed that the solution needs to focus on the patient and must be workable.

Ms. Herold provided some historical perspective on the compounding regulations and discussed the ultimate goal of patient safety. She stated that the ability to reconstruct records is necessary for patient care. Ms. Herold requested that additional comments be directed to her attention.

Public Comment on Matters Not on the Agenda

No public comment was provided.

The meeting was adjourned at 1:45 p.m.