Summary of Changes to the Board of Pharmacy's Proposed Regulations about Compounding

The California State Board of Pharmacy changed its proposed compounding regulations based on public feedback. This summary highlights some of the main changes. These updates aim to address concerns about costs and access to medications.

The Final Statement of Reasons will list all changes to the proposed text made during rulemaking.

Sterile Compounding with Bulk Drug Substances on the FDA 503A Category 1 List

The earlier version of the proposed regulations permitted compounding using these substances only during emergencies. This required approval from a public health officer. Changes were made to expand compounding with these substances, but with specific testing requirements.

The fourth modified version of the proposed regulations no longer requires facilities to do specific tests. Facilities must still follow federal law, federal guidance, and national standards, like USP Chapter 797. They must now have policies to show how they follow the laws and standards.

Note: The current regulations don't allow compounding with these substances.

Compounding for Animal Patients

The earlier version of the proposed regulations limited a pharmacy to give a five-day supply of compounded animal medications to veterinarians.

The fourth modified version of the proposed regulations includes several changes:

1. Pharmacies can give a veterinarian a 14-day supply of a nonsterile preparation.
2. Pharmacies can give a veterinarian a 7-day supply of a sterile, non-ophthalmic product.
3. Pharmacies can give a veterinarian a 28-day supply of a sterile eye medication.
4. References to the FDA's guidance for veterinary medications were added.

Note: Under the current rules, pharmacies can only give a 5-day (120-hour) supply of compounded animal medications to veterinarians.

Compounding in Hospitals

The Board changed the proposed regulations in response to comments that relate to hospital practices.

The fourth modified version of the proposed regulations includes several changes:

1. Extra flexibility to compound medications that are commercially available products.
2. Extra provisions for immediate use compounding including when equipment or environment failures happen.
3. Establishing provisions for using competency assessments across many compounding locations.
4. A supervising pharmacist can oversee compounding, even if they fail a competency test. Specific conditions apply.
5. Flexibility on how to document the rate of infusion.

Handling of Hazardous Drugs (HD)

The Board changed the proposed regulations in response to comments that relate to handling hazardous drugs.

The fourth modified version of the proposed regulations includes several changes:

1. The regulations apply to facilities that compound hazardous drugs. They also apply to facilities that crush HD tablets or open HD capsules.
2. Language about pass-through doors and secondary engineering controls has been removed.
3. The proposed regulations about changing gloves now refer to USP Chapter 800.
4. The proposed regulations create flexibility in workflow management of compounding HD in certain environments.
5. Sterile preparation mats are no longer required.

Using Flavoring Agents

The earlier version of the proposed regulations required facilities to follow all nonsterile compounding requirements when adding a flavoring agent.

The fourth modified version of the proposed regulations makes changes, including:

1. Facilities that only add flavoring to an FDA approved drug don't have to follow all compounding rules. Specific conditions apply.
2. Pharmacists can add flavoring agents to FDA approved drugs without approval from the prescriber.

Note: USP Chapter 795 says that adding flavoring to an FDA approved drug is compounding.

Note and Disclaimer: The above information is a plain language summary of certain changes the Board of Pharmacy has made to the proposed compounding regulations as the rulemaking process has progressed. It is not legal advice, is not a part of the rulemaking file, and is provided as general guidance only. Compounding is a complex area of pharmacy practice. Stakeholders are encouraged to read the proposed fourth modified text, available here, in full, to make sure they understand the proposed regulations.