§ 6831. Special provisions relating to outsourcing facilities. 1. Registration. Any outsourcing facility that is engaged in the compounding of sterile drugs in this state shall be registered as an outsourcing facility under the Federal Food, Drug and Cosmetic Act and be registered as an outsourcing facility pursuant to this article.

2. New drugs. Sections 502(f)(1), 505 and 582 of the Federal Food, Drug and Cosmetic Act shall not apply to a drug compounded in an outsourcing facility registered under the Federal Food, Drug and Cosmetic Act.

3. Prescriptions. Notwithstanding any other provision of law to the contrary, no outsourcing facility may distribute or dispense any drug to any person pursuant to a prescription unless it is also registered as a pharmacy in this state and meets all other applicable requirements of federal and state law.

4. Restrictions. Any drugs compounded in an outsourcing facility registered pursuant to this article shall be compounded in accordance with all applicable federal and state laws.

5. Labeling. Notwithstanding any other provision of law to the contrary, the label of any drug compounded by an outsourcing facility shall include, but not be limited to the following:

(a) a statement that the drug is a compounded drug or a reasonable comparable alternative statement that prominently identifies the drug as a compounded drug;

(b) the name, address, and phone number of the applicable outsourcing facility; and

(c) with respect to the drug:

(i) the lot or batch number;

(ii) the established name of the drug;

(iii) the dosage form and strength;

(iv) the statement of quantity or volume, as appropriate;

(v) the date that the drug was compounded;

(vi) the expiration date;

(vii) storage and handling instructions;

(viii) the National Drug Code number, if available;

(ix) the statement that the drug is not for resale, and the statement "Office Use Only"; and

(x) a list of the active and inactive ingredients, identified by established name, and the quantity or proportion of each ingredient.

6. Container. The container from which the individual units of the drug are removed for dispensing or for administration (such as a plastic bag containing individual product syringes) shall include:

(a) a list of active and inactive ingredients, identified by established name, and the quantity or proportion of each ingredient; and

(b) any other information required by regulations promulgated by the commissioner to facilitate adverse event reporting in accordance with the requirements established in section 310.305 of title 21 of the code of federal regulations.

7. Bulk drugs. A drug may only be compounded in an outsourcing facility that does not compound using bulk drug substances as defined in section 207.3(a)(4) of title 21 of the code of federal regulations or any successor regulation unless:

(a) the bulk drug substance appears on a list established by the secretary of health and human services identifying bulk drug substances for which there is a clinical need;

(b) the drug is compounded from a bulk drug substance that appears on the federal drug shortage list in effect at the time of compounding, distributing, and dispensing;

(c) if an applicable monograph exists under the United States Pharmacopeia, the national formulary, or another compendium or pharmacopeia recognized by the secretary of health and human services and the bulk drug substances each comply with the monograph;

(d) the bulk drug substances are each manufactured by an establishment that is registered with the federal government.

8. Ingredients. If an outsourcing facility uses ingredients, other than bulk drug substances, such ingredients must comply with the standards of the applicable United States pharmacopeia or national formulary monograph, if such monograph exists, or of another compendium

or pharmacopeia recognized by the secretary of health and human services for purposes of this subdivision, if any.

9. Unsafe or ineffective drugs. No outsourcing facility may compound a drug that appears on a list published by the secretary of health and human services that has been withdrawn or removed from the market because such drugs or components of such drugs have been found to be unsafe or not effective.

10. Prohibition on wholesaling. No compounded drug will be sold or transferred by any entity other than the outsourcing facility that compounded such drug. This does not prohibit the administration of a drug in a health care setting or dispensing a drug pursuant to a properly executed prescription.

11. Prohibition against copying an approved drug. No outsourcing facility may compound a drug that is essentially a copy of one or more approved drugs.

12. Prohibition against compounding drugs presenting demonstrable difficulties. No outsourcing facility may compound a drug:

i. that is identified, directly or as part of a category of drugs, on a list published by the secretary of health and human services that present demonstrable difficulties for compounding that are reasonably likely to lead to an adverse effect on the safety or effectiveness of the drug or category of drugs, taking into account the risks and benefits to patients; or

ii. that is compounded in accordance with all applicable conditions identified on the drug list as conditions that are necessary to prevent the drug or category of drugs from presenting demonstrable difficulties.

13. Adverse event reports. Outsourcing facilities shall submit a copy of all adverse event reports submitted to the secretary of health and human services in accordance with the content and format requirements established in section 310.305 of title 21 of the code of federal

regulations, or any successor regulation, to the executive secretary for the state board of pharmacy.

14. Reports. The commissioner, in consultation with the commissioner of health, shall prepare and submit a report to the governor and the legislature, due eighteen months from the effective date of this section, evaluating the effectiveness of the registration and oversight of outsourcing facilities related to compounding.