151.253 COMPOUNDING.

Subdivision 1. **Exemption from manufacturing licensure requirement.** Section 151.252 shall not apply to:

(1) a practitioner engaged in extemporaneous compounding, anticipatory compounding, or compounding not done pursuant to a prescription drug order when permitted by this chapter or the rules of the board; and

(2) a pharmacy in which a pharmacist is engaged in extemporaneous compounding, anticipatory compounding, or compounding not done pursuant to a prescription drug order when permitted by this chapter or the rules of the board.

Subd. 2. **Compounded drug.** A drug product may be compounded under this section if a pharmacist or practitioner:

(1) compounds the drug product using bulk drug substances, as defined in the federal regulations published in Code of Federal Regulations, title 21, section 207.3(a)(4):

(i) that:

(A) comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding;

(B) if such a monograph does not exist, are drug substances that are components of drugs approved for use in this country by the United States Food and Drug Administration; or

(C) if such a monograph does not exist and the drug substance is not a component of a drug approved for use in this country by the United States Food and Drug Administration, that appear on a list developed by the United States Food and Drug Administration through regulations issued by the secretary of the federal Department of Health and Human Services pursuant to section 503A of the Food, Drug and Cosmetic Act under paragraph (d);

(ii) that are manufactured by an establishment that is registered under section 360 of the federal Food, Drug and Cosmetic Act, including a foreign establishment that is registered under section 360(i) of that act; and

(iii) that are accompanied by valid certificates of analysis for each bulk drug substance;

(2) compounds the drug product using ingredients, other than bulk drug substances, that comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapters on pharmacy compounding;

(3) does not compound a drug product that appears on a list published by the secretary of the federal Department of Health and Human Services in the Federal Register of drug products that have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective;

(4) does not compound any drug products that are essentially copies of a commercially available drug product; and

(5) does not compound any drug product that has been identified pursuant to United States Code, title 21, section 353a, as a drug product that presents demonstrable difficulties for compounding that reasonably demonstrate an adverse effect on the safety or effectiveness of that drug product.

The term "essentially a copy of a commercially available drug product" does not include a drug product in which there is a change, made for an identified individual patient, that produces for that patient a significant difference, as determined by the prescribing practitioner, between the compounded drug and the comparable commercially available drug product.

Subd. 3. **Exceptions.** This section shall not apply to:

(1) compounded positron emission tomography drugs as defined in section 151.01, subdivision 38; or

(2) radiopharmaceuticals.

History: *2014 c 291 art 5 s 9*