126.11 Exemptions in cases of drugs and devices — dispensing by prescription only.

1. The board shall adopt rules exempting from any labeling or packaging requirement of this chapter drugs and devices which are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packaged, on condition that such drugs and devices are not adulterated or misbranded upon removal from the processing, labeling, or repacking establishment.

2. Drug and device labeling or packaging exemptions adopted pursuant to the federal Act shall apply to drugs and devices in this state except insofar as modified or rejected by rules adopted by the board.

3. *a.* (1) This paragraph *"a"* applies to a drug intended for use by humans which is any of the following:

(a) Is a habit-forming drug to which section 126.10, subsection 1, paragraph *"d"* applies.

(b) Because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer the drug.

(c) Is limited by an approved application under section 505 of the federal Act to use under the professional supervision of a practitioner licensed by law to administer the drug.

(2) Such a drug shall be dispensed only upon a written, electronic, or facsimile prescription of a practitioner licensed by law to administer the drug, or upon an oral prescription of such a practitioner which is reduced promptly to writing and filed by the pharmacist, or by refilling any such written, electronic, facsimile, or oral prescription if the refilling is authorized by the prescriber either in the original written, electronic, or facsimile prescription or by oral order which is reduced promptly to writing and filed by the pharmacist. The act of dispensing a drug contrary to this paragraph *"a"* while the drug is held for sale results in the drug being misbranded.

b. A drug dispensed by filling or refilling a written, electronic, facsimile, or oral prescription of a practitioner licensed by law to administer the drug is exempt from section 126.10, except subsection 1, paragraph *"a"* and paragraph *"i"*, subparagraphs (2) and (3), and subsection 1, paragraphs *"k"* and *"l"*, and the packaging requirements of subsection 1, paragraphs *"g"*, *"h"*, and *"p"*, if the drug bears a label containing the name and address of the dispenser, the date of the prescription or of its filling, the name of the prescriber, and, if stated in the prescription, the name of the patient, and the directions for use and cautionary statements, if any, contained in the prescription. This exemption does not apply to a drug dispensed in the course of the conduct of the business of dispensing drugs pursuant to diagnosis by mail, or to a drug dispensed in violation of paragraph *"a"* of this subsection.

c. The board may, by rule, remove a drug subject to section 126.10, subsection 1, paragraph *"d"*, and section 505 of the federal Act from the requirements of paragraph *"a"* of this subsection when such requirements are not necessary for the protection of the public health.

d. A drug which is subject to paragraph *"a"* of this subsection is misbranded if, at any time prior to dispensing, its label fails to bear the statement: "Caution: Federal Law Prohibits Dispensing Without Prescription", or "Caution: State Law Prohibits Dispensing Without Prescription". A drug to which paragraph *"a"* of this subsection does not apply is misbranded if, at any time prior to dispensing, its label bears the caution statement quoted in the preceding sentence.

e. Prescription drug samples dispensed by a practitioner licensed by law to administer such drugs are exempt from section 126.10.

f. All electronic or facsimile prescriptions transmitted under this section shall comply with section 155A.27.

89 Acts, ch 197, §11
CS89, §203B.11
C93, §126.11
2004 Acts, ch 1036, §5 – 7; 2009 Acts, ch 41, §190