### FIRST REGULAR SESSION

#### HOUSE COMMITTEE SUBSTITUTE FOR

# SENATE BILL NO. 284

## 96TH GENERAL ASSEMBLY

1412L.04C D. ADAM CRUMBLISS, Chief Clerk

### AN ACT

To repeal sections 144.030, 338.055, and 338.330, RSMo, and to enact in lieu thereof three new sections relating to pharmacy, with an emergency clause for a certain section.

Be it enacted by the General Assembly of the state of Missouri, as follows:

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Section A. Sections 144.030, 338.055, and 338.330, RSMo, are repealed and three new sections enacted in lieu thereof, to be known as sections 144.030, 338.055, and 338.330, to read as follows:

144.030. 1. There is hereby specifically exempted from the provisions of sections 144.010 to 144.525 and from the computation of the tax levied, assessed or payable pursuant to sections 144.010 to 144.525 such retail sales as may be made in commerce between this state and any other state of the United States, or between this state and any foreign country, and any retail sale which the state of Missouri is prohibited from taxing pursuant to the Constitution or laws of the United States of America, and such retail sales of tangible personal property which the general assembly of the state of Missouri is prohibited from taxing or further taxing by the constitution of this state.

- 2. There are also specifically exempted from the provisions of the local sales tax law as defined in section 32.085, section 238.235, and sections 144.010 to 144.525 and 144.600 to 144.761 and from the computation of the tax levied, assessed or payable pursuant to the local sales tax law as defined in section 32.085, section 238.235, and sections 144.010 to 144.525 and 144.600 to 144.745:
- (1) Motor fuel or special fuel subject to an excise tax of this state, unless all or part of such excise tax is refunded pursuant to section 142.824; or upon the sale at retail of fuel to be consumed in manufacturing or creating gas, power, steam, electrical current or in furnishing water to be sold ultimately at retail; or feed for livestock or poultry; or grain to be converted into

EXPLANATION — Matter enclosed in bold-faced brackets [thus] in the above bill is not enacted and is intended to be omitted from the law. Matter in **bold-face** type in the above bill is proposed language.

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foodstuffs which are to be sold ultimately in processed form at retail; or seed, limestone or fertilizer which is to be used for seeding, liming or fertilizing crops which when harvested will be sold at retail or will be fed to livestock or poultry to be sold ultimately in processed form at retail; economic poisons registered pursuant to the provisions of the Missouri pesticide registration law (sections 281.220 to 281.310) which are to be used in connection with the growth or production of crops, fruit trees or orchards applied before, during, or after planting, the crop of which when harvested will be sold at retail or will be converted into foodstuffs which are to be sold ultimately in processed form at retail;

- (2) Materials, manufactured goods, machinery and parts which when used in manufacturing, processing, compounding, mining, producing or fabricating become a component part or ingredient of the new personal property resulting from such manufacturing, processing, compounding, mining, producing or fabricating and which new personal property is intended to be sold ultimately for final use or consumption; and materials, including without limitation, gases and manufactured goods, including without limitation slagging materials and firebrick, which are ultimately consumed in the manufacturing process by blending, reacting or interacting with or by becoming, in whole or in part, component parts or ingredients of steel products intended to be sold ultimately for final use or consumption;
- (3) Materials, replacement parts and equipment purchased for use directly upon, and for the repair and maintenance or manufacture of, motor vehicles, watercraft, railroad rolling stock or aircraft engaged as common carriers of persons or property;
- (4) Replacement machinery, equipment, and parts and the materials and supplies solely required for the installation or construction of such replacement machinery, equipment, and parts, used directly in manufacturing, mining, fabricating or producing a product which is intended to be sold ultimately for final use or consumption; and machinery and equipment, and the materials and supplies required solely for the operation, installation or construction of such machinery and equipment, purchased and used to establish new, or to replace or expand existing, material recovery processing plants in this state. For the purposes of this subdivision, a "material recovery processing plant" means a facility that has as its primary purpose the recovery of materials into a useable product or a different form which is used in producing a new product and shall include a facility or equipment which are used exclusively for the collection of recovered materials for delivery to a material recovery processing plant but shall not include motor vehicles used on highways. For purposes of this section, the terms motor vehicle and highway shall have the same meaning pursuant to section 301.010. Material recovery is not the reuse of materials within a manufacturing process or the use of a product previously recovered. The material recovery processing plant shall qualify under the provisions of this section regardless of ownership of the material being recovered;

(5) Machinery and equipment, and parts and the materials and supplies solely required for the installation or construction of such machinery and equipment, purchased and used to establish new or to expand existing manufacturing, mining or fabricating plants in the state if such machinery and equipment is used directly in manufacturing, mining or fabricating a product which is intended to be sold ultimately for final use or consumption;

- (6) Tangible personal property which is used exclusively in the manufacturing, processing, modification or assembling of products sold to the United States government or to any agency of the United States government;
  - (7) Animals or poultry used for breeding or feeding purposes;
- (8) Newsprint, ink, computers, photosensitive paper and film, toner, printing plates and other machinery, equipment, replacement parts and supplies used in producing newspapers published for dissemination of news to the general public;
- (9) The rentals of films, records or any type of sound or picture transcriptions for public commercial display;
- (10) Pumping machinery and equipment used to propel products delivered by pipelines engaged as common carriers;
- (11) Railroad rolling stock for use in transporting persons or property in interstate commerce and motor vehicles licensed for a gross weight of twenty-four thousand pounds or more or trailers used by common carriers, as defined in section 390.020, in the transportation of persons or property;
- (12) Electrical energy used in the actual primary manufacture, processing, compounding, mining or producing of a product, or electrical energy used in the actual secondary processing or fabricating of the product, or a material recovery processing plant as defined in subdivision (4) of this subsection, in facilities owned or leased by the taxpayer, if the total cost of electrical energy so used exceeds ten percent of the total cost of production, either primary or secondary, exclusive of the cost of electrical energy so used or if the raw materials used in such processing contain at least twenty-five percent recovered materials as defined in section 260.200. There shall be a rebuttable presumption that the raw materials used in the primary manufacture of automobiles contain at least twenty-five percent recovered materials. For purposes of this subdivision, "processing" means any mode of treatment, act or series of acts performed upon materials to transform and reduce them to a different state or thing, including treatment necessary to maintain or preserve such processing by the producer at the production facility;
- (13) Anodes which are used or consumed in manufacturing, processing, compounding, mining, producing or fabricating and which have a useful life of less than one year;
- (14) Machinery, equipment, appliances and devices purchased or leased and used solely for the purpose of preventing, abating or monitoring air pollution, and materials and supplies

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solely required for the installation, construction or reconstruction of such machinery, equipment,appliances and devices;

- (15) Machinery, equipment, appliances and devices purchased or leased and used solely for the purpose of preventing, abating or monitoring water pollution, and materials and supplies solely required for the installation, construction or reconstruction of such machinery, equipment, appliances and devices;
  - (16) Tangible personal property purchased by a rural water district;
- (17) All amounts paid or charged for admission or participation or other fees paid by or other charges to individuals in or for any place of amusement, entertainment or recreation, games or athletic events, including museums, fairs, zoos and planetariums, owned or operated by a municipality or other political subdivision where all the proceeds derived therefrom benefit the municipality or other political subdivision and do not inure to any private person, firm, or corporation;
- (18) All sales of insulin, diabetic accessories and supplies including, but not limited to, blood sugar testing monitors and test strips, lancet devices, lancets, and blood sugar control solutions, and prosthetic or orthopedic devices as defined on January 1, 1980, by the federal Medicare program pursuant to Title XVIII of the Social Security Act of 1965, including the items specified in Section 1862(a)(12) of that act, and also specifically including hearing aids and hearing aid supplies and all sales of drugs which may be legally dispensed by a licensed pharmacist only upon a lawful prescription of a practitioner licensed to administer those items, including samples and materials used to manufacture samples which may be dispensed by a practitioner authorized to dispense such samples and all sales or rental of medical oxygen, home respiratory equipment and accessories, hospital beds and accessories and ambulatory aids, all sales or rental of manual and powered wheelchairs, stairway lifts, Braille writers, electronic Braille equipment and, if purchased or rented by or on behalf of a person with one or more physical or mental disabilities to enable them to function more independently, all sales or rental of scooters, reading machines, electronic print enlargers and magnifiers, electronic alternative and augmentative communication devices, and items used solely to modify motor vehicles to permit the use of such motor vehicles by individuals with disabilities or sales of over-the-counter or nonprescription drugs [to individuals with disabilities] as prescribed by a practitioner, or any medical equipment, supplies, or devices that are provided to a person on or by the order of a physician, or that are otherwise paid for by a third-party health insurer, Medicare, or Medicaid;
- (19) All sales made by or to religious and charitable organizations and institutions in their religious, charitable or educational functions and activities and all sales made by or to all

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elementary and secondary schools operated at public expense in their educational functions and activities;

(20) All sales of aircraft to common carriers for storage or for use in interstate commerce and all sales made by or to not-for-profit civic, social, service or fraternal organizations, including fraternal organizations which have been declared tax-exempt organizations pursuant to Section 501(c)(8) or (10) of the 1986 Internal Revenue Code, as amended, in their civic or charitable functions and activities and all sales made to eleemosynary and penal institutions and industries of the state, and all sales made to any private not-for-profit institution of higher education not otherwise excluded pursuant to subdivision (19) of this subsection or any institution of higher education supported by public funds, and all sales made to a state relief agency in the exercise of relief functions and activities;

(21) All ticket sales made by benevolent, scientific and educational associations which are formed to foster, encourage, and promote progress and improvement in the science of agriculture and in the raising and breeding of animals, and by nonprofit summer theater organizations if such organizations are exempt from federal tax pursuant to the provisions of the Internal Revenue Code and all admission charges and entry fees to the Missouri state fair or any fair conducted by a county agricultural and mechanical society organized and operated pursuant to sections 262.290 to 262.530;

(22) All sales made to any private not-for-profit elementary or secondary school, all sales of feed additives, medications or vaccines administered to livestock or poultry in the production of food or fiber, all sales of pesticides used in the production of crops, livestock or poultry for food or fiber, all sales of bedding used in the production of livestock or poultry for food or fiber, all sales of propane or natural gas, electricity or diesel fuel used exclusively for drying agricultural crops, natural gas used in the primary manufacture or processing of fuel ethanol as defined in section 142.028, natural gas, propane, and electricity used by an eligible new generation cooperative or an eligible new generation processing entity as defined in section 348.432, and all sales of farm machinery and equipment, other than airplanes, motor vehicles and trailers. As used in this subdivision, the term "feed additives" means tangible personal property which, when mixed with feed for livestock or poultry, is to be used in the feeding of livestock or poultry. As used in this subdivision, the term "pesticides" includes adjuvants such as crop oils, surfactants, wetting agents and other assorted pesticide carriers used to improve or enhance the effect of a pesticide and the foam used to mark the application of pesticides and herbicides for the production of crops, livestock or poultry. As used in this subdivision, the term "farm machinery and equipment" means new or used farm tractors and such other new or used farm machinery and equipment and repair or replacement parts thereon, and supplies and lubricants used exclusively, solely, and directly for producing crops, raising and feeding livestock, fish,

poultry, pheasants, chukar, quail, or for producing milk for ultimate sale at retail, including field drain tile, and one-half of each purchaser's purchase of diesel fuel therefor which is:

- (a) Used exclusively for agricultural purposes;
- (b) Used on land owned or leased for the purpose of producing farm products; and
- (c) Used directly in producing farm products to be sold ultimately in processed form or otherwise at retail or in producing farm products to be fed to livestock or poultry to be sold ultimately in processed form at retail;
- (23) Except as otherwise provided in section 144.032, all sales of metered water service, electricity, electrical current, natural, artificial or propane gas, wood, coal or home heating oil for domestic use and in any city not within a county, all sales of metered or unmetered water service for domestic use:
- (a) "Domestic use" means that portion of metered water service, electricity, electrical current, natural, artificial or propane gas, wood, coal or home heating oil, and in any city not within a county, metered or unmetered water service, which an individual occupant of a residential premises uses for nonbusiness, noncommercial or nonindustrial purposes. Utility service through a single or master meter for residential apartments or condominiums, including service for common areas and facilities and vacant units, shall be deemed to be for domestic use. Each seller shall establish and maintain a system whereby individual purchases are determined as exempt or nonexempt;
- (b) Regulated utility sellers shall determine whether individual purchases are exempt or nonexempt based upon the seller's utility service rate classifications as contained in tariffs on file with and approved by the Missouri public service commission. Sales and purchases made pursuant to the rate classification "residential" and sales to and purchases made by or on behalf of the occupants of residential apartments or condominiums through a single or master meter, including service for common areas and facilities and vacant units, shall be considered as sales made for domestic use and such sales shall be exempt from sales tax. Sellers shall charge sales tax upon the entire amount of purchases classified as nondomestic use. The seller's utility service rate classification and the provision of service thereunder shall be conclusive as to whether or not the utility must charge sales tax;
- (c) Each person making domestic use purchases of services or property and who uses any portion of the services or property so purchased for a nondomestic use shall, by the fifteenth day of the fourth month following the year of purchase, and without assessment, notice or demand, file a return and pay sales tax on that portion of nondomestic purchases. Each person making nondomestic purchases of services or property and who uses any portion of the services or property so purchased for domestic use, and each person making domestic purchases on behalf of occupants of residential apartments or condominiums through a single or master meter,

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including service for common areas and facilities and vacant units, under a nonresidential utility service rate classification may, between the first day of the first month and the fifteenth day of the fourth month following the year of purchase, apply for credit or refund to the director of revenue and the director shall give credit or make refund for taxes paid on the domestic use portion of the purchase. The person making such purchases on behalf of occupants of residential apartments or condominiums shall have standing to apply to the director of revenue for such credit or refund;

- (24) All sales of handicraft items made by the seller or the seller's spouse if the seller or the seller's spouse is at least sixty-five years of age, and if the total gross proceeds from such sales do not constitute a majority of the annual gross income of the seller;
- (25) Excise taxes, collected on sales at retail, imposed by Sections 4041, 4061, 4071, 4081, 4091, 4161, 4181, 4251, 4261 and 4271 of Title 26, United States Code. The director of revenue shall promulgate rules pursuant to chapter 536 to eliminate all state and local sales taxes on such excise taxes;
- (26) Sales of fuel consumed or used in the operation of ships, barges, or waterborne vessels which are used primarily in or for the transportation of property or cargo, or the conveyance of persons for hire, on navigable rivers bordering on or located in part in this state, if such fuel is delivered by the seller to the purchaser's barge, ship, or waterborne vessel while it is afloat upon such river;
- (27) All sales made to an interstate compact agency created pursuant to sections 70.370 to 70.441 or sections 238.010 to 238.100 in the exercise of the functions and activities of such agency as provided pursuant to the compact;
- (28) Computers, computer software and computer security systems purchased for use by architectural or engineering firms headquartered in this state. For the purposes of this subdivision, "headquartered in this state" means the office for the administrative management of at least four integrated facilities operated by the taxpayer is located in the state of Missouri;
- (29) All livestock sales when either the seller is engaged in the growing, producing or feeding of such livestock, or the seller is engaged in the business of buying and selling, bartering or leasing of such livestock;
- (30) All sales of barges which are to be used primarily in the transportation of property or cargo on interstate waterways;
- 228 (31) Electrical energy or gas, whether natural, artificial or propane, water, or other 229 utilities which are ultimately consumed in connection with the manufacturing of cellular glass 230 products or in any material recovery processing plant as defined in subdivision (4) of this 231 subsection;

- 232 (32) Notwithstanding other provisions of law to the contrary, all sales of pesticides or 233 herbicides used in the production of crops, aquaculture, livestock or poultry;
  - (33) Tangible personal property and utilities purchased for use or consumption directly or exclusively in the research and development of agricultural/biotechnology and plant genomics products and prescription pharmaceuticals consumed by humans or animals;
    - (34) All sales of grain bins for storage of grain for resale;
  - (35) All sales of feed which are developed for and used in the feeding of pets owned by a commercial breeder when such sales are made to a commercial breeder, as defined in section 273.325, and licensed pursuant to sections 273.325 to 273.357;
  - (36) All purchases by a contractor on behalf of an entity located in another state, provided that the entity is authorized to issue a certificate of exemption for purchases to a contractor under the provisions of that state's laws. For purposes of this subdivision, the term "certificate of exemption" shall mean any document evidencing that the entity is exempt from sales and use taxes on purchases pursuant to the laws of the state in which the entity is located. Any contractor making purchases on behalf of such entity shall maintain a copy of the entity's exemption certificate as evidence of the exemption. If the exemption certificate issued by the exempt entity to the contractor is later determined by the director of revenue to be invalid for any reason and the contractor has accepted the certificate in good faith, neither the contractor or the exempt entity shall be liable for the payment of any taxes, interest and penalty due as the result of use of the invalid exemption certificate. Materials shall be exempt from all state and local sales and use taxes when purchased by a contractor for the purpose of fabricating tangible personal property which is used in fulfilling a contract for the purpose of constructing, repairing or remodeling facilities for the following:
  - (a) An exempt entity located in this state, if the entity is one of those entities able to issue project exemption certificates in accordance with the provisions of section 144.062; or
  - (b) An exempt entity located outside the state if the exempt entity is authorized to issue an exemption certificate to contractors in accordance with the provisions of that state's law and the applicable provisions of this section;
  - (37) All sales or other transfers of tangible personal property to a lessor who leases the property under a lease of one year or longer executed or in effect at the time of the sale or other transfer to an interstate compact agency created pursuant to sections 70.370 to 70.441 or sections 238.010 to 238.100;
  - (38) Sales of tickets to any collegiate athletic championship event that is held in a facility owned or operated by a governmental authority or commission, a quasi-governmental agency, a state university or college or by the state or any political subdivision thereof, including a municipality, and that is played on a neutral site and may reasonably be played at a site located

outside the state of Missouri. For purposes of this subdivision, "neutral site" means any site that is not located on the campus of a conference member institution participating in the event;

- (39) All purchases by a sports complex authority created under section 64.920, and all sales of utilities by such authority at the authority's cost that are consumed in connection with the operation of a sports complex leased to a professional sports team;
- (40) Beginning January 1, 2009, but not after January 1, 2015, materials, replacement parts, and equipment purchased for use directly upon, and for the modification, replacement, repair, and maintenance of aircraft, aircraft power plants, and aircraft accessories;
- (41) Sales of sporting clays, wobble, skeet, and trap targets to any shooting range or similar places of business for use in the normal course of business and money received by a shooting range or similar places of business from patrons and held by a shooting range or similar place of business for redistribution to patrons at the conclusion of a shooting event.
- 338.055. 1. The board may refuse to issue any certificate of registration or authority, permit or license required pursuant to this chapter for one or any combination of causes stated in subsection 2 of this section or if the designated pharmacist-in-charge, manager-in-charge, or any officer, owner, manager, or controlling shareholder of the applicant has committed any act or practice in subsection 2 of this section. The board shall notify the applicant in writing of the reasons for the refusal and shall advise the applicant of his or her right to file a complaint with the administrative hearing commission as provided by chapter 621.
- 2. The board may cause a complaint to be filed with the administrative hearing commission as provided by chapter 621 against any holder of any certificate of registration or authority, permit or license required by this chapter or any person who has failed to renew or has surrendered his or her certificate of registration or authority, permit or license for any one or any combination of the following causes:
- (1) Use of any controlled substance, as defined in chapter 195, or alcoholic beverage to an extent that such use impairs a person's ability to perform the work of any profession licensed or regulated by this chapter;
- (2) The person has been finally adjudicated and found guilty, or entered a plea of guilty or nolo contendere, in a criminal prosecution under the laws of any state or of the United States, for any offense reasonably related to the qualifications, functions or duties of any profession licensed or regulated under this chapter, for any offense an essential element of which is fraud, dishonesty or an act of violence, or for any offense involving moral turpitude, whether or not sentence is imposed;
- (3) Use of fraud, deception, misrepresentation or bribery in securing any certificate of registration or authority, permit or license issued pursuant to this chapter or in obtaining permission to take any examination given or required pursuant to this chapter;

25 (4) Obtaining or attempting to obtain any fee, charge, tuition or other compensation by fraud, deception or misrepresentation;

- (5) Incompetence, misconduct, gross negligence, fraud, misrepresentation or dishonesty in the performance of the functions or duties of any profession licensed or regulated by this chapter;
- (6) Violation of, or assisting or enabling any person to violate, any provision of this chapter, or of any lawful rule or regulation adopted pursuant to this chapter;
- (7) Impersonation of any person holding a certificate of registration or authority, permit or license or allowing any person to use his or her certificate of registration or authority, permit, license, or diploma from any school;
- (8) Denial of licensure to an applicant or disciplinary action against an applicant or the holder of a license or other right to practice any profession regulated by this chapter granted by another state, territory, federal agency, or country whether or not voluntarily agreed to by the licensee or applicant, including, but not limited to, surrender of the license upon grounds for which denial or discipline is authorized in this state;
  - (9) A person is finally adjudged incapacitated by a court of competent jurisdiction;
- (10) Assisting or enabling any person to practice or offer to practice any profession licensed or regulated by this chapter who is not registered and currently eligible to practice under this chapter;
- (11) Issuance of a certificate of registration or authority, permit or license based upon a material mistake of fact;
- (12) Failure to display a valid certificate or license if so required by this chapter or any rule promulgated hereunder;
  - (13) Violation of any professional trust or confidence;
- (14) Use of any advertisement or solicitation which is false, misleading or deceptive to the general public or persons to whom the advertisement or solicitation is primarily directed;
- (15) Violation of the drug laws or rules and regulations of this state, any other state or the federal government;
- (16) The intentional act of substituting or otherwise changing the content, formula or brand of any drug prescribed by written or oral prescription without prior written or oral approval from the prescriber for the respective change in each prescription; provided, however, that nothing contained herein shall prohibit a pharmacist from substituting or changing the brand of any drug as provided under section 338.056, and any such substituting or changing of the brand of any drug as provided for in section 338.056 shall not be deemed unprofessional or dishonorable conduct unless a violation of section 338.056 occurs;

- 60 (17) Personal use or consumption of any controlled substance unless it is prescribed, 61 dispensed, or administered by a health care provider who is authorized by law to do so.
  - 3. After the filing of such complaint, the proceedings shall be conducted in accordance with the provisions of chapter 621. Upon a finding by the administrative hearing commission that the grounds, provided in subsection 2 of this section, for disciplinary action are met, the board may, singly or in combination, censure or place the person named in the complaint on probation on such terms and conditions as the board deems appropriate for a period not to exceed five years, or may suspend, for a period not to exceed three years, or revoke the license, certificate, or permit. The board may impose additional discipline on a licensee, registrant, or permittee found to have violated any disciplinary terms previously imposed under this section or by agreement. The additional discipline may include, singly or in combination, censure, placing the licensee, registrant, or permittee named in the complaint on additional probation on such terms and conditions as the board deems appropriate, which additional probation shall not exceed five years, or suspension for a period not to exceed three years, or revocation of the license, certificate, or permit.
  - 4. If the board concludes that a licensee or registrant has committed an act or is engaging in a course of conduct which would be grounds for disciplinary action which constitutes a clear and present danger to the public health and safety, the board may file a complaint before the administrative hearing commission requesting an expedited hearing and specifying the activities which give rise to the danger and the nature of the proposed restriction or suspension of the licensee's or registrant's license.
  - Within fifteen days after service of the complaint on the licensee or registrant, the administrative hearing commission shall conduct a preliminary hearing to determine whether the alleged activities of the licensee or registrant appear to constitute a clear and present danger to the public health and safety which justify that the licensee's or registrant's license or registration be immediately restricted or suspended. The burden of proving that the actions of a licensee or registrant constitute a clear and present danger to the public health and safety shall be upon the state board of pharmacy. The administrative hearing commission shall issue its decision immediately after the hearing and shall either grant to the board the authority to suspend or restrict the license or dismiss the action.
  - 5. If the administrative hearing commission grants temporary authority to the board to restrict or suspend the licensee's or registrant's license, such temporary authority of the board shall become final authority if there is no request by the licensee or registrant for a full hearing within thirty days of the preliminary hearing. The administrative hearing commission shall, if requested by the licensee or registrant named in the complaint, set a date to hold a full hearing

under the provisions of chapter 621 regarding the activities alleged in the initial complaint filedby the board.

- 6. If the administrative hearing commission dismisses the action filed by the board pursuant to subsection 4 of this section, such dismissal shall not bar the board from initiating a subsequent action on the same grounds.
  - 338.330. As used in sections 338.300 to 338.370, the following terms mean:
- 2 (1) "Legend drug", any drug or biological product;
  - (a) Subject to section 503(b) of the Federal Food, Drug and Cosmetic Act, including finished dosage forms and active ingredients subject to section 503(b); or
  - (b) Required under federal law to be labeled with one of the following statements prior to being dispensed or delivered:
    - a. "Caution: Federal law prohibits dispensing without prescription";
- 8 **b.** "Caution: Federal law restricts this drug to use by or on the order of a licensed 9 veterinarian";
  - c. "Rx Only"; or

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- (c) Required by an applicable federal or state law or regulation to be dispensed by prescription only or that is restricted to use by practitioners only; and
  - (d) The term "drug", "prescription drug", or "legend drug" shall not include:
- a. An investigational new drug, as defined by 21 CFR 312.3(b), that is being utilized for the purposes of conducting a clinical investigation of that drug or product that is governed by, and being conducted pursuant to, 21 CFR 312, et. seq.;
- b. Any drug product being utilized for the purposes of conducting a clinical investigation that is governed by, and being conducted pursuant to, 21 CFR 312, et. seq.; or
  - c. Any drug product being utilized for the purposes of conducting a clinical investigation that is governed or approved by an institutional review board subject to 21 CFR Part 56 or 45 CFR Part 46;
- 23 **(2)** "Out-of-state wholesale drug distributor", a wholesale drug distributor with no physical facilities located in the state;
  - [(2)] (3) "Pharmacy distributor", any licensed pharmacy, as defined in section 338.210, engaged in the delivery or distribution of legend drugs to any other licensed pharmacy where such delivery or distribution constitutes at least five percent of the total gross sales of such pharmacy;
  - [(3)] (4) "Wholesale drug distributor", anyone engaged in the delivery or distribution of legend drugs from any location and who is involved in the actual, constructive or attempted transfer of a drug or drug-related device in this state, other than to the ultimate consumer. This

shall include, but not be limited to, drug wholesalers, repackagers and manufacturers which are engaged in the delivery or distribution of drugs in this state, with facilities located in this state or in any other state or jurisdiction. A wholesale drug distributor shall not include any common carrier or individual hired solely to transport legend drugs. Any locations where drugs are delivered on a consignment basis, as defined by the board, shall be exempt from licensure as a drug distributor, and those standards of practice required of a drug distributor but shall be open for inspection by board of pharmacy representatives as provided for in section 338.360.

Section B. Because immediate action is necessary to ensure the continuance of clinical trials in this state, the repeal and reenactment of section 338.330 of section A of this act is deemed necessary for the immediate preservation of the public health, welfare, peace, and safety, and is hereby declared to be an emergency act within the meaning of the constitution, and the repeal and reenactment of section 338.330 of section A of this act shall be in full force and effect upon its passage and approval.

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