126.18 Inspections.

1. *a.* For purposes of enforcement of this chapter, the board or any of its authorized agents, upon presenting appropriate credentials to the owner, operator, or agent in charge, may do both of the following:

(1) Enter at reasonable times any factory, warehouse, or other establishment in which drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into commerce or after such introduction; or enter a vehicle being used to transport or hold drugs, devices, or cosmetics in commerce.

(2) Inspect at reasonable times and within reasonable limits and in a reasonable manner such a factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein, and obtain samples necessary to the enforcement of this chapter. In the case of a factory, warehouse, establishment, or consulting laboratory in which prescription drugs are manufactured, processed, packed, or held, the inspection shall extend to all things therein, including records, files, papers, processes, controls, and facilities, bearing on whether prescription drugs or restricted devices which are adulterated or misbranded or which may not be manufactured, introduced into commerce, or sold or offered for sale by reason of any provision of this chapter, have been or are being manufactured, processed, packed, transported, or held in violation of or bearing on a violation of this chapter. An inspection authorized for prescription drugs by the preceding sentence shall not extend to financial data, sales data other than shipment data, pricing data, personnel data other than data as to qualifications of technical and professional personnel performing functions subject to this chapter, and research data other than data relating to new drugs, and antibiotic drugs, and devices, and subject to reporting and inspection under regulations lawfully issued pursuant to section 505(i) or 505(j), or section 507(d) or 507(g), section 519, or section 520(g) of the federal Act, and data, relating to other drugs, or devices which in the case of a new drug would be subject to reporting or inspection under lawful regulations issued pursuant to section 505(j) of the federal Act. The inspection shall be commenced and completed with reasonable promptness.

b. Paragraph *"a"* does not apply to any of the following:

(1) Pharmacies which maintain establishments in conformance with laws of this state regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs, or devices, upon prescription of practitioners licensed to administer the drugs or devices to patients under the care of the practitioners in the course of their professional practice, and which do not, either through a subsidiary or otherwise, manufacture, prepare, propagate, compound, or process drugs or devices for sale other than in the regular course of their business of dispensing or selling drugs or devices at retail.

(2) Practitioners licensed by law to prescribe or administer drugs or prescribe or use devices, and who manufacture, prepare, propagate, compound, or process drugs, or manufacture or process devices solely for use in the course of their professional practice.

(3) Persons who manufacture, prepare, propagate, compound, or process drugs, or manufacture or process devices solely for use in research, teaching, or chemical analysis and not for sale.

(4) Duly employed sales representatives of pharmaceutical companies acting in the normal and customary performance of their duties.

(5) Other classes of persons the board exempts from the application of this section by rule upon a finding that inspection as applied to such classes of persons in accordance with this section is not necessary for the protection of the public health.

2. *a.* Upon completion of an inspection of a factory, warehouse, consulting laboratory, or other establishment and prior to leaving the premises, the authorized agent making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by the authorized agent which, in the judgment of the authorized agent, indicate that any drug, device, or cosmetic in the establishment meets either of the following:

(1) Consists in whole or in part of a filthy, putrid, or decomposed substance.

(2) Has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

b. A copy of the report shall be sent promptly to the board.

3. If the authorized agent making an inspection of a factory, warehouse, or other establishment has obtained a sample in the course of the inspection, upon completion of the inspection and prior to leaving the premises the authorized agent shall give to the owner, operator, or agent in charge a receipt describing the sample obtained.

4. A person required under this chapter or section 519 or 520(g) of the federal Act to maintain records and a person who is in charge or custody of such records shall, upon request of an authorized agent designated by the board, permit the authorized agent at all reasonable times to have access and to copy and verify such records.

5. For the purposes of enforcing this chapter, carriers engaged in commerce, and persons receiving drugs, devices, or cosmetics in commerce or holding such articles so received, shall, upon the request of a duly authorized agent of the board, permit the agent, at reasonable times, to have access to and to copy all records showing the movement in commerce of a drug, device, or cosmetic, or the holding thereof during or after such movement, and the quantity, shipper, and consignee thereof. It is unlawful for any such carrier or person to fail to permit such access to and copying of any such record so requested when the request is accompanied by a statement in writing specifying the nature or kind of drug, device, or cosmetic to which the request relates.

6. Evidence obtained under this section or evidence which is directly or indirectly derived from such evidence obtained under this section, shall not be used in a criminal prosecution of the person from whom the evidence was obtained; and carriers are not subject to the other provisions of this chapter by reason of their receipt, carriage, holding, or delivery of drugs, devices, or cosmetics in the usual course of business as carriers.

89 Acts, ch 197, §17
CS89, §203B.18
C93, §126.18
2009 Acts, ch 41, §263
Referred to in §126.3