PA 18-16—sSB 195
General Law Committee

AN ACT CONCERNING CHANGES TO PHARMACY AND DRUG CONTROL STATUTES

S**UMMARY:** This act makes the following changes in laws concerning pharmacies, pharmacists, and controlled substances:

1. specifies that the Pharmacy Commission's civil penalties of up to $1,000 for violations of pharmacy practice laws may be assessed per violation (§ 1);
2. extends to nonresident pharmacies the same fees and deadlines that apply to resident pharmacies when they notify the Department of Consumer Protection (DCP) of a change in officers, directors, name, ownership, or management (§ 2);
3. requires DCP-registered drug manufacturers and wholesalers to identify and report suspicious controlled substance orders to the department's Drug Control Division (§ 3);
4. requires specified individuals and entities manufacturing, distributing, administering, dispensing, or having custody of controlled substances to conduct a controlled substances inventory annually, rather than biennially (§ 4);
5. requires retail and institutional pharmacies to maintain a perpetual inventory of schedule II controlled substances (e.g., methadone, morphine, and oxycodone) (§ 5); and
6. makes a technical change updating a statutory reference to the United States Pharmacopeia's provisions on preparing compounded sterile drugs (§ 6).

EFFECTIVE DATE: January 1, 2019

§ 2 — FEES FOR NONRESIDENT PHARMACIES

The act extends to nonresident pharmacies the same fees and deadlines that apply to resident pharmacies when they notify DCP of a change in officers, directors, name, ownership, or management. Under the act, nonresident pharmacies must notify DCP within 10 days of a change in their officers, directors, name, ownership, or management. The fee for notice of a change to officers or directors is $60 and the fee for notice of a change in name, ownership, or management is $90. Pharmacies that do not submit this information within 10 days of the change must pay an additional $50 late fee. (PA 18-141 § 11, also requires nonresident pharmacies to notify DCP within these deadlines and pay filing fees.)

By law, nonresident pharmacies are pharmacies that are not located in Connecticut but ship, mail, or deliver prescription drugs or devices to Connecticut residents (CGS § 20-627).

§ 3 — REPORTING SUSPICIOUS ORDERS

The act requires DCP-registered drug manufacturers and wholesalers to operate a system to identify suspicious controlled substance orders. When they identify such orders, the manufacturers and wholesalers must immediately inform the director of DCP's Drug Control Division.

The act also requires these manufacturers and wholesalers to send the Drug Control Division a copy of any suspicious order report that they submit to the federal Drug Enforcement Administration. Federal law requires such reporting by people that manufacture, distribute, dispense, import, or export controlled substances, or seek to do so. Under the act and federal law, "suspicious orders" include orders that are of an unusual size or frequency or deviate substantially from a normal pattern.

The act extends existing penalties for violations of drug manufacturer and wholesaler registration requirements to reporting violations. As under existing law, violators are subject to a fine of up to $500, imprisonment of up to six months, or both.

§ 4 — CONTROLLED SUBSTANCES RECORDKEEPING

The act requires annual, rather than biennial, inventories of controlled substances by (1) prescribing practitioners, (e.g., physicians, physician assistants, advanced practice registered nurses, dentists, veterinarians, and certain scientific investigators); (2) drug manufacturers and wholesalers; and (3) certain healthcare institutions, including pharmacies, certain hospitals and nursing homes, clinics, infirmaries, freestanding ambulatory surgical centers, and laboratories.

The act also eliminates a provision that allows such individuals and entities to be deemed compliant with state controlled substances recordkeeping requirements if they comply with substantially similar federal requirements.

§ 5 — PERPETUAL INVENTORY OF SCHEDULE II DRUGS

The act requires retail and institutional pharmacies to maintain a perpetual inventory of schedule II controlled substances. The inventory records must be:

1. kept on the pharmacy's premises and maintained in an orderly manner separate from other records,
2. filed by date,
3. retained for at least three years, and
4. made immediately available for inspection and copying by the DCP commissioner or her representative or other authorized inspectors, pursuant to existing prescription inspection procedures.

Under the act, perpetual inventories must be reconciled on a monthly basis. Any discovered controlled substance loss, theft, or unauthorized destruction must

be reported to the DCP commissioner within 72 hours.

The act allows the DCP commissioner to adopt regulations to implement the perpetual inventory requirements.