General Assembly

Governor's Bill No. 7159

January Session, 2019

LCO No. **4550**

Referred to Committee on GENERAL LAW

Introduced by:
REP. ARESIMOWICZ, 30th Dist.
REP. RITTER M., 1st Dist.
SEN. LOONEY, 11th Dist.
SEN. DUFF, 25th Dist.

AN ACT ADDRESSING OPIOID USE.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

Section 1. Section 20-614 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective October 1, 2019*):

(a) A prescription shall be transmitted in either an oral, written or electronic manner to a pharmacy.

(b) Whenever a pharmacy, or an institutional pharmacy in a hospital dispensing a drug or device for outpatient use or dispensing a drug or device that is prescribed for an employee of the hospital or for the employee's spouse or dependent children, receives an oral or electronically-transmitted prescription, except for a controlled drug, as defined in section 21a-240, a record of such prescription shall be maintained in writing or electronically. The pharmacist or pharmacy intern shall, not later than the end of the business day when the

prescription was received, record the prescription on a prescription form or in an electronic record including: (1) The name and address of the prescribing practitioner; (2) the date of the prescription; (3) the name, dosage form, strength, where applicable, and the amount of the drug prescribed; (4) the name and address of the patient or, for veterinary prescriptions, the name and address of the owner and the species of the animal; (5) the directions for use; (6) any required cautionary statements; and (7) the number of times the prescription may be refilled, including the use of refill terms "PRN" and "ad lib" in lieu of a specific number of authorized refills.

(c) A written prescription shall bear: (1) The written signature of the prescribing practitioner or shall comply with the requirements of section 19a-509c; (2) the address of the practitioner; (3) the date of the prescription; (4) the name, dosage form, strength, where applicable, and amount of the drug prescribed; (5) the name and address of the patient or, for veterinary prescriptions, the name and address of the owner and the species of the animal; (6) the directions for use; (7) any required cautionary statements; and (8) the number of times the prescription may be refilled, including the use of refill terms "PRN" and "ad lib" in lieu of a specific number of authorized refills. No written prescription form for a schedule II substance may contain an order for any other legend drug or device.

(d) Prior to or simultaneous with the dispensing of a drug pursuant to subsection (b) of this section, a pharmacist shall, whenever practicable, offer, in person, to discuss the drug to be dispensed and to counsel the patient on the usage of the drug, except when the person obtaining the prescription is other than the person named on the prescription form or electronic record or the pharmacist determines it is appropriate to make such offer in writing. Any such written offer shall include an offer to communicate with the patient either in person at the pharmacy or by telephone.

(e) Nothing in this section shall be construed to require a pharmacist to provide counseling to a patient who refuses such counseling. The

pharmacist shall keep a record of such counseling, any refusal by or inability of the patient to accept counseling or a refusal by the patient to provide information regarding such counseling. Records kept pursuant to this subsection shall be maintained for the same length of time as prescription records are maintained pursuant to section 20-615.

[(d)**]** (f) (1) As used in this subsection, "electronic data intermediary" means an entity that provides the infrastructure that connects the computer systems or other electronic devices utilized by prescribing practitioners with those used by pharmacies in order to facilitate the secure transmission of electronic prescription orders, refill authorization requests, communications and other patient care information between such entities.

(2) An electronic data intermediary may transfer electronically transmitted data between a prescribing practitioner licensed and authorized to prescribe and a pharmacy of the patient's choice, licensed pursuant to this chapter or licensed under the laws of any other state or territory of the United States. Electronic data intermediaries shall not alter the transmitted data except as necessary for technical processing purposes. Electronic data intermediaries may archive copies of only that electronic data related to such transmissions necessary to provide for proper auditing and security of such transmissions. Such data shall only be maintained for the period necessary for auditing purposes. Electronic data intermediaries shall maintain patient privacy and confidentiality of all archived information as required by state and federal law.

(3) No electronic data intermediary shall operate without the approval of the Commissioner of Consumer Protection. An electronic data intermediary seeking approval shall apply to the Commission of Pharmacy in the manner prescribed by the commissioner. The commissioner, with the advice and assistance of the commission, shall adopt regulations, in accordance with the provisions of chapter 54, to establish criteria for the approval of electronic data intermediaries, to ensure that (A) procedures to be used for the transmission and

retention of prescription data by an intermediary, and (B) mechanisms to be used by an intermediary to safeguard the confidentiality of such data, are consistent with the provisions and purposes of this section.

Sec. 2. Section 20-612 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective October 1, 2019*):

Subject to the provisions of subsection **[**(d)**]** (f) of section 20-614, as amended by this act, only a pharmacy shall accept a prescription for dispensing. No employee, personnel or owner of a place of business or establishment not licensed as a pharmacy may accept a prescription for transfer to or for collection for a pharmacy.

Sec. 3. Subsection (j) of section 21a-254 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective from passage*):

(j) (1) The commissioner shall, within available appropriations, establish an electronic prescription drug monitoring program to collect, by electronic means, prescription information for schedules II, III, IV and V controlled substances that are dispensed by pharmacies, nonresident pharmacies, as defined in section 20-627, outpatient pharmacies in hospitals or institutions or by any other dispenser. The program shall be designed to provide information regarding the prescription of controlled substances in order to prevent the improper or illegal use of the controlled substances and shall not infringe on the legitimate prescribing of a controlled substance by a prescribing practitioner acting in good faith and in the course of professional practice.

(2) The commissioner may identify other products or substances to be included in the electronic prescription drug monitoring program established pursuant to subdivision (1) of this subsection.

(3) Prior to July 1, 2016, each pharmacy, nonresident pharmacy, as defined in section 20-627, outpatient pharmacy in a hospital or institution and dispenser shall report to the commissioner, at least

weekly, by electronic means or, if a pharmacy or outpatient pharmacy does not maintain records electronically, in a format approved by the commissioner, the following information for all controlled substance prescriptions dispensed by such pharmacy or outpatient pharmacy: (A) Dispenser identification number; (B) the date the prescription for the controlled substance was filled; (C) the prescription number; (D) whether the prescription for the controlled substance is new or a refill; (E) the national drug code number for the drug dispensed; (F) the amount of the controlled substance dispensed and the number of days' supply of the controlled substance; (G) a patient identification number; (H) the patient's first name, last name and street address, including postal code; (I) the date of birth of the patient; (J) the date the prescription for the controlled substance was issued by the prescribing practitioner and the prescribing practitioner's Drug Enforcement Agency's identification number; and (K) the type of payment.

(4) (A) Except as provided in this subdivision, on and after July 1, 2016, each pharmacy, nonresident pharmacy, as defined in section 20-627, outpatient pharmacy in a hospital or institution, and dispenser shall report to the commissioner by electronic means, in a format approved by the commissioner, the following information for all controlled substance prescriptions dispensed by such pharmacy or outpatient pharmacy immediately upon, but in no event later than the next business day after, dispensing such prescriptions: (i) Dispenser identification number; (ii) the date the prescription for the controlled substance was filled; (iii) the prescription number; (iv) whether the prescription for the controlled substance is new or a refill; (v) the national drug code number for the drug dispensed; (vi) the amount of the controlled substance dispensed and the number of days' supply of the controlled substance; (vii) a patient identification number; (viii) the patient's first name, last name and street address, including postal code; (ix) the date of birth of the patient; (x) the date the prescription for the controlled substance was issued by the prescribing practitioner and the prescribing practitioner's Drug Enforcement Agency's identification number; and (xi) the type of payment.

(B) If the electronic prescription drug monitoring program is not operational, such pharmacy or dispenser shall report the information described in this subdivision not later than the next business day after regaining access to such program. For purposes of this subdivision, "business day" means any day during which the pharmacy is open to the public.

(C) Each veterinarian, licensed pursuant to chapter 384, who dispenses a controlled substance prescription shall report to the commissioner the information described in subparagraph (A) of this subdivision, at least weekly, by electronic means or, if the veterinarian does not maintain records electronically, in a format approved by the commissioner.

(5) The commissioner may contract with a vendor for purposes of electronically collecting such controlled substance prescription information. The commissioner and any such vendor shall maintain the information in accordance with the provisions of chapter 400j.

(6) The commissioner and any such vendor shall not disclose controlled substance prescription information reported pursuant to subdivisions (3) and (4) of this subsection, except as authorized pursuant to the provisions of sections 21a-240 to 21a-283, inclusive. Any person who knowingly violates any provision of this subdivision or subdivision (5) of this subsection shall be guilty of a class D felony.

(7) The commissioner shall provide, upon request, controlled substance prescription information obtained in accordance with subdivisions (3) and (4) of this subsection to the following: (A) The prescribing practitioner or such practitioner's authorized agent, who is treating or has treated a specific patient, provided the information is obtained for purposes related to the treatment of the patient, including the monitoring of controlled substances obtained by the patient; (B) the prescribing practitioner with whom a patient has made contact for the purpose of seeking medical treatment or such practitioner's authorized agent, provided the request is accompanied by a written consent,

signed by the prospective patient, for the release of controlled substance prescription information; or (C) the pharmacist who is dispensing controlled substances for a patient, or such pharmacist's authorized pharmacy technician, provided the information is obtained for purposes related to the scope of the pharmacist's practice and management of the patient's drug therapy, including the monitoring of controlled substances obtained by the patient. The prescribing practitioner, such practitioner's authorized agent, **[**or**]** the pharmacist or such pharmacist's authorized pharmacy technician shall submit a written and signed request to the commissioner for controlled substance prescription information. Such prescribing practitioner**,** **[**or**]** pharmacist or pharmacist's authorized pharmacy technician shall not disclose any such request except as authorized pursuant to sections 20-570 to 20-630, inclusive, or sections 21a-240 to 21a-283, inclusive.

(8) No person or employer shall prohibit, discourage or impede a prescribing practitioner**,** **[**or**]** pharmacist or pharmacist's authorized pharmacy technician from requesting controlled substance prescription information pursuant to this subsection.

(9) Prior to prescribing greater than a seventy-two-hour supply of any controlled substance to any patient, the prescribing practitioner or such practitioner's authorized agent shall review the patient's records in the electronic prescription drug monitoring program established pursuant to this subsection. Whenever a prescribing practitioner prescribes a controlled substance, other than a schedule V nonnarcotic controlled substance, for the continuous or prolonged treatment of any patient, such prescriber, or such prescriber's authorized agent, shall review, not less than once every ninety days, the patient's records in such prescription drug monitoring program. Whenever a prescribing practitioner prescribes a schedule V nonnarcotic controlled substance, for the continuous or prolonged treatment of any patient, such prescribing practitioner, or such prescribing practitioner's authorized agent, shall review, not less than annually, the patient's records in such prescription drug monitoring program. If such electronic prescription drug monitoring program is not operational, such prescribing

practitioner may prescribe greater than a seventy-two-hour supply of a controlled substance to a patient during the time of such program's inoperability, provided such prescribing practitioner or such authorized agent reviews the records of such patient in such program not more than twenty-four hours after regaining access to such program.

(10) (A) A prescribing practitioner may designate an authorized agent to review the electronic prescription drug monitoring program and patient controlled substance prescription information on behalf of the prescribing practitioner. The prescribing practitioner shall ensure that any authorized agent's access to such program and patient controlled substance prescription information is limited to the purposes described in this section and occurs in a manner that protects the confidentiality of information that is accessed through such program. The prescribing practitioner and any authorized agent shall be subject to the provisions of 45 CFR 164.308, as amended from time to time, concerning administrative safeguards for the protection of electronic protected health information. A prescribing practitioner may **[**receive**]** be subject to disciplinary action for acts of the authorized agent as provided in section 21a-322.

(B) Notwithstanding the provisions of subparagraph (A) of this subdivision, a prescribing practitioner who is employed by or provides professional services to a hospital shall, prior to designating an authorized agent to review the electronic prescription drug monitoring program and patient controlled substance prescription information on behalf of the prescribing practitioner, (i) submit a request to designate one or more authorized agents for such purposes and a written protocol for oversight of the authorized agent or agents to the commissioner, in the form and manner prescribed by the commissioner, and (ii) receive the commissioner's approval to designate such authorized agent or agents and of such written protocol. Such written protocol shall designate either the hospital's medical director, a hospital department head, who is a prescribing practitioner, or another prescribing practitioner as the person

responsible for ensuring that the authorized agent's or agents' access to such program and patient controlled substance prescription information is limited to the purposes described in this section and occurs in a manner that protects the confidentiality of information that is accessed through such program. A hospital medical director, a hospital department head, who is a prescribing practitioner, or another prescribing practitioner designated as the person responsible for overseeing an authorized agent's or agents' access to such program and information in the written protocol approved by the commissioner may **[**receive**]** be subject to disciplinary action for acts of the authorized agent or agents as provided in section 21a-322. The commissioner may inspect hospital records to determine compliance with written protocols approved in accordance with this section.

(C) A pharmacist may designate a pharmacy technician to access the electronic prescription drug monitoring program and patient controlled substance prescription information on behalf of the pharmacist only for the purposes of facilitating the pharmacist's review of such patient information. The pharmacist shall ensure that any such pharmacy technician's access to such program and patient controlled substance prescription information is limited to the purposes described in this section and occurs in a manner that protects the confidentiality of information that is accessed through such program. The pharmacist and any authorized pharmacy technician shall be subject to the provisions of 45 CFR 164.308, as amended from time to time, concerning administrative safeguards for the protection of electronic protected health information. A pharmacist may be subject to disciplinary action for acts of the authorized pharmacy technician.

(D) Prior to designating a pharmacy technician to access the electronic prescription drug monitoring program and patient controlled substance prescription information on behalf of the pharmacist, the supervising pharmacist shall develop a written protocol for oversight of authorized pharmacy technicians. Such written protocol shall designate a pharmacist as the person responsible

for ensuring that the authorized pharmacy technician's access to such program and patient controlled substance prescription information is limited to the purposes described in this section and occurs in a manner that protects the confidentiality of information that is accessed through such program. A pharmacist designated as the person responsible for overseeing the pharmacy technician's access to such program and information in the written protocol may be subject to disciplinary action for acts of the authorized pharmacy technician. The commissioner may inspect records to determine compliance with written protocols in accordance with this section.

(11) The commissioner shall adopt regulations, in accordance with chapter 54, concerning the reporting, evaluation, management and storage of electronic controlled substance prescription information.

(12) The provisions of this section shall not apply to (A) samples of controlled substances dispensed by a physician to a patient, or (B) any controlled substances dispensed to hospital inpatients.

(13) The provisions of this section shall not apply to any institutional pharmacy or pharmacist's drug room operated by a facility, licensed under section 19a-495 and regulations adopted pursuant to said section 19a-495, that dispenses or administers directly to a patient an opioid agonist for treatment of a substance use disorder.

(14) The commissioner may provide controlled substance prescription information obtained in accordance with subdivisions (3) and (4) of this subsection to other state agencies, pursuant to an agreement between the commissioner and the head of such agency, provided the information is obtained for a study of disease prevention and control related to opioid abuse or the study of morbidity and mortality caused by overdoses of controlled substances. The provision of such information shall be in accordance with all applicable state and federal confidentiality requirements.

(15) Nothing in this section shall prohibit a prescribing practitioner or such prescribing practitioner's authorized agent from disclosing

controlled substance prescription information submitted pursuant to subdivisions (3) and (4) of this subsection to the Department of Social Services for the purposes of administering any of said department's medical assistance programs.

Sec. 4. Subsection (i) of section 21a-70 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective October 1, 2019*):

(i) (1) Each registered manufacturer or wholesaler of drugs shall operate a system to identify suspicious orders of controlled substances and shall immediately inform the Director of the Drug Control Division of suspicious orders. Suspicious orders include, but are not limited to, orders of unusual size, orders deviating substantially from a normal pattern and orders of unusual frequency. Each registered manufacturer or wholesaler of drugs shall also send the Drug Control Division a copy of any suspicious activity reporting submitted to the federal Drug Enforcement Administration pursuant to 21 CFR 1301.74.

(2) Each registered manufacturer or wholesaler of drugs that ceases or declines distribution of a schedule II, III, IV or V controlled substance to an individual in the state of Connecticut shall report the name of the individual, location of the individual and the reasons for ceasing or declining distribution of such controlled substance in writing to the Director of the Drug Control Division not later than five business days after ceasing or declining distribution of such controlled substance.

Sec. 5. (NEW) (*Effective October 1, 2019*) Notwithstanding any provision of the general statutes, no life insurance or annuity policy or contract shall be delivered, issued for delivery, renewed or continued in this state that excludes coverage solely on the basis of receipt of a prescription for naloxone, commonly referred to as an opioid antagonist, or any naloxone biosimilar or naloxone generic, nor shall any application, rider or endorsement to such policy or contract be used in connection therewith that excludes coverage solely on the basis

of receipt of such a prescription, biosimilar or generic.

Sec. 6. (NEW) (*Effective October 1, 2019*) When a prescribing practitioner, as defined in section 20-14c of the general statutes, prescribes an opioid drug, as defined in section 20-14o of the general statutes, for human use, the prescribing practitioner shall include on the prescription a diagnosis code, consistent with the most recent edition of the International Classification of Diseases, for the medical condition being treated for the patient who was issued the prescription. Nothing in this section shall require the diagnosis information to be included on the label of the prescription or prohibit the pharmacist from adding the information after consultation with the prescribing practitioner.

Sec. 7. (NEW) (*Effective October 1, 2019*) A prescribing practitioner, as defined in section 20-14c of the general statutes, who prescribes an opioid drug, as defined in section 20-14o of the general statutes, for the treatment of pain for a patient for a duration greater than twelve weeks shall establish a treatment agreement with the patient. The treatment agreement shall, at a minimum, include treatment goals, risks of using opioids, urine drug screens, discontinuation of opioids and expectations regarding the continuing treatment of pain with opioids.

This act shall take effect as follows and shall amend the following sections:		
Section 1	*October 1, 2019*	20-614
Sec. 2	*October 1, 2019*	20-612
Sec. 3	*from passage*	21a-254(j)
Sec. 4	*October 1, 2019*	21a-70(i)
Sec. 5	*October 1, 2019*	New section
Sec. 6	*October 1, 2019*	New section
Sec. 7	*October 1, 2019*	New section

Statement of Purpose:
To implement the Governor's budget recommendations.

[Proposed deletions are enclosed in brackets. Proposed additions are indicated by underline, except that when the entire text of a bill or resolution or a section of a bill or resolution is new, it is not underlined.]