General Assembly **Substitute Bill No. 7052**

January Session, 2017 *____HB07052PH___041117___*

AN ACT PREVENTING PRESCRIPTION OPIOID DIVERSION AND ABUSE.

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

Section 1. Subsection (j) of section 21a-254 of the general statutes is amended by adding subdivision (11) as follows (*Effective from passage*):

(NEW) (11) 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.

Sec. 2. Section 21a-262 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective from passage*):

(a) The Commissioner of Consumer Protection may receive, take into custody or destroy excess or undesired controlled substances and may in his <u>or her</u> discretion deliver, upon application, to any hospital, laboratory, incorporated college, scientific institution or any state or municipal agency or institution not operated for private gain, any

controlled substances that have come into his or her custody by authority of this section. In the case of a care-giving or correctional or juvenile training institution having an institutional pharmacy, the Commissioner of Consumer Protection shall deliver such controlled substances only to the licensed pharmacist in charge of such pharmacy. The Commissioner of Consumer Protection may receive and take into custody excess or undesired controlled substances from pharmacists, manufacturers and wholesalers or any other registrant. Said commissioner shall keep a full and complete record of all substances received and of all substances disposed of, showing the exact kinds, quantities and forms of such substances, the persons from whom received and to whom delivered, by whose authority received, delivered and destroyed, and the dates of the receipt, disposal or destruction. Controlled substances and preparations shall at all times be properly safeguarded and securely kept. Minimum security and safeguard standards for the storage, manufacture, sale or distribution of all controlled substances shall be established by regulations adopted hereunder. Controlled substances seized or held as contraband or controlled substances, the title to which cannot be resolved, which controlled substances are not held by law enforcement agencies or court officials as evidence in criminal proceedings, shall be, upon the order of the court, destroyed by the seizing authority or delivered to the Commissioner of Consumer Protection as soon as possible upon resolution of the case or upon ascertaining the status of the unclaimed substance. The agent of the Commissioner of Consumer Protection shall issue a receipt for all such substance obtained. Any loss, destruction or theft of controlled substances shall be reported by a registrant within seventy-two hours to the Commissioner of Consumer Protection as follows: (1) Where, through breakage of the container or other accident, otherwise than in transit, controlled substances are lost or destroyed, the person having title thereto shall make a signed statement as to the kinds and quantities of controlled substances lost or destroyed and the circumstances involved, and immediately forward the statement to the Commissioner of Consumer Protection. A copy of such statement shall be retained by the registrant; (2) where controlled

substances are lost by theft, or otherwise lost or destroyed in transit, the consignee shall, immediately upon ascertainment of the occurrence, file with the Commissioner of Consumer Protection a signed statement of the facts, including a list of the controlled substances stolen, lost or destroyed and documentary evidence that the local authorities were notified. A copy of the statement shall be retained by the registrant. As used in this section, "care-giving institution", "correctional or juvenile training institution", "institutional pharmacy" and "pharmacist" have the same meanings as provided in section 20-571.

(b) For each long-term care facility, two or more of the following persons may jointly dispose of excess stock of controlled substances: A nursing home administrator, a pharmacist consultant, a director of nursing services or an assistant director of nursing services. Such facility shall maintain documentation of any such destruction and disposal for a period of three years and such documentation shall be maintained in a separate log and on a form prescribed by the department.

(c) For each outpatient surgical facility, as defined in section 19a-493b, two or more of the following persons may jointly dispose of excess stock of controlled substances: An administrator, a clinical director or chief of staff, or a nursing supervisor. Such facility shall maintain documentation of any such destruction and disposal for a period of three years and such documentation shall be maintained in a separate log and on a form prescribed by the department.

(d) A registered nurse licensed by the Department of Public Health and employed by a home health care agency, as defined in section 19a-490, may, along with a designated representative of the patient, oversee the destruction and disposal of the patient's controlled substances, using the recommendations for the proper disposal of prescription drugs on the Internet web site of the Department of Consumer Protection. Such registered nurse shall maintain written or electronic documentation for a period of three years of any such

destruction and disposal on a form prescribed by the Commissioner of Consumer Protection. Such written or electronic documentation shall be maintained with the patient's medical record. Nothing in this subsection shall prevent the registered nurse and patient representative from depositing the patient's controlled substances in a police department prescription drug drop box.

Sec. 3. Section 21a-249 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective January 1, 2018*):

(a) All prescriptions for controlled drugs shall include (1) the name and address of the patient, or the name and address of the owner of an animal and the species of the animal, (2) whether the patient is an adult or a child, or his specific age, (3) the compound or preparation prescribed and the amount thereof, (4) directions for use of the medication, (5) the name and address of the prescribing practitioner, (6) the date of issuance, and (7) the Federal Registry number of the practitioner. No prescription blank containing a prescription for a schedule II substance shall contain more than one prescription. No prescription or order for a controlled substance issued by a practitioner to an inanimate object or thing shall be considered a valid prescription within the meaning of this chapter.

(b) **[**Written prescriptions shall be written in ink or in indelible pencil or by typewriter. No duplicate, carbon or photographic copies and no printed or rubber-stamped orders shall be considered valid prescriptions within the meaning of this chapter. No prescription or order for any controlled substance issued by a practitioner to an inanimate object or thing shall be considered a valid prescription within the meaning of this chapter.**]** Each licensed practitioner who the Department of Consumer Protection authorizes to prescribe controlled substances, within the scope of practice of his or her license, shall electronically transmit the controlled substance prescription to a pharmacy. Electronically transmitted prescriptions shall be promptly printed out in hardcopy or created as an electronic record and filed by the prescriber. Electronically transmitted prescriptions shall be

consistent with the requirements of the federal Controlled Substances Act, 21 USC 801, as amended from time to time. All records shall be kept on the premises of the licensed practitioner and maintained in such form as to be readily available for inspection by the commissioner, his or her authorized agent or other persons, as authorized in section 21a-265, at reasonable times and shall be kept on file for three years. For purposes of this subsection and subsections (c), (d) and (e) of this section, the term "electronically transmit" means to transmit by computer modem or other similar electronic device.

(c) A licensed practitioner shall not be required to electronically transmit a prescription when:

(1) Electronic transmission is not available due to a temporary technological or electrical failure. For purposes of this subsection, "temporary technological or electrical failure" means failure of a computer system, application or device or the loss of electrical power to such system, application or device, or any other service interruption to such system, application or device that reasonably prevents the practitioner from utilizing his or her certified application to electronically transmit the prescription in accordance with subsection (b) of this section. In the event of a temporary technological or electrical failure, the practitioner shall, without undue delay, reasonably attempt to correct any cause for the failure that is within his or her control. A practitioner who issues a prescription, but fails to electronically transmit the prescription, as permitted by this subsection, shall document the reason for the practitioner's failure to electronically transmit the prescription in the patient's medical record as soon as practicable, but in no instance more than seventy-two hours following the end of the technological or electrical failure that prevented the electronic transmittal of the prescription;

(2) The practitioner reasonably determines that it would be impractical for the patient to obtain substances prescribed by an electronically transmitted prescription in a timely manner and that such delay would adversely impact the patient's medical condition,

provided if such prescription is for a controlled substance, the quantity of such controlled substance does not exceed a five-day supply for the patient, if the controlled substance was used in accordance with the directions for use. A practitioner who issues a prescription, but fails to electronically transmit the prescription, as permitted by this subsection, shall document the reason for the practitioner's failure to electronically transmit the prescription in the patient's medical record;

(3) The prescription is to be dispensed by a pharmacy located outside this state. A practitioner who issues a prescription, but fails to electronically transmit the prescription, as permitted by this subsection, shall document the reason for the practitioner's failure to electronically transmit the prescription in the patient's medical record;

(4) Use of an electronically transmitted prescription may negatively impact patient care, such as a prescription containing two or more products to be compounded by a pharmacist, a prescription for direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion, a prescription that contains long or complicated directions, a prescription that requires certain elements to be included by the federal Food and Drug and Administration, or an oral prescription communicated to a pharmacist by a health care practitioner for a patient in a chronic and convalescent nursing home, licensed pursuant to chapter 368v; or

(5) Before July 1, 2019, the practitioner demonstrates, in a form and manner prescribed by the commissioner, that such practitioner does not have the technological capacity to issue electronically transmitted prescriptions. For the purposes of this subsection, "technological capacity" means possession of a computer system, hardware or device that can be used to electronically transmit controlled substance prescriptions consistent with the requirements of the federal Controlled Substances Act, 21 USC 801, as amended from time to time.

(d) Any prescription issued instead of an electronically transmitted prescription pursuant to subsection (c) of this section may be issued as

a written order or, to the extent permitted by the federal Controlled Substance Act, 21 USC 801, as from time to time amended, as an oral order or transmitted by facsimile machine. Such oral order or order transmitted by facsimile machine shall be promptly reduced to writing on a prescription blank or a hardcopy printout or created as an electronic record and filed by the pharmacist filling it. No duplicate, carbon or photographic copies and no printed or rubber-stamped orders shall be considered valid prescriptions within the meaning of this chapter.

[(c)**]** (e) Prescriptions for schedule II substances **[**, if in writing,**]** shall be **[**signed**]** electronically transmitted by the prescribing practitioner at the time of issuance and previously signed orders for such schedule II substances shall not be considered valid prescriptions within the meaning of this chapter. No practitioner shall prescribe, dispense or administer schedule II sympathomimetic amines as anorectics, except as may be authorized by regulations adopted by the Departments of Public Health and Consumer Protection acting jointly. To the extent permitted by the federal Controlled Substances Act, 21 USC 801, as from time to time amended, in an emergency, the dispensing of schedule II substances may be made upon the oral order of a prescribing registrant known to or confirmed by the filling pharmacist who shall promptly reduce the oral order to writing on a prescription blank, provided, in such case, such oral order shall be confirmed by the proper completion and mailing or delivery of a prescription prepared by the prescribing registrant to the pharmacist filling such oral order within seventy-two hours after the oral order has been given. Such prescription of the registrant shall be affixed to the temporary prescription prepared by the pharmacist and both prescriptions shall be maintained on file as required in this chapter. The Department of Public Health and the Department of Consumer Protection, acting jointly, may adopt regulations, in accordance with chapter 54, allowing practitioners to prescribe, dispense or administer schedule II sympathomimetic amines as anorectics under certain specific circumstances. Nothing in this subsection shall be construed to require

a licensed pharmacist to determine the diagnosis of a patient prior to dispensing a prescription for such substances to a patient.

[(d) To the extent permitted by the federal Controlled Substances Act, 21 USC 801, as from time to time amended, a prescribing practitioner may issue an oral order or an electronically transmitted prescription order and, except as otherwise provided by regulations adopted pursuant to sections 21a-243, 21a-244 and 21a-244a, such oral order or electronically transmitted prescription order shall be promptly reduced to writing on a prescription blank or a hardcopy printout or created as an electronic record and filed by the pharmacist filling it. For the purposes of subsections (d) and (h) of this section the term "electronically transmitted" means transmitted by facsimile machine, computer modem or other similar electronic device.

(e) To the extent permitted by the federal Controlled Substances Act, in an emergency the dispensing of schedule II substances may be made upon the oral order of a prescribing registrant known to or confirmed by the filling pharmacist who shall promptly reduce the oral order to writing on a prescription blank, provided, in such cases such oral order shall be confirmed by the proper completion and mailing or delivery of a prescription prepared by the prescribing registrant to the pharmacist filling such oral order within seventy-two hours after the oral order has been given. Such prescription of the registrant shall be affixed to the temporary prescription prepared by the pharmacist and both prescriptions shall be maintained on file as required in this chapter.**]**

(f) All prescriptions for controlled substances shall comply fully with any additional requirements of the federal food and drug laws, the federal Controlled Substances Act, and state laws and regulations adopted under this chapter.

(g) Repealed by P.A. 82-419, S. 46, 47.

(h) Except when dispensed directly by a practitioner, other than a

pharmacy, to an ultimate user, a controlled substance included in schedule III or IV, which is a prescription drug as determined under federal food and drug laws, shall not be dispensed without a written, electronically transmitted or oral prescription of a practitioner. The prescription shall not be filled or refilled more than six months after the date thereof or be refilled more than five times, unless renewed by the practitioner.

(i) A controlled substance included in schedule V shall not be distributed or dispensed other than for a medical purpose.

(j) A pharmacy may sell and dispense controlled substances upon the prescription of a prescribing practitioner, as defined in subdivision (22) of section 20-571.

(k) Pharmacies shall file filled prescriptions for controlled substances separately from other prescriptions. All schedule II prescriptions shall be filed in a separate file or in an electronic file. All schedule III, IV and V prescriptions shall be filed in another separate file or in an electronic file, except as otherwise provided for in regulations adopted pursuant to section 21a-243, 21a-244 or 21a-244a. All written controlled substance prescriptions shall, immediately upon filling, be filed chronologically and consecutively.

(l) Any pharmacy may transfer prescriptions for controlled substances included in schedules III, IV and V to any other pharmacy in accordance with the requirements set forth in the federal Controlled Substances Act 21 USC 801 et seq. and the regulations promulgated thereunder, as from time to time amended.

(m) A practitioner authorized to prescribe controlled substances shall not prescribe anabolic steroids for the sole purpose of enhancing a patient's athletic ability or performance.

(n) Each pharmacy, as defined in section 20-571, shall accept an electronically transmitted prescription for a controlled substance from a practitioner, as defined in section 21a-316. All records shall be kept

on the premises of the pharmacy and maintained current and separate from other business records in such form as to be readily available at the pharmacy for inspection by the Commissioner of Consumer Protection, his or her authorized agent or other persons, as authorized in section 21a-265, at reasonable times and shall be kept on file for three years. Prescription records received from the practitioner electronically may be stored electronically, provided the files are maintained in the pharmacy computer system for not less than three years. If the electronically transmitted prescription is printed, it shall be filed as required in subsection (l) of this section.

Sec. 4. (NEW) (*Effective October 1, 2017*) (a) As used in this section:

(1) "Opioid drug" has the same meaning as provided in 42 CFR 8.2, as amended from time to time;

(2) "Prescribing practitioner" has the same meaning as provided in section 20-14c of the general statutes; and

(3) "Voluntary nonopioid directive form" means a form that is voluntarily filed by a patient with a prescribing practitioner that indicates such patient's request to not be issued a prescription or medication order for an opioid drug.

(b) The Department of Public Health, in consultation with the Departments of Consumer Protection and Mental Health and Addiction Services, shall establish a voluntary nonopioid directive form and publish such form on its Internet web site for public use. Any person who does not wish to be issued a prescription or medication order for an opioid drug may file such form with a prescribing practitioner. Upon receipt of a voluntary nonopioid directive form, a prescribing practitioner shall document such receipt in the patient's medical record.

(c) The voluntary nonopioid directive form established by the department shall allow a patient to appoint a duly authorized guardian or health care proxy to override a previously recorded

voluntary nonopioid directive form. Such patient, duly authorized guardian or health care proxy may revoke the directive, orally or in writing, for any reason, at any time.

(d) An electronically transmitted prescription to a pharmacy shall be presumed to be valid for the purposes of this section and a pharmacist shall not be held in violation of this section for dispensing a controlled substance in contradiction to a voluntary nonopioid directive form.

(e) No prescribing practitioner acting with reasonable care shall be liable for damages in a civil action or subject to criminal prosecution or be deemed to have violated the standard of care for such prescribing practitioner for refusing to issue a prescription or medication order for an opioid pursuant to a voluntary nonopioid directive form.

(f) No person acting in good faith as a duly authorized guardian or health care proxy shall be liable for damages in a civil action or subject to criminal prosecution for revoking or overriding a voluntary nonopioid directive form.

(g) A prescribing practitioner who wilfully fails to comply with a patient's voluntary nonopioid directive form may be subject to disciplinary action pursuant to section 19a-17 of the general statutes.

Sec. 5. Section 20-14o of the general statutes is repealed and the following is substituted in lieu thereof (*Effective July 1, 2017*):

(a) As used in this section:

(1) "Opioid drug" has the same meaning as provided in 42 CFR 8.2, as amended from time to time;

(2) "Adult" means a person who is at least eighteen years of age;

(3) "Prescribing practitioner" has the same meaning as provided in section 20-14c;

(4) "Minor" means a person who is under eighteen years of age;

(5) "Opioid agonist" means a medication that binds to the opiate receptors and provides relief to individuals in treatment for abuse of or dependence on an opioid drug;

(6) "Opiate receptor" means a specific site on a cell surface that interacts in a highly selective fashion with an opioid drug;

(7) "Palliative care" means specialized medical care to improve the quality of life of patients and their families facing the problems associated with a life-threatening illness; and

(8) "Opioid antagonist" has the same meaning as provided in section 17a-714a.

(b) When issuing a prescription for an opioid drug to an adult patient for the first time for outpatient use, a prescribing practitioner who is authorized to prescribe an opioid drug shall not issue a prescription for more than a seven-day supply of such drug, as recommended in the National Centers for Disease Control and Prevention's Guideline for Prescribing Opioids for Chronic Pain.

(c) A prescribing practitioner shall not issue a prescription for an opioid drug to a minor for more than a seven-day supply of such drug at any time. **[**When issuing a prescription for an opioid drug to a minor for less than a seven-day supply of such drug, the prescribing practitioner shall discuss the risks associated with use of an opioid drug, including, but not limited to, the risks of addiction and overdose associated with opioid drugs and the dangers of taking opioid drugs with alcohol, benzodiazepines and other central nervous system depressants, and the reasons why the prescription is necessary with (1) the minor, and (2) the custodial parent, guardian or other person having legal custody of the minor if such parent, guardian or other person is present at the time of issuance.**]**

(d) Notwithstanding the provisions of subsections (b) and (c) of this section, if, in the professional medical judgment of a prescribing practitioner, more than a seven-day supply of an opioid drug is

required to treat an adult patient's or minor patient's acute medical condition, as determined by the prescribing practitioner, or is necessary for the treatment of chronic pain, pain associated with a cancer diagnoses or for palliative care, then the prescribing practitioner may issue a prescription for the quantity needed to treat the acute medical condition, chronic pain, pain associated with a cancer diagnosis or pain experienced while the patient is in palliative care. The condition triggering the prescription of an opioid drug for more than a seven-day supply shall be documented in the patient's medical record and the practitioner shall indicate that an alternative to the opioid drug was not appropriate to address the medical condition.

(e) The provisions of subsections (b), (c) and (d) of this section shall not apply to medications designed for the treatment of abuse of or dependence on an opioid drug, including, but not limited to, opioid agonists and opioid antagonists.

(f) When issuing a prescription for an opioid drug to an adult or minor patient, the prescribing practitioner shall discuss with the patient the risks associated with the use of such opioid drug, including, but not limited to, the risks of addiction and overdose associated with opioid drugs and the dangers of taking opioid drugs with alcohol, benzodiazepines and other central nervous system depressants, and the reasons the prescription is necessary, and, if applicable, with the custodial parent, guardian or other person having legal custody of the minor if such parent, guardian or other person is present at the time of issuance of the prescription.

This act shall take effect as follows and shall amend the following sections:		
Section 1	*from passage*	21a-254(j)
Sec. 2	*from passage*	21a-262
Sec. 3	*January 1, 2018*	21a-249
Sec. 4	*October 1, 2017*	New section
Sec. 5	*July 1, 2017*	20-14o

GL *Joint Favorable Subst. -LCO*

PH *Joint Favorable*