SB3147

LRB10109463JRG54561b

101ST GENERAL ASSEMBLY

State of Illinois

2019 and 2020

SB3147

Introduced 2/6/2020, by Sen. Sara Feigenholtz

SYNOPSIS AS INTRODUCED:

20 ILCS 2310/2310-701 new
215 ILCS 5/356z.33 new
225 ILCS 85/3
305 ILCS 5/5-5.12c new

Amends the Department of Public Health Powers and Duties Law of the Civil Administrative Code of Illinois. Provides that the Director of Public Health shall establish a standing order complete with the issuance of a prescription for a smoking cessation product. Prescribes minimum requirements for the standing order. Amends the Illinois Insurance Code. Provides that a group or individual policy of accident and health insurance or a managed care plan that is amended, delivered, issued, or renewed after the effective date of the amendatory Act shall provide coverage for patient care services provided by a pharmacist for smoking cessation assessments and consultations. Amends the Pharmacy Practice Act. Provides that the "practice of pharmacy" includes the assessment and consultation of patients and dispensing of tobacco and nicotine cessation drugs and products. Amends the Illinois Public Aid Code. Provides that, subject to approval by the federal Centers for Medicare and Medicaid Services, the medical assistance program shall cover patient care services provided by a pharmacist for smoking cessation assessments and consultations. Defines terms. Effective January 1, 2020.

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FISCAL NOTE ACT
MAY APPLY

A BILL FOR

AN ACT concerning regulation.

Be it enacted by the People of the State of Illinois, represented in the General Assembly:

Section 5. The Department of Public Health Powers and Duties Law of the Civil Administrative Code of Illinois is amended by adding Section 2310-701 as follows:

(20 ILCS 2310/2310-701 new)

Sec. 2310-701. Tobacco and nicotine cessation drugs and products; standing order.

(a) If the Director of Public Health is a physician licensed to practice medicine in all its branches in the State, the Director shall establish a standing order complete with the issuance of a prescription for a smoking cessation product in accordance with this Section. If the Director is not a physician licensed to practice medicine in all its branches in the State, then the Medical Director of the Department of Public Health shall establish a standing order in accordance with this Section.

(b) The standing order, at a minimum, shall require compliance with the following before a smoking cessation product may be dispensed:

(1) A pharmacist shall have the patient complete the self-screening risk assessment tool. The self-screening

risk assessment tool is to be based on the Modified Fagerstrom Test for Nicotine Dependence, or United States Food and Drug Administration-approved functional equivalent for nicotine dependence.

(2) Based upon the results of the self-screening risk assessment and the patient assessment the pharmacist shall use his or her professional and clinical judgment as to when a patient should be referred to the patient's physician or another health care provider.

(3) The pharmacist shall provide counseling and education about all available smoking cessation products during the patient assessment and consultation, including the indications, contraindications, proper use, effectiveness of smoking cessation products, and any other information that is required to be given to a patient during the counseling process.

(4) The patient consultation shall take place in a private manner consistent with rules adopted by the Department of Financial and Professional Regulation.

(c) The Department shall adopt rules that require a pharmacist to:

(1) complete an educational training program accredited by the Accreditation Council for Pharmacy Education and approved by the Department that is related to the patient self-screening risk assessment, patient assessment, smoking cessation counseling and education,

and dispensation of smoking cessation products; and

(2) dispense smoking cessation products to patients as soon as practicable after meeting the requirements of paragraph (1) of subsection (b).

(d) All State and federal laws governing insurance coverage of smoking cessation products shall apply to smoking cessation products dispensed by a pharmacist under this Section.

(e) Nothing in this Section prohibits a licensed pharmacist from participating in the initiation, management, modification, and discontinuation of therapy through a standing order as allowed in this Section.

(f) In this Section, "smoking cessation product" means a prescribed medically acceptable oral drug, transdermal patch, chewing gum, or lozenge that is approved by the United States Food and Drug Administration to quit smoking.

Section 10. The Illinois Insurance Code is amended by adding Section 356z.33 as follows:

(215 ILCS 5/356z.33 new)

Sec. 356z.33. Coverage for smoking cessation services and products. A group or individual policy of accident and health insurance or a managed care plan that is amended, delivered, issued, or renewed after the effective date of this amendatory Act of the 101st General Assembly shall provide coverage for patient care services and smoking cessation products provided

by a pharmacist for smoking cessation assessments and consultation.

Section 15. The Pharmacy Practice Act is amended by changing Section 3 as follows:

(225 ILCS 85/3)

(Section scheduled to be repealed on January 1, 2020)

Sec. 3. Definitions. For the purpose of this Act, except where otherwise limited therein:

(a) "Pharmacy" or "drugstore" means and includes every store, shop, pharmacy department, or other place where pharmacist care is provided by a pharmacist (1) where drugs, medicines, or poisons are dispensed, sold or offered for sale at retail, or displayed for sale at retail; or (2) where prescriptions of physicians, dentists, advanced practice registered nurses, physician assistants, veterinarians, podiatric physicians, or optometrists, within the limits of their licenses, are compounded, filled, or dispensed; or (3) which has upon it or displayed within it, or affixed to or used in connection with it, a sign bearing the word or words "Pharmacist", "Druggist", "Pharmacy", "Pharmaceutical Care", "Apothecary", "Drugstore", "Medicine Store", "Prescriptions", "Drugs", "Dispensary", "Medicines", or any word or words of similar or like import, either in the English language or any other language; or (4) where the characteristic prescription

sign (Rx) or similar design is exhibited; or (5) any store, or shop, or other place with respect to which any of the above words, objects, signs or designs are used in any advertisement.

(b) "Drugs" means and includes (1) articles recognized in the official United States Pharmacopoeia/National Formulary (USP/NF), or any supplement thereto and being intended for and having for their main use the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals, as approved by the United States Food and Drug Administration, but does not include devices or their components, parts, or accessories; and (2) all other articles intended for and having for their main use the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals, as approved by the United States Food and Drug Administration, but does not include devices or their components, parts, or accessories; and (3) articles (other than food) having for their main use and intended to affect the structure or any function of the body of man or other animals; and (4) articles having for their main use and intended for use as a component or any articles specified in clause (1), (2) or (3); but does not include devices or their components, parts or accessories.

(c) "Medicines" means and includes all drugs intended for human or veterinary use approved by the United States Food and Drug Administration.

(d) "Practice of pharmacy" means:

(1) the interpretation and the provision of assistance

in the monitoring, evaluation, and implementation of prescription drug orders;

(2) the dispensing of prescription drug orders;

(3) participation in drug and device selection;

(4) drug administration limited to the administration of oral, topical, injectable, and inhalation as follows:

(A) in the context of patient education on the proper use or delivery of medications;

(B) vaccination of patients 14 years of age and older pursuant to a valid prescription or standing order, by a physician licensed to practice medicine in all its branches, upon completion of appropriate training, including how to address contraindications and adverse reactions set forth by rule, with notification to the patient's physician and appropriate record retention, or pursuant to hospital pharmacy and therapeutics committee policies and procedures; and

(C) administration of injections of alpha-hydroxyprogesterone caproate, pursuant to a valid prescription, by a physician licensed to practice medicine in all its branches, upon completion of appropriate training, including how to address contraindications and adverse reactions set forth by rule, with notification to the patient's physician and appropriate record retention, or pursuant to hospital

pharmacy and therapeutics committee policies and procedures;

(5) vaccination of patients ages 10 through 13 limited to the Influenza (inactivated influenza vaccine and live attenuated influenza intranasal vaccine) and Tdap (defined as tetanus, diphtheria, acellular pertussis) vaccines, pursuant to a valid prescription or standing order, by a physician licensed to practice medicine in all its branches, upon completion of appropriate training, including how to address contraindications and adverse reactions set forth by rule, with notification to the patient's physician and appropriate record retention, or pursuant to hospital pharmacy and therapeutics committee policies and procedures;

(6) drug regimen review;

(7) drug or drug-related research;

(8) the provision of patient counseling;

(9) the practice of telepharmacy;

(10) the provision of those acts or services necessary to provide pharmacist care;

(11) medication therapy management; ~~and~~

(12) the responsibility for compounding and labeling of drugs and devices (except labeling by a manufacturer, repackager, or distributor of non-prescription drugs and commercially packaged legend drugs and devices), proper and safe storage of drugs and devices, and maintenance of

required records; and.

(13) the assessment and consultation of patients and dispensing of tobacco and nicotine cessation drugs and products pursuant to the standing order under Section 2310-701 of the Department of Public Health Powers and Duties Law of the Civil Administrative Code of Illinois.

A pharmacist who performs any of the acts defined as the practice of pharmacy in this State must be actively licensed as a pharmacist under this Act.

(e) "Prescription" means and includes any written, oral, facsimile, or electronically transmitted order for drugs or medical devices, issued by a physician licensed to practice medicine in all its branches, dentist, veterinarian, podiatric physician, or optometrist, within the limits of his or her license, by a physician assistant in accordance with subsection (f) of Section 4, or by an advanced practice registered nurse in accordance with subsection (g) of Section 4, containing the following: (1) name of the patient; (2) date when prescription was issued; (3) name and strength of drug or description of the medical device prescribed; and (4) quantity; (5) directions for use; (6) prescriber's name, address, and signature; and (7) DEA registration number where required, for controlled substances. The prescription may, but is not required to, list the illness, disease, or condition for which the drug or device is being prescribed. DEA registration numbers shall not be required on inpatient drug orders. A prescription for medication other than

controlled substances shall be valid for up to 15 months from the date issued for the purpose of refills, unless the prescription states otherwise.

(f) "Person" means and includes a natural person, partnership, association, corporation, government entity, or any other legal entity.

(g) "Department" means the Department of Financial and Professional Regulation.

(h) "Board of Pharmacy" or "Board" means the State Board of Pharmacy of the Department of Financial and Professional Regulation.

(i) "Secretary" means the Secretary of Financial and Professional Regulation.

(j) "Drug product selection" means the interchange for a prescribed pharmaceutical product in accordance with Section 25 of this Act and Section 3.14 of the Illinois Food, Drug and Cosmetic Act.

(k) "Inpatient drug order" means an order issued by an authorized prescriber for a resident or patient of a facility licensed under the Nursing Home Care Act, the ID/DD Community Care Act, the MC/DD Act, the Specialized Mental Health Rehabilitation Act of 2013, the Hospital Licensing Act, or the University of Illinois Hospital Act, or a facility which is operated by the Department of Human Services (as successor to the Department of Mental Health and Developmental Disabilities) or the Department of Corrections.

(k-5) "Pharmacist" means an individual health care professional and provider currently licensed by this State to engage in the practice of pharmacy.

(l) "Pharmacist in charge" means the licensed pharmacist whose name appears on a pharmacy license and who is responsible for all aspects of the operation related to the practice of pharmacy.

(m) "Dispense" or "dispensing" means the interpretation, evaluation, and implementation of a prescription drug order, including the preparation and delivery of a drug or device to a patient or patient's agent in a suitable container appropriately labeled for subsequent administration to or use by a patient in accordance with applicable State and federal laws and regulations. "Dispense" or "dispensing" does not mean the physical delivery to a patient or a patient's representative in a home or institution by a designee of a pharmacist or by common carrier. "Dispense" or "dispensing" also does not mean the physical delivery of a drug or medical device to a patient or patient's representative by a pharmacist's designee within a pharmacy or drugstore while the pharmacist is on duty and the pharmacy is open.

(n) "Nonresident pharmacy" means a pharmacy that is located in a state, commonwealth, or territory of the United States, other than Illinois, that delivers, dispenses, or distributes, through the United States Postal Service, commercially acceptable parcel delivery service, or other common carrier, to

Illinois residents, any substance which requires a prescription.

(o) "Compounding" means the preparation and mixing of components, excluding flavorings, (1) as the result of a prescriber's prescription drug order or initiative based on the prescriber-patient-pharmacist relationship in the course of professional practice or (2) for the purpose of, or incident to, research, teaching, or chemical analysis and not for sale or dispensing. "Compounding" includes the preparation of drugs or devices in anticipation of receiving prescription drug orders based on routine, regularly observed dispensing patterns. Commercially available products may be compounded for dispensing to individual patients only if all of the following conditions are met: (i) the commercial product is not reasonably available from normal distribution channels in a timely manner to meet the patient's needs and (ii) the prescribing practitioner has requested that the drug be compounded.

(p) (Blank).

(q) (Blank).

(r) "Patient counseling" means the communication between a pharmacist or a student pharmacist under the supervision of a pharmacist and a patient or the patient's representative about the patient's medication or device for the purpose of optimizing proper use of prescription medications or devices. "Patient counseling" may include without limitation (1)

obtaining a medication history; (2) acquiring a patient's allergies and health conditions; (3) facilitation of the patient's understanding of the intended use of the medication; (4) proper directions for use; (5) significant potential adverse events; (6) potential food-drug interactions; and (7) the need to be compliant with the medication therapy. A pharmacy technician may only participate in the following aspects of patient counseling under the supervision of a pharmacist: (1) obtaining medication history; (2) providing the offer for counseling by a pharmacist or student pharmacist; and (3) acquiring a patient's allergies and health conditions.

(s) "Patient profiles" or "patient drug therapy record" means the obtaining, recording, and maintenance of patient prescription information, including prescriptions for controlled substances, and personal information.

(t) (Blank).

(u) "Medical device" or "device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component part or accessory, required under federal law to bear the label "Caution: Federal law requires dispensing by or on the order of a physician". A seller of goods and services who, only for the purpose of retail sales, compounds, sells, rents, or leases medical devices shall not, by reasons thereof, be required to be a licensed pharmacy.

(v) "Unique identifier" means an electronic signature,

handwritten signature or initials, thumb print, or other acceptable biometric or electronic identification process as approved by the Department.

(w) "Current usual and customary retail price" means the price that a pharmacy charges to a non-third-party payor.

(x) "Automated pharmacy system" means a mechanical system located within the confines of the pharmacy or remote location that performs operations or activities, other than compounding or administration, relative to storage, packaging, dispensing, or distribution of medication, and which collects, controls, and maintains all transaction information.

(y) "Drug regimen review" means and includes the evaluation of prescription drug orders and patient records for (1) known allergies; (2) drug or potential therapy contraindications; (3) reasonable dose, duration of use, and route of administration, taking into consideration factors such as age, gender, and contraindications; (4) reasonable directions for use; (5) potential or actual adverse drug reactions; (6) drug-drug interactions; (7) drug-food interactions; (8) drug-disease contraindications; (9) therapeutic duplication; (10) patient laboratory values when authorized and available; (11) proper utilization (including over or under utilization) and optimum therapeutic outcomes; and (12) abuse and misuse.

(z) "Electronically transmitted prescription" means a prescription that is created, recorded, or stored by electronic means; issued and validated with an electronic signature; and

transmitted by electronic means directly from the prescriber to a pharmacy. An electronic prescription is not an image of a physical prescription that is transferred by electronic means from computer to computer, facsimile to facsimile, or facsimile to computer.

(aa) "Medication therapy management services" means a distinct service or group of services offered by licensed pharmacists, physicians licensed to practice medicine in all its branches, advanced practice registered nurses authorized in a written agreement with a physician licensed to practice medicine in all its branches, or physician assistants authorized in guidelines by a supervising physician that optimize therapeutic outcomes for individual patients through improved medication use. In a retail or other non-hospital pharmacy, medication therapy management services shall consist of the evaluation of prescription drug orders and patient medication records to resolve conflicts with the following:

(1) known allergies;

(2) drug or potential therapy contraindications;

(3) reasonable dose, duration of use, and route of administration, taking into consideration factors such as age, gender, and contraindications;

(4) reasonable directions for use;

(5) potential or actual adverse drug reactions;

(6) drug-drug interactions;

(7) drug-food interactions;

(8) drug-disease contraindications;

(9) identification of therapeutic duplication;

(10) patient laboratory values when authorized and available;

(11) proper utilization (including over or under utilization) and optimum therapeutic outcomes; and

(12) drug abuse and misuse.

"Medication therapy management services" includes the following:

(1) documenting the services delivered and communicating the information provided to patients' prescribers within an appropriate time frame, not to exceed 48 hours;

(2) providing patient counseling designed to enhance a patient's understanding and the appropriate use of his or her medications; and

(3) providing information, support services, and resources designed to enhance a patient's adherence with his or her prescribed therapeutic regimens.

"Medication therapy management services" may also include patient care functions authorized by a physician licensed to practice medicine in all its branches for his or her identified patient or groups of patients under specified conditions or limitations in a standing order from the physician.

"Medication therapy management services" in a licensed hospital may also include the following:

(1) reviewing assessments of the patient's health status; and

(2) following protocols of a hospital pharmacy and therapeutics committee with respect to the fulfillment of medication orders.

(bb) "Pharmacist care" means the provision by a pharmacist of medication therapy management services, with or without the dispensing of drugs or devices, intended to achieve outcomes that improve patient health, quality of life, and comfort and enhance patient safety.

(cc) "Protected health information" means individually identifiable health information that, except as otherwise provided, is:

(1) transmitted by electronic media;

(2) maintained in any medium set forth in the definition of "electronic media" in the federal Health Insurance Portability and Accountability Act; or

(3) transmitted or maintained in any other form or medium.

"Protected health information" does not include individually identifiable health information found in:

(1) education records covered by the federal Family Educational Right and Privacy Act; or

(2) employment records held by a licensee in its role as an employer.

(dd) "Standing order" means a specific order for a patient

or group of patients issued by a physician licensed to practice medicine in all its branches in Illinois.

(ee) "Address of record" means the designated address recorded by the Department in the applicant's application file or licensee's license file maintained by the Department's licensure maintenance unit.

(ff) "Home pharmacy" means the location of a pharmacy's primary operations.

(gg) "Email address of record" means the designated email address recorded by the Department in the applicant's application file or the licensee's license file, as maintained by the Department's licensure maintenance unit.

(Source: P.A. 99-180, eff. 7-29-15; 100-208, eff. 1-1-18; 100-497, eff. 9-8-17; 100-513, eff. 1-1-18; 100-804, eff. 1-1-19; 100-863, eff. 8-14-18.)

Section 20. The Illinois Public Aid Code is amended by adding Section 5-5.12c as follows:

(305 ILCS 5/5-5.12c new)

Sec. 5-5.12c. Coverage for patient care services for tobacco and nicotine cessation drugs and products provided by a pharmacist.

(a) Subject to approval by the federal Centers for Medicare and Medicaid Services, the medical assistance program, including both the fee-for-service and managed care medical

assistance programs established under this Article, shall cover patient care services provided by a pharmacist for smoking cessation assessments and consultations.

(b) The Department shall establish a fee schedule for patient care services provided by a pharmacist for smoking cessation assessments and consultations.

(c) The rate of reimbursement for patient care services provided by a pharmacist for smoking cessation assessments and consultations shall be at 85% of the fee schedule for physician services by the medical assistance program.

(d) A pharmacist must be enrolled in the medical assistance program as an ordering and referring provider prior to providing smoking cessation assessments and consultations that are submitted by a pharmacy or pharmacist provider for reimbursement pursuant to this Section.

(e) The Director shall seek any necessary federal waivers or approvals to implement this Section. This Section shall not be implemented until the receipt of all necessary federal waivers or approvals or until January 1, 2022, whichever comes first. If federal approval is not obtained by January 1, 2022, the provisions of this Section shall be implemented using State funds.

(f) This Section does not restrict or prohibit any services currently provided by pharmacists as authorized by law, including, but not limited to, pharmacist services provided under this Code.

(g) The Department shall adopt administrative rules for this Section as soon as practicable but no later than May 1, 2020.

Section 99. Effective date. This Act takes effect January 1, 2020.