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1 AN ACT concerning regulation.

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

4 Section 5. The Pharmacy Practice Act is amended by 5 changing Section 3 as follows:

6 (225 ILCS 85/3)

7 (Section scheduled to be repealed on January 1, 2028)

8 Sec. 3. Definitions. For the purpose of this Act, except 9 where otherwise limited therein:

(a) "Pharmacy" or "drugstore" means and includes every 10 shop, pharmacy department, or other place where 11 store, pharmacist care is provided by a pharmacist (1) where drugs, 12 13 medicines, or poisons are dispensed, sold or offered for sale 14 at retail, or displayed for sale at retail; or (2) where prescriptions of physicians, dentists, advanced practice 15 16 registered nurses, physician assistants, veterinarians, 17 podiatric physicians, or optometrists, within the limits of their licenses, are compounded, filled, or dispensed; or (3) 18 19 which has upon it or displayed within it, or affixed to or used in connection with it, a sign bearing the word or words 20 "Pharmacist", "Druggist", "Pharmacy", "Pharmaceutical Care", 21 "Apothecary", "Drugstore", "Medicine Store", "Prescriptions", 22 "Drugs", "Dispensary", "Medicines", or any word or words of 23

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similar or like import, either in the English language or any 1 2 other language; or (4) where the characteristic prescription sign (Rx) or similar design is exhibited; or (5) any store, or 3 shop, or other place with respect to which any of the above 4 5 words, objects, signs or designs are used in any 6 advertisement.

7 (b) "Drugs" means and includes (1) articles recognized in 8 the official United States Pharmacopoeia/National Formulary 9 (USP/NF), or any supplement thereto and being intended for and 10 having for their main use the diagnosis, cure, mitigation, 11 treatment or prevention of disease in man or other animals, as 12 approved by the United States Food and Drug Administration, 13 but does not include devices or their components, parts, or accessories; and (2) all other articles intended for and 14 having for their main use the diagnosis, cure, mitigation, 15 16 treatment or prevention of disease in man or other animals, as 17 approved by the United States Food and Drug Administration, but does not include devices or their components, parts, or 18 accessories; and (3) articles (other than food) having for 19 20 their main use and intended to affect the structure or any function of the body of man or other animals; and (4) articles 21 22 having for their main use and intended for use as a component 23 or any articles specified in clause (1), (2) or (3); but does not include devices or their components, parts or accessories. 24

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

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1 Drug Administration.

2 (d) "Practice of pharmacy" means: 3 (1) the interpretation and the provision of assistance in the monitoring, evaluation, and implementation of 4 5 prescription drug orders; (2) the dispensing of prescription drug orders; 6 7 (3) participation in drug and device selection; (4) drug administration limited to the administration 8 9 of oral, topical, injectable, and inhalation as follows: 10 (A) in the context of patient education on the 11 proper use or delivery of medications; 12 (B) vaccination of patients 7 years of age and older pursuant to a valid prescription or standing 13 14 order, by a physician licensed to practice medicine in 15 all its branches, except for vaccinations covered by 16 paragraph (15), upon completion of appropriate 17 training, including how to address contraindications reactions set forth by rule, with 18 and adverse 19 notification to the patient's physician and 20 appropriate record retention, or pursuant to hospital

21 pharmacy and therapeutics committee policies and 22 procedures. Eligible vaccines are those listed on the 23 U.S. Centers for Disease Control and Prevention (CDC) 24 Recommended Immunization Schedule, the CDC's Health 25 Information for International Travel, or the U.S. Food 26 and Drug Administration's Vaccines Licensed and HB5530 Enrolled - 4 - LRB103 37122 RTM 67241 b

Authorized for Use in the United States. As applicable to the State's Medicaid program and other payers, vaccines ordered and administered in accordance with this subsection shall be covered and reimbursed at no less than the rate that the vaccine is reimbursed when ordered and administered by a physician;

7 (blank); following the initial (B-5) administration of long acting or extended release form 8 opioid antagonists by a physician licensed to practice 9 10 medicine in all its branches, administration of 11 injections of long-acting or extended-release form 12 opioid antagonists for the treatment of substance use 13 disorder, pursuant to a valid prescription by a 14 physician licensed to practice medicine in all its 15 branches, upon completion of appropriate training, 16 including how to address contraindications and adverse 17 reactions, including, but not limited to, respiratory depression and the performance of cardiopulmonary 18 19 resuscitation, set forth by rule, with notification to 20 the patient's physician and appropriate record 21 retention, or pursuant to hospital pharmacy and 22 therapeutics committee policies and procedures;

(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

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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

7 (D) administration of <u>long-acting injectables for</u> 8 mental health or substance use disorders injections of 9 long term antipsychotic medications pursuant to a valid prescription by <u>the patient's</u> a physician 10 11 licensed to practice medicine in all its branches, 12 advanced practice registered nurse, or physician 13 assistant upon completion of appropriate training Accreditation 14 conducted bv an Council of 15 Pharmaceutical Education accredited provider, 16 including how to address contraindications and adverse 17 reactions set forth by rule, with notification to the patient's physician and appropriate record retention, 18 or pursuant to hospital pharmacy and therapeutics 19 20 committee policies and procedures; -

- 21 (5) (blank);
- 22 (6) drug regimen review;
- 23 (7) drug or drug-related research;
- 24 (8) the provision of patient counseling;
- 25 (9) the practice of telepharmacy;
- 26 (10) the provision of those acts or services necessary

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to provide pharmacist care;

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(11) medication therapy management;

3 (12) the responsibility for compounding and labeling 4 of drugs and devices (except labeling by a manufacturer, 5 repackager, or distributor of non-prescription drugs and 6 commercially packaged legend drugs and devices), proper 7 and safe storage of drugs and devices, and maintenance of 8 required records;

9 (13) the assessment and consultation of patients and
10 dispensing of hormonal contraceptives;

(14) the initiation, dispensing, or administration of drugs, laboratory tests, assessments, referrals, and consultations for human immunodeficiency virus pre-exposure prophylaxis and human immunodeficiency virus post-exposure prophylaxis under Section 43.5;

16 (15) vaccination of patients 7 years of age and older 17 for COVID-19 or influenza subcutaneously, intramuscularly, 18 or orally as authorized, approved, or licensed by the 19 United States Food and Drug Administration, pursuant to 20 the following conditions:

(A) the vaccine must be authorized or licensed by
the United States Food and Drug Administration;

(B) the vaccine must be ordered and administered
 according to the Advisory Committee on Immunization
 Practices standard immunization schedule;

(C) the pharmacist must complete a course of

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1 training accredited by the Accreditation Council on 2 Pharmacy Education or a similar health authority or 3 professional body approved by the Division of 4 Professional Regulation;

(D) the pharmacist must have a current certificate in basic cardiopulmonary resuscitation;

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7 (E) the pharmacist must complete, during each 8 State licensing period, a minimum of 2 hours of 9 immunization-related continuing pharmacy education 10 approved by the Accreditation Council on Pharmacy 11 Education;

12 (F) the pharmacist must comply with recordkeeping 13 and reporting requirements of the jurisdiction in 14 which the pharmacist administers vaccines, including 15 informing the patient's primary-care provider, when 16 available, and complying with requirements whereby the 17 person administering a vaccine must review the vaccine registry or other vaccination records prior to 18 19 administering the vaccine; and

20 (G) the pharmacist must inform the pharmacist's 21 patients who are less than 18 years old, as well as the 22 adult caregiver accompanying the child, of the 23 importance of a well-child visit with a pediatrician 24 or other licensed primary-care provider and must refer 25 patients as appropriate;

(16) the ordering and administration of COVID-19

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therapeutics subcutaneously, intramuscularly, or orally 1 with notification to the patient's physician 2 and 3 appropriate record retention or pursuant to hospital therapeutics committee policies 4 pharmacy and and 5 procedures. Eligible therapeutics are those approved, authorized, or licensed by the United States Food and Drug 6 Administration and must be administered subcutaneously, 7 8 intramuscularly, or orally in accordance with that 9 approval, authorization, or licensing; and

10 (17) the ordering and administration of tests and 11 screenings for (i) influenza, (ii) SARS-COV 2, and (iii) 12 health conditions identified by a statewide public health 13 emergency, as defined in the Illinois Emergency Management 14 Agency Act, with notification to the patient's physician 15 and appropriate record retention or pursuant to hospital 16 pharmacy and therapeutics committee policies and 17 procedures. Eligible tests and screenings are those approved, authorized, or licensed by the United States 18 19 Food and Drug Administration and must be administered in 20 accordance with that approval, authorization, or 21 licensing.

A pharmacist who orders or administers tests or screenings for health conditions described in this paragraph may use a test that may guide clinical decision-making for the health condition that is waived under the federal Clinical Laboratory Improvement Amendments of 1988 and regulations promulgated thereunder or any established screening procedure that is established under a statewide protocol.

A pharmacist may delegate the administrative and technical tasks of performing a test for the health conditions described in this paragraph to a registered pharmacy technician or student pharmacist acting under the supervision of the pharmacist.

9 A pharmacist who performs any of the acts defined as the 10 practice of pharmacy in this State must be actively licensed 11 as a pharmacist under this Act.

12 (e) "Prescription" means and includes any written, oral, facsimile, or electronically transmitted order for drugs or 13 14 medical devices, issued by a physician licensed to practice 15 medicine in all its branches, dentist, veterinarian, podiatric 16 physician, or optometrist, within the limits of his or her 17 license, by a physician assistant in accordance with subsection (f) of Section 4, or by an advanced practice 18 registered nurse in accordance with subsection (q) of Section 19 4, containing the following: (1) name of the patient; (2) date 20 when prescription was issued; (3) name and strength of drug or 21 22 description of the medical device prescribed; and (4) 23 quantity; (5) directions for use; (6) prescriber's name, 24 address, and signature; and (7) DEA registration number where 25 required, for controlled substances. The prescription may, but 26 is not required to, list the illness, disease, or condition HB5530 Enrolled - 10 - LRB103 37122 RTM 67241 b

1 for which the drug or device is being prescribed. DEA 2 registration numbers shall not be required on inpatient drug 3 orders. A prescription for medication other than controlled 4 substances shall be valid for up to 15 months from the date 5 issued for the purpose of refills, unless the prescription 6 states otherwise.

7 (f) "Person" means and includes a natural person, 8 partnership, association, corporation, government entity, or 9 any other legal entity.

10 (g) "Department" means the Department of Financial and 11 Professional Regulation.

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

15 (i) "Secretary" means the Secretary of Financial and16 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 HB5530 Enrolled - 11 -LRB103 37122 RTM 67241 b

operated by the Department of Human Services (as successor to 1 2 the Department of Mental Health and Developmental Disabilities) or the Department of Corrections. 3

(k-5) "Pharmacist" means an individual health care 4 5 professional and provider currently licensed by this State to 6 engage in the practice of pharmacy.

7 (1) "Pharmacist in charge" means the licensed pharmacist 8 appears on a pharmacy license and who whose name is 9 responsible for all aspects of the operation related to the 10 practice of pharmacy.

11 (m) "Dispense" or "dispensing" means the interpretation, 12 evaluation, and implementation of a prescription drug order, 13 including the preparation and delivery of a drug or device to a 14 patient or patient's agent in a suitable container 15 appropriately labeled for subsequent administration to or use 16 by a patient in accordance with applicable State and federal 17 laws and regulations. "Dispense" or "dispensing" does not mean the 18 physical delivery to a patient or а patient's 19 representative in a home or institution by a designee of a pharmacist or by common carrier. "Dispense" or "dispensing" 20 21 also does not mean the physical delivery of a drug or medical 22 device to a patient or patient's representative by a 23 pharmacist's designee within a pharmacy or drugstore while the pharmacist is on duty and the pharmacy is open. 24

"Nonresident pharmacy" means a pharmacy that is 25 (n) 26 located in a state, commonwealth, or territory of the United

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1 States, other than Illinois, that delivers, dispenses, or 2 distributes, through the United States Postal Service, 3 commercially acceptable parcel delivery service, or other 4 common carrier, to Illinois residents, any substance which 5 requires a prescription.

6 (o) "Compounding" means the preparation and mixing of 7 components, excluding flavorings, (1) as the result of a 8 prescriber's prescription drug order or initiative based on 9 the prescriber-patient-pharmacist relationship in the course 10 of professional practice or (2) for the purpose of, or 11 incident to, research, teaching, or chemical analysis and not 12 for sale or dispensing. "Compounding" includes the preparation 13 of drugs or devices in anticipation of receiving prescription drug orders based on routine, regularly observed dispensing 14 15 patterns. Commercially available products may be compounded 16 for dispensing to individual patients only if all of the 17 following conditions are met: (i) the commercial product is not reasonably available from normal distribution channels in 18 a timely manner to meet the patient's needs and (ii) the 19 20 prescribing practitioner has requested that the drug be 21 compounded.

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(p) (Blank).

23 (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 HB5530 Enrolled - 13 - LRB103 37122 RTM 67241 b

the patient's medication or device for the purpose of 1 2 optimizing proper use of prescription medications or devices. "Patient counseling" may include without limitation 3 (1) obtaining a medication history; (2) acquiring a patient's 4 5 allergies and health conditions; (3) facilitation of the patient's understanding of the intended use of the medication; 6 (4) proper directions for use; (5) significant potential 7 8 adverse events; (6) potential food-drug interactions; and (7) 9 the need to be compliant with the medication therapy. A 10 pharmacy technician may only participate in the following 11 aspects of patient counseling under the supervision of a 12 pharmacist: (1) obtaining medication history; (2) providing 13 the offer for counseling by a pharmacist or student pharmacist; and (3) acquiring a patient's allergies and health 14 15 conditions.

16 (s) "Patient profiles" or "patient drug therapy record" 17 means the obtaining, recording, and maintenance of patient 18 prescription information, including prescriptions for 19 controlled substances, and personal information.

20 (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.

4 (v) "Unique identifier" means an electronic signature,
5 handwritten signature or initials, thumb print, or other
6 acceptable biometric or electronic identification process as
7 approved by the Department.

8 (w) "Current usual and customary retail price" means the 9 price that a pharmacy charges to a non-third-party payor.

10 (x) "Automated pharmacy system" means a mechanical system 11 located within the confines of the pharmacy or remote location 12 that performs operations or activities, other than compounding 13 or administration, relative to storage, packaging, dispensing, 14 or distribution of medication, and which collects, controls, 15 and maintains all transaction information.

16 "Drug regimen review" means and includes the (V) 17 evaluation of prescription drug orders and patient records for allergies; (2) 18 (1)known drug or potential therapy 19 contraindications; (3) reasonable dose, duration of use, and 20 route of administration, taking into consideration factors such as age, gender, and contraindications; (4) reasonable 21 22 directions for use; (5) potential or actual adverse drug 23 reactions; (6) drug-drug interactions; (7) drug-food (8) drug-disease contraindications; 24 interactions; (9)25 therapeutic duplication; (10) patient laboratory values when 26 authorized and available; (11) proper utilization (including over or under utilization) and optimum therapeutic outcomes;
 and (12) abuse and misuse.

"Electronically transmitted prescription" means 3 (Z) а prescription that is created, recorded, or 4 stored bv 5 electronic means; issued and validated with an electronic signature; and transmitted by electronic means directly from 6 7 the prescriber to a pharmacy. An electronic prescription is 8 not an image of a physical prescription that is transferred by 9 electronic means from computer to computer, facsimile to facsimile, or facsimile to computer. 10

"Medication therapy management services" means a 11 (aa) 12 distinct service or group of services offered by licensed pharmacists, physicians licensed to practice medicine in all 13 14 its branches, advanced practice registered nurses authorized 15 in a written agreement with a physician licensed to practice 16 medicine in all its branches, or physician assistants 17 authorized in guidelines by a supervising physician that optimize therapeutic outcomes for individual patients through 18 improved medication use. In a retail or other non-hospital 19 20 pharmacy, medication therapy management services shall consist 21 of the evaluation of prescription drug orders and patient 22 medication records to resolve conflicts with the following:

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known allergies;

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(2) drug or potential therapy contraindications;

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

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age, gender, and contraindications; 1 2 (4) reasonable directions for use; 3 (5) potential or actual adverse drug reactions; (6) drug-drug interactions; 4 5 (7) drug-food interactions; (8) drug-disease contraindications; 6 7 (9) identification of therapeutic duplication; (10) patient laboratory values when authorized and 8 9 available: 10 (11) proper utilization (including over or under 11 utilization) and optimum therapeutic outcomes; and 12 (12) drug abuse and misuse. 13 "Medication therapy management services" includes the 14 following: delivered 15 (1)documenting the services and 16 communicating the information provided to patients' 17 prescribers within an appropriate time frame, not to exceed 48 hours: 18 19 (2) providing patient counseling designed to enhance a 20 patient's understanding and the appropriate use of his or her medications; and 21 22 (3) providing information, support services, and 23 resources designed to enhance a patient's adherence with 24 his or her prescribed therapeutic regimens. 25 "Medication therapy management services" may also include 26 patient care functions authorized by a physician licensed to

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1 practice medicine in all its branches for his or her 2 identified patient or groups of patients under specified 3 conditions or limitations in a standing order from the 4 physician.

5 "Medication therapy management services" in a licensed6 hospital may also include the following:

7 (1) reviewing assessments of the patient's health8 status; and

9 (2) following protocols of a hospital pharmacy and 10 therapeutics committee with respect to the fulfillment of 11 medication orders.

12 (bb) "Pharmacist care" means the provision by a pharmacist 13 of medication therapy management services, with or without the 14 dispensing of drugs or devices, intended to achieve outcomes 15 that improve patient health, quality of life, and comfort and 16 enhance patient safety.

17 (cc) "Protected health information" means individually 18 identifiable health information that, except as otherwise 19 provided, is:

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(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

24 (3) transmitted or maintained in any other form or 25 medium.

26 "Protected health information" does not include

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1 individually identifiable health information found in:

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

4 (2) employment records held by a licensee in its role 5 as an employer.

6 (dd) "Standing order" means a specific order for a patient 7 or group of patients issued by a physician licensed to 8 practice medicine in all its branches in Illinois.

9 (ee) "Address of record" means the designated address 10 recorded by the Department in the applicant's application file 11 or licensee's license file maintained by the Department's 12 licensure maintenance unit.

13 (ff) "Home pharmacy" means the location of a pharmacy's 14 primary operations.

15 (gg) "Email address of record" means the designated email 16 address recorded by the Department in the applicant's 17 application file or the licensee's license file, as maintained 18 by the Department's licensure maintenance unit.

19 (Source: P.A. 102-16, eff. 6-17-21; 102-103, eff. 1-1-22; 20 102-558, eff. 8-20-21; 102-813, eff. 5-13-22; 102-1051, eff. 21 1-1-23; 103-1, eff. 4-27-23.)