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AN ACT concerning regulation.

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

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

6 (225 ILCS 85/3)

7 (Section scheduled to be repealed on January 1, 2018)

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 medicines, or poisons are dispensed, sold or offered for sale 13 14 at retail, or displayed for sale at retail; or (2) where prescriptions of physicians, dentists, advanced practice 15 16 nurses, physician assistants, veterinarians, podiatric 17 physicians, or optometrists, within the limits of their licenses, are compounded, filled, or dispensed; or (3) which 18 19 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

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 6 7 the official United States Pharmacopoeia/National Formulary 8 (USP/NF), or any supplement thereto and being intended for and 9 having for their main use the diagnosis, cure, mitigation, 10 treatment or prevention of disease in man or other animals, as 11 approved by the United States Food and Drug Administration, but 12 does not include devices or their components, parts, or 13 accessories; and (2) all other articles intended for and having 14 for their main use the diagnosis, cure, mitigation, treatment 15 or prevention of disease in man or other animals, as approved 16 by the United States Food and Drug Administration, but does not 17 include devices or their components, parts, or accessories; and (3) articles (other than food) having for their main use and 18 19 intended to affect the structure or any function of the body of man or other animals; and (4) articles having for their main 20 21 use and intended for use as a component or any articles 22 specified in clause (1), (2) or (3); but does not include 23 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.

SB0317 Enrolled

- 3 - LRB100 05102 MJP 15112 b

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(d) "Practice of pharmacy" means:

(1) the interpretation and the provision of assistance
in the monitoring, evaluation, and implementation of
prescription drug orders;

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(2) the dispensing of prescription drug orders;

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(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;

11 (B) vaccination of patients 14 years of age and 12 older pursuant to a valid prescription or standing 13 order, by a physician licensed to practice medicine in 14 all its branches, upon completion of appropriate 15 training, including how to address contraindications 16 and adverse reactions set forth by rule, with 17 notification the patient's physician to and appropriate record retention, or pursuant to hospital 18 19 pharmacy and therapeutics committee policies and 20 procedures; and

21 <u>(C) administration of injections of</u> 22 <u>alpha-hydroxyprogesterone caproate, pursuant to a</u> 23 <u>valid prescription, by a physician licensed to</u> 24 <u>practice medicine in all its branches, upon completion</u> 25 <u>of appropriate training, including how to address</u> 26 <u>contraindications and adverse reactions set forth by</u>

1	rule, with notification to the patient's physician and
2	appropriate record retention, or pursuant to hospital
3	pharmacy and therapeutics committee policies and
4	procedures;

5 (5) vaccination of patients ages 10 through 13 limited to the Influenza (inactivated influenza vaccine and live 6 7 attenuated influenza intranasal vaccine) and Tdap (defined 8 tetanus, diphtheria, acellular pertussis) vaccines, as 9 pursuant to a valid prescription or standing order, by a 10 physician licensed to practice medicine in all its 11 branches, upon completion of appropriate training, 12 including how to address contraindications and adverse 13 reactions set forth by rule, with notification to the patient's physician and appropriate record retention, or 14 15 pursuant to hospital pharmacy and therapeutics committee 16 policies and procedures;

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(6) drug regimen review;

18 (7) drug or drug-related research;

19 (8) the provision of patient counseling;

20 (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

SB0317 Enrolled - 5 - LRB100 05102 MJP 15112 b

commercially packaged legend drugs and devices), proper and safe storage of drugs and devices, and maintenance of required records.

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, 7 8 facsimile, or electronically transmitted order for drugs or 9 medical devices, issued by a physician licensed to practice 10 medicine in all its branches, dentist, veterinarian, podiatric 11 physician, or optometrist, within the limits of their licenses, 12 by a physician assistant in accordance with subsection (f) of Section 4, or by an advanced practice nurse in accordance with 13 14 subsection (g) of Section 4, containing the following: (1) name 15 of the patient; (2) date when prescription was issued; (3) name 16 and strength of drug or description of the medical device prescribed; and (4) quantity; (5) directions for use; (6) 17 prescriber's name, address, and signature; and (7) DEA number 18 where required, for controlled substances. The prescription 19 20 may, but is not required to, list the illness, disease, or condition for which the drug or device is being prescribed. DEA 21 22 numbers shall not be required on inpatient drug orders.

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

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(g) "Department" means the Department of Financial and

SB0317 Enrolled - 6 - LRB100 05102 MJP 15112 b

1 Professional Regulation.

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

5 (i) "Secretary" means the Secretary of Financial and6 Professional Regulation.

7 (j) "Drug product selection" means the interchange for a 8 prescribed pharmaceutical product in accordance with Section 9 25 of this Act and Section 3.14 of the Illinois Food, Drug and 10 Cosmetic Act.

11 (k) "Inpatient drug order" means an order issued by an 12 authorized prescriber for a resident or patient of a facility 13 licensed under the Nursing Home Care Act, the ID/DD Community 14 Care Act, the MC/DD Act, the Specialized Mental Health Rehabilitation Act of 2013, or the Hospital Licensing Act, or 15 16 "An Act in relation to the founding and operation of the 17 University of Illinois Hospital and the conduct of University of Illinois health care programs", approved July 3, 1931, as 18 amended, or a facility which is operated by the Department of 19 20 Human Services (as successor to the Department of Mental Health 21 and Developmental Disabilities) or the Department of 22 Corrections.

23 (k-5) "Pharmacist" means an individual health care 24 professional and provider currently licensed by this State to 25 engage in the practice of pharmacy.

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(1) "Pharmacist in charge" means the licensed pharmacist

1 whose name appears on a pharmacy license and who is responsible 2 for all aspects of the operation related to the practice of 3 pharmacy.

(m) "Dispense" or "dispensing" means the interpretation, 4 5 evaluation, and implementation of a prescription drug order, including the preparation and delivery of a drug or device to a 6 7 or patient's agent in а suitable patient container 8 appropriately labeled for subsequent administration to or use 9 by a patient in accordance with applicable State and federal 10 laws and regulations. "Dispense" or "dispensing" does not mean 11 the physical delivery to а patient or patient's а 12 representative in a home or institution by a designee of a 13 pharmacist or by common carrier. "Dispense" or "dispensing" also does not mean the physical delivery of a drug or medical 14 15 device to a patient or patient's representative by a 16 pharmacist's designee within a pharmacy or drugstore while the 17 pharmacist is on duty and the pharmacy is open.

(n) "Nonresident pharmacy" means a pharmacy that is located 18 19 in a state, commonwealth, or territory of the United States, 20 other than Illinois, that delivers, dispenses, or distributes, 21 through the United States Postal Service, commercially 22 acceptable parcel delivery service, or other common carrier, to 23 Illinois residents, any substance which requires а 24 prescription.

(o) "Compounding" means the preparation and mixing of
 components, excluding flavorings, (1) as the result of a

SB0317 Enrolled - 8 - LRB100 05102 MJP 15112 b

prescriber's prescription drug order or initiative based on the 1 2 prescriber-patient-pharmacist relationship in the course of 3 professional practice or (2) for the purpose of, or incident to, research, teaching, or chemical analysis and not for sale 4 5 or dispensing. "Compounding" includes the preparation of drugs or devices in anticipation of receiving prescription drug 6 7 orders based on routine, regularly observed dispensing 8 patterns. Commercially available products may be compounded 9 for dispensing to individual patients only if all of the 10 following conditions are met: (i) the commercial product is not 11 reasonably available from normal distribution channels in a 12 timely manner to meet the patient's needs and (ii) the 13 prescribing practitioner has requested that the drug be 14 compounded.

- 15 (p) (Blank).
- 16 (q) (Blank).

(r) "Patient counseling" means the communication between a 17 pharmacist or a student pharmacist under the supervision of a 18 19 pharmacist and a patient or the patient's representative about 20 the patient's medication or device for the purpose of 21 optimizing proper use of prescription medications or devices. 22 "Patient counseling" may include without limitation (1) 23 obtaining a medication history; (2) acquiring a patient's allergies and health conditions; (3) facilitation of the 24 patient's understanding of the intended use of the medication; 25 26 (4) proper directions for use; (5) significant potential SB0317 Enrolled - 9 - LRB100 05102 MJP 15112 b

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.

8 (s) "Patient profiles" or "patient drug therapy record" 9 means the obtaining, recording, and maintenance of patient 10 prescription information, including prescriptions for 11 controlled substances, and personal information.

12 (t) (Blank).

13 "Medical device" means an instrument, apparatus, (u) 14 implement, machine, contrivance, implant, in vitro reagent, or 15 other similar or related article, including any component part 16 or accessory, required under federal law to bear the label 17 "Caution: Federal law requires dispensing by or on the order of a physician". A seller of goods and services who, only for the 18 19 purpose of retail sales, compounds, sells, rents, or leases 20 medical devices shall not, by reasons thereof, be required to 21 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.

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(w) "Current usual and customary retail price" means the

SB0317 Enrolled - 10 - LRB100 05102 MJP 15112 b

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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.

8 (y) "Drug regimen review" means and includes the evaluation 9 of prescription drug orders and patient records for (1) known 10 allergies; (2) drug or potential therapy contraindications; 11 (3) reasonable dose, duration of use, and route of 12 administration, taking into consideration factors such as age, gender, and contraindications; (4) reasonable directions for 13 14 use; (5) potential or actual adverse drug reactions; (6) 15 drug-drug interactions; (7) drug-food interactions; (8) 16 drug-disease contraindications; (9) therapeutic duplication; 17 (10) patient laboratory values when authorized and available; (11) proper utilization (including over or under utilization) 18 19 and optimum therapeutic outcomes; and (12) abuse and misuse.

"Electronic transmission prescription" means any 20 (Z) prescription order for which a facsimile or electronic image of 21 22 the order is electronically transmitted from a licensed "Electronic 23 prescriber pharmacy. transmission to а prescription" includes both data and image prescriptions. 24

(aa) "Medication therapy management services" means a
 distinct service or group of services offered by licensed

pharmacists, physicians licensed to practice medicine in all 1 2 its branches, advanced practice nurses authorized in a written 3 agreement with a physician licensed to practice medicine in all its branches, or physician assistants authorized in guidelines 4 5 by a supervising physician that optimize therapeutic outcomes 6 for individual patients through improved medication use. In a 7 retail or other non-hospital pharmacy, medication therapy management services shall consist of the evaluation of 8 9 prescription drug orders and patient medication records to 10 resolve conflicts with the following:

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(1) 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
age, gender, and contraindications;

- (4) reasonable directions for use;
- 17 (5) potential or actual adverse drug reactions;
- 18 (6) drug-drug interactions;
- 19 (7) drug-food interactions;
- 20 (8) drug-disease contraindications;
- 21 (9) identification of therapeutic duplication;
- 22 (10) patient laboratory values when authorized and 23 available;
- (11) proper utilization (including over or under
 utilization) and optimum therapeutic outcomes; and
 (12) drug abuse and misuse.

SB0317 Enrolled

- 12 - LRB100 05102 MJP 15112 b

1 "Medication therapy management services" includes the 2 following:

3 (1) documenting the services delivered and 4 communicating the information provided to patients' 5 prescribers within an appropriate time frame, not to exceed 6 48 hours;

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

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

13 "Medication therapy management services" may also include 14 patient care functions authorized by a physician licensed to 15 practice medicine in all its branches for his or her identified 16 patient or groups of patients under specified conditions or 17 limitations in a standing order from the physician.

18 "Medication therapy management services" in a licensed 19 hospital may also include the following:

20 (1) reviewing assessments of the patient's health 21 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.

4 (cc) "Protected health information" means individually 5 identifiable health information that, except as otherwise 6 provided, is:

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(1) transmitted by electronic media;

8 (2) maintained in any medium set forth in the 9 definition of "electronic media" in the federal Health 10 Insurance Portability and Accountability Act; or

11 (3) transmitted or maintained in any other form or 12 medium.

13 "Protected health information" does not include 14 individually identifiable health information found in:

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

17 (2) employment records held by a licensee in its role18 as an employer.

19 (dd) "Standing order" means a specific order for a patient 20 or group of patients issued by a physician licensed to practice 21 medicine in all its branches in Illinois.

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

26 (ff) "Home pharmacy" means the location of a pharmacy's

SB0317 Enrolled - 14 - LRB100 05102 MJP 15112 b

- 1 primary operations.
- 2 (Source: P.A. 98-104, eff. 7-22-13; 98-214, eff. 8-9-13;
- 3 98-756, eff. 7-16-14; 99-180, eff. 7-29-15.)