HB5890

LRB09618739ASK34124b

96TH GENERAL ASSEMBLY

State of Illinois

2009 and 2010

HB5890

Introduced 2/10/2010, by Rep. Sandra M. Pihos

SYNOPSIS AS INTRODUCED:

225 ILCS 85/3

Amends the Pharmacy Practice Act. In the definition of "prescription", provides that an order may contain, at the discretion of the individual issuing the order, information on the indicated use of the drug or device as approved by the United States Food and Drug Administration (FDA). Effective immediately.

LRB096 18739 ASK 34124 b

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

(225 ILCS 85/3)

(Text of Section before amendment by P.A. 96-339)

(Section scheduled to be repealed on January 1, 2018)

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 nurses, physician assistants, veterinarians, podiatrists, 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 (l) 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 (l), (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: in the context of patient education on the proper use or delivery of medications; 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; (5) drug regimen review; (6) drug or drug-related research; (7) the provision of patient counseling; (8) the practice of telepharmacy; (9) the provision of those acts or services necessary to provide pharmacist care; (10) medication therapy management; and (11) 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. 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, or podiatrist, or optometrist, within the limits of their licenses, by a physician assistant in accordance with subsection (f) of Section 4, or by an advanced practice nurse in accordance with subsection (g) of Section 4, containing the following: (l) 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 number where required, for controlled substances; and (8), at the discretion of the individual issuing the order, the indicated use of the drug or device as approved by the United States Food and Drug Administration (FDA). DEA 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.

(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 or the Hospital Licensing Act, or "An Act in relation to the founding and operation of the University of Illinois Hospital and the conduct of University of Illinois health care programs", approved July 3, 1931, as amended, 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" 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) "Electronic transmission prescription" means any prescription order for which a facsimile or electronic image of the order is electronically transmitted from a licensed prescriber to a pharmacy. "Electronic transmission prescription" includes both data and image prescriptions.

(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 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 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.

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

(Source: P.A. 95-689, eff. 10-29-07; 96-673, eff. 1-1-10.)

(Text of Section after amendment by P.A. 96-339)

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

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 nurses, physician assistants, veterinarians, podiatrists, 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 (l) 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 (l), (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: in the context of patient education on the proper use or delivery of medications; 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; (5) drug regimen review; (6) drug or drug-related research; (7) the provision of patient counseling; (8) the practice of telepharmacy; (9) the provision of those acts or services necessary to provide pharmacist care; (10) medication therapy management; and (11) 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. 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, or podiatrist, or optometrist, within the limits of their licenses, by a physician assistant in accordance with subsection (f) of Section 4, or by an advanced practice nurse in accordance with subsection (g) of Section 4, containing the following: (l) 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 number where required, for controlled substances. DEA numbers shall not be required on inpatient drug orders, and (8), at the discretion of the individual issuing the order, the indicated use of the drug or device as approved by the United States Food and Drug Administration (FDA).

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

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to the founding and operation of the University of Illinois Hospital and the conduct of University of Illinois health care programs", approved July 3, 1931, as amended, 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.

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(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.

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(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.

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(u) "Medical 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) "Electronic transmission prescription" means any prescription order for which a facsimile or electronic image of the order is electronically transmitted from a licensed prescriber to a pharmacy. "Electronic transmission prescription" includes both data and image prescriptions.

(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 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:

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(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 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.

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

(Source: P.A. 95-689, eff. 10-29-07; 96-339, eff. 7-1-10; 96-673, eff. 1-1-10; revised 10-1-09.)

Section 99. Effective date. This Act takes effect upon becoming law.