



99TH GENERAL ASSEMBLY

State of Illinois

2015 and 2016

HB5809

by Rep. Michelle Mussman

SYNOPSIS AS INTRODUCED:

225 ILCS 85/3
225 ILCS 85/19.7 new

Amends the Pharmacy Practice Act. Provides that "practice of pharmacy" includes the prescribing and dispensing of hormonal contraceptive patches and self-administered oral hormonal contraceptives. Defines "hormonal contraceptive patch" as a transdermal patch applied to the skin of a patient, by the patient or by a practitioner, that releases a drug composed of a combination of hormones that is approved by the United States Food and Drug Administration to prevent pregnancy and "self-administered oral hormonal contraceptive" as a drug composed of a combination of hormones that is approved by the United States Food and Drug Administration to prevent pregnancy and that the patient to whom the drug is prescribed may take orally. Allows pharmacists to prescribe and dispense contraceptives to a person over 18 years of age and a person under 18 years of age only if the person has evidence of a previous prescription from a primary care or a women's health care practitioner. Requires the Department of Financial and Professional Regulation to adopt rules to establish standard procedures for pharmacists to prescribe contraceptives. Provides requirements for the rules to be adopted by the Department. Provides that all State and federal laws governing insurance coverage of contraceptive drugs and products shall apply to this Section.

LRB099 17756 SMS 42118 b

1 AN ACT concerning regulation.

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

4 Section 5. The Pharmacy Practice Act is amended by changing
5 Section 3 and by adding Section 19.7 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7 (Section scheduled to be repealed on January 1, 2018)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:

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

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

6 (b) "Drugs" means and includes (1) articles recognized in
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
18 (3) articles (other than food) having for their main use and
19 intended to affect the structure or any function of the body of
20 man or other animals; and (4) articles having for their main
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.

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

1 (d) "Practice of pharmacy" means (1) the interpretation and
2 the provision of assistance in the monitoring, evaluation, and
3 implementation of prescription drug orders; (2) the dispensing
4 of prescription drug orders; (3) participation in drug and
5 device selection; (4) drug administration limited to the
6 administration of oral, topical, injectable, and inhalation as
7 follows: in the context of patient education on the proper use
8 or delivery of medications; vaccination of patients 14 years of
9 age and older pursuant to a valid prescription or standing
10 order, by a physician licensed to practice medicine in all its
11 branches, upon completion of appropriate training, including
12 how to address contraindications and adverse reactions set
13 forth by rule, with notification to the patient's physician and
14 appropriate record retention, or pursuant to hospital pharmacy
15 and therapeutics committee policies and procedures; (5)
16 vaccination of patients ages 10 through 13 limited to the
17 Influenza (inactivated influenza vaccine and live attenuated
18 influenza intranasal vaccine) and Tdap (defined as tetanus,
19 diphtheria, acellular pertussis) vaccines, pursuant to a valid
20 prescription or standing order, by a physician licensed to
21 practice medicine in all its branches, upon completion of
22 appropriate training, including how to address
23 contraindications and adverse reactions set forth by rule, with
24 notification to the patient's physician and appropriate record
25 retention, or pursuant to hospital pharmacy and therapeutics
26 committee policies and procedures; (6) drug regimen review; (7)

1 drug or drug-related research; (8) the provision of patient
2 counseling; (9) the practice of telepharmacy; (10) the
3 provision of those acts or services necessary to provide
4 pharmacist care; (11) medication therapy management; ~~and~~ (12)
5 the responsibility for compounding and labeling of drugs and
6 devices (except labeling by a manufacturer, repackager, or
7 distributor of non-prescription drugs and commercially
8 packaged legend drugs and devices), proper and safe storage of
9 drugs and devices, and maintenance of required records; and
10 (13) the prescribing and dispensing of hormonal contraceptive
11 patches and self-administered oral hormonal contraceptives. A
12 pharmacist who performs any of the acts defined as the practice
13 of pharmacy in this State must be actively licensed as a
14 pharmacist under this Act.

15 (e) "Prescription" means and includes any written, oral,
16 facsimile, or electronically transmitted order for drugs or
17 medical devices, issued by a physician licensed to practice
18 medicine in all its branches, dentist, veterinarian, podiatric
19 physician, or optometrist, within the limits of their licenses,
20 by a physician assistant in accordance with subsection (f) of
21 Section 4, or by an advanced practice nurse in accordance with
22 subsection (g) of Section 4, containing the following: (1) name
23 of the patient; (2) date when prescription was issued; (3) name
24 and strength of drug or description of the medical device
25 prescribed; and (4) quantity; (5) directions for use; (6)
26 prescriber's name, address, and signature; and (7) DEA number

1 where required, for controlled substances. The prescription
2 may, but is not required to, list the illness, disease, or
3 condition for which the drug or device is being prescribed. DEA
4 numbers shall not be required on inpatient drug orders.

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

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

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

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

15 (j) "Drug product selection" means the interchange for a
16 prescribed pharmaceutical product in accordance with Section
17 25 of this Act and Section 3.14 of the Illinois Food, Drug and
18 Cosmetic Act.

19 (k) "Inpatient drug order" means an order issued by an
20 authorized prescriber for a resident or patient of a facility
21 licensed under the Nursing Home Care Act, the ID/DD Community
22 Care Act, the MC/DD Act, the Specialized Mental Health
23 Rehabilitation Act of 2013, or the Hospital Licensing Act, or
24 "An Act in relation to the founding and operation of the
25 University of Illinois Hospital and the conduct of University
26 of Illinois health care programs", approved July 3, 1931, as

1 amended, or a facility which is operated by the Department of
2 Human Services (as successor to the Department of Mental Health
3 and Developmental Disabilities) or the Department of
4 Corrections.

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

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

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

26 (n) "Nonresident pharmacy" means a pharmacy that is located

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

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

23 (p) (Blank).

24 (q) (Blank).

25 (r) "Patient counseling" means the communication between a
26 pharmacist or a student pharmacist under the supervision of a

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

21 (u) "Medical device" means an instrument, apparatus,
22 implement, machine, contrivance, implant, in vitro reagent, or
23 other similar or related article, including any component part
24 or accessory, required under federal law to bear the label
25 "Caution: Federal law requires dispensing by or on the order of
26 a physician". A seller of goods and services who, only for the

1 purpose of retail sales, compounds, sells, rents, or leases
2 medical devices shall not, by reasons thereof, be required to
3 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 (y) "Drug regimen review" means and includes the evaluation
17 of prescription drug orders and patient records for (1) known
18 allergies; (2) drug or potential therapy contraindications;
19 (3) reasonable dose, duration of use, and route of
20 administration, taking into consideration factors such as age,
21 gender, and contraindications; (4) reasonable directions for
22 use; (5) potential or actual adverse drug reactions; (6)
23 drug-drug interactions; (7) drug-food interactions; (8)
24 drug-disease contraindications; (9) therapeutic duplication;
25 (10) patient laboratory values when authorized and available;
26 (11) proper utilization (including over or under utilization)

1 and optimum therapeutic outcomes; and (12) abuse and misuse.

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

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

- 19 (1) known allergies;
- 20 (2) drug or potential therapy contraindications;
- 21 (3) reasonable dose, duration of use, and route of
22 administration, taking into consideration factors such as
23 age, gender, and contraindications;
- 24 (4) reasonable directions for use;
- 25 (5) potential or actual adverse drug reactions;
- 26 (6) drug-drug interactions;

- 1 (7) drug-food interactions;
- 2 (8) drug-disease contraindications;
- 3 (9) identification of therapeutic duplication;
- 4 (10) patient laboratory values when authorized and
- 5 available;
- 6 (11) proper utilization (including over or under
- 7 utilization) and optimum therapeutic outcomes; and
- 8 (12) drug abuse and misuse.

9 "Medication therapy management services" includes the
10 following:

- 11 (1) documenting the services delivered and
- 12 communicating the information provided to patients'
- 13 prescribers within an appropriate time frame, not to exceed
- 14 48 hours;
- 15 (2) providing patient counseling designed to enhance a
- 16 patient's understanding and the appropriate use of his or
- 17 her medications; and
- 18 (3) providing information, support services, and
- 19 resources designed to enhance a patient's adherence with
- 20 his or her prescribed therapeutic regimens.

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

26 "Medication therapy management services" in a licensed

1 hospital may also include the following:

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

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

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

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

15 (1) transmitted by electronic media;

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

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

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

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

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

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

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

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

10 (Source: P.A. 98-104, eff. 7-22-13; 98-214, eff. 8-9-13;
11 98-756, eff. 7-16-14; 99-180, eff. 7-29-15.)

12 (225 ILCS 85/19.7 new)

13 Sec. 19.7. Contraceptive drugs and products.

14 (a) As used in this Section:

15 "Hormonal contraceptive patch" means a transdermal patch
16 applied to the skin of a patient, by the patient or by a
17 practitioner, that releases a drug composed of a combination of
18 hormones that is approved by the United States Food and Drug
19 Administration to prevent pregnancy.

20 "Self-administered oral hormonal contraceptives" means a
21 drug composed of a combination of hormones that is approved by
22 the United States Food and Drug Administration to prevent
23 pregnancy and that the patient to whom the drug is prescribed
24 may take orally.

25 (b) A pharmacist may prescribe and dispense hormonal

1 contraceptive patches and self-administered oral hormonal
2 contraceptives to a person who is:

3 (1) at least 18 years of age, regardless of whether the
4 person has evidence of a previous prescription from a
5 primary care practitioner or a women's health care
6 practitioner for a hormonal contraceptive patch or
7 self-administered oral hormonal contraceptive; or

8 (2) under 18 years of age only if the person has
9 evidence of a previous prescription from a primary care
10 practitioner or a women's health care practitioner for a
11 hormonal contraceptive patch or self-administered oral
12 hormonal contraceptive.

13 (b) The Department shall adopt rules to establish, in
14 consideration of guidelines established by the American
15 Congress of Obstetricians and Gynecologists, standard
16 procedures for the prescribing of hormonal contraceptive
17 patches and self-administered oral hormonal contraceptives by
18 pharmacists.

19 (c) The rules adopted under this Section must require a
20 pharmacist to:

21 (1) complete a training program approved by the
22 Department that is related to prescribing hormonal
23 contraceptive patches and self-administered oral hormonal
24 contraceptives;

25 (2) provide a self-screening risk assessment tool that
26 the patient must use prior to the pharmacist's prescribing

1 the hormonal contraceptive patch or self-administered oral
2 hormonal contraceptive;

3 (3) refer the patient to the patient's primary care
4 practitioner or women's health care practitioner upon
5 prescribing and dispensing the hormonal contraceptive
6 patch or self-administered oral hormonal contraceptive;

7 (4) provide the patient with a written record of the
8 hormonal contraceptive patch or self-administered oral
9 hormonal contraceptive prescribed and dispensed and advise
10 the patient to consult with a primary care practitioner or
11 women's health care practitioner; and

12 (5) dispense the hormonal contraceptive patch or
13 self-administered oral hormonal contraceptive to the
14 patient as soon as practicable after the pharmacist issues
15 the prescription.

16 (c) The rules adopted under this Section must prohibit a
17 pharmacist from:

18 (1) requiring a patient to schedule an appointment with
19 the pharmacist for the prescribing or dispensing of a
20 hormonal contraceptive patch or self-administered oral
21 hormonal contraceptive; and

22 (2) prescribing and dispensing a hormonal
23 contraceptive patch or self-administered oral hormonal
24 contraceptive to a patient who does not have evidence of a
25 clinical visit for women's health within the 3 years
26 immediately following the initial prescription and

1 dispensation of a hormonal contraceptive patch or
2 self-administered oral hormonal contraceptive by a
3 pharmacist to the patient.

4 (d) All State and federal laws governing insurance coverage
5 of contraceptive drugs, devices, products, and services shall
6 apply to hormonal contraceptive patches and self-administered
7 oral hormonal contraceptives prescribed by a pharmacist under
8 this section.