



100TH GENERAL ASSEMBLY

State of Illinois

2017 and 2018

HB5747

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 the provisions.

LRB100 18501 XWW 33719 b

FISCAL NOTE ACT
MAY APPLY

A BILL FOR

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7 (Section scheduled to be repealed on January 1, 2020)

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 registered nurses, physician assistants, veterinarians,
17 podiatric physicians, or optometrists, within the limits of
18 their licenses, are compounded, filled, or dispensed; or (3)
19 which has upon it or displayed within it, or affixed to or used
20 in 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:

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

5 (2) the dispensing of prescription drug orders;

6 (3) participation in drug and device selection;

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

9 (A) in the context of patient education on the
10 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 to the patient's physician and
18 appropriate record retention, or pursuant to hospital
19 pharmacy and therapeutics committee policies and
20 procedures; and

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

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
6 to the Influenza (inactivated influenza vaccine and live
7 attenuated influenza intranasal vaccine) and Tdap (defined
8 as tetanus, diphtheria, acellular pertussis) vaccines,
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
14 patient's physician and appropriate record retention, or
15 pursuant to hospital pharmacy and therapeutics committee
16 policies and procedures;

17 (6) drug regimen review;

18 (7) drug or drug-related research;

19 (8) the provision of patient counseling;

20 (9) the practice of telepharmacy;

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

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

24 (12) the responsibility for compounding and labeling
25 of drugs and devices (except labeling by a manufacturer,
26 repackager, or distributor of non-prescription drugs and

1 commercially packaged legend drugs and devices), proper
2 and safe storage of drugs and devices, and maintenance of
3 required records; and-

4 (13) the prescribing and dispensing of hormonal
5 contraceptive patches and self-administered oral hormonal
6 contraceptives.

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

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

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

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

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

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

11 (j) "Drug product selection" means the interchange for a
12 prescribed pharmaceutical product in accordance with Section
13 25 of this Act and Section 3.14 of the Illinois Food, Drug and
14 Cosmetic Act.

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

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

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

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

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

1 Illinois residents, any substance which requires a
2 prescription.

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

19 (p) (Blank).

20 (q) (Blank).

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

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

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

16 (t) (Blank).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

14 (1) transmitted by electronic media;

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

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

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

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

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

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

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

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

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

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

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

15 (225 ILCS 85/19.7 new)

16 Sec. 19.7. Contraceptive drugs and products.

17 (a) As used in this Section:

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

23 "Self-administered oral hormonal contraceptives" means a
24 drug composed of a combination of hormones that is approved by
25 the United States Food and Drug Administration to prevent

1 pregnancy and that the patient to whom the drug is prescribed
2 may take orally.

3 (b) A pharmacist may prescribe and dispense hormonal
4 contraceptive patches and self-administered oral hormonal
5 contraceptives to a person who is:

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

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

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

22 (d) The rules adopted under this Section must require a
23 pharmacist to:

24 (1) complete a training program approved by the
25 Department that is related to prescribing hormonal
26 contraceptive patches and self-administered oral hormonal

1 contraceptives;

2 (2) provide a self-screening risk assessment tool that
3 the patient must use prior to the pharmacist's prescribing
4 the hormonal contraceptive patch or self-administered oral
5 hormonal contraceptive;

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

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

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

19 (e) The rules adopted under this Section must prohibit a
20 pharmacist from:

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

25 (2) prescribing and dispensing a hormonal
26 contraceptive patch or self-administered oral hormonal

1 contraceptive to a patient who does not have evidence of a
2 clinical visit for women's health within the 3 years
3 immediately following the initial prescription and
4 dispensation of a hormonal contraceptive patch or
5 self-administered oral hormonal contraceptive by a
6 pharmacist to the patient.

7 (f) All State and federal laws governing insurance coverage
8 of contraceptive drugs, devices, products, and services shall
9 apply to hormonal contraceptive patches and self-administered
10 oral hormonal contraceptives prescribed by a pharmacist under
11 this Section.