

By Representative Morroni

1 A bill to be entitled
2 An act relating to pharmacy practice; amending
3 s. 465.003, F.S.; revising and providing
4 definitions; amending s. 465.014, F.S.;
5 providing additional duties of pharmacy
6 technicians; increasing the number of pharmacy
7 technicians who may be supervised by a licensed
8 pharmacist; correcting a cross reference;
9 amending ss. 465.015, 465.0196, and 499.003,
10 F.S.; correcting cross references; amending s.
11 465.017, F.S.; providing additional persons and
12 entities to whom records relating to the
13 filling of prescriptions and the dispensing of
14 medicinal drugs that are maintained by a
15 pharmacy may be furnished; providing
16 restrictions on such records when transmitted
17 through a data communication device; amending
18 s. 465.026, F.S.; revising provisions relating
19 to the filling of prescriptions transferred by
20 electronic or other means; amending s. 465.035,
21 F.S.; authorizing the dispensing of certain
22 controlled substances pursuant to facsimile
23 receipt of the original prescription; providing
24 an effective date.

25
26 Be It Enacted by the Legislature of the State of Florida:

27
28 Section 1. Section 465.003, Florida Statutes, is
29 amended to read:

30 465.003 Definitions.--As used in this chapter, the
31 term:

1 (1) "Administration" means the obtaining and giving of
2 a single dose of medicinal drugs by a legally authorized
3 person to a patient for his consumption.

4 (2) "Board" means the Board of Pharmacy.

5 (3) "Consultant pharmacist" means a pharmacist
6 licensed by the department and certified as a consultant
7 pharmacist pursuant to s. 465.0125.

8 (4) "Data communication device" means an electronic
9 device that receives electronic information from one source
10 and transmits or routes it to another, including, but not
11 limited to, any such bridge, router, switch, or gateway.

12 ~~(5)(4)~~ "Department" means the Department of Health
13 ~~Business and Professional Regulation.~~

14 ~~(6)(5)~~ "Dispense" means the transfer of possession of
15 one or more doses of a medicinal drug by a pharmacist to the
16 ultimate consumer or his agent. As an element of dispensing,
17 the pharmacist shall, prior to the actual physical transfer,
18 interpret and assess the prescription order for potential
19 adverse reactions, interactions, and dosage regimen he deems
20 appropriate in the exercise of his professional judgment, and
21 he shall certify that the medicinal drug called for by the
22 prescription is ready for transfer. The pharmacist shall also
23 provide counseling on proper drug usage, either orally or in
24 writing, if in the exercise of his professional judgment
25 counseling is necessary. The actual sales transaction and
26 delivery of such drug shall not be considered dispensing. The
27 administration shall not be considered dispensing.

28 ~~(7)(6)~~ "Institutional formulary system" means a method
29 whereby the medical staff evaluates, appraises, and selects
30 those medicinal drugs or proprietary preparations which in the
31 medical staff's clinical judgment are most useful in patient

1 care, and which are available for dispensing by a practicing
2 pharmacist in a Class II institutional pharmacy.

3 (8)~~(7)~~ "Medicinal drugs" or "drugs" means those
4 substances or preparations commonly known as "prescription" or
5 "legend" drugs which are required by federal or state law to
6 be dispensed only on a prescription, but shall not include
7 patents or proprietary preparations as hereafter defined.

8 (9)~~(8)~~ "Patent or proprietary preparation" means a
9 medicine in its unbroken, original package which is sold to
10 the public by, or under the authority of, the manufacturer or
11 primary distributor thereof and which is not misbranded under
12 the provisions of the Florida Drug and Cosmetic Act.

13 (10)~~(9)~~ "Pharmacist" means any person licensed
14 pursuant to this chapter to practice the profession of
15 pharmacy.

16 (11)(a)~~(10)~~ "Pharmacy" includes a community pharmacy,
17 an institutional pharmacy, a nuclear pharmacy, and a special
18 pharmacy.

19 1.(a) The term "community pharmacy" includes every
20 location where medicinal drugs are compounded, dispensed,
21 stored, or sold or where prescriptions are filled or dispensed
22 on an outpatient basis.

23 2.(b) The term "institutional pharmacy" includes every
24 location in a hospital, clinic, nursing home, dispensary,
25 sanitarium, extended care facility, or other facility,
26 hereinafter referred to as "health care institutions," where
27 medicinal drugs are compounded, dispensed, stored, or sold.

28 3.(c) The term "nuclear pharmacy" includes every
29 location where radioactive drugs and chemicals within the
30 classification of medicinal drugs are compounded, dispensed,
31 stored, or sold. The term "nuclear pharmacy" does not include

1 hospitals licensed under chapter 395 or the nuclear medicine
2 facilities of such hospitals.

3 4.~~(d)~~ The term "special pharmacy" includes every
4 location where medicinal drugs are compounded, dispensed,
5 stored, or sold if such locations are not otherwise defined in
6 this subsection.

7 (b) The pharmacy department of any permittee shall be
8 considered closed whenever a Florida-licensed pharmacist is
9 not present and on duty. The term "not present and on duty"
10 may not be construed to prevent a pharmacist from exiting the
11 prescription department for the purposes of consulting or
12 responding to inquiries or providing assistance to patients or
13 customers, attending to personal hygiene needs, or performing
14 any other function for which the pharmacist is responsible,
15 provided that such activities are conducted in a manner
16 consistent with the pharmacist's responsibility to provide
17 pharmacy services.

18 (12)~~(11)~~ "Pharmacy intern" means a person who is
19 currently registered in, and attending, a duly accredited
20 college or school of pharmacy, or who is a graduate of such a
21 school or college of pharmacy, and who is duly and properly
22 registered with the department as provided for under its
23 rules.

24 (13)~~(12)~~ "Practice of the profession of pharmacy"
25 includes compounding, dispensing, and consulting concerning
26 contents, therapeutic values, and uses of any medicinal drug
27 and consulting concerning therapeutic values and interactions
28 of patent or proprietary preparations, whether pursuant to
29 prescriptions or in the absence and entirely independent of
30 such prescriptions or orders, and other related cognitive
31 services. The phrase also includes any other act, service,

1 operation, or transaction incidental to, or forming a part of,
2 any of the foregoing acts, requiring, involving, or employing
3 the science or art of any branch of the pharmaceutical
4 profession, study, or training, and shall expressly permit a
5 pharmacist to transmit information from persons authorized to
6 prescribe medicinal drugs to their patients.

7 (14)~~(13)~~ "Prescription" includes any order for drugs
8 or medicinal supplies written or transmitted by any means of
9 communication by a duly licensed practitioner authorized by
10 the laws of the state to prescribe such drugs or medicinal
11 supplies and intended to be dispensed by a pharmacist. The
12 term also includes an orally transmitted order by the lawfully
13 designated agent of such practitioner. The term also includes
14 an order written or transmitted by a practitioner licensed to
15 practice in a jurisdiction other than this state, but only if
16 the pharmacist called upon to dispense such order determines,
17 in the exercise of his professional judgment, that the order
18 is valid and necessary for the treatment of a chronic or
19 recurrent illness. The term "prescription" also includes a
20 pharmacist's order for a product selected from the formulary
21 created pursuant to s. 465.186. Prescriptions may be retained
22 in written form or the pharmacist may cause it to be recorded
23 in a data processing system, provided that such order can be
24 produced in printed form upon lawful request.

25 (15)~~(14)~~ "Nuclear pharmacist" means a pharmacist
26 licensed by the department and certified as a nuclear
27 pharmacist pursuant to s. 465.0126.

28 Section 2. Section 465.014, Florida Statutes, is
29 amended to read:

30 465.014 Pharmacy technician.--No person other than a
31 licensed pharmacist or pharmacy intern may engage in the

1 practice of the profession of pharmacy, except that a licensed
2 pharmacist may delegate to nonlicensed pharmacy technicians
3 those duties, tasks, and functions which do not fall within
4 the purview of s. 465.003(13)(12). All such delegated acts
5 shall be performed under the direct supervision of a licensed
6 pharmacist who shall be responsible for all such acts
7 performed by persons under his supervision. A pharmacy
8 technician, under the direct supervision of a licensed
9 pharmacist, may initiate or receive communications with a
10 practitioner, on behalf of the patient, regarding refill
11 authorization requests and related information.No licensed
12 pharmacist shall supervise more than one pharmacy technician
13 unless otherwise permitted by the guidelines adopted by the
14 board. The board shall establish guidelines to be followed by
15 licensees or permittees in determining the circumstances under
16 which a licensed pharmacist may supervise more than one but
17 not more than three ~~two~~ pharmacy technicians.

18 Section 3. Paragraph (c) of subsection (2) of section
19 465.015, Florida Statutes, is amended to read:

20 465.015 Violations and penalties.--

21 (2) It is unlawful for any person:

22 (c) To sell or dispense drugs as defined in s.
23 465.003(8)(7)without first being furnished with a
24 prescription.

25 Section 4. Subsection (2) of section 465.017, Florida
26 Statutes, is amended to read:

27 465.017 Authority to inspect.--

28 (2) Except as permitted by this chapter, and chapters
29 406, 409, 455, 499, and 893, records maintained by ~~in~~ a
30 pharmacy relating to the filling of prescriptions and the
31 dispensing of medicinal drugs shall not be furnished, except

1 upon the written authorization of the patient,to any person
2 other than ~~to~~ the patient for whom the drugs were dispensed,
3 ~~or his legal representative, or to the department pursuant to~~
4 ~~existing law,~~or, in the event that the patient is
5 incapacitated or unable to request said records, his spouse;
6 to the department pursuant to existing law; to treating
7 practitioners and other pharmacists when, in the professional
8 judgment of the pharmacist, such release protects or benefits
9 the patient's health, well-being, or treatment; or, to
10 insurance carriers or other payors authorized by the patient
11 to receive such records. For purposes of this section, records
12 held in a pharmacy shall be considered held by the owner of
13 the pharmacy ~~except upon the written authorization of such~~
14 ~~patient.~~ Such records may be furnished in any civil or
15 criminal proceeding, upon the issuance of a subpoena from a
16 court of competent jurisdiction and proper notice to the
17 patient or his legal representative by the party seeking such
18 records. Such records or any part thereof, if transmitted
19 through a data communication device and not directly between a
20 pharmacy and a treating practitioner, may not be accessed,
21 used, or maintained by the operator or owner of the data
22 communication device unless specifically authorized by this
23 section.

24 Section 5. Section 465.0196, Florida Statutes, is
25 amended to read:

26 465.0196 Special pharmacy permits.--Any person
27 desiring a permit to operate a pharmacy which does not fall
28 within the definitions set forth in s. 465.003~~(11)~~~~(10)~~(a)1.,
29 2.(b), and 3.(c)shall apply to the department for a special
30 pharmacy permit. If the board certifies that the application
31 complies with the applicable laws and rules of the board

1 governing the practice of the profession of pharmacy, the
2 department shall issue the permit. No permit shall be issued
3 unless a licensed pharmacist is designated to undertake the
4 professional supervision of the compounding and dispensing of
5 all drugs dispensed by the pharmacy. The licensed pharmacist
6 shall be responsible for maintaining all drug records and for
7 providing for the security of the area in the facility in
8 which the compounding, storing, and dispensing of medicinal
9 drugs occurs. The permittee shall notify the department within
10 10 days of any change of the licensed pharmacist responsible
11 for such duties.

12 Section 6. Section 465.026, Florida Statutes, is
13 amended to read:

14 465.026 Filling of certain prescriptions.--Nothing
15 contained in this chapter shall be construed to prohibit a
16 pharmacist licensed in this state from filling or refilling a
17 valid prescription which is on file in a pharmacy located in
18 this state or in another state and has been transferred from
19 one pharmacy to another by any means, including any electronic
20 means transfer by way of electronic data processing equipment,
21 under the following conditions:

22 (1) Prior to dispensing any transferred ~~pursuant to~~
23 ~~any such~~ prescription, the dispensing pharmacist must, either
24 verbally or by any electronic means, do all of the following
25 shall:

26 (a) Advise the patient that the prescription on file
27 at the such other pharmacy must be canceled before it may be
28 filled or refilled ~~he will be able to fill or refill it.~~

29 (b) Determine ~~from the requested pharmacist~~ that the
30 prescription is valid and on file at the such other pharmacy
31 and that the such prescription may be filled or refilled, as

1 requested, in accordance with the prescriber's intent
2 expressed on the ~~such~~ prescription.

3 (c) Notify the pharmacist or ~~at the~~ pharmacy where the
4 prescription is on file that the prescription must be
5 canceled.

6 (d) Record in writing, or by any electronic means, ~~or~~
7 ~~cause to be recorded by data processing equipment~~ the
8 prescription order, the name of the pharmacy at which the
9 prescription was on file, the prescription number, the name of
10 the drug and the original amount dispensed, the date of
11 original dispensing, and the number of remaining authorized
12 refills.

13 (e) Obtain the consent of the prescriber to the
14 refilling of the prescription when the prescription, in the
15 dispensing pharmacist's professional judgment ~~of the~~
16 ~~dispensing pharmacist~~, so requires. Any interference with the
17 professional judgment of the dispensing pharmacist by any
18 pharmacist or pharmacy permittee, or its agents, or employees,
19 shall be grounds for discipline ~~revocation or suspension of~~
20 ~~the permit issued to the pharmacy.~~

21 (2) Upon receipt of a ~~request for~~ prescription
22 transfer request information set forth in paragraph (1)(d), if
23 the ~~requested~~ pharmacist is satisfied in his professional
24 judgment that the ~~such~~ request is valid, or if the request has
25 been validated by any electronic means, the ~~requested~~
26 pharmacist or pharmacy must do all of the following shall:

27 (a) Transfer the information required by paragraph
28 ~~(1)(d) Provide such information~~ accurately and completely.

29 (b) Record on the prescription, or by any electronic
30 means, ~~or record with data processing equipment~~ the name of
31

1 the requesting pharmacy and pharmacist and the date of
2 request.

3 (c) Cancel the prescription on file by electronic
4 means or by recording the word "void" on the prescription
5 record. No further prescription information shall be given or
6 medication dispensed pursuant to the ~~said~~ original
7 prescription.

8 (3) If a transferred prescription is not dispensed
9 within a reasonable time, the pharmacist shall, by any means,
10 so notify the transferring pharmacy. ~~In the event that, after~~
11 ~~the information set forth in paragraph (1)(d) has been~~
12 ~~provided, a prescription is not dispensed by the requesting~~
13 ~~pharmacist, then such pharmacist shall provide notice of this~~
14 ~~fact to the pharmacy from which said information was obtained.~~
15 Such notice shall serve to revalidate the canceled ~~voided~~
16 prescription. The pharmacist who has served such notice shall
17 then cancel the prescription in the same manner as set forth
18 in paragraph (2)(c).

19 (4) In the case of a prescription to be transferred
20 from or to a pharmacy located in another ~~outside of the state,~~
21 it shall be the responsibility of the pharmacist or pharmacy
22 located in the State of Florida to verify, whether by
23 electronic means or otherwise, ~~assure~~ that the person or
24 entity involved in the ~~performing the act of transfer~~ is a
25 licensed pharmacist or pharmacy in the other state ~~from~~
26 ~~outside the state is a practitioner licensed to practice~~
27 ~~pharmacy in the jurisdiction wherein the non-Florida pharmacy~~
28 ~~involved is located.~~

29 (5) Electronic transfers of prescriptions are
30 permitted regardless of whether the transferor or transferee
31 pharmacy is open for business.

1 ~~(6)(5)~~ The transfer of a prescription for medicinal
2 drugs listed in Schedules III, IV, and V appearing in chapter
3 893 for the purpose of refill dispensing is permissible,
4 ~~between pharmacies on a one-time basis~~ subject to the
5 requirements of this section and federal law. Compliance with
6 federal law shall be deemed compliance with the requirements
7 of this section.

8 Section 7. Section 465.035, Florida Statutes, is
9 amended to read:

10 465.035 Dispensing of medicinal ~~medical~~ drugs pursuant
11 to facsimile of prescription.--

12 (1) Notwithstanding any other provision of this
13 chapter, it is lawful for a pharmacy to dispense medicinal
14 drugs, including controlled substances as provided in this
15 section, based on reception of an electronic facsimile of the
16 original prescription if all of the following conditions are
17 met:

18 (a) In the course of the transaction the pharmacy
19 complies with laws and administrative rules relating to
20 pharmacies and pharmacists.

21 (b) Except in the case of the transmission of a
22 prescription by a person authorized by law to prescribe
23 medicinal drugs:

24 1. The facsimile system making the transmission
25 provides the pharmacy receiving the transmission with audio
26 communication via telephonic, electronic, or similar means
27 with the person presenting the prescription.

28 2. At the time of the delivery of the medicinal drugs,
29 the pharmacy has in its possession the original prescription
30 for the medicinal drug involved.

31

1 3. The recipient of the prescription shall sign a log
2 and shall indicate the name and address of both the recipient
3 and the patient for whom the medicinal drug was prescribed.

4 ~~(2) This section does not apply to the dispensing of~~
5 Controlled substances listed in Schedule II as defined in s.
6 893.03(2) may be dispensed as provided in 21 C.F.R. s.
7 1306.11.

8 Section 8. Subsection (19) of section 499.003, Florida
9 Statutes, is amended to read:

10 499.003 Definitions of terms used in ss.

11 499.001-499.081.--As used in ss. 499.001-499.081, the term:

12 (19) "Legend drug," "prescription drug," or "medicinal
13 drug" means any drug, including, but not limited to, finished
14 dosage forms, or active ingredients subject to, defined by, or
15 described by s. 503(b) of the Federal Food, Drug, and Cosmetic
16 Act or s. 465.003(8)(7), s. 499.007(12), or s. 499.0122(1)(b)
17 or (c).

18 Section 9. This act shall take effect July 1, 1997.

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21 HOUSE SUMMARY

22

23 Revises and provides definitions relating to pharmacy
24 practice. Authorizes pharmacy technicians, under direct
25 supervision of a licensed pharmacist, to initiate and
26 receive communications with a practitioner, on behalf of
27 patients, regarding refill authorization requests and
28 related information. Increases to three the number of
29 pharmacy technicians who may be supervised by a licensed
30 pharmacist. Provides additional persons and entities to
31 whom records relating to the filling of prescriptions and
the dispensing of medicinal drugs that are maintained by
a pharmacy may be furnished, and provides restrictions on
such records when transmitted through a data
communication device. Revises provisions relating to the
filling of prescriptions transferred by electronic or
other means. Authorizes the dispensing of certain
Schedule II controlled substances pursuant to facsimile
receipt of the original prescription. See bill for
details.