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Bill No. HB 4119, 1st Eng.

Amendment No. ____ (for drafter's use only)

	<u>Senate</u>	CHAMBER ACTION	<u>House</u>
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2		.	
3		.	
4		.	

ORIGINAL STAMP BELOW

Representative(s) Kelly offered the following:

Amendment (with title amendment)

On page 17, between lines 7 and 8, of the bill

insert:

Section 13. Effective July 1, 1998, subsection (12) of section 465.003, Florida Statutes, is amended, subsections (4) through (14) are renumbered as subsections (5) through (15), respectively, and a new subsection (4) is added to said section, to read:

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

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

(13)(12) "Practice of the profession of pharmacy" includes compounding, dispensing, and consulting concerning contents, therapeutic values, and uses of any medicinal drug; ~~and consulting concerning therapeutic values and interactions~~

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1 of patent or proprietary preparations, whether pursuant to
2 prescriptions or in the absence and entirely independent of
3 such prescriptions or orders; and other pharmaceutical
4 services. For purposes of this subsection, "other
5 pharmaceutical services" means the evaluation and monitoring
6 of the patient's health as it relates to drug therapy and
7 assisting the patient in the management of his or her drug
8 therapy, and includes the assessment of the patient's drug
9 therapy and communication with the patient and the patient's
10 prescribing health care provider as licensed under chapter
11 458, chapter 459, chapter 461, or chapter 466, or similar
12 statutory provision in another jurisdiction, or such
13 provider's agent or such other persons as specifically
14 authorized by the patient, regarding the drug therapy.
15 "Practice of the profession of pharmacy"~~The phrase~~ also
16 includes any other act, service, operation, research, or
17 transaction incidental to, or forming a part of, any of the
18 foregoing acts, requiring, involving, or employing the science
19 or art of any branch of the pharmaceutical profession, study,
20 or training, and shall expressly permit a pharmacist to
21 transmit information from persons authorized to prescribe
22 medicinal drugs to their patients. In addition to the
23 authority to order and dispense medicinal drugs independently
24 of an established protocol as set forth in s. 465.186, a
25 pharmacist may also administer immunizations within the
26 framework of an established protocol under a supervisory
27 practitioner who is a physician licensed under chapter 458 or
28 chapter 459 or by written agreement with a county health
29 department. Each protocol must contain specific procedures to
30 address any unforeseen allergic reaction to an immunization. A
31 pharmacist may not enter into a protocol unless he or she

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1 maintains at least \$200,000 of professional liability
 2 insurance, and not until the pharmacist has completed training
 3 in immunizations as may be required by the board. The decision
 4 by a supervisory practitioner to enter into such a protocol is
 5 a professional decision of the practitioner, and no person may
 6 interfere with a supervisory practitioner's decision as to
 7 whether to enter into such a protocol. A pharmacist may not
 8 enter into a protocol that is to be performed while acting as
 9 an employee without the written approval of the owner of the
 10 pharmacy.

11 Section 14. Effective July 1, 1998, a new paragraph
 12 (q) is added to subsection (1) of section 465.016, Florida
 13 Statutes, to read:

14 465.016 Disciplinary actions.--

15 (1) The following acts shall be grounds for
 16 disciplinary action set forth in this section:

17 (q) Using or releasing a patient's records except as
 18 authorized by this chapter and chapter 455.

19 Section 15. Effective July 1, 1998, subsection (2) of
 20 section 465.017, Florida Statutes, is amended to read:

21 465.017 Authority to inspect.--

22 (2) Except as permitted by this chapter, and chapters
 23 406, 409, 455, 499, and 893, records maintained by in a
 24 pharmacy relating to the filling of prescriptions and the
 25 dispensing of medicinal drugs shall not be furnished, except
 26 upon the written authorization of the patient, to any person
 27 other than to the patient for whom the drugs were dispensed,
 28 ~~or her or his legal representative, or to the department~~
 29 ~~pursuant to existing law,~~ or, in the event that the patient is
 30 incapacitated or unable to request said records, her or his
 31 spouse; to the department pursuant to existing law; to health

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1 care practitioners and pharmacists consulting or dispensing to
2 the patient; or to insurance carriers or other payors
3 authorized by the patient to receive such records. For
4 purposes of this section, records held in a pharmacy shall be
5 considered owned by the owner of the pharmacy. The pharmacy
6 owner may use such records in the aggregate without patient
7 identification data, regardless of where such records are
8 held, for purposes reasonably related to the business and
9 practice of pharmacy ~~except upon the written authorization of~~
10 ~~such patient.~~ Such records may be furnished in any civil or
11 criminal proceeding, upon the issuance of a subpoena from a
12 court of competent jurisdiction and proper notice to the
13 patient or her or his legal representative by the party
14 seeking such records. Such records or any part thereof, if
15 transmitted through a data communication device and not
16 directly between a pharmacy and a treating practitioner, may
17 not be accessed, used, or maintained by the operator or owner
18 of the data communication device unless specifically
19 authorized by this section. It is the intent of this
20 subsection to allow the use and sharing of such records to
21 improve patient care, provided the pharmacist acts in the best
22 interests of their patient. Nothing herein shall be construed
23 to authorize or expand solicitation or marketing to patients
24 or potential patients in any manner not otherwise specifically
25 authorized by law.

26 Section 16. Effective July 1, 1998, subsection (4) of
27 section 465.019, Florida Statutes, is amended to read:

28 465.019 Institutional pharmacies; permits.--

29 (4) Medicinal drugs shall be dispensed in an
30 institutional pharmacy to outpatients only when that
31 institution has secured a community pharmacy permit from the

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1 department. However, an individual licensed to prescribe
2 medicinal drugs in this state may dispense up to a 24-hour
3 supply of a medicinal drug to any patient of an emergency
4 department of a hospital that operates a Class II
5 institutional pharmacy, provided the physician treating the
6 patient in such hospital's emergency department determines
7 that the medicinal drug is warranted and that community
8 pharmacy services are not readily accessible, geographically
9 or otherwise, to the patient. Such dispensing from the
10 emergency department shall be in accordance with the
11 procedures of the hospital. For any such patient for whom a
12 medicinal drug is warranted for a period to exceed 24 hours,
13 an individual licensed to prescribe such drug shall dispense a
14 24-hour supply of such drug to the patient and shall provide
15 the patient a prescription for such drug for use after the
16 initial 24-hour period. The board may adopt rules necessary to
17 carry out the provisions of this subsection.

18 Section 17. Effective July 1, 1998, section 465.014,
19 Florida Statutes, is amended to read:

20 465.014 Pharmacy technician.--No person other than a
21 licensed pharmacist or pharmacy intern may engage in the
22 practice of the profession of pharmacy, except that a licensed
23 pharmacist may delegate to nonlicensed pharmacy technicians
24 those duties, tasks, and functions which do not fall within
25 the purview of s. 465.003(13)(12). All such delegated acts
26 shall be performed under the direct supervision of a licensed
27 pharmacist who shall be responsible for all such acts
28 performed by persons under his or her supervision. A pharmacy
29 technician, under the supervision of a pharmacist, may
30 initiate or receive communications with a practitioner or his
31 or her agent, on behalf of a patient, regarding refill

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1 authorization requests. No licensed pharmacist shall supervise
2 more than one pharmacy technician unless otherwise permitted
3 by the guidelines adopted by the board. The board shall
4 establish guidelines to be followed by licensees or permittees
5 in determining the circumstances under which a licensed
6 pharmacist may supervise more than one but not more than three
7 pharmacy technicians.

8 Section 18. Effective July 1, 1998, paragraph (c) of
9 subsection (2) of section 465.015, Florida Statutes, is
10 amended to read:

11 465.015 Violations and penalties.--

12 (2) It is unlawful for any person:

13 (c) To sell or dispense drugs as defined in s.

14 465.003(8)(~~7~~)without first being furnished with a
15 prescription.

16 Section 19. Effective July 1, 1998, section 465.0196,
17 Florida Statutes, is amended to read:

18 465.0196 Special pharmacy permits.--Any person
19 desiring a permit to operate a pharmacy which does not fall
20 within the definitions set forth in s. 465.003(11)(~~10~~)(a)1.,
21 2., and 3. shall apply to the department for a special
22 pharmacy permit. If the board certifies that the application
23 complies with the applicable laws and rules of the board
24 governing the practice of the profession of pharmacy, the
25 department shall issue the permit. No permit shall be issued
26 unless a licensed pharmacist is designated to undertake the
27 professional supervision of the compounding and dispensing of
28 all drugs dispensed by the pharmacy. The licensed pharmacist
29 shall be responsible for maintaining all drug records and for
30 providing for the security of the area in the facility in
31 which the compounding, storing, and dispensing of medicinal

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1 drugs occurs. The permittee shall notify the department
2 within 10 days of any change of the licensed pharmacist
3 responsible for such duties.

4 Section 20. Effective July 1, 1998, subsection (3) of
5 section 468.812, Florida Statutes, is amended to read:

6 468.812 Exemptions from licensure.--

7 (3) The provisions of this act relating to orthotics
8 or pedorthics do not apply to any licensed pharmacist or to
9 any person acting under the supervision of a licensed
10 pharmacist. The practice of orthotics or pedorthics by a
11 pharmacist or any of the pharmacist's employees acting under
12 the supervision of a pharmacist shall be construed to be
13 within the meaning of the term "practice of the profession of
14 pharmacy" as set forth in s. 465.003(13)(~~12~~), and shall be
15 subject to regulation in the same manner as any other pharmacy
16 practice. The Board of Pharmacy shall develop rules regarding
17 the practice of orthotics and pedorthics by a pharmacist. Any
18 pharmacist or person under the supervision of a pharmacist
19 engaged in the practice of orthotics or pedorthics shall not
20 be precluded from continuing that practice pending adoption of
21 these rules.

22 Section 21. Effective July 1, 1998, subsection (19) of
23 section 499.003, Florida Statutes, is amended to read:

24 499.003 Definitions of terms used in ss.

25 499.001-499.081.--As used in ss. 499.001-499.081, the term:

26 (19) "Legend drug," "prescription drug," or "medicinal
27 drug" means any drug, including, but not limited to, finished
28 dosage forms, or active ingredients subject to, defined by, or
29 described by s. 503(b) of the Federal Food, Drug, and Cosmetic
30 Act or s. 465.003(8)(~~7~~), s. 499.007(12), or s. 499.0122(1)(b)
31 or (c).

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1 Section 22. Effective July 1, 1998, paragraph (a) of
2 subsection (1) of section 499.012, Florida Statutes, is
3 amended to read:

4 499.012 Wholesale distribution; definitions; permits;
5 general requirements.--

6 (1) As used in this section, the term:

7 (a) "Wholesale distribution" means distribution of
8 prescription drugs to persons other than a consumer or
9 patient, but does not include lawful dispensing of a
10 prescription drug in accordance with chapter 465; however:

11 1. As used in s. 499.005(21), the term "wholesale
12 distribution" does not include any of the following activities
13 if the activity is conducted in accordance with s. 499.014:

14 a.1. The purchase or other acquisition by a hospital
15 or other health care entity that is a member of a group
16 purchasing organization of a prescription drug for its own use
17 from the group purchasing organization or from other hospitals
18 or health care entities that are members of that organization;

19 b.2. The sale, purchase, or trade of a prescription
20 drug or an offer to sell, purchase, or trade a prescription
21 drug by a charitable organization described in s. 501(c)(3) of
22 the Internal Revenue Code of 1986, as amended and revised, to
23 a nonprofit affiliate of the organization to the extent
24 otherwise permitted by law;

25 c.3. The sale, purchase, or trade of a prescription
26 drug or an offer to sell, purchase, or trade a prescription
27 drug among hospitals or other health care entities that are
28 under common control. For purposes of this section, "common
29 control" means the power to direct or cause the direction of
30 the management and policies of a person or an organization,
31 whether by ownership of stock, by voting rights, by contract,

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1 or otherwise.

2 2. As used in s. 499.005(21), the term "wholesale
3 distribution" also does not include any of the following
4 activities if the activity is done in accordance with rules
5 established by the department:

6 a.4. The sale, purchase, or trade of a prescription
7 drug among federal, state, or local government health care
8 entities that are under common control and are authorized to
9 purchase such prescription drug.

10 b. The sale, purchase, trade, or other transfer of a
11 prescription drug from or for any of the following entities: a
12 federal, state, or local government agency or any entity
13 eligible to purchase prescription drugs at public health
14 services prices pursuant to s. 602 of Pub. L. No. 102-585 to a
15 contract provider or its subcontractor for eligible patients
16 of the entity if:

17 (I) The entity obtains written authorization for the
18 sale, purchase, trade, or other transfer of a prescription
19 drug under this paragraph from the Secretary of Health. This
20 written authorization must be based on a favorable
21 recommendation by the Drug Regulation Advisory Group after the
22 group has reviewed the entity's submission to the department
23 of a detailed plan and justification for the sale, purchase,
24 trade, or other transfer of a prescription drug under this
25 paragraph and must enhance the public's health by improving
26 needed access, quality, or safety because current patient drug
27 delivery systems are inadequate;

28 (II) The contract provider or subcontractor is
29 authorized by law to administer or dispense prescription
30 drugs;

31 (III) In the case of a subcontractor, the entity is a

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1 party to and executes the subcontract;

2 (IV) A contract provider or subcontractor maintains
3 separate and apart any prescription drugs of the entity in its
4 possession from other prescription drug inventory;

5 (V) The contract provider and subcontractor maintains
6 and produces immediately for inspection all records of
7 movement or transfer of all the prescription drugs belonging
8 to the entity, including, but not limited to, the records of
9 receipt and disposition of prescription drugs. Each contractor
10 and subcontractor dispensing or administering these drugs must
11 maintain and produce records documenting the dispensing or
12 administration. Records that are required to be maintained
13 include, but are not limited to, a perpetual inventory
14 itemizing drugs received and drugs dispensed by prescription
15 number or administered by patient identifier, which must be
16 submitted to the entity monthly;

17 (VI) The contract provider or subcontractor either
18 administers or dispenses the prescription drugs only to the
19 eligible patients of the entity or returns the prescription
20 drug for or to the entity. The contract provider or
21 subcontractor must require proof from each person seeking to
22 fill a prescription or obtain treatment that the person is an
23 eligible patient of the entity and must, at a minimum,
24 maintain a copy of this proof as part of the records of the
25 contractor or subcontractor required under
26 sub-sub-subparagraph (V);

27 (VII) The prescription drugs transferred pursuant to
28 this paragraph may not be billed to Medicaid; and

29 (VIII) In addition to the departmental inspection
30 authority set forth in s. 499.051, the establishment of the
31 contract provider and subcontractor and all records pertaining

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1 to prescription drugs subject to this sub-subparagraph are
 2 subject to inspection by the entity. All records relating to
 3 prescription drugs of a manufacturer under this
 4 sub-subparagraph are subject to audit by the manufacturer of
 5 those drugs, without identifying individual patient
 6 information.

7 c.5. The sale, purchase, or trade of a prescription
 8 drug or an offer to sell, purchase, or trade a prescription
 9 drug for emergency medical reasons; for purposes of this
 10 sub-subparagraph ~~subparagraph~~, the term "emergency medical
 11 reasons" includes transfers of prescription drugs by a retail
 12 pharmacy to another retail pharmacy to alleviate a temporary
 13 shortage.†

14 d.6. The transfer purchase or acquisition of a
 15 prescription drug acquired by a medical director on behalf of
 16 a licensed ~~an~~ emergency medical services provider to that
 17 ~~medical director for use by~~ emergency medical services
 18 provider and its transport vehicles for use in accordance with
 19 the provider's license under ~~providers acting within the scope~~
 20 ~~of their professional practice pursuant to chapter 401.~~

21 7. ~~The dispensing of a prescription drug pursuant to a~~
 22 ~~prescription†~~

23 e.8. The distribution of prescription drug samples by
 24 manufacturers' representatives or distributors'
 25 representatives conducted in accordance with s. 499.028.† ~~or~~

26 f.9. The sale, purchase, or trade of blood and blood
 27 components intended for transfusion. As used in this section,
 28 the term "blood" means whole blood collected from a single
 29 donor and processed either for transfusion or further
 30 manufacturing, and the term "blood components" means that part
 31 of the blood separated by physical or mechanical means.

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1 Section 23. Effective July 1, 1998, section 499.0722,
2 Florida Statutes, is created to read:

3 499.0722 Drug Regulation Advisory Group; exemptions.--

4 (1) There is created the Drug Regulation Advisory
5 Group, which is an independent advisory group composed of at
6 least 11 members appointed by the Secretary of Health and
7 including:

8 (a) One member representing the prescription drug
9 wholesale industry in this state;

10 (b) One member representing pharmaceutical
11 manufacturers, who may represent pharmaceutical manufacturers
12 nationwide;

13 (c) One member who is a practicing pharmacist;

14 (d) One member representing the Agency for Health Care
15 Administration;

16 (e) One member who is a physician licensed under
17 chapter 458 or chapter 459;

18 (f) One consumer representative;

19 (g) One member representing the cosmetic industry;

20 (h) One member representing the compressed medical gas
21 industry;

22 (i) One member representing the medical device
23 manufacturing industry;

24 (j) The Executive Director of the Board of Pharmacy,
25 who shall be an ex officio member; and

26 (k) One member representing the department, who shall
27 chair group meetings.

28 (l) One member representing hospitals.

29 (m) One member representing the long-term care
30 industry.

31 (2) Members shall be appointed for terms of 4 years,

1 except for the Executive Director of the Board of Pharmacy and
2 the departmental representative, who may serve indefinitely.
3 Members of the group may be reappointed. A vacancy in
4 membership which occurs before the expiration of a term shall
5 be filled by a member appointed by the Secretary of Health for
6 a full term.

7 (3) The group shall meet upon request of the
8 department, but no more than four times a year. Members of the
9 group shall serve without compensation, but may be reimbursed
10 for per diem and travel expenses as provided in s. 112.061.

11 (4) The purposes and duties of the Drug Regulation
12 Advisory Group include, but are not limited to:

13 (a) Making recommendations to the Secretary of Health
14 regarding authorizations for the sale, purchase, trade, or
15 other transfer of a prescription drug under s. 499.012(1)(b)2.

16 (b) Making recommendations to the department regarding
17 enforcement priorities under this chapter.

18 (c) Briefing the department on industry trends that
19 affect this chapter.

20 (d) Providing information and guidance on issues
21 submitted by the department to the group.

22 (e) Facilitating the dissemination of relevant
23 information concerning current issues affecting the public
24 health within the scope and responsibility of this chapter.

25 (5) The department may publish compliance policy
26 guidelines that set forth enforcement priorities or other
27 recommendations of the Drug Regulation Advisory Group when
28 that is in the best interest of the public health.

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1 ===== T I T L E A M E N D M E N T =====

2 And the title is amended as follows:

3 On page 2, line 2, after the semicolon

4

5 insert:

6 amending s. 465.003, F.S.; defining the term
7 "data communication device"; revising the
8 definition of the term "practice of the
9 profession of pharmacy"; amending s. 465.016,
10 F.S.; providing a ground for which a pharmacist
11 may be subject to discipline by the Board of
12 Pharmacy; amending s. 465.017, F.S.; providing
13 additional persons and entities to whom records
14 relating to the filling of prescriptions and
15 the dispensing of medicinal drugs that are
16 maintained by a pharmacy may be furnished;
17 specifying authorized uses of patient records
18 by pharmacy owners; providing restrictions on
19 such records when transmitted through a data
20 communication device; amending s. 465.019,
21 F.S.; providing for certain dispensing of
22 medicinal drugs to patients in emergency
23 departments of certain hospitals; amending ss.
24 465.014, 465.015, 465.0196, 468.812, and
25 499.003, F.S.; correcting cross references, to
26 conform; amending s. 499.012, F.S.; redefining
27 the term "wholesale distribution," relating to
28 the distribution of prescription drugs, by
29 providing for the exclusion of certain
30 activities; creating s. 499.0722, F.S.;

31 creating the Drug Regulation Advisory Group;

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1 providing membership; providing terms of
2 office; providing for meetings, for
3 reimbursement of expenses, and for purposes and
4 duties of the group; allowing the Department of
5 Health to publish compliance policy guidelines
6 that include recommendations of the group;
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