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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

11 Representative(s) Kelly offered the following:

13 **Amendment (with title amendment)**

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

16 insert:

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

22 465.003 Definitions.--As used in this chapter, the
23 term:

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

28 (13)(12) "Practice of the profession of pharmacy"
29 includes compounding, dispensing, and consulting concerning
30 contents, therapeutic values, and uses of any medicinal drug;
31 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 review of the patient's drug therapy
9 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. Nothing
15 herein shall be interpreted to permit an alteration of a
16 prescriber's directions, unless otherwise permitted by law.
17 "Practice of the profession of pharmacy"~~The phrase~~ also
18 includes any other act, service, operation, research, or
19 transaction incidental to, or forming a part of, any of the
20 foregoing acts, requiring, involving, or employing the science
21 or art of any branch of the pharmaceutical profession, study,
22 or training, and shall expressly permit a pharmacist to
23 transmit information from persons authorized to prescribe
24 medicinal drugs to their patients. A pharmacist may also
25 administer immunizations within the framework of an
26 established protocol under a supervisory practitioner who is a
27 physician licensed under chapter 458 or chapter 459 or by
28 written agreement with a county health department. Each
29 protocol must contain specific procedures to address any
30 unforeseen allergic reaction to an immunization. A pharmacist
31 may not enter into a protocol unless he or she maintains at

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

10 Section 14. Paragraph (1) of subsection (1) of section
 11 465.016, Florida Statutes, is amended to read:

12 465.016 Disciplinary actions.--

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

15 (1) Placing in the stock of any pharmacy any part of
 16 any prescription compounded or dispensed which is returned by
 17 a patient; however, in a hospital, nursing home, correctional
 18 facility, or extended care facility in which unit-dose
 19 medication is dispensed to inpatients, each dose being
 20 individually sealed and the individual unit dose or unit-dose
 21 system labeled with the name of the drug, dosage strength,
 22 manufacturer's control number, and expiration date, if any,
 23 the unused unit dose of medication may be returned to the
 24 pharmacy for redispensing. Each pharmacist shall maintain
 25 appropriate records for any unused or returned medicinal
 26 drugs.

27 Section 15. Effective July 1, 1998, a new paragraph
 28 (q) is added to subsection (1) of section 465.016, Florida
 29 Statutes, to read:

30 465.016 Disciplinary actions.--

31 (1) The following acts shall be grounds for

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1 disciplinary action set forth in this section:

2 (g) Using or releasing a patient's records except as
3 authorized by this chapter and chapter 455.

4 Section 16. Effective July 1, 1998, subsection (2) of
5 section 465.017, Florida Statutes, is amended to read:

6 465.017 Authority to inspect.--

7 (2) Except as permitted by this chapter, and chapters
8 406, 409, 455, 499, and 893, records maintained by in a
9 pharmacy relating to the filling of prescriptions and the
10 dispensing of medicinal drugs shall not be furnished, except
11 upon the written authorization of the patient, to any person
12 other than to the patient for whom the drugs were dispensed,
13 ~~or her or his legal representative, or to the department~~
14 ~~pursuant to existing law,~~ or, in the event that the patient is
15 incapacitated or unable to request said records, her or his
16 spouse; to the department pursuant to existing law; to health
17 care practitioners and pharmacists consulting or dispensing to
18 the patient; or to insurance carriers or other payors
19 authorized by the patient to receive such records. For
20 purposes of this section, records held in a pharmacy shall be
21 considered owned by the owner of the pharmacy. The pharmacy
22 owner may use such records in the aggregate without patient
23 identification data, regardless of where such records are
24 held, for purposes reasonably related to the business and
25 practice of pharmacy ~~except upon the written authorization of~~
26 ~~such patient.~~ Such records may be furnished in any civil or
27 criminal proceeding, upon the issuance of a subpoena from a
28 court of competent jurisdiction and proper notice to the
29 patient or her or his legal representative by the party
30 seeking such records. Such records or any part thereof, if
31 transmitted through a data communication device and not

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1 directly between a pharmacy and a treating practitioner, may
2 not be accessed, used, or maintained by the operator or owner
3 of the data communication device unless specifically
4 authorized by this section. It is the intent of this
5 subsection to allow the use and sharing of such records to
6 improve patient care, provided the pharmacist acts in the best
7 interests of their patient. Nothing herein shall be construed
8 to authorize or expand solicitation or marketing to patients
9 or potential patients in any manner not otherwise specifically
10 authorized by law.

11 Section 17. Effective July 1, 1998, subsection (4) of
12 section 465.019, Florida Statutes, is amended to read:

13 465.019 Institutional pharmacies; permits.--

14 (4) Medicinal drugs shall be dispensed in an
15 institutional pharmacy to outpatients only when that
16 institution has secured a community pharmacy permit from the
17 department. However, an individual licensed to prescribe
18 medicinal drugs in this state may dispense up to a 24-hour
19 supply of a medicinal drug to any patient of an emergency
20 department of a hospital that operates a Class II
21 institutional pharmacy, provided the physician treating the
22 patient in such hospital's emergency department determines
23 that the medicinal drug is warranted and that community
24 pharmacy services are not readily accessible, geographically
25 or otherwise, to the patient. Such dispensing from the
26 emergency department shall be in accordance with the
27 procedures of the hospital. For any such patient for whom a
28 medicinal drug is warranted for a period to exceed 24 hours,
29 an individual licensed to prescribe such drug shall dispense a
30 24-hour supply of such drug to the patient and shall provide
31 the patient a prescription for such drug for use after the

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1 initial 24-hour period. The board may adopt rules necessary to
2 carry out the provisions of this subsection.

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

5 465.014 Pharmacy technician.--No person other than a
6 licensed pharmacist or pharmacy intern may engage in the
7 practice of the profession of pharmacy, except that a licensed
8 pharmacist may delegate to nonlicensed pharmacy technicians
9 those duties, tasks, and functions which do not fall within
10 the purview of s. 465.003(13)(12). All such delegated acts
11 shall be performed under the direct supervision of a licensed
12 pharmacist who shall be responsible for all such acts
13 performed by persons under his or her supervision. A pharmacy
14 technician, under the supervision of a pharmacist, may
15 initiate or receive communications with a practitioner or his
16 or her agent, on behalf of a patient, regarding refill
17 authorization requests. No licensed pharmacist shall supervise
18 more than one pharmacy technician unless otherwise permitted
19 by the guidelines adopted by the board. The board shall
20 establish guidelines to be followed by licensees or permittees
21 in determining the circumstances under which a licensed
22 pharmacist may supervise more than one but not more than three
23 pharmacy technicians.

24 Section 19. Effective July 1, 1998, paragraph (c) of
25 subsection (2) of section 465.015, Florida Statutes, is
26 amended to read:

27 465.015 Violations and penalties.--

28 (2) It is unlawful for any person:

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

30 465.003(8)(7)without first being furnished with a
31 prescription.

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1 Section 20. Effective July 1, 1998, section 465.0196,
2 Florida Statutes, is amended to read:

3 465.0196 Special pharmacy permits.--Any person
4 desiring a permit to operate a pharmacy which does not fall
5 within the definitions set forth in s. 465.003(11)~~(10)~~(a)1.,
6 2., and 3. shall apply to the department for a special
7 pharmacy permit. If the board certifies that the application
8 complies with the applicable laws and rules of the board
9 governing the practice of the profession of pharmacy, the
10 department shall issue the permit. No permit shall be issued
11 unless a licensed pharmacist is designated to undertake the
12 professional supervision of the compounding and dispensing of
13 all drugs dispensed by the pharmacy. The licensed pharmacist
14 shall be responsible for maintaining all drug records and for
15 providing for the security of the area in the facility in
16 which the compounding, storing, and dispensing of medicinal
17 drugs occurs. The permittee shall notify the department
18 within 10 days of any change of the licensed pharmacist
19 responsible for such duties.

20 Section 21. Effective July 1, 1998, subsection (3) of
21 section 468.812, Florida Statutes, is amended to read:

22 468.812 Exemptions from licensure.--
23 (3) The provisions of this act relating to orthotics
24 or pedorthics do not apply to any licensed pharmacist or to
25 any person acting under the supervision of a licensed
26 pharmacist. The practice of orthotics or pedorthics by a
27 pharmacist or any of the pharmacist's employees acting under
28 the supervision of a pharmacist shall be construed to be
29 within the meaning of the term "practice of the profession of
30 pharmacy" as set forth in s. 465.003(13)~~(12)~~, and shall be
31 subject to regulation in the same manner as any other pharmacy

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1 practice. The Board of Pharmacy shall develop rules regarding
 2 the practice of orthotics and pedorthics by a pharmacist. Any
 3 pharmacist or person under the supervision of a pharmacist
 4 engaged in the practice of orthotics or pedorthics shall not
 5 be precluded from continuing that practice pending adoption of
 6 these rules.

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

9 499.003 Definitions of terms used in ss.
 10 499.001-499.081.--As used in ss. 499.001-499.081, the term:
 11 (19) "Legend drug," "prescription drug," or "medicinal
 12 drug" means any drug, including, but not limited to, finished
 13 dosage forms, or active ingredients subject to, defined by, or
 14 described by s. 503(b) of the Federal Food, Drug, and Cosmetic
 15 Act or s. 465.003(8)(~~7~~), s. 499.007(12), or s. 499.0122(1)(b)
 16 or (c).

17 Section 23. Effective July 1, 1998, paragraph (a) of
 18 subsection (1) of section 499.012, Florida Statutes, is
 19 amended to read:

20 499.012 Wholesale distribution; definitions; permits;
 21 general requirements.--

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

23 (a) "Wholesale distribution" means distribution of
 24 prescription drugs to persons other than a consumer or
 25 patient, but does not include lawful dispensing of a
 26 prescription drug in accordance with chapter 465; however:
 27 1. As used in s. 499.005(21), the term "wholesale
 28 distribution" does not include any of the following activities
 29 if the activity is conducted in accordance with s. 499.014:

30 a.1. The purchase or other acquisition by a hospital
 31 or other health care entity that is a member of a group

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1 purchasing organization of a prescription drug for its own use
2 from the group purchasing organization or from other hospitals
3 or health care entities that are members of that organization;

4 ~~b.2.~~ The sale, purchase, or trade of a prescription
5 drug or an offer to sell, purchase, or trade a prescription
6 drug by a charitable organization described in s. 501(c)(3) of
7 the Internal Revenue Code of 1986, as amended and revised, to
8 a nonprofit affiliate of the organization to the extent
9 otherwise permitted by law;

10 ~~c.3.~~ The sale, purchase, or trade of a prescription
11 drug or an offer to sell, purchase, or trade a prescription
12 drug among hospitals or other health care entities that are
13 under common control. For purposes of this section, "common
14 control" means the power to direct or cause the direction of
15 the management and policies of a person or an organization,
16 whether by ownership of stock, by voting rights, by contract,
17 or otherwise.

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

22 ~~a.4.~~ The sale, purchase, or trade of a prescription
23 drug among federal, state, or local government health care
24 entities that are under common control and are authorized to
25 purchase such prescription drug.

26 b. The sale, purchase, trade, or other transfer of a
27 prescription drug from or for any of the following entities: a
28 federal, state, or local government agency or any entity
29 eligible to purchase prescription drugs at public health
30 services prices pursuant to s. 602 of Pub. L. No. 102-585 to a
31 contract provider or its subcontractor for eligible patients

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1 of the entity if:

2 (I) The entity obtains written authorization for the
3 sale, purchase, trade, or other transfer of a prescription
4 drug under this paragraph from the Secretary of Health. This
5 written authorization must be based on a favorable
6 recommendation by the Drug Regulation Advisory Group after the
7 group has reviewed the entity's submission to the department
8 of a detailed plan and justification for the sale, purchase,
9 trade, or other transfer of a prescription drug under this
10 paragraph and must enhance the public's health by improving
11 needed access, quality, or safety because current patient drug
12 delivery systems are inadequate;

13 (II) The contract provider or subcontractor is
14 authorized by law to administer or dispense prescription
15 drugs;

16 (III) In the case of a subcontractor, the entity is a
17 party to and executes the subcontract;

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

21 (V) The contract provider and subcontractor maintains
22 and produces immediately for inspection all records of
23 movement or transfer of all the prescription drugs belonging
24 to the entity, including, but not limited to, the records of
25 receipt and disposition of prescription drugs. Each contractor
26 and subcontractor dispensing or administering these drugs must
27 maintain and produce records documenting the dispensing or
28 administration. Records that are required to be maintained
29 include, but are not limited to, a perpetual inventory
30 itemizing drugs received and drugs dispensed by prescription
31 number or administered by patient identifier, which must be

1 submitted to the entity monthly;

2 (VI) The contract provider or subcontractor either
3 administers or dispenses the prescription drugs only to the
4 eligible patients of the entity or returns the prescription
5 drug for or to the entity. The contract provider or
6 subcontractor must require proof from each person seeking to
7 fill a prescription or obtain treatment that the person is an
8 eligible patient of the entity and must, at a minimum,
9 maintain a copy of this proof as part of the records of the
10 contractor or subcontractor required under
11 sub-sub-subparagraph (V);

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

14 (VIII) In addition to the departmental inspection
15 authority set forth in s. 499.051, the establishment of the
16 contract provider and subcontractor and all records pertaining
17 to prescription drugs subject to this sub-subparagraph are
18 subject to inspection by the entity. All records relating to
19 prescription drugs of a manufacturer under this
20 sub-subparagraph are subject to audit by the manufacturer of
21 those drugs, without identifying individual patient
22 information.

23 c.5. The sale, purchase, or trade of a prescription
24 drug or an offer to sell, purchase, or trade a prescription
25 drug for emergency medical reasons; for purposes of this
26 sub-subparagraph ~~subparagraph~~, the term "emergency medical
27 reasons" includes transfers of prescription drugs by a retail
28 pharmacy to another retail pharmacy to alleviate a temporary
29 shortage.

30 d.6. The ~~transfer purchase or acquisition~~ of a
31 prescription drug acquired by a medical director on behalf of

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1 a licensed an emergency medical services provider to that
2 ~~medical director for use by~~ emergency medical services
3 provider and its transport vehicles for use in accordance with
4 the provider's license under providers acting within the scope
5 of their professional practice pursuant to chapter 401.

6 ~~7. The dispensing of a prescription drug pursuant to a~~
7 ~~prescription;~~

8 ~~e.8.~~ The distribution of prescription drug samples by
9 manufacturers' representatives or distributors'
10 representatives conducted in accordance with s. 499.028. ~~or~~

11 ~~f.9.~~ The sale, purchase, or trade of blood and blood
12 components intended for transfusion. As used in this section,
13 the term "blood" means whole blood collected from a single
14 donor and processed either for transfusion or further
15 manufacturing, and the term "blood components" means that part
16 of the blood separated by physical or mechanical means.

17 Section 24. Effective July 1, 1998, section 499.0722,
18 Florida Statutes, is created to read:

19 499.0722 Drug Regulation Advisory Group; exemptions.--

20 (1) There is created the Drug Regulation Advisory
21 Group, which is an independent advisory group composed of at
22 least 11 members appointed by the Secretary of Health and
23 including:

24 (a) One member representing the prescription drug
25 wholesale industry in this state;

26 (b) One member representing pharmaceutical
27 manufacturers, who may represent pharmaceutical manufacturers
28 nationwide;

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

30 (d) One member representing the Agency for Health Care
31 Administration;

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- 1 (e) One member who is a physician licensed under
2 chapter 458 or chapter 459;
- 3 (f) One consumer representative;
- 4 (g) One member representing the cosmetic industry;
- 5 (h) One member representing the compressed medical gas
6 industry;
- 7 (i) One member representing the medical device
8 manufacturing industry;
- 9 (j) The Executive Director of the Board of Pharmacy,
10 who shall be an ex officio member; and
- 11 (k) One member representing the department, who shall
12 chair group meetings.
- 13 (l) One member representing hospitals.
- 14 (m) One member representing the long-term care
15 industry.
- 16 (2) Members shall be appointed for terms of 4 years,
17 except for the Executive Director of the Board of Pharmacy and
18 the departmental representative, who may serve indefinitely.
19 Members of the group may be reappointed. A vacancy in
20 membership which occurs before the expiration of a term shall
21 be filled by a member appointed by the Secretary of Health for
22 a full term.
- 23 (3) The group shall meet upon request of the
24 department, but no more than four times a year. Members of the
25 group shall serve without compensation, but may be reimbursed
26 for per diem and travel expenses as provided in s. 112.061.
- 27 (4) The purposes and duties of the Drug Regulation
28 Advisory Group include, but are not limited to:
- 29 (a) Making recommendations to the Secretary of Health
30 regarding authorizations for the sale, purchase, trade, or
31 other transfer of a prescription drug under s. 499.012(1)(b)2.

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1 (b) Making recommendations to the department regarding
2 enforcement priorities under this chapter.

3 (c) Briefing the department on industry trends that
4 affect this chapter.

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

7 (e) Facilitating the dissemination of relevant
8 information concerning current issues affecting the public
9 health within the scope and responsibility of this chapter.

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

14
15

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

17 And the title is amended as follows:

18 On page 2, line 2, after the semicolon

19

20 insert:

21 amending s. 465.003, F.S.; defining the term
22 "data communication device"; revising the
23 definition of the term "practice of the
24 profession of pharmacy"; amending s. 465.016,
25 F.S.; authorizing the redispensing of unused or
26 returned unit-dose medication by correctional
27 facilities under certain conditions; amending
28 s. 465.016, F.S.; providing a ground for which
29 a pharmacist may be subject to discipline by
30 the Board of Pharmacy; amending s. 465.017,
31 F.S.; providing additional persons and entities

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1 to whom records relating to the filling of
2 prescriptions and the dispensing of medicinal
3 drugs that are maintained by a pharmacy may be
4 furnished; specifying authorized uses of
5 patient records by pharmacy owners; providing
6 restrictions on such records when transmitted
7 through a data communication device; amending
8 s. 465.019, F.S.; providing for certain
9 dispensing of medicinal drugs to patients in
10 emergency departments of certain hospitals;
11 amending ss. 465.014, 465.015, 465.0196,
12 468.812, and 499.003, F.S.; correcting cross
13 references, to conform; amending s. 499.012,
14 F.S.; redefining the term "wholesale
15 distribution," relating to the distribution of
16 prescription drugs, by providing for the
17 exclusion of certain activities; creating s.
18 499.0722, F.S.; creating the Drug Regulation
19 Advisory Group; providing membership; providing
20 terms of office; providing for meetings, for
21 reimbursement of expenses, and for purposes and
22 duties of the group; allowing the Department of
23 Health to publish compliance policy guidelines
24 that include recommendations of the group;

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