1	A bill to be entitled
2	An act relating to the regulation of health
3	professionals; amending s. 458.348, F.S.;
4	providing that a licensed advanced registered
5	nurse practitioner, or physician assistant,
6	practicing under a protocol with a physician
7	licensed under ch. 458, F.S., or ch. 459, F.S.,
8	need not be a licensed electrologist to perform
9	certain hair removal procedures; amending s.
10	458.307, F.S.; revising membership
11	requirements; providing for expiration of terms
12	of current members, appointment of new members
13	to staggered terms, and appointment and terms
14	of successors; providing for applicability;
15	amending s. 458.311, F.S.; providing for an
16	externship; amending ss. 458.331 and 459.015,
17	F.S.; providing for membership on certain
18	probable cause panels; providing that a
19	practitioner licensed in ch. 458, F.S., may use
20	as a defense that the practitioner relied in
21	good faith on the representations made to the
22	practitioner by a drug manufacturer and that
23	the practitioner had no intent to violate the
24	law; requiring the Department of Health to
25	notify health care providers if the department
26	learns that a drug that has not been approved
27	by the United States Food and Drug
28	Administration for human use has been sold to
29	identified health care providers in this state;
30	amending s. 465.003, F.S.; redefining the term
31	"practice of the profession of pharmacy" to

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1	include the administering of influenza virus
2	immunizations to adults by a pharmacist within
3	an established protocol and under a supervisory
4	practitioner who is a licensed physician or by
5	written agreement with a county health
6	department; providing requirements for the
7	protocol; requiring professional liability
8	insurance, training and certification in
9	immunization, and employer approval before
10	entering into a protocol; requiring a
11	pharmacist to maintain and make available
12	patient records for a certain time period;
13	providing requirements for the certification
14	program; providing an effective date.
15	
16	Be It Enacted by the Legislature of the State of Florida:
17	
18	Section 1. Subsections (2) and (3) of section 458.307,
19	Florida Statutes, are amended to read:
20	458.307 Board of Medicine
21	(2) Twelve members of the board must be licensed
22	physicians in good standing in this state who are residents of
23	the state and who have been engaged in the active practice or
24	teaching of medicine in this state with a full and
25	<u>unrestricted medical license</u> for at least <u>5</u> 4 years
26	immediately preceding their appointment. One of the physicians
27	must be on the full-time faculty of a medical school in this
28	state, and one of the physicians must be in private practice
29	and on the full-time staff of a statutory teaching hospital in
30	this state as defined in s. 408.07. At least one of the
31	physicians must be a graduate of a foreign medical school.

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1	Four consumer members The remaining three members must be
2	residents of the state who <u>have lived in the state for at</u>
3	least 5 years immediately preceding their appointments, have
4	never been licensed as a health care practitioner under
5	chapter 456 or the applicable practice act, and do not have a
6	substantial personal, business, professional, or pecuniary
7	connection with a licensed health care practitioner or with a
8	medical education or health care facility, except as patients
9	or potential patients are not, and never have been, licensed
10	health care practitioners. The final One member must be the
11	<u>chief operations officer of a hospital</u> a health care risk
12	manager licensed under <u>chapter 395 who has lived in the state</u>
13	and held this position for at least 5 years immediately
14	preceding his or her appointment s. 395.10974. At least one
15	member of the board must be 60 years of age or older. The
16	requirements of this subsection shall be a continuing
17	condition of membership on the board. Any member who ceases to
18	meet the requirements of this subsection shall be removed from
19	the board, and a qualified new member shall be appointed to
20	fill the vacancy for the remainder of that member's term.
21	(3) As the terms of the members expire, the Governor
22	shall appoint successors for terms of 4 years, and such
23	members shall serve until their successors are appointed.
24	Section 2. The requirements of section 458.307,
25	Florida Statutes, as amended by this act, shall not be
26	construed to end the term of any member of the Board of
27	Medicine holding that appointment on the effective date of
28	this act, but the requirements of section 458.307, Florida
29	Statutes, as amended by this act, shall apply to any
30	appointment made after the effective date of this act to a
31	term that expires on or after November 1, 2005.

Second Engrossed

Section 3. Present subsections (2) through (8) of 1 2 section 458.311, Florida Statutes, are redesignated as subsections (3) through (9), respectively, present subsection 3 (7) of that section is amended, and a new subsection (2) is 4 added to that section, to read: 5 458.311 Licensure by examination; requirements; б 7 fees.--8 (2) Notwithstanding sub-subparagraphs (1)(f)1.c., 9 2.c., and 3.c. and paragraph (3)(d), except for passing part II of the National Board of Medical Examiners examination or 10 the Educational Commission for Foreign Medical Graduates 11 examination equivalent as referred to in paragraph (3)(d), the 12 13 board may develop procedures for an applicant for licensure as 14 a physician pursuant to this chapter to meet postgraduate training requirements by completing a 2-year externship at a 15 nonstatutory teaching hospital licensed in this state. The 16 training provided in the externship must be substantially 17 18 similar, as defined by board rule, to the training provided in 19 an approved residency as described in sub-subparagraphs (1)(f)1.c., 2.c., or 3.c. In order for the externship to meet 20 the requirements of this section, it must be approved by the 21 board before the applicant enters into the externship. The 2.2 applicant may not be licensed under this section unless the 23 24 board finds that the applicant has successfully completed the externship. The board may adopt rules to administer this 25 section, including the implementation of fees to cover costs. 26 Section 4. Subsection (2) of section 458.331, Florida 27 28 Statutes, is amended, and subsections (11) and (12) are added 29 to that section, to read: 30 458.331 Grounds for disciplinary action; action by the 31 board and department.--

Second Engrossed

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1	(2) The board may enter an order denying licensure or
2	imposing any of the penalties in s. 456.072(2) against any
3	applicant for licensure or licensee who is found guilty of
4	violating any provision of subsection (1) of this section or
5	who is found guilty of violating any provision of s.
б	456.072(1). <u>A probable cause panel considering disciplinary</u>
7	action against a physician assistant pursuant to s. 456.073
8	shall include a licensed physician assistant designated by the
9	<u>Council on Physician Assistants unless a physician assistant</u>
10	is not available. In determining what action is appropriate,
11	the board must first consider what sanctions are necessary to
12	protect the public or to compensate the patient. Only after
13	those sanctions have been imposed may the disciplining
14	authority consider and include in the order requirements
15	designed to rehabilitate the physician. All costs associated
16	with compliance with orders issued under this subsection are
17	the obligation of the physician.
18	(11) Notwithstanding any law to the contrary, a
19	practitioner licensed under this chapter has as a defense to
20	an alleged violation, by the preponderance of the evidence,
21	that the practitioner relied in good faith on the
22	representations made to the practitioner by a drug
23	manufacturer or its representatives and that the practitioner
24	had no intent to violate the law.
25	(12) If the department learns that a drug, as defined
26	under s. 499.003(17), which has not been approved by the
27	<u>United States Food and Drug Administration for human use, has</u>
28	been sold to identified health care providers in this state
29	and licensed under this chapter, the department shall
30	immediately notify the providers by certified mail of the
31	status of the drug as an unapproved product. The department
I	

shall also post the information on its website to advise other 1 2 providers and consumers of the unapproved status of the drug. 3 Section 5. Subsection (2) of section 459.015, Florida Statutes, is amended to read: 4 5 459.015 Grounds for disciplinary action; action by the б board and department. --7 (2) The board may enter an order denying licensure or 8 imposing any of the penalties in s. 456.072(2) against any 9 applicant for licensure or licensee who is found guilty of violating any provision of subsection (1) of this section or 10 who is found guilty of violating any provision of s. 11 456.072(1). <u>A probable cause panel considering disciplinary</u> 12 13 action against a physician assistant pursuant to s. 456.073 14 shall include a licensed physician assistant designated by the Council on Physician Assistants unless a physician assistant 15 is not available. In determining what action is appropriate, 16 the board must first consider what sanctions are necessary to 17 18 protect the public or to compensate the patient. Only after 19 those sanctions have been imposed may the disciplining authority consider and include in the order requirements 20 designed to rehabilitate the physician. All costs associated 21 with compliance with orders issued under this subsection are 2.2 23 the obligation of the physician. 24 Section 6. Subsection (13) of section 465.003, Florida 25 Statutes, is amended to read: 465.003 Definitions.--As used in this chapter, the 26 27 term: 28 (13) "Practice of the profession of pharmacy" includes 29 compounding, dispensing, and consulting concerning contents, therapeutic values, and uses of any medicinal drug; consulting 30 31 concerning therapeutic values and interactions of patent or 6

proprietary preparations, whether pursuant to prescriptions or 1 2 in the absence and entirely independent of such prescriptions or orders; and other pharmaceutical services. For purposes of 3 this subsection, "other pharmaceutical services" means the 4 monitoring of the patient's drug therapy and assisting the 5 б patient in the management of his or her drug therapy, and 7 includes review of the patient's drug therapy and 8 communication with the patient's prescribing health care 9 provider as licensed under chapter 458, chapter 459, chapter 461, or chapter 466, or similar statutory provision in another 10 jurisdiction, or such provider's agent or such other persons 11 as specifically authorized by the patient, regarding the drug 12 13 therapy. However, nothing in this subsection may be 14 interpreted to permit an alteration of a prescriber's directions, the diagnosis or treatment of any disease, the 15 initiation of any drug therapy, the practice of medicine, or 16 the practice of osteopathic medicine, unless otherwise 17 18 permitted by law. "Practice of the profession of pharmacy" 19 also includes any other act, service, operation, research, or 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, 2.2 23 or training, and shall expressly permit a pharmacist to 24 transmit information from persons authorized to prescribe medicinal drugs to their patients. "Practice of the profession 25 of pharmacy" also includes the administering to adults of 26 influenza virus immunizations by a pharmacist within the 27 28 framework of an established protocol under a supervisory 29 practitioner who is a physician licensed under chapter 458 or chapter 459 or by written agreement with a county health 30 department. Each protocol must contain specific procedures to 31

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address any unforeseen allergic reaction to an immunization. A pharmacist may not enter into a protocol unless he or she maintains at least \$200,000 of professional liability insurance and not until the pharmacist has completed training in immunizations as provided in this subsection. A pharmacist administering an influenza vaccine shall maintain and make available patient records using the same standards for confidentiality and maintenance of such records as those that are imposed on health care practitioners by s. 456.057. These records must be maintained for a minimum of 5 years. The decision by a supervisory practitioner to enter into such a protocol is a professional decision of the practitioner's decision as to whether to enter into such a protocol. A pharmacist may not enter into a protocol that is to be performed while acting as an employee without the written approval of the owner of the pharmacy. Any pharmacist seeking to immunize patients under this subsection must be certified to administer immunizations pursuant to a certification program approved by the Board of Pharmacy upon consultation with the Board of Medicine. The certification program must, at a minimum, require that a pharmacist attend at least 20 hours of continuing education classes approved by the Board of Pharmacy. The program must have a curriculum of instruction
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25 gengerning the sete and effective edministration of
25 <u>concerning the safe and effective administration of</u>
26 immunizations, including, but not limited to, potential
27 allergic reactions to immunizations. The certification to
28 perform inactivated influenza vaccinations shall include, but
29 need not be limited to, the following compliance criteria:
30
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1	(a) Compliance with all provisions of s. 381.003
2	relating to communicable disease and AIDS prevention and
3	<u>control;</u>
4	(b) Compliance with all provisions of s. 381.0031
5	relating to reporting of diseases of public health
6	significance to the department;
7	(c) Compliance with all provisions of s. 381.0098
8	relating to biomedical waste;
9	(d) Compliance with all Occupational Safety and Health
10	Administration standards for management, handling, and
11	disposal of sharps; and
12	(e) Completion of and compliance with the Centers for
13	<u>Disease Control Influenza Update for the year in which</u>
14	influenza vaccinations will be offered.
15	
16	The pharmacist's certification must be obtained prior to
17	advertising to the public and administering inactivated
18	influenza vaccinations. The pharmacist shall submit to the
19	Board of Pharmacy a copy of the protocol or written agreement
20	to administer inactivated influenza vaccine.
21	Section 7. Subsection (4) of section 456.041, Florida
22	Statutes, is amended to read:
23	456.041 Practitioner profile; creation
24	(4) The Department of Health shall include, with
25	respect to a practitioner licensed under chapter 458 or
26	chapter 459, a statement of how the practitioner has elected
27	to comply with the financial responsibility requirements of s.
28	458.320 or s. 459.0085. The department shall include, with
29	respect to practitioners subject to s. 456.048, a statement of
30	how the practitioner has elected to comply with the financial
31	responsibility requirements of that section. The department

Second Engrossed

shall include, with respect to practitioners licensed under 1 2 chapter 461, information relating to liability actions which has been reported under s. 456.049 or s. 627.912 within the 3 previous 10 years for any paid claim that exceeds \$5,000. The 4 department shall include, with respect to practitioners 5 licensed under chapter 458 or chapter 459, information б 7 relating to liability actions which has been reported under 8 ss. 456.049 and 627.912 within the previous 10 years for any paid claim that exceeds \$100,000. Such claims information 9 shall be reported in the context of comparing an individual 10 practitioner's claims to the experience of other practitioners 11 within the same specialty, or profession if the practitioner 12 13 is not a specialist. The department must provide a hyperlink 14 in such practitioner's profile to all such comparison reports. If information relating to a liability action is included in a 15 practitioner's practitioner profile, the profile must also 16 include the following statement: "Settlement of a claim may 17 18 occur for a variety of reasons that do not necessarily reflect negatively on the professional competence or conduct of the 19 practitioner. A payment in settlement of a medical 20 malpractice action or claim should not be construed as 21 creating a presumption that medical malpractice has occurred." 2.2 23 Section 8. Paragraph (f) of subsection (5) of section 24 458.320, Florida Statutes, is amended to read: 458.320 Financial responsibility.--25 (5) The requirements of subsections (1), (2), and (3) 26 do not apply to: 27 28 (f) Any person holding an active license under this 29 chapter who meets all of the following criteria: 30 31

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1. The licensee has held an active license to practice 1 2 in this state or another state or some combination thereof for 3 more than 15 years. 4 2. The licensee has either retired from the practice 5 of medicine or maintains a part-time practice of no more than 1,000 patient contact hours per year. б 7 3. The licensee has had no more than two claims for 8 medical malpractice resulting in an indemnity exceeding \$25,000 within the previous 5-year period. 9 4. The licensee has not been convicted of, or pled 10 guilty or nolo contendere to, any criminal violation specified 11 in this chapter or the medical practice act of any other 12 13 state. 14 5. The licensee has not been subject within the last 10 years of practice to license revocation or suspension for 15 any period of time; probation for a period of 3 years or 16 longer; or a fine of \$500 or more for a violation of this 17 18 chapter or the medical practice act of another jurisdiction. The regulatory agency's acceptance of a physician's 19 relinquishment of a license, stipulation, consent order, or 20 other settlement, offered in response to or in anticipation of 21 22 the filing of administrative charges against the physician's 23 license, constitutes action against the physician's license 24 for the purposes of this paragraph. 6. The licensee has submitted a form supplying 25 necessary information as required by the department and an 26 affidavit affirming compliance with this paragraph. 27 28 7. The licensee must submit biennially to the 29 department certification stating compliance with the provisions of this paragraph. The licensee must, upon request, 30 31

demonstrate to the department information verifying compliance 1 2 with this paragraph. 3 4 A licensee who meets the requirements of this paragraph must post notice in the form of a sign prominently displayed in the 5 reception area and clearly noticeable by all patients and on б 7 each visit or provide a written statement to any person to 8 whom medical services are being provided. The sign or statement must read as follows: "Under Florida law, physicians 9 are generally required to carry medical malpractice insurance 10 or otherwise demonstrate financial responsibility to cover 11 potential claims for medical malpractice. However, certain 12 13 part-time physicians who meet state requirements are exempt 14 from the financial responsibility law. YOUR DOCTOR MEETS THESE REQUIREMENTS AND HAS DECIDED NOT TO CARRY MEDICAL MALPRACTICE 15 INSURANCE. This notice is provided pursuant to Florida law." 16 Section 9. Paragraph (f) of subsection (5) of section 17 18 459.0085, Florida Statutes, is amended to read: 459.0085 Financial responsibility.--19 (5) The requirements of subsections (1), (2), and (3) 20 do not apply to: 21 22 (f) Any person holding an active license under this 23 chapter who meets all of the following criteria: 24 1. The licensee has held an active license to practice in this state or another state or some combination thereof for 25 more than 15 years. 26 2. The licensee has either retired from the practice 27 28 of osteopathic medicine or maintains a part-time practice of 29 osteopathic medicine of no more than 1,000 patient contact 30 hours per year. 31

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1	3. The licensee has had no more than two claims for
2	medical malpractice resulting in an indemnity exceeding
3	\$25,000 within the previous 5-year period.
4	4. The licensee has not been convicted of, or pled
5	guilty or nolo contendere to, any criminal violation specified
6	in this chapter or the practice act of any other state.
7	5. The licensee has not been subject within the last
8	10 years of practice to license revocation or suspension for
9	any period of time, probation for a period of 3 years or
10	longer, or a fine of \$500 or more for a violation of this
11	chapter or the medical practice act of another jurisdiction.
12	The regulatory agency's acceptance of an osteopathic
13	physician's relinquishment of a license, stipulation, consent
14	order, or other settlement, offered in response to or in
15	anticipation of the filing of administrative charges against
16	the osteopathic physician's license, constitutes action
17	against the physician's license for the purposes of this
18	paragraph.
19	6. The licensee has submitted a form supplying
20	necessary information as required by the department and an
21	affidavit affirming compliance with this paragraph.
22	7. The licensee must submit biennially to the
23	department a certification stating compliance with this
24	paragraph. The licensee must, upon request, demonstrate to the
25	department information verifying compliance with this
26	paragraph.
27	
28	A licensee who meets the requirements of this paragraph must
29	post notice in the form of a sign prominently displayed in the
30	reception area and clearly noticeable by all patients <u>and on</u>
31	<u>each visit</u> or provide a written statement to any person to
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whom medical services are being provided. The sign or 1 2 statement must read as follows: "Under Florida law, 3 osteopathic physicians are generally required to carry medical malpractice insurance or otherwise demonstrate financial 4 responsibility to cover potential claims for medical 5 malpractice. However, certain part-time osteopathic physicians б 7 who meet state requirements are exempt from the financial 8 responsibility law. YOUR OSTEOPATHIC PHYSICIAN MEETS THESE REQUIREMENTS AND HAS DECIDED NOT TO CARRY MEDICAL MALPRACTICE 9 INSURANCE. This notice is provided pursuant to Florida law." 10 Section 10. Subsection (3) of section 458.348, Florida 11 Statutes, is amended to read: 12 13 458.348 Formal supervisory relationships, standing 14 orders, and established protocols; notice; standards.--(3) PROTOCOLS REQUIRING DIRECT SUPERVISION.--All 15 protocols relating to electrolysis or electrology using laser 16 or light-based hair removal or reduction by persons other than 17 18 physicians licensed under this chapter or chapter 459 shall require the person performing such service to be appropriately 19 trained and work only under the direct supervision and 20 responsibility of a physician licensed under this chapter or 21 22 chapter 459. <u>A licensed advanced registered nurse practitioner</u> or physician assistant practicing under a protocol with a 23 24 physician licensed under chapter 458 or chapter 459 shall not be required to obtain licensure as an electrologist in order 25 to perform laser or light-based hair removal procedures. 26 27 Section 11. This act shall take effect upon becoming a 28 law. 29 30 31