Revised

Health Care Regulation Committee

Wednesday, March 15, 2006
8:45 AM - 11:00 AM
212 Knott Building

Allan G. Bense
Speaker

Rene Garcia
Chair

House of Representatives

Committee on Health Care Regulation

AGENDA

March 15, 2006
8:45 AM - 11:00 AM
212 Knott Building

I. Opening Remarks by Chair Garcia

II. Consideration of the following bills:

HB 181 – Administration of Medication by Rep. Hays

HB 715 – Trauma Services by Rep. Grimsley

HB 859 – Physician Assistants by Rep. Baxley

HB 881 – Physician Licensure Requirements by Rep. Flores

HB 7045 – Review under the Open Government Sunset Review Act regarding Supplemental Rebate Agreements by Governmental Operations Committee

III. Consideration of the following Proposed Committee bills:

PCB HCR 06-02 – Licensure of Health Care Providers

PCB HCR 06-04 – Electronic Prescribing

IV. Closing Remarks

V. Adjournment

210 House Office Building, 402 South Monroe Street, Tallahassee, Florida 32399-1300 (850) 487-3771

HB 181

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 181 Administration of Medication
SPONSOR(S): Hays
TIED BILLS: **IDEN./SIM. BILLS:** SB 170

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Care Regulation Committee		Hamrick	Mitchell
2) Elder & Long-Term Care Committee			
3) Health & Families Council			
4)			
5)			

SUMMARY ANALYSIS

HB 181 allows unlicensed direct care services staff to administer prescription medications to persons with developmental disabilities who reside in a comprehensive transitional education program, under the general supervision of a registered nurse.

The bill allows such programs to train unlicensed direct care staff to administer or assist in administering oral, otic, transdermal, ophthalmic, inhaled, rectal or topical prescription medications.

The bill provides an exemption to the Nurse Practice Act, which allows unlicensed direct care providers to administer medication without fear of prosecution for practicing nursing without a license. The nursing practice act does not prohibit a registered nurse or licensed practical nurse from delegating the administration of medication, but does require the nurse to determine the competency of the unlicensed person.

The bill expands the existing provision (s. 393.506, F.S.) for unlicensed direct care staff to include the administration of otic, ophthalmic and rectal prescription medications.

Current statute, (ss. 400.488, 400.4256, 400.9685, and 1006.062, F.S.) provides statutory authority with specific guidelines for unlicensed individuals to administer medication. Sections 400.488 and 400.4256, F.S., specifically state that assistance with self-administration does not include administration of rectal medications. These sections also limit the administration of medications by unlicensed care providers, and prohibit the administration of medications where judgment or discretion is needed to determine the time of administration, the amount, the strength of dosage, the method of administration, or the reason for administration. The bill does not include any specific guidelines or limitations that are provided in statute for other entities.

The bill also changes "day programs" to "day habilitation services" to reference existing definitions within ch. 393, F.S, and provides the Agency for Persons with Disabilities the authority to promulgate rules.

Fiscal Impact: This bill does not appear to have a fiscal impact on state or local governments.

This bill will take effect upon becoming a law.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Safeguard individual liberty-Increases the options for a comprehensive transitional education program to provide care to their clients. This may adversely affect a client's safety if the unlicensed direct care staff is not sufficiently trained.

B. EFFECT OF PROPOSED CHANGES:

The bill allows comprehensive transitional education programs to train unlicensed direct care services staff to administer or assist in administering oral, otic, transdermal, ophthalmic, inhaled, rectal or topical prescription medications to persons with developmental disabilities, under the general supervision of a registered nurse.

The bill provides an exemption to the Nurse Practice Act, which allows the unlicensed direct care staff to administration medication without fear of prosecution for practicing nursing without a license.

The bill expands the existing provision (s. 393.506, F.S.) for unlicensed direct care staff to include the administration of otic, ophthalmic and rectal prescription medications.

Current statute, (ss. 400.488, 400.4256, 400.9685, and 1006.062, F.S.) provides statutory authority, with specific guidelines, for unlicensed individuals to administer medication. Sections 400.488 and 400.4256, F.S., specifically state that assistance with self-administration does not include administration of rectal medications. These sections also limit the administration of medications by unlicensed care providers and prohibit the administration of medications where judgment or discretion is needed to determine the time of administration, the amount, the strength of dosage, the method of administration, or the reason for administration. The bill does not include the specific guidelines or limitations that are provided in statute for other entities.

The bill changes "day programs" to "day habilitation services" to reference existing definitions within ch. 393, F.S, and provides the Agency for Persons with Disabilities with the authority to promulgate rules.

PRESENT SITUATION

Nurse Practice Act, Supervision and Delegation of Authority

The nursing practice act and rules do not expressly prohibit a registered nurse or licensed practical nurse from delegating the administration of medication but, in effect, requires the nurse to determine the competency of the unlicensed person who is delegated any nursing task or activity, to ensure that the person is competent and that the person's competency has been validated.

Chapter 464, Part I, F.S., provides for the regulation of nursing in Florida by the Board of Nursing in the Department of Health. The board has adopted administrative rules relating to the delegation of tasks to unlicensed assistive personnel.[1]

These rules provide that a registered nurse or licensed practical nurse must use nursing judgment in considering the task or activity to be delegated. The delegation process must include communication to the unlicensed assistive personnel to identify the task or activity, the expected or desired outcome, the limits of authority, the time frame for the delegation, the nature of the supervision required, verification that the delegate understands the assignment, verification of monitoring, and supervision.

[1] See Chapter 64B9-14, Florida Administrative Code.

A registered nurse or licensed practical nurse may *not* delegate activities that are not within the delegating or supervising nurse's scope of practice.

Nursing activities that require the special knowledge and use of nursing processes, judgment, or skills of a registered or practical nurse, may *not* be delegated to unlicensed assistive personnel.

Examples of such nursing activities that may *not* be delegated include:

- initial nursing assessment or any subsequent assessments;
- determination of the nursing diagnosis or interpretations of nursing assessments;
- establishment of nursing care goals and development of the plan of care; and
- evaluation of progress in relationship to the plan of care.

Comprehensive Transitional Education Program

Currently, there is one comprehensive transitional education program licensed in Florida.[2] The comprehensive transitional educational program is a large program that has the capacity to serve as many as 120 residents who reside in smaller residential units in three locations. According to the program, they currently provide services to 91 residents, of whom at least 97% take some type of medication. According to the website for the program, it treats clients who have been diagnosed with conditions such as autism, developmental disabilities, severe emotional disturbances, dual diagnoses, conduct disorders and other related diagnoses.[3]

The facility currently has (1) full-time registered nurse and (1) licensed practical nurse on staff. These individuals are available 24-hours a day. Over the weekends (2) Registered Nurses are on call. According to the facility, all unlicensed direct care staff are required to attend training on how to administer medications and identify adverse reactions. The training is administered locally and the participants receive a certificate of completion.

Chapter 393, F.S., defines "comprehensive transitional education program" to mean a group of jointly operating centers or units, the collective purpose of which is to provide a sequential series of educational care, training, treatment, habilitation, and rehabilitation services to persons who have developmental disabilities and who have severe or moderate maladaptive behaviors. The services that are provided by a comprehensive transitional education program must be temporary in nature and delivered in a structured residential setting with the primary goal of incorporating the normalization principle to establish permanent residence for persons with maladaptive behaviors in facilities not associated with the program.[4]

Section 393.063, F.S., defines "developmental disability" as a disorder or syndrome that is attributable to retardation, cerebral palsy, autism, spina bifida, or Prader-Willi syndrome and that constitutes a substantial handicap that can reasonably be expected to continue indefinitely.

The services provided by the comprehensive transitional education program are funded under a Medicaid program waiver.

Surrogate Family and Smaller Residential Settings

In smaller residential settings, properly trained persons or direct care staff may administer medications, as long as smaller residential settings function as a surrogate family. Under current statute incidental care may be provided to sick or non-institutionalized persons, as long as the care is performed by

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[2] Advoserv-Carlton Palms, *Our Florida Locations*, available at http://www.advoserv.com/florida.html (January 4, 2006).
[3] Ibid.
[4] See s. 393.062(7), F.S.

friends or members of the family, domestic servants, or a surrogate family.[5] This provision provides an exemption to the Nurse Practice Act, which allows unlicensed care to provide care to a surrogate family member without fear of prosecution for practicing nursing without a license.

In day programs, the director of a facility or program must designate in writing that an unlicensed direct care services staff is eligible to be trained in how to assist in the administration or is able to administer medication directly.[6]

In an intermediate care facility, the director of a facility or program for the developmentally disabled may designate unlicensed staff that may provide medication assistance under the general supervision of a Florida-licensed registered nurse.[7]

Types of Medications Administered to Persons with Developmental Disabilities

Currently, the administration of medication to persons with developmental disabilities in the comprehensive transitional educational program is performed by a nurse. The bill allows unlicensed direct care staff to administer medication under the general supervision of a registered nurse in such programs.

Currently, in day programs and intermediate care facilities, unlicensed direct care staff may administer oral, transdermal, inhaled or topical prescription medications to persons with developmental disabilities.[8] The bill expands this provision by allowing unlicensed direct care services to include the administration of otic, ophthalmic and rectal prescription medications.

Training Requirements of Unlicensed Direct Care Staff

Each facility, institution, or program under the purview of s. 393.506, F.S., must include in its policies and procedures a plan for training designated staff to ensure the safe handling, storage, and administration of prescription medication. These policies and procedures must be approved by the Agency for Persons with Disabilities before an unlicensed direct care staff assists with the administration of medication. The policies and procedures must include, at a minimum, the following provisions:

- An expressed and informed consent for each client;
- The director of the facility, program, or provider must maintain a copy of the written prescription, and that prescription must include the name of the medication, the dosage and administration schedule, the reason for the prescription, and the termination date; and
- Each prescribed medication must be kept in its original container and in a secure location.

The training required in s. 393.506, F.S., must be conducted by a registered nurse or a Florida-licensed medical physician or osteopathic physician.

Clarification of Terminology for Day Programs and Day Habilitation Facilities

Section 393.506, F.S., refers to "day programs" as defined in s. 393.063, F.S., but s. 393.063, F.S., does not define "day programs." Section 393.063(8), F.S., does define "day habilitation facility" and "day habilitation services." The bill corrects the inconsistency in terminology.

- A "day habilitation facility" is defined as any nonresidential facility which provides day habilitation services.

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[5] See s. 464.022(1), F.S.
[6] See s. 393.506, F.S.
[7] Ibid.
[8] See s. 393.506, F.S.

- A "day habilitation service" is defined as a service that provides assistance with the acquisition, retention, or improvement in self-help, socialization, and adaptive skills which takes place in a nonresidential setting, separate from the home or facility in which the individual resides. Day habilitation services shall focus on enabling the individual to attain or maintain his or her maximum functional level and shall be coordinated with any physical, occupational, or speech therapies listed in the plan of care.

C. SECTION DIRECTORY:

Section 1. Amends s. 393.506, F.S., relating to the administration of medication by unlicensed direct care staff in a comprehensive transitional education program, and grants rule making authority to the Agency for Persons with Disabilities.
Section 2. Provides the bill will take effect upon becoming a law.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The Comprehensive Transitional Education Program (CTEP) may economically benefit from implementation of this bill. They would no longer be required to have medications administered by a nurse and may be able to decrease their nursing staff.

D. FISCAL COMMENTS:

There may be costs associated with rule promulgation by the Agency for Persons with Disabilities.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   This bill does not require counties or municipalities to spend funds or take an action requiring the expenditure of funds. This bill does not reduce the percentage of a state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenue.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

This bill provides the Agency for Persons with Disabilities the authority to adopt rules to facilitate implementation.

C. DRAFTING ISSUES OR OTHER COMMENTS:

According to the Department of Health, the Board of Nursing has client safety concerns regarding the administration of medications by unlicensed personnel and feels that any authority to do so should mimic the requirements for education/training and supervision by a registered nurse as provided in chapter 400, F.S.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

1 A bill to be entitled
2 An act relating to the administration of medication;
3 amending s. 393.506, F.S.; authorizing certain staff
4 members to administer prescription medications under the
5 supervision of a registered nurse to persons with
6 developmental disabilities at a comprehensive transitional
7 education program; directing the Agency for Persons with
8 Disabilities to adopt rules to implement s. 393.506, F.S.;
9 providing an effective date.
10
11 Be It Enacted by the Legislature of the State of Florida:
12
13 Section 1. Section 393.506, Florida Statutes, is amended
14 to read:
15 393.506 Administration of medication.--
16 (1) Notwithstanding the provisions of part I of chapter
17 464, the Nurse Practice Act, unlicensed direct care services
18 staff providing services to persons with developmental
19 disabilities may administer oral, transdermal, inhaled, or
20 topical prescription medications as provided in this section.
21 (a) For day habitation services ~~programs~~, as defined in s.
22 393.063, the director of the facility or program shall designate
23 in writing unlicensed direct care services staff who are
24 eligible to be trained to assist in the administration of or to
25 administer medication.
26 (b) For intermediate care facilities for the
27 developmentally disabled licensed pursuant to part XI of chapter
28 400, unlicensed staff designated by the director may provide

29 medication assistance under the general supervision of a
30 registered nurse licensed pursuant to chapter 464.
31 (2) Notwithstanding part I of chapter 464, the Nurse
32 Practice Act, unlicensed direct care staff who provide services
33 to persons with developmental disabilities in a comprehensive
34 transitional education program licensed pursuant to s. 393.067
35 and who are designated by the director of such program may
36 administer, or assist in the administration of, oral, otic,
37 transdermal, ophthalmic, inhaled, rectal, or topical
38 prescription medications under the general supervision of a
39 registered nurse licensed pursuant to chapter 464 as provided in
40 this section.
41 (3) ~~(2)~~ Each facility, institution, or program must include
42 in its policies and procedures a plan for training designated
43 staff to ensure the safe handling, storage, and administration
44 of prescription medication. These policies and procedures must
45 be approved by the agency before unlicensed direct care services
46 staff assist with medication.
47 (4) ~~(3)~~ The policies and procedures must include, at a
48 minimum, the following provisions:
49 (a) An expressed and informed consent for each client.
50 (b) The director of the facility, program, or provider
51 must maintain a copy of the written prescription, and that
52 prescription must include the name of the medication, the dosage
53 and administration schedule, the reason for the prescription,
54 and the termination date.
55 (c) Each prescribed medication shall be kept in its
56 original container and in a secure location.

57 (5) ~~(4)~~ The training required in this section shall be
58 conducted by a registered nurse or a physician licensed pursuant
59 to chapter 458 or chapter 459.
60 (6) The Agency for Persons with Disabilities shall adopt
61 rules to implement this section.
62 Section 2. This act shall take effect upon becoming a law.

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1 (for drafter's use only)

Bill No. **HB 181**

COUNCIL/COMMITTEE ACTION

ADOPTED	__	(Y/N)
ADOPTED AS AMENDED	__	(Y/N)
ADOPTED W/O OBJECTION	__	(Y/N)
FAILED TO ADOPT	__	(Y/N)
WITHDRAWN	__	(Y/N)
OTHER	____	

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1 Council/Committee hearing bill: Health Care Regulation
2 Representative(s) Hays offered the following:
3
4 **Amendment (with directory and title amendments)**
5 Remove everything after the enacting clause and insert:
6
7 Section 1. Section 393.506, Florida Statutes, is amended
8 to read:
9 393.506 Administration of medication.--
10 (1) A ~~Notwithstanding the provisions of part I of chapter~~
11 ~~464, the Nurse Practice Act, unlicensed~~ direct service provider
12 who is not currently licensed to administer medication ~~care~~
13 ~~services staff providing services to persons with developmental~~
14 ~~disabilities~~ may supervise the self-administration of or may
15 administer oral, transdermal, ophthalmic, otic, rectal, inhaled,
16 or topical prescription medications to a client as provided in
17 this section.
18 (2) In order to supervise the self-administration of
19 medication or to administer medications as provided in
20 subsection (1), a direct service provider must satisfactorily
21 complete a medication administration training course of not less

22 than 4 hours in medication administration and be found competent
23 to supervise the self-administration of medication by a client
24 or to administer medication to a client in a safe and sanitary
25 manner. Competency must be assessed and validated at least
26 annually in an onsite setting and must include personally
27 observing that the direct service provider satisfactorily:
28 (a) Supervised the self-administration of medication by a
29 client.
30 (b) Administered medication to a client.
31 (3) A direct service provider may supervise the self-
32 administration of medication by a client or may administer
33 medication to a client only if the client, or the client's
34 guardian or legal representative, has given his or her informed
35 consent to self-administering medication under the supervision
36 of an unlicensed direct service provider or to receiving
37 medication administered by an unlicensed direct service
38 provider. Such informed consent must be based on a description
39 of the medication routes and procedures that the direct service
40 provider is authorized to supervise or administer. Only a direct
41 service provider who has received appropriate training and has
42 been validated as competent may supervise the self-
43 administration of medication by a client or may administer
44 medication to a client.
45 (4) The determination of competency and annual validation
46 required under this section shall be conducted by a registered
47 nurse licensed pursuant to chapter 464.
48 (5) The agency shall establish by rule standards and
49 procedures that a direct service provider must follow when
50 supervising the self-administration of medication by a client
51 and when administering medication to a client. Such rules must,

52 at a minimum, address requirements for labeling medication,
53 documentation and recordkeeping, the storage and disposal of
54 medication, instructions concerning the safe administration of
55 medication or supervision of self-administered medication,
56 informed-consent requirements and records, and the training
57 curriculum and validation procedures.
58 ~~(a) For day programs, as defined in s. 393.063, the~~
59 ~~director of the facility or program shall designate in writing~~
60 ~~unlicensed direct care services staff who are eligible to be~~
61 ~~trained to assist in the administration of or to administer~~
62 ~~medication.~~
63 ~~(b) For intermediate care facilities for the~~
64 ~~developmentally disabled licensed pursuant to part XI of chapter~~
65 ~~400, unlicensed staff designated by the director may provide~~
66 ~~medication assistance under the general supervision of a~~
67 ~~registered nurse licensed pursuant to chapter 464.~~
68 ~~(2) Each facility, institution, or program must include in~~
69 ~~its policies and procedures a plan for training designated staff~~
70 ~~to ensure the safe handling, storage, and administration of~~
71 ~~prescription medication. These policies and procedures must be~~
72 ~~approved by the agency before unlicensed direct care services~~
73 ~~staff assist with medication.~~
74 ~~(3) The policies and procedures must include, at a~~
75 ~~minimum, the following provisions:~~
76 ~~(a) An expressed and informed consent for each client.~~
77 ~~(b) The director of the facility, program, or provider~~
78 ~~must maintain a copy of the written prescription, and that~~
79 ~~prescription must include the name of the medication, the dosage~~
80 ~~and administration schedule, the reason for the prescription,~~
81 ~~and the termination date.~~

82 ~~(c) Each prescribed medication shall be kept in its~~
83 ~~original container and in a secure location.~~
84 ~~(4) The training required in this section shall be~~
85 ~~conducted by a registered nurse or a physician licensed pursuant~~
86 ~~to chapter 458 or chapter 459.~~
87 Section 2. This act shall take effect upon becoming a law.
88
89 ========== T I T L E A M E N D M E N T ==========
90 Remove the entire title and insert:
91 A bill to be entitled
92 An act relating to administration of medication; amending
93 s. 393.506, F.S.; deleting requirements for unlicensed
94 staff members of direct care service facilities to
95 administer prescribed medications to persons with
96 developmental disabilities; authorizing direct service
97 providers to administer medication to clients or to
98 supervise the self-administration of medication by
99 clients; providing requirements for direct service
100 providers to demonstrate competency regarding supervising
101 the self-administration of medication by clients or
102 administering medication to clients; requiring the Agency
103 for Persons with Disabilities to adopt rules to establish
104 standards and procedures governing the supervision of
105 self-administered medications and the administration of
106 medications by direct service providers; providing an
107 effective date.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 715 Trauma Services
SPONSOR(S): Grimsley
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Care Regulation Committee		Bell AJB	Mitchell
2) Health Care Appropriations Committee			
3) Health & Families Council			
4)			
5)			

SUMMARY ANALYSIS

In the 2005 session the Legislature passed HB 715 and HB 1697, which provided additional funding to trauma centers through traffic infraction fines and court assessments. Revenues generated through these additional funds are appropriated into the Department of Health Administrative (DOH) Trust Fund, from which up to $7.5 million is earmarked to provide funding for trauma centers on the basis of caseload and the severity of trauma patients. Currently, $1 million dollars has been raised by the increased fee.

HB 715 addresses the allocation and distribution of trauma center funds. The bill changes a number of provisions related to the distribution and determination of trauma payments to current verified trauma centers. The changes include:

- Requires an annual audit of trauma registry data;
- Changes the way trauma centers determine the severity of patients (by requiring trauma centers to evaluate patients with the International Classification Injury Severity Score (ICISS) instead of the Injury Severity Score (ISS); and
- Provides definitions for ICISS, trauma caseload volume, and trauma patient.

The Department of Health (DOH) estimates that the fiscal impact of the oversight provisions of the bill is $844,327 in the first year and $877,361 in the second year.

The effective date of the bill is July 1, 2006.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Promote Limited Government – The bill provides new definitions, changes the way verified trauma centers determine the severity of trauma patients that may alter the distribution of trauma center funds, and requires a yearly independent audit of the trauma registry data. The Department of Health estimates that the fiscal impact of the bill auditing requirements is $844,327 in the first year and $877,361 in the second year.

B. EFFECT OF PROPOSED CHANGES:

Present Situation

In the 2005 session the Legislature passed HB 715 and HB 1697, both of which provide additional funding to trauma centers through traffic infraction fines and court assessments. HB 715 increased the civil penalties for drivers who failed to obey red traffic signals from $60 to $125. HB 1697 allocated funds from mandatory civil penalties to this same DOH Administrative Trust Fund, to provide financial support to trauma centers throughout the state.

Revenues generated through these additional funds are appropriated into the Department of Health Administrative (DOH) Trust Fund, from which up to $7.5 million is earmarked to provide funding for trauma centers on the basis of caseload and the severity of trauma patients. Currently, $1 million dollars has been raised by the increased fee.

Trauma center funding is weighted based on the severity of trauma patients (40%), the trauma caseload volume (40%), and availability of local funding contributions (20%). The severity of trauma patients is determined by the ISS score and the caseload volume is determined by DOH's Trauma Registry Data.

The severity of trauma patients and caseload volume is collected and entered into the Department of Health Trauma Registry. The classification currently used to rate severity of trauma is the Injury Severity Score (ISS).

Trauma Registry data is currently verified by DOH staff during the yearly trauma center site survey. The DOH survey takes a very small sample of Trauma Registry records to evaluate trauma staffing and procedures. This survey does not focus on the validity of the Trauma Registry ISS.

Currently, funds collected for distribution to trauma centers are based on the calendar year and not the state fiscal year.

Effects of the Bill

HB 715 amends ss. 395.404 & 395.4035, F.S., to address the allocation of trauma center funds. It changes a number of provisions related to the determination and distribution of trauma payments to current verified trauma centers.

The bill requires an independent entity to annually audit the Trauma Registry data and to submit the audit report to the Department of Health (DOH).

The bill changes the standard by which trauma centers report injuries to DOH. Currently the severity of trauma patients is determined and coded with Injury Severity Scores (ISS), which only considers a maximum of three patient injuries. The bill requires trauma severity to be determined by the International Classification Injury Severity Scores (ICISS), the current standard, and other statistically

valid and scientifically accepted methods of stratifying a trauma patient's severity of injury, risk of mortality, and resource consumption as adopted by DOH by rule. The impact of the change in injury determination methodology may change payment calculations for determining the amount of funding allotted to each trauma center.

The bill provides that DOH's Administrative Trust Fund may be used to maximize federal funds available to trauma centers. The total funds distributed to trauma centers may include revenue from DOH's Administrative Trust Fund and federal funds for which revenue from DOH's Administrative Trust Fund is used to meet state or local matching requirements, including Medicaid.

The bill changes the period for distribution of funds from calendar year to state fiscal year.

The bill repeals s. 395.4035, F.S., the Trauma Trust Fund. This has no impact on trauma centers because the Trauma Trust Fund has never been used by DOH. Funds collected for distribution to trauma centers have been deposited into either the Emergency Medical Services Trust Fund or the DOH Administrative Trust Fund.

The bill amends s. 395.4001, F.S., to provide definitions for the International Classification Injury Severity Score (ICISS), trauma caseload volume, and trauma patient. These are new statutory definitions.

The effective date of the bill is July 1, 2006.

BACKGROUND

Chapter 395, F.S., defines a trauma center as a facility within a general medical hospital determined by the Department of Health to be in compliance with trauma center verification standards. These centers treat individuals who have incurred blunt or penetrating injuries or burns, and
who require immediate medical intervention and treatment. Trauma center patients require urgent, lifesaving care. Trauma centers must be ready at all times and have designated suites reserved to treat patients at all times. Emergency rooms are not trauma centers. A trauma center has dozens of specialists, many of whom are available 24-hours-a-day, seven days a week. Trauma centers have access to air emergency whose job is to be available for the moment a serious accident occurs.

The effectiveness of a trauma center lies in the speed and quality of treatment. Getting a patient definitive care within the first hour, or golden hour, of injury drastically increases their chances of survival. Trauma mortality is reduced by 15-20% when a very seriously injured patient is treated at a trauma center versus a non-trauma center.

Florida's trauma system has been under development since the passage of landmark trauma legislation in the late 1980's. Key components of this system include trauma centers, trauma agencies, trauma service areas, and trauma regions, as well as trauma transport protocols and trauma triage criteria for emergency medical service providers.

Florida Trauma Registry

The Florida Trauma Registry (FTR) collects patient-level data from the state's twenty-one trauma centers. As a state designated facility, a trauma center must maintain a comprehensive database of those injured patients treated within the hospital. The trauma registry supports the trauma centers required activities, including performance improvement, outcomes research, and resource utilization as well as providing the state public health system with the necessary data for state-wide planning and injury prevention initiatives.

Comparing the ISS and the ICISS

Characterization of injury severity is crucial to the study and treatment of trauma. The measurement of injury severity began just over 50 years ago with the Abbreviated Injury Scale (AIS), a method developed to grade the severity of individual injuries. The AIS has been modified many times, most recently in 1990, and is the basis for the Injury Severity Score (ISS). The Injury Severity Score (ISS) was for many decades the standard summary measure of human trauma. However, it has two weaknesses. First, the ISS considers a maximum of only three of an individual patient's injuries which may not even be the patient's most severe injuries. Second, the ISS requires that all patients have their injuries described using an expensive assessment method unavailable at most hospitals, especially those that do not specialize in trauma.[1]

A more recent approach to injury scoring is based on the *International Classification of Disease, Ninth Edition* (*ICD-9*) codes and is referred to as the *ICD-9* Injury Severity Score (ICISS). The ICISS is a data-driven alternative to ISS that uses empirically-derived injury severity measures, and considers all of an individual patient's injuries rather than just a few. The use of the standard ICD-9 classification scheme adds to the statistical appeal of the ICISS and avoids the need for costly AIS coding.[2]

In terms of methodology, the ICISS uses survival risk ratios (SRRs) calculated for each *ICD-9* discharge diagnosis. SRRs are derived by dividing the number of survivors in each *ICD-9* code by the total number of patients with the same *ICD-9* code. ICISS is calculated as the simple product of the SRRs for each of the patient's injuries.[3] For example, if a population of 1,000 patients with femoral fractures included 100 patients who died, then the single SRR for that particular diagnoses would be .9 or [1-(100/1000)]. A patient with two injuries, one having a SRR of .9 and the other having a SRR of .5, would have a total probability of survival of .9 multiplied by .5, yielding an overall probability of survival of .45.[4]

ICISS has demonstrated a greater reliability than ISS, and offers many advantages for predicting the severity of an illness and injury. The ICISS values may also be used as predictors of resource utilization, and may be used as an assessment tool in quality improvement efforts. Research has shown benefits of the ICISS over other scoring systems include:[5]

1. It represents a true continuous variable that takes on values between 0 and 1.
2. It includes all injuries.
3. *ICD-9* codes are readily available and do not require special training or expertise to determine.
4. *ICD-9* has better predictive power when compared to the ISS.
5. ICISS has the potential to better account for the effects of comorbidity on outcome by including the SRR for each comorbidity present.
6. The ICISS outperforms the ISS in predicting other outcomes of interest (e.g., hospital length of stay, hospital charges).
7. Compared to all over available severity adjustment systems, ICISS was most accurate.
8. ICISS can be more precisely population-based.
9. ICISS requires no additional software manipulation of data. ICDMAP-90 software for risk stratification converts International Classification of Disease (ICD) discharge diagnoses to injury severity scores to allow standardized outcome comparison.

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[1] Osler, T., Rutledge, R., et al. ***ICISS*: An International Classification of Disease-9 Based Injury Severity Score.** *Journal of Trauma-Injury Infection & Critical Care.* 41(3):380-388, September 1996. Available online at http://www.jtrauma.com/.

[2] Sposato, E.M. "The End of the Injury Severity Score (ISS) and the Trauma and Injury Severity Score (TRISS): ICISS, an International Classification of Diseases, Ninth Revision-Based Prediction Tool, Outperforms Both ISS and TRISS as Predictors of Trauma Patient Survival, Hospital Charges, and Hospital Length of Stay. *Journal of Trauma Nursing.* Jan-March, 1999. Available online at http://www.allbusiness.com/periodicals/article/350114-1.html

[3] Offner, P. Trauma Scoring Systems. *EMedicine.* 4/25/02. http://www.emedicine.com/med/topic3214.htm

[4] https://jobs.orhs.org/trauma/report-feb-05.pdf

[5] http://www.emedicine.com/med/topic3214.htm and https://jobs.orhs.org/trauma/report-feb-05.pdf

C. SECTION DIRECTORY:

Section 1. – Amends s. 395.4001, F.S., to provide definitions.

Section 2. – Repeals s. 395.4035, F.S.

Section 3. – Amends s. 395.4036, F.S., to require that funds distributed to trauma centers be based on audited Trauma Registry caseload volume for the previous calendar year.

Section 4. – Amends s. 395.404, F.S., to require an independent entity to audit the Trauma Registry data.

Section 5. – Provides the bill will take effect July 1, 2006.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

Department of Health Estimated Expenditures		(Annualized/Recurr.)
Salaries		
1 Operations & Management Consultant II @ $35,668	$34,241	$45,655
1 Computer System Analyst @ $30,021 (FTE computed w/28% fringe and 25% lapse)	$28,820	$38,426
Expense		
2 FTE @ std DOH professional Pkg. w/limited travel @ $13,733	$27,466	$20,780
Independent Entity Contract for Audit of Trauma Registry Data	$750,000 (estimated)	$772,500 (5% estimated inflation)
Operating Capital Outlay		
2 FTE @ Std DOH professional pkg.	$3,800	$
Total Estimated Expenditures	**$844,327**	**$877,361**

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The bill alters the way trauma centers determine the severity of trauma patients. Forty percent of trauma center funding is distributed by the ISS coded severity of trauma patients. Thus, the bill has the potential to increase or decrease trauma center payments depending on the results of the severity ranking system. Additionally, 40% of trauma center funding is distributed based on trauma caseload Trauma Registry data. The bill requires the Trauma Registry data to be audited yearly. If the audit finds inaccurate data it may increase or decrease trauma center payments.

D. FISCAL COMMENTS:

Department of Health Fiscal Estimates

According to the Department of Health (DOH), there will be a fiscal impact to contract with an independent entity to provide contract management and conduct an annual audit of Trauma Registry data at each of the 21 trauma centers. It would cost at least $750,000 annually to contract with an independent entity to conduct a yearly onsite audit at each of the 21 trauma centers. This cost is based on the review of approximately 5,000 (10% of the estimated total trauma registry volume reported to the DOH Trauma Registry) trauma medical records. The average cost to conduct an audit is $100 an hour per medical record. A medical record coder can code/audit one medical record per hour at a total cost of $500,000. An additional $250,000 would be needed to cover an independent entity's personnel travel, expenses and for preparing and submitting reports for each trauma center to DOH.

According to DOH, an Operations and Management Consultant II would be needed to handle the request to negotiate the contract, ongoing contract management, and management of the independent entity. This position would also be responsible for collecting cost data and resource consumption data from each of the 21 trauma centers. A Computer System Analyst would be needed to develop and maintain the computerized algorithms for calculating the survival risk ratios (SRR) for each reported ICD-9 diagnosis code and subsequent determination of the ICD-9 Injury Severity Score (ICISS), resource utilization and cost ratios.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill does not require counties or municipalities to spend funds or take action requiring the expenditure of funds. This bill does not reduce the percentage of state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenue.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The Department of Health has sufficient rule making authority to implement the provisions in the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

1 A bill to be entitled
2 An act relating to trauma services; amending s. 395.4001,
3 F.S.; providing definitions; repealing s. 395.4035, F.S.,
4 to terminate the Trauma Services Trust Fund; amending s.
5 395.4036, F.S.; revising provisions relating to
6 distribution of funds to trauma centers and use thereof;
7 amending s. 395.404, F.S.; requiring an annual audit of
8 Trauma Registry data; providing an effective date.
9
10 Be It Enacted by the Legislature of the State of Florida:
11
12 Section 1. Section 395.4001, Florida Statutes, is amended
13 to read:
14 395.4001 Definitions.--As used in this part, the term:
15 (1) "Agency" means the Agency for Health Care
16 Administration.
17 (2) "Charity care" or "uncompensated trauma care" means
18 that portion of hospital charges reported to the agency for
19 which there is no compensation, other than restricted or
20 unrestricted revenues provided to a hospital by local
21 governments or tax districts regardless of method of payment,
22 for care provided to a patient whose family income for the 12
23 months preceding the determination is less than or equal to 200
24 percent of the federal poverty level, unless the amount of
25 hospital charges due from the patient exceeds 25 percent of the
26 annual family income. However, in no case shall the hospital
27 charges for a patient whose family income exceeds four times the

28 federal poverty level for a family of four be considered
29 charity.
30 (3) "Department" means the Department of Health.
31 (4) "Interfacility trauma transfer" means the transfer of
32 a trauma victim between two facilities licensed under this
33 chapter, pursuant to this part.
34 (5) "International Classification Injury Severity Score"
35 means the statistical method for computing the severity of
36 injury sustained by trauma patients. The International
37 Classification Injury Severity Score shall be the methodology
38 used by the department and trauma centers to report the severity
39 of an injury.
40 (6) ~~(5)~~ "Level I trauma center" means a trauma center that:
41 (a) Has formal research and education programs for the
42 enhancement of trauma care; is verified by the department to be
43 in substantial compliance with Level I trauma center and
44 pediatric trauma center standards; and has been approved by the
45 department to operate as a Level I trauma center.
46 (b) Serves as a resource facility to Level II trauma
47 centers, pediatric trauma centers, and general hospitals through
48 shared outreach, education, and quality improvement activities.
49 (c) Participates in an inclusive system of trauma care,
50 including providing leadership, system evaluation, and quality
51 improvement activities.
52 (7) ~~(6)~~ "Level II trauma center" means a trauma center
53 that:
54 (a) Is verified by the department to be in substantial
55 compliance with Level II trauma center standards and has been

56 approved by the department to operate as a Level II trauma
57 center.
58 (b) Serves as a resource facility to general hospitals
59 through shared outreach, education, and quality improvement
60 activities.
61 (c) Participates in an inclusive system of trauma care.
62 (8) ~~(7)~~ "Pediatric trauma center" means a hospital that is
63 verified by the department to be in substantial compliance with
64 pediatric trauma center standards as established by rule of the
65 department and has been approved by the department to operate as
66 a pediatric trauma center.
67 (9) ~~(8)~~ "Provisional trauma center" means a hospital that
68 has been verified by the department to be in substantial
69 compliance with the requirements in s. 395.4025 and has been
70 approved by the department to operate as a provisional Level I
71 trauma center, Level II trauma center, or pediatric trauma
72 center.
73 (10) ~~(9)~~ "Trauma agency" means a department-approved agency
74 established and operated by one or more counties, or a
75 department-approved entity with which one or more counties
76 contract, for the purpose of administering an inclusive regional
77 trauma system.
78 (11) ~~(10)~~ "Trauma alert victim" means a person who has
79 incurred a single or multisystem injury due to blunt or
80 penetrating means or burns, who requires immediate medical
81 intervention or treatment, and who meets one or more of the
82 adult or pediatric scorecard criteria established by the
83 department by rule.

84 (12) "Trauma caseload volume" means the number of trauma
85 patients reported by individual trauma centers to the Trauma
86 Registry and validated by the department.
87 (13) ~~(11)~~ "Trauma center" means a hospital that has been
88 verified by the department to be in substantial compliance with
89 the requirements in s. 395.4025 and has been approved by the
90 department to operate as a Level I trauma center, Level II
91 trauma center, or pediatric trauma center.
92 (14) "Trauma patient" means a person who has incurred a
93 physical injury or wound caused by trauma and has accessed a
94 trauma center.
95 (15) ~~(12)~~ "Trauma scorecard" means a statewide methodology
96 adopted by the department by rule under which a person who has
97 incurred a traumatic injury is graded as to the severity of his
98 or her injuries or illness and which methodology is used as the
99 basis for making destination decisions.
100 (16) ~~(13)~~ "Trauma transport protocol" means a document
101 which describes the policies, processes, and procedures
102 governing the dispatch of vehicles, the triage, prehospital
103 transport, and interfacility trauma transfer of trauma victims.
104 (17) ~~(14)~~ "Trauma victim" means any person who has incurred
105 a single or multisystem injury due to blunt or penetrating means
106 or burns and who requires immediate medical intervention or
107 treatment.
108 Section 2. Section 395.4035, Florida Statutes, is
109 repealed.
110 Section 3. Subsection (1) of section 395.4036, Florida
111 Statutes, is amended to read:

112 395.4036 Trauma payments.--
113 (1) Recognizing the Legislature's stated intent to provide
114 financial support to the current verified trauma centers and to
115 provide incentives for the establishment of additional trauma
116 centers as part of a system of state-sponsored trauma centers,
117 the department shall utilize funds collected under s.
118 318.18(15) ~~(14)~~ and deposited into the Administrative Trust Fund
119 of the department to ensure the availability and accessibility
120 of trauma services throughout the state as provided in this
121 subsection.
122 (a) Twenty percent of the total funds collected under this
123 subsection during the state fiscal year shall be distributed to
124 verified trauma centers ~~located in a region~~ that have ~~has~~ a
125 local funding contribution as of December 31. Distribution of
126 funds under this paragraph shall be based on the department's
127 audited Trauma Registry trauma caseload volume for the previous
128 calendar year.
129 (b) Forty percent of the total funds collected under this
130 subsection shall be distributed to verified trauma centers based
131 on trauma caseload volume of the previous calendar year. The
132 determination of caseload volume for distribution of funds under
133 this paragraph shall be based on the department's audited Trauma
134 Registry data.
135 (c) Forty percent of the total funds collected under this
136 subsection shall be distributed to verified trauma centers based
137 on severity of trauma patients. The determination of severity
138 for distribution of funds under this paragraph shall be based on
139 the department's audited Trauma Registry International

140 Classification Injury Severity Scores and other statistically
141 valid and scientifically accepted methods of stratifying a
142 trauma patient's severity of injury, risk of mortality, and
143 resource consumption as adopted by the department by rule,
144 weighted based on the costs associated with and incurred by the
145 trauma center in treating trauma patients. The weighting of
146 scores shall be established by the department by rule ~~scores of~~
147 ~~1-14 and 15 plus~~.
148
149 Funds deposited in the department's Administrative Trust Fund
150 for verified trauma centers may be used to maximize the receipt
151 of federal funds that may be available for such trauma centers.
152 Notwithstanding this section and s. 318.14, distributions to
153 trauma centers may be adjusted in a manner to ensure that total
154 payments to trauma centers represent the same proportional
155 allocation as set forth in this section and s. 318.14. For
156 purposes of this section and s. 318.14, total funds distributed
157 to trauma centers may include revenue from the Administrative
158 Trust Fund and federal funds for which revenue from the
159 Administrative Trust Fund is used to meet state or local
160 matching requirements. ~~Trauma centers may request that their~~
161 ~~distributions from the Administrative Trust Fund be used as~~
162 ~~intergovernmental transfer funds in the Medicaid program.~~
163 Section 4. Paragraph (c) is added to subsection (1) of
164 section 395.404, Florida Statutes, to read:
165 395.404 Review of trauma registry data; report to central
166 registry; confidentiality and limited release.--
167 (1)

168 (c) An independent entity shall annually audit Trauma
169 Registry data and submit the audit report to the department.
170 Section 5. This act shall take effect July 1, 2006.

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1 (for drafter's use only)

Bill No. **HB 715**

COUNCIL/COMMITTEE ACTION

ADOPTED	__	(Y/N)
ADOPTED AS AMENDED	__	(Y/N)
ADOPTED W/O OBJECTION	__	(Y/N)
FAILED TO ADOPT	__	(Y/N)
WITHDRAWN	__	(Y/N)
OTHER	____	

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1 Council/Committee hearing bill: Health Care Regulation
2 Representative(s) Grimsley offered the following:
3
4 **Amendment (with title amendment)**
5 Remove everything after the enacting clause and insert:
6
7 Section 1. Section 395.4001, Florida Statutes, is amended
8 to read:
9 395.4001 Definitions.--As used in this part, the term:
10 (1) "Agency" means the Agency for Health Care
11 Administration.
12 (2) "Charity care" or "uncompensated trauma care" means
13 that portion of hospital charges reported to the agency for
14 which there is no compensation, other than restricted or
15 unrestricted revenues provided to a hospital by local
16 governments or tax districts regardless of method of payment,
17 for care provided to a patient whose family income for the 12
18 months preceding the determination is less than or equal to 200
19 percent of the federal poverty level, unless the amount of
20 hospital charges due from the patient exceeds 25 percent of the
21 annual family income. However, in no case shall the hospital
22 charges for a patient whose family income exceeds four times the

23 federal poverty level for a family of four be considered
24 charity.
25 (3) "Department" means the Department of Health.
26 (4) "Interfacility trauma transfer" means the transfer of
27 a trauma victim between two facilities licensed under this
28 chapter, pursuant to this part.
29 (5) "International Classification Injury Severity Score"
30 means the statistical method for computing the severity of
31 injury sustained by trauma patients. The International
32 Classification Injury Severity Score shall be the methodology
33 used by the department and trauma centers to report the severity
34 of an injury.
35 (6) ~~(5)~~ "Level I trauma center" means a trauma center that:
36 (a) Has formal research and education programs for the
37 enhancement of trauma care; is verified by the department to be
38 in substantial compliance with Level I trauma center and
39 pediatric trauma center standards; and has been approved by the
40 department to operate as a Level I trauma center.
41 (b) Serves as a resource facility to Level II trauma
42 centers, pediatric trauma centers, and general hospitals through
43 shared outreach, education, and quality improvement activities.
44 (c) Participates in an inclusive system of trauma care,
45 including providing leadership, system evaluation, and quality
46 improvement activities.
47 (7) ~~(6)~~ "Level II trauma center" means a trauma center
48 that:
49 (a) Is verified by the department to be in substantial
50 compliance with Level II trauma center standards and has been
51 approved by the department to operate as a Level II trauma
52 center.

53 (b) Serves as a resource facility to general hospitals
54 through shared outreach, education, and quality improvement
55 activities.
56 (c) Participates in an inclusive system of trauma care.
57 (8) "Local funding contribution" means local municipal,
58 county or tax district funding exclusive of any patient specific
59 funds received pursuant to ss. 154.301-154.316; private
60 foundation funding; or public or private grant funding of at
61 least $150,000 received by a hospital or health care system that
62 operates a trauma center.
63 (9) ~~(7)~~ "Pediatric trauma center" means a hospital that is
64 verified by the department to be in substantial compliance with
65 pediatric trauma center standards as established by rule of the
66 department and has been approved by the department to operate as
67 a pediatric trauma center.
68 (10) ~~(8)~~ "Provisional trauma center" means a hospital that
69 has been verified by the department to be in substantial
70 compliance with the requirements in s. 395.4025 and has been
71 approved by the department to operate as a provisional Level I
72 trauma center, Level II trauma center, or pediatric trauma
73 center.
74 (11) ~~(9)~~ "Trauma agency" means a department-approved agency
75 established and operated by one or more counties, or a
76 department-approved entity with which one or more counties
77 contract, for the purpose of administering an inclusive regional
78 trauma system.
79 (12) ~~(10)~~ "Trauma alert victim" means a person who has
80 incurred a single or multisystem injury due to blunt or
81 penetrating means or burns, who requires immediate medical
82 intervention or treatment, and who meets one or more of the

83 adult or pediatric scorecard criteria established by the
84 department by rule.
85 (13) "Trauma caseload volume" means the number of trauma
86 patients reported by individual trauma centers to the Trauma
87 Registry and validated by the department.
88 (14) ~~(11)~~ "Trauma center" means a hospital that has been
89 verified by the department to be in substantial compliance with
90 the requirements in s. 395.4025 and has been approved by the
91 department to operate as a Level I trauma center, Level II
92 trauma center, or pediatric trauma center.
93 (15) "Trauma patient" means a person who has incurred a
94 physical injury or wound caused by trauma and has accessed a
95 trauma center.
96 (16) ~~(12)~~ "Trauma scorecard" means a statewide methodology
97 adopted by the department by rule under which a person who has
98 incurred a traumatic injury is graded as to the severity of his
99 or her injuries or illness and which methodology is used as the
100 basis for making destination decisions.
101 (17) ~~(13)~~ "Trauma transport protocol" means a document
102 which describes the policies, processes, and procedures
103 governing the dispatch of vehicles, the triage, prehospital
104 transport, and interfacility trauma transfer of trauma victims.
105 (18) ~~(14)~~ "Trauma victim" means any person who has incurred
106 a single or multisystem injury due to blunt or penetrating means
107 or burns and who requires immediate medical intervention or
108 treatment.
109 Section 2. Section 395.4035, Florida Statutes, is
110 repealed.
111 Section 3. Subsection (1) of section 395.4036, Florida
112 Statutes, is amended to read:
113 395.4036 Trauma payments.--

114 (1) Recognizing the Legislature's stated intent to provide
115 financial support to the current verified trauma centers and to
116 provide incentives for the establishment of additional trauma
117 centers as part of a system of state-sponsored trauma centers,
118 the department shall utilize funds collected under s.
119 318.18(15) ~~(14)~~ and deposited into the Administrative Trust Fund
120 of the department to ensure the availability and accessibility
121 of trauma services throughout the state as provided in this
122 subsection.
123 (a) Twenty percent of the total funds collected under this
124 subsection during the state fiscal year shall be distributed to
125 verified trauma centers ~~located in a region~~ that have ~~has~~ a
126 local funding contribution as of December 31. Distribution of
127 funds under this paragraph shall be based on trauma caseload
128 volume for the most recent calendar year available.
129 (b) Forty percent of the total funds collected under this
130 subsection shall be distributed to verified trauma centers based
131 on trauma caseload volume of the most recent ~~previous~~ calendar
132 year available. The determination of caseload volume for
133 distribution of funds under this paragraph shall be based on the
134 department's Trauma Registry data.
135 (c) Forty percent of the total funds collected under this
136 subsection shall be distributed to verified trauma centers based
137 on severity of trauma patients for the most recent calendar year
138 available. The determination of severity for distribution of
139 funds under this paragraph shall be based on the department's
140 Trauma Registry International Classification Injury Severity
141 Scores or other statistically valid and scientifically accepted
142 methods of stratifying a trauma patient's severity of injury,
143 risk of mortality, and resource consumption as adopted by the
144 department by rule, weighted based on the costs associated with

145 and incurred by the trauma center in treating trauma patients.
146 The weighting of scores shall be established by the department
147 by rule ~~scores of 1-14 and 15 plus~~.
148
149 Funds deposited in the department's Administrative Trust Fund
150 for verified trauma centers may be used to maximize the receipt
151 of federal funds that may be available for such trauma centers.
152 Notwithstanding this section and s. 318.14, distributions to
153 trauma centers may be adjusted in a manner to ensure that total
154 payments to trauma centers represent the same proportional
155 allocation as set forth in this section and s. 318.14. For
156 purposes of this section and s. 318.14, total funds distributed
157 to trauma centers may include revenue from the Administrative
158 Trust Fund and federal funds for which revenue from the
159 Administrative Trust Fund is used to meet state or local
160 matching requirements. ~~Trauma centers may request that their~~
161 ~~distributions from the Administrative Trust Fund be used as~~
162 ~~intergovernmental transfer funds in the Medicaid program.~~
163 Funds collected under ss. 318.14 and 318.18(15) and deposited in
164 the Administrative Trust Fund of the department shall be
165 distributed to trauma centers on a quarterly basis using the
166 most recent calendar year data available. Such data shall not be
167 used for more than four quarterly distributions, unless there
168 are extenuating circumstances as determined by the department,
169 in which case the most recent calendar year data available will
170 continue to be used and as soon as the more recent data becomes
171 available adjustments will be made accordingly.
172 Section 4. Section 395.65, Florida Statutes, is created to
173 read:
174 395.65 Trauma center start-up.--There is established a
175 trauma center start-up grant program.

176 (1) The Legislature recognizes the need for a statewide,
177 cohesive, uniform and integrated trauma system, and the
178 Legislature acknowledges that the state has been divided into
179 trauma service areas. Each of the trauma service areas should
180 have at least one trauma center; however some trauma service
181 areas do not have a trauma center because of the significant up-
182 front investment of capital incurred by hospitals to develop the
183 physical space, equipment, and qualified personnel necessary to
184 provide quality trauma services.
185 (2) An acute care general hospital that has submitted a
186 letter of intent and an application to become a trauma center
187 pursuant to s. 395.4025 may apply to the department for a start-
188 up grant. The grant applicant must demonstrate that:
189 (a) There are currently no other trauma centers in the
190 hospital's trauma service area as established under s. 395.402.
191 (b) There is not a trauma center within a 100-mile radius
192 of the proposed trauma center.
193 (c) The hospital has received a local funding contribution
194 as defined under s. 395.4001.
195 (d) The hospital has incurred start-up costs in excess of
196 the amount of grant funding requested.
197 (e) The hospital is pursuing the establishment of a
198 residency program in emergency medicine.
199 (3) Any hospital receiving start-up grant funding that
200 does not become a provisional trauma center within 24-months
201 after submitting an application to become a trauma center must
202 forfeit any state grant funds received pursuant to this section.
203 Section 5. For the 2006-2007 fiscal year only, $500,000 is
204 appropriated from the General Revenue Fund for deposit into the
205 Administrative Trust Fund in the Department of Health for the
206 purpose of providing trauma center start-up grants under s.

207 395.60. No one hospital may receive in excess of $500,000,
208 start-up grant funding must be matched dollar for dollar with a
209 local funding contribution, and start-up grant funding will only
210 be provided to a hospital one-time.
211 Section 6. This act shall take effect July 1, 2006.
212
213 ========== T I T L E A M E N D M E N T ==========
214 Remove the entire title and insert:
215 A bill to be entitled
216 An act relating to trauma services; amending s. 395.4001,
217 F.S.; providing definitions; repealing s. 395.4035, F.S.,
218 to terminate the Trauma Services Trust Fund; amending s.
219 395.4036, F.S.; revising provisions relating to
220 distribution of funds to trauma centers and use thereof;
221 providing grant funding for a trauma center in
222 Tallahassee; providing an appropriation; providing an
223 effective date.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 859 Physician Assistants
SPONSOR(S): Baxley
TIED BILLS: **IDEN./SIM. BILLS:** SB 1690

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Care Regulation Committee		Hamrick	Mitchell
2) Health & Families Council			
3)			
4)			
5)			

SUMMARY ANALYSIS

HB 859 requires a licensed physician assistant designated by the Council on Physician Assistants to be a member of a probable cause panel considering disciplinary action against a licensed physician assistant.

The bill also removes a requirement that a physician cosign the medical charts and records that are prepared by a physician assistant, if the supervising licensed physician is located on the business premises.

Identical language is added to the practice acts for allopathic and osteopathic physicians.

The bill does not appear to have a significant fiscal impact on state or local governments.

The bill takes effect on July 1, 2006.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Promote personal responsibility-The bill provides that a physician assistant who is under investigation by a probable cause panel will have a physician assistant sit on the probable cause panel. This provides physician assistants a voice in determining the disciplinary action of members of their profession.

B. EFFECT OF PROPOSED CHANGES:

The bill requires a probable cause panel considering disciplinary action against a licensed physician assistant to require that a licensed physician assistant designated by the Council on Physician Assistants be on the disciplinary panel, if one is available.

The bill removes the requirement that a physician cosign the medical charts and records prepared by a physician assistant, if the supervising licensed physician is located on the business premises.

Identical language is added to the practice acts for allopathic and osteopathic physicians.

PRESENT SITUATION

Currently, there are about 3,000 licensed physician assistants and 33,000 licensed allopathic and osteopathic physicians in Florida. Physician assistants practice under the indirect supervision of allopathic and osteopathic physicians. Physician assistants are governed under identical provisions within the practice act for medicine and osteopathic medicine respectively, ss. 458.347 and 459.022. F.S.

Council on Physician Assistants
The Council on Physician Assistants is created within the Department of Health and consists of five members: (3) doctors from the Board of Medicine, one of whom must supervise a physician assistant, (1) doctor from the Board of Osteopathic Medicine, and (1) licensed physician assistant appointed by the Secretary of the department. The Council on Physician Assistants may not adopt rules unless they are accepted and approved by the Board of Medicine and the Board of Osteopathic Medicine.

The Board of Medicine or the Board of Osteopathic Medicine may impose any of the penalties on physician assistants that are authorized in ss. 456.072 and 458.331(2) or 459.015(2), F.S.

Membership Requirements for Probable Cause Panels
Section 456.073(4), F.S. provides that a probable cause panel must be composed of at least two members; one or more of the members may be a former board member; one member must be one of the board's former or present consumer members, if one is available. Any probable cause panel must include a former or present professional board member with an active license for the profession they are representing.

Cosignature of Medical Records and Charts
Currently in rule, all tasks and procedures performed by a physician assistant must be documented in the appropriate medical record and later reviewed, signed, and dated by the supervising physician. According to the Board of Medicine, the cosigning of medical records and charts is the primary tool used by the board to determine whether a physician assistant is having duties appropriately delegated to them by a supervising physician and if the physician assistant is operating within their scope of practice.

C. SECTION DIRECTORY:

Section 1. Amends s. 458.331, F.S., to require that when a probable cause panel is considering disciplinary action against a physician assistant, the probable cause panel of the Board of Medicine must include a physician assistant that is recommended by the Council on Physician Assistants, unless one is not available,.
Section 2. Amends s. 458.347, F.S., to provide that medical charts and records do not require a cosignature by a licensed physician, if they are prepared by a physician assistant who is under the supervision of a licensed physician located on the business premises.
Section 3. Amends s. 459.015, F.S., to require that when a probable cause panel is considering disciplinary action against a physician assistant, the probable cause panel of the Board of Osteopathic Medicine must include a physician assistant that is recommended by the Council on Physician Assistants, unless one is not available.
Section 4. Amends s. 459.022, F.S., to provide that medical charts and records do not require a cosignature by a licensed physician, if they are prepared by a physician assistant who is under the supervision of a licensed physician located on the business premises.
Section 5. Provides that this bill will take effect on July 1, 2006.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None. (See "D. FISCAL COMMENTS.")

D. FISCAL COMMENTS:

According to the Department of Health, there will be some costs involved in having an additional person attend a probable cause panel meeting. The cost will not be significant.

The bill allows more efficient handling of medical records and charts by removing the requirement for physician cosignature that is not required of comparable health care practitioners. Advanced registered nurse practitioner's (ANRP's) perform services similar to that of a physician assistant, but are not required to have medical records or charts reviewed and cosigned by a supervising physician.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   This bill does not require counties or municipalities to spend funds or take an action requiring the expenditure of funds. This bill does not reduce the percentage of a state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenue.

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

No additional rule-making authority is needed to implement the provisions of this bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

According to the Department of Health, the bill does not define "business premises." This could be interpreted to mean that any location where the supervising physician sees patients, no matter how infrequently would be a "business premises."

Section 458.307(4), F.S., provides that no member of the Board of Medicine will participate or be part of a probable cause panel unless he or she has completed a disciplinary training program. Since the physician assistant is not an appointed member of a board, they would not be required to attend disciplinary training program. The disciplinary training program provides probable cause members the knowledge needed to determine the grounds for disciplinary action, changes in relevant statutes and rules, and any relevant judicial and administrative decisions.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

1 A bill to be entitled
2 An act relating to physician assistants; amending ss.
3 458.331 and 459.015, F.S.; placing a physician assistant
4 on probable cause panels of the Board of Medicine and the
5 Board of Osteopathic Medicine considering discipline of
6 physician assistants; amending ss. 458.347 and 459.022,
7 F.S.; authorizing the preparation of certain medical
8 charts and records without the cosignature of a licensed
9 physician; providing an effective date.
10
11 Be It Enacted by the Legislature of the State of Florida:
12
13 Section 1. Subsection (2) of section 458.331, Florida
14 Statutes, is amended to read:
15 458.331 Grounds for disciplinary action; action by the
16 board and department.--
17 (2) The board may enter an order denying licensure or
18 imposing any of the penalties in s. 456.072(2) against any
19 applicant for licensure or licensee who is found guilty of
20 violating any provision of subsection (1) of this section or who
21 is found guilty of violating any provision of s. 456.072(1). A
22 probable cause panel considering disciplinary action against a
23 physician assistant under s. 456.073 must include a licensed
24 physician assistant designated by the Council on Physician
25 Assistants unless a physician assistant is not available. In
26 determining what action is appropriate, the board must first
27 consider what sanctions are necessary to protect the public or
28 to compensate the patient. Only after those sanctions have been

29 imposed may the disciplining authority consider and include in
30 the order requirements designed to rehabilitate the physician.
31 All costs associated with compliance with orders issued under
32 this subsection are the obligation of the physician.
33 Section 2. Paragraph (g) is added to subsection (4) of
34 section 458.347, Florida Statutes, to read:
35 458.347 Physician assistants.--
36 (4) PERFORMANCE OF PHYSICIAN ASSISTANTS.--
37 (g) The medical charts and records prepared by a physician
38 assistant who is under the supervision of a licensed physician
39 on the business premises do not require cosignature by the
40 licensed physician.
41 Section 3. Subsection (2) of section 459.015, Florida
42 Statutes, is amended to read:
43 459.015 Grounds for disciplinary action; action by the
44 board and department.--
45 (2) The board may enter an order denying licensure or
46 imposing any of the penalties in s. 456.072(2) against any
47 applicant for licensure or licensee who is found guilty of
48 violating any provision of subsection (1) of this section or who
49 is found guilty of violating any provision of s. 456.072(1). A
50 probable cause panel considering disciplinary action against a
51 physician assistant under s. 456.073 must include a licensed
52 physician assistant designated by the Council on Physician
53 Assistants unless a physician assistant is not available. In
54 determining what action is appropriate, the board must first
55 consider what sanctions are necessary to protect the public or
56 to compensate the patient. Only after those sanctions have been

57 imposed may the disciplining authority consider and include in
58 the order requirements designed to rehabilitate the physician.
59 All costs associated with compliance with orders issued under
60 this subsection are the obligation of the physician.
61 Section 4. Paragraph (f) is added to subsection (4) of
62 section 459.022, Florida Statutes, to read:
63 459.022 Physician assistants.--
64 (4) PERFORMANCE OF PHYSICIAN ASSISTANTS.--
65 (f) The medical charts and records prepared by a physician
66 assistant who is under the supervision of a licensed physician
67 on the business premises do not require cosignature by the
68 licensed physician.
69 Section 5. This act shall take effect July 1, 2006.

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1 (for drafter's use only)

Bill No. **HB 859**

COUNCIL/COMMITTEE ACTION

ADOPTED	__	(Y/N)
ADOPTED AS AMENDED	__	(Y/N)
ADOPTED W/O OBJECTION	__	(Y/N)
FAILED TO ADOPT	__	(Y/N)
WITHDRAWN	__	(Y/N)
OTHER	____	

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1 Council/Committee hearing bill:
2 Representative(s) Baxley offered the following:
3
4 **Amendment (with title amendment)**
5 Remove everything after the enacting clause and insert:
6
7 Section 1. Subsection (2) of section 458.331, Florida
8 Statutes, is amended to read:
9 458.331 Grounds for disciplinary action; action by the
10 board and department.--
11 (2) The board may enter an order denying licensure or
12 imposing any of the penalties in s. 456.072(2) against any
13 applicant for licensure or licensee who is found guilty of
14 violating any provision of subsection (1) of this section or who
15 is found guilty of violating any provision of s. 456.072(1). A
16 probable cause panel considering disciplinary action against a
17 physician assistant pursuant to s. 456.073 shall include one
18 physician assistant holding an active Florida license to
19 practice as a physician assistant who has been designated by the
20 Council on Physician Assistants. The designated physician
21 assistant shall only hear cases involving disciplinary action
22 against physician assistants. If the designated physician

23 assistant is not available at the time the case is heard, the
24 panel may consider and vote on the case in the absence of the
25 designated physician assistant. The training requirement set
26 forth in s. 456.307(4) does not apply to the designated
27 physician assistant. Rulemaking as set forth in s. 456.073(4) is
28 not required to implement this section. In determining what
29 action is appropriate, the board must first consider what
30 sanctions are necessary to protect the public or to compensate
31 the patient. Only after those sanctions have been imposed may
32 the disciplining authority consider and include in the order
33 requirements designed to rehabilitate the physician. All costs
34 associated with compliance with orders issued under this
35 subsection are the obligation of the physician.
36 Section 2. Subsection (2) of section 459.015, Florida
37 Statutes, is amended to read:
38 459.015 Grounds for disciplinary action; action by the
39 board and department.--
40 (2) The board may enter an order denying licensure or
41 imposing any of the penalties in s. 456.072(2) against any
42 applicant for licensure or licensee who is found guilty of
43 violating any provision of subsection (1) of this section or who
44 is found guilty of violating any provision of s. 456.072(1). A
45 probable cause panel considering disciplinary action against a
46 physician assistant pursuant to s. 456.073 shall include one
47 physician assistant holding an active Florida license to
48 practice as a physician assistant who has been designated by the
49 Council on Physician Assistants. The designated physician
50 assistant shall only hear cases involving disciplinary action
51 against physician assistants. If the designated physician
52 assistant is not available at the time the case is heard, the
53 panel may consider and vote on the case in the absence of the

54 designated physician assistant. The training requirement set
55 forth in s. 456.307(4) does not apply to the designated
56 physician assistant. Rulemaking as set forth in s. 456.073(4) is
57 not required to implement this section. In determining what
58 action is appropriate, the board must first consider what
59 sanctions are necessary to protect the public or to compensate
60 the patient. Only after those sanctions have been imposed may
61 the disciplining authority consider and include in the order
62 requirements designed to rehabilitate the physician. All costs
63 associated with compliance with orders issued under this
64 subsection are the obligation of the physician.
65 Section 3. This act shall take effect July 1, 2006.
66
67 ========== T I T L E A M E N D M E N T ==========
68 Remove the entire title and insert:
69 A bill to be entitled
70 An act relating to physician assistants; amending ss.
71 458.331 and 459.015, F.S.; placing a physician assistant
72 on probable cause panels of the Board of Medicine and the
73 Board of Osteopathic Medicine considering discipline of
74 physician assistants; providing exceptions; providing an
75 effective date.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 881 Physician Licensure Requirements
SPONSOR(S): Flores
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Care Regulation Committee		Hamrick	Mitchell
2) Colleges & Universities Committee			
3) Health Care Appropriations Committee			
4) Health & Families Council			
5)			

SUMMARY ANALYSIS

To be eligible for a license to practice medicine, medical doctors must complete an approved residency program. Residency is the period of clinical education in a medical specialty that follows graduation from medical school and prepares physicians for the independent practice of medicine.

HB 881 provides that in lieu of a residency program individuals may opt, with approval by the board of medicine, to complete a 2-year community-based internship at a hospital licensed in the state. If a doctor successfully completes the community-based internship, they meet the residency education requirement. The bill provides that the community-based internship must be "substantially equivalent" to the current residency program. The bill provides that if the community-based internship is provided in a hospital that is not licensed in the state, the department will impose a condition, limitation, or restriction on a license.

The community-based internship location and program must be approved by the board prior to an individual entering the internship. The bill provides the board the authority to adopt rules to implement the community-based internship, to include the implementation of fees to cover administrative costs. The bill provides the board of medicine the authority to determine by rule what is "substantially equivalent" to the current residency program and whether a medical doctor has successfully completed the community-based internship.

Fiscal Impact: According to the Department of Health, implementation of the bill will involve added costs for public hearings and the rulemaking authority, the exact cost is indeterminate.

The bill takes effect on July 1, 2006.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Promote personal responsibility-The bill allows individuals to work in the profession for which they were trained.

B. EFFECT OF PROPOSED CHANGES:

To be eligible for a license to practice medicine, medical doctors must complete an approved clinical residency program after graduation from medical school that prepares them for the independent practice of medicine.

The bill provides that in lieu of a residency program individuals may with approval by the board of medicine, complete a 2-year community-based internship at a hospital licensed in the state. The bill provides that the community-based internship must be "substantially equivalent" to the current residency program. The bill provides that if the community-based internship is provided in a hospital that is not licensed in the state, the department will impose a condition, limitation, or restriction on a license.

The community-based internship location and program must be approved by the board prior to entering the internship. The bill provides the board the authority to adopt rules to implement the community-based internship, and implement fees to cover administrative costs. The bill provides the board of medicine the authority to determine by rule what is "substantially equivalent" to the current residency program and whether a medical doctor has successfully completed the community-based internship.

PRESENT SITUATION

Accredited by the Council for Graduate Medical Education (ACGME) and Residency Programs

The Accreditation Council for Graduate Medical Education (ACGME) is responsible for the Accreditation of post-MD (residency) medical training programs within the United States. Accreditation is accomplished through a peer review process and is based upon established standards and guidelines.[1] ACGME accredits nearly 7,800 residency education programs.

To gain and maintain accreditation, residency programs are expected to comply with the Accreditation Standards for their discipline and adhere to a set of Institutional Requirements. Compliance with the ACGME's standards are measured through periodic reviews of all programs.

Educational Commission for Foreign Medical Graduates (ECFMG) Program Certification

The Educational Commission for Foreign Medical Graduates (ECFMG), through its program of certification, assesses whether international medical graduates are ready to enter residency or fellowship programs in the United States that are accredited by the Accreditation Council for Graduate Medical Education (ACGME).[2]

ECFMG and its organizational members define an international medical graduate as a physician who received his/her basic medical degree or qualification from a medical school located outside the United States and Canada. ECFMG Certification assures directors of ACGME-accredited residency and

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[1]Accreditation Council for Graduate Medical Education. *About ACGME.* http://www.acgme.org/acWebsite/home/home.asp (February 12, 2006).
[2] ECFMG Information Booklet. *Frequently Asked Questions.* http://www.ecfmg.org/2006ib/ibfaq.html (February 12, 2006)

fellowship programs, and the people of the United States, that international medical graduates have met minimum standards of eligibility required to enter such programs. International medical graduates(IMG), who were formally referred to as foreign trained medical graduates, must have had at least four credit years (or academic years for which credit has been given toward completion of the medical curriculum) in attendance at a medical school listed in the International Medical Education Directory (IMED).

In general, an international medical graduate is defined as a physician whose basic medical degree or qualification was conferred by a medical school located outside the United States, Canada, and Puerto Rico.

United States Medical Licensing Examination (USMLE) Examination and Credentialing

To be eligible for certification by ECFMG, international medical graduates must meet an examination and medical education credential requirement. The examination requirement requires applicants to pass Step 1 and both parts of Step 2 of the United States Medical Licensing Examination (USMLE). Step 2 of the exam has two separately administered components: the Clinical Knowledge (CK) component and the Clinical Skills (CS) component.[3] The medical education credential requirement requires applicants to provide their medical education credentials, which includes their final medical diploma and final medical school transcript. ECFMG certification is one of the eligibility requirements to take Step 3 of the USMLE examination.

Examination Requirements that were formally available to International Medical Graduates

The 1-day ECFMG medicine examination, the 2-day Visa Qualifying Examination, the Part I and Part II examinations of the National Board of Medical Examiners (NBME), and Day 1 and Day 2 of the Foreign Medical Graduate Examination in the Medical Sciences are no longer administered, but a passing performance on any of those medical science examinations is accepted for ECFMG certification

The 3-day Federation Licensing Examination (FLEX) is accepted for ECFMG certification if taken prior to June 1985 with a score of 75 or higher on each of the 3 days of a single administration.

While foreign national physicians may meet the medical science examination requirement for ECFMG certification based on the former 1-day ECFMG examination that was last administered in February 1984, or the FLEX examination taken prior to June 1985, these examinations are not currently recognized by the US Secretary of Health and Human Services as meeting the medical science examination requirement to obtain a visa to enter the United States.

Fifth Pathway Program provided by the Liaison Committee on Medical Education (LCME)

The Liaison Committee on Medical Education (LCME) is the nationally recognized accrediting authority for medical education programs leading to the M.D. degree in U.S. and Canadian medical schools. The LCME is sponsored by the Association of American Medical Colleges and the American Medical Association. Accreditation by the Liaison Committee on Medical Education (LCME) is required for schools to receive federal grants for medical education and to participate in federal loan programs.[4]

The LCME also accredits the Fifth Pathway Program that provides an alternative for clinical residency. Currently, only two medical schools provide the Fifth Pathway Program. They are located in New York and Puerto Rico.[5]

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[3] Ibid.
[4] Liaison Committee on Medical Education. Overview: Accreditation and the LCME. http://www.lcme.org/ (February 12, 2006).
[5] Accreditation Council for Graduate Medical Education. Section I: Graduate Medical Education Useful Information. http://www.acgme.org/acWebsite/GME_info/gme_sect1Policy.asp (February 13, 2006).

The Fifth Pathway Program is an academic year of supervised clinical education provided in a medical school accredited by the Liaison Committee on Medical Education (LCME). It is available to persons who meet all of the following conditions:

- Have completed, an accredited US college or university, undergraduate premedical work of the quality acceptable for matriculation in an accredited US medical school;
- Have studied medicine in a medical school located outside the United States, Puerto Rico, and Canada that is listed in the World Directory of Medical Schools, published by the World Health Organization;
- Have completed all of the formal requirements of the non-US medical school except internship and/or social service. (Those who have completed all of these requirements, including internship and/or social service, are not eligible for a fifth pathway program.)

Students who have completed the academic curriculum in residence at a non-US medical school and who meet the above conditions may be offered the opportunity to substitute, an academic year of supervised clinical training provided in a medical school accredited by the LCME, for an internship and/or social service required by a non-US medical school.

Before beginning the supervised clinical training, students must pass an examination acceptable to the sponsoring medical school.

Physicians who have a Fifth Pathway Certificate and have passed Steps I and II of the United States Medical Licensing Examination (USMLE) are eligible for appointment to a residency program. They must also meet requirements established by the state medical board in the state where the residency program is located and must be accepted for appointment by the director of the residency program. Any medical school accredited by the LCME can provide Fifth Pathway education.

Statutory Provisions for Foreign Trained Physicians

Restricted License

Section 458.312, F.S., expired on December 31, 2000. This section provided an exemption to foreign trained medical graduates that allowed them to apply to take Step III of the USMLE examination if they successfully complete a two-year period of direct and indirect supervised training as a restricted licensee. Applicants for the restricted license had to have at least legally practiced medicine for 5 years in the county where they received their medical degree, received ECFMG certification, and been a resident of Florida since July 1, 1996.

Under this program, the applicant was required to practice for the first year under the direct supervision of a licensed medical doctor, approved by the Board of Medicine. For the second year, they were required to practice under indirect supervision in a community service setting that served the indigent population.

If the foreign trained medical graduate completed the two-year period of supervised training and successfully passed part III of the USMLE examination they were eligible for full licensure.

Graduates of a Medical School may work in Hospitals

Section 458.345, F.S., provides that a person who is at least 21 years of age, has not committed any act or offense within or outside the state that would constitute grounds for disciplinary action, and is a graduate of a medical school or college is eligible to work in a hospital as a house physician, resident physician, assistant resident physician, intern, or fellow in fellowship training. Registration under this provision expires every two years.

According to the Department of Health, currently, there are 307 individuals licensed as a house physician.

C. SECTION DIRECTORY:

Section 1. Amends s. 458.311, F.S., to provide a definition for "community-based internship," and provide an option to licensure applicants to compete an internship; to require the Department of Health to develop procedures and an approval process relating to the completion of the internship requirements; to authorize the department to adopt rules to implement the internship requirements and set fees to cover costs; to allow the department to impose conditions, limitations, or restrictions of a license for an individual who completes a community-based internship.
Sections 2 through 6 amend ss. 458.313, 458.316, 458.3165, 458.317, and 458.347, F.S., to correct cross-references.
Section 7. Provides that the bill will take effect on July 1, 2006.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   See "D. FISCAL COMMENTS."

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The community-based internship will allow medical doctors who have practiced medicine in their native countries and who are older than the traditional medical student, the opportunity to practice medicine in their community. Medical doctors from other states who do not receive a slot in a traditional residency program may seek licensure in Florida by successfully completing a community-based internship.

D. FISCAL COMMENTS:

Implementing a two-year community-based internship will involve added costs for public hearings and the rulemaking process by both the Department of Health and the Board of Medicine. Board review of these training programs to determine whether they are "substantially similar" to approved residency programs will increase meeting, travel, and administrative costs. The costs are indeterminate, but may be substantial if Florida faces a strong demand for community-based internships.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   This bill does not require counties or municipalities to spend funds or take an action requiring the expenditure of funds. This bill does not reduce the percentage of a state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenue.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The bill provides the rulemaking authority to the Department of Health and the Board of Medicine to implement the community-based internship requirements.

C. DRAFTING ISSUES OR OTHER COMMENTS:

The bill sponsor has prepared a strike-all amendment to address these issues.

DRAFTING ISSUES:
According to the Department of Health, the bill is not intended to change the need to pass the ECFMG examination; however, the way it is drafted may cause unintended consequences and may cause controversy as to whether it allows applicants under the Fifth Pathway option to sit for Part III of the USMLE examination.

Due to the fact that only two schools offer the Fifth Pathway, controversy over this issue would probably be minimal.

OTHER COMMENTS:
According to DOH, the department and the Board of Medicine do not have the resources or the expertise to evaluate and manage postgraduate training in the form of "community-based internships" in Florida. The department and the Board of Medicine would be tasked with investigating and credentialing special training programs in Florida hospitals and with evaluating whether the training is substantially equivalent to Florida's residency programs. This task is new to the department and Board of Medicine regulatory mission and will require additional time, resources and staff. The number of programs that would seek approval is unknown. The proposed program may attract national attention for those who have been unable to find a residency as well as those who have taken and failed to successfully complete a residency.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

1 A bill to be entitled
2 An act relating to physician licensure requirements;
3 amending s. 458.311, F.S.; providing a definition;
4 providing an option for certain applicants for physician
5 licensure to complete an internship; authorizing the
6 Department of Health to develop procedures relating to
7 completion of the internship; requiring board approval of
8 internships; authorizing the board to adopt rules to
9 implement internship requirements, including fees to cover
10 costs; revising the requirement of the department to
11 impose conditions, limitations, or restrictions on a
12 license; amending ss. 458.313, 458.316, 458.3165, 458.317,
13 and 458.347, F.S.; correcting cross-references; providing
14 an effective date.
15
16 Be It Enacted by the Legislature of the State of Florida:
17
18 Section 1. Subsections (2) through (8) of section 458.311,
19 Florida Statutes, are renumbered as subsections (3) through (9),
20 respectively, present subsections (5) and (7) are amended, and a
21 new subsection (2) is added to that section, to read:
22 458.311 Licensure by examination; requirements; fees.--
23 (2)(a) As used in this section, the term "community-based
24 internship" means a program approved by the board in which a
25 graduate from a foreign medical school obtains required
26 postgraduate clinical experience at a hospital licensed in this
27 state.

28 (b) Notwithstanding sub-subparagraphs(1)(f)1.c., 2.c., and
29 3.c. and paragraph (4)(d), except for passing part II of the
30 National Board of Medical Examiners examination or the
31 Educational Commission for Foreign Medical Graduates examination
32 equivalent as referred to in paragraph (4)(d), the department
33 may develop procedures for an applicant for licensure to meet
34 postgraduate training requirements by completion of a 2-year
35 community-based internship at a hospital licensed in this state.
36 The training provided in the community-based internship shall be
37 substantially similar, as defined by board rule, to the training
38 provided in an approved residency as provided in sub-
39 subparagraph (1)(f)1.c., sub-subparagraph (1)(f)2.c., or sub-
40 subparagraph (1)(f)3.c. In order for the community-based
41 internship to meet the requirements of this subsection, the
42 community-based internship must be approved by the board prior
43 to the applicant's entering into the community-based internship.
44 The applicant shall not be licensed under this subsection unless
45 the board finds that the applicant has successfully completed
46 the community-based internship. The board may adopt rules to
47 implement this subsection, including rules setting fees, which
48 may not exceed the actual costs of administering this
49 subsection.
50 (6) ~~(5)~~ The board may not certify to the department for
51 licensure any applicant who is under investigation in another
52 jurisdiction for an offense which would constitute a violation
53 of this chapter until such investigation is completed. Upon
54 completion of the investigation, the provisions of s. 458.331
55 shall apply. Furthermore, the department may not issue an

56 unrestricted license to any individual who has committed any act
57 or offense in any jurisdiction which would constitute the basis
58 for disciplining a physician pursuant to s. 458.331. When the
59 board finds that an individual has committed an act or offense
60 in any jurisdiction which would constitute the basis for
61 disciplining a physician pursuant to s. 458.331, then the board
62 may enter an order imposing one or more of the terms set forth
63 in subsection (9) ~~(8)~~.
64 (8) ~~(7)~~ Upon certification by the board, the department
65 shall impose conditions, limitations, or restrictions on a
66 license if the applicant is on probation in another jurisdiction
67 for an act which would constitute a violation of this chapter or
68 if the community-based internship requirement provided in
69 subsection (2) was complied with at a hospital that is not
70 licensed in this state.
71 Section 2. Paragraph (a) of subsection (1) of section
72 458.313, Florida Statutes, is amended to read:
73 458.313 Licensure by endorsement; requirements; fees.--
74 (1) The department shall issue a license by endorsement to
75 any applicant who, upon applying to the department on forms
76 furnished by the department and remitting a fee set by the board
77 not to exceed $500, the board certifies:
78 (a) Has met the qualifications for licensure in s.
79 458.311(1)(b)-(g) or in s. 458.311(1)(b)-(e) and (g) and (4)
80 ~~(3)~~;
81 Section 3. Subsection (1) of section 458.316, Florida
82 Statutes, is amended to read:
83 458.316 Public health certificate.--

84 (1) Any person desiring to obtain a public health
85 certificate shall submit an application fee not to exceed $300
86 and shall demonstrate to the board that he or she is a graduate
87 of an accredited medical school and holds a master of public
88 health degree or is board eligible or certified in public health
89 or preventive medicine, or is licensed to practice medicine
90 without restriction in another jurisdiction in the United States
91 and holds a master of public health degree or is board eligible
92 or certified in public health or preventive medicine, and shall
93 meet the requirements in s. 458.311(1)(a)-(g) and (6) ~~(5)~~.
94 Section 4. Section 458.3165, Florida Statutes, is amended
95 to read:
96 458.3165 Public psychiatry certificate.--The board shall
97 issue a public psychiatry certificate to an individual who
98 remits an application fee not to exceed $300, as set by the
99 board, who is a board-certified psychiatrist, who is licensed to
100 practice medicine without restriction in another state, and who
101 meets the requirements in s. 458.311(1)(a)-(g) and (6) ~~(5)~~. A
102 recipient of a public psychiatry certificate may use the
103 certificate to work at any public mental health facility or
104 program funded in part or entirely by state funds.
105 (1) Such certificate shall:
106 (a) Authorize the holder to practice only in a public
107 mental health facility or program funded in part or entirely by
108 state funds.
109 (b) Be issued and renewable biennially if the secretary of
110 the Department of Health and the chair of the department of
111 psychiatry at one of the public medical schools or the chair of

112 the department of psychiatry at the accredited medical school at
113 the University of Miami recommend in writing that the
114 certificate be issued or renewed.
115 (c) Automatically expire if the holder's relationship with
116 a public mental health facility or program expires.
117 (d) Not be issued to a person who has been adjudged
118 unqualified or guilty of any of the prohibited acts in this
119 chapter.
120 (2) The board may take disciplinary action against a
121 certificateholder for noncompliance with any part of this
122 section or for any reason for which a regular licensee may be
123 subject to discipline.
124 Section 5. Paragraph (a) of subsection (1) of section
125 458.317, Florida Statutes, is amended to read:
126 458.317 Limited licenses.--
127 (1)(a) Any person desiring to obtain a limited license
128 shall:
129 1. Submit to the board, with an application and fee not to
130 exceed $300, an affidavit stating that he or she has been
131 licensed to practice medicine in any jurisdiction in the United
132 States for at least 10 years and intends to practice only
133 pursuant to the restrictions of a limited license granted
134 pursuant to this section. However, a physician who is not fully
135 retired in all jurisdictions may use a limited license only for
136 noncompensated practice. If the person applying for a limited
137 license submits a notarized statement from the employing agency
138 or institution stating that he or she will not receive
139 compensation for any service involving the practice of medicine,

140 the application fee and all licensure fees shall be waived.
141 However, any person who receives a waiver of fees for a limited
142 license shall pay such fees if the person receives compensation
143 for the practice of medicine.
144 2. Meet the requirements in s. 458.311(1)(b)-(g) and (6)
145 ~~(5)~~. If the applicant graduated from medical school prior to
146 1946, the board or its appropriate committee may accept military
147 medical training or medical experience as a substitute for the
148 approved 1-year residency requirement in s. 458.311(1)(f).
149
150 Nothing herein limits in any way any policy by the board,
151 otherwise authorized by law, to grant licenses to physicians
152 duly licensed in other states under conditions less restrictive
153 than the requirements of this section. Notwithstanding the other
154 provisions of this section, the board may refuse to authorize a
155 physician otherwise qualified to practice in the employ of any
156 agency or institution otherwise qualified if the agency or
157 institution has caused or permitted violations of the provisions
158 of this chapter which it knew or should have known were
159 occurring.
160 Section 6. Paragraph (b) of subsection (7) of section
161 458.347, Florida Statutes, is amended to read:
162 458.347 Physician assistants.--
163 (7) PHYSICIAN ASSISTANT LICENSURE.--
164 (b)1. Notwithstanding subparagraph (a)2. and sub-
165 subparagraph (a)3.a., the department shall examine each
166 applicant who the Board of Medicine certifies:

167 a. Has completed the application form and remitted a
168 nonrefundable application fee not to exceed $500 and an
169 examination fee not to exceed $300, plus the actual cost to the
170 department to provide the examination. The examination fee is
171 refundable if the applicant is found to be ineligible to take
172 the examination. The department shall not require the applicant
173 to pass a separate practical component of the examination. For
174 examinations given after July 1, 1998, competencies measured
175 through practical examinations shall be incorporated into the
176 written examination through a multiple-choice format. The
177 department shall translate the examination into the native
178 language of any applicant who requests and agrees to pay all
179 costs of such translation, provided that the translation request
180 is filed with the board office no later than 9 months before the
181 scheduled examination and the applicant remits translation fees
182 as specified by the department no later than 6 months before the
183 scheduled examination, and provided that the applicant
184 demonstrates to the department the ability to communicate orally
185 in basic English. If the applicant is unable to pay translation
186 costs, the applicant may take the next available examination in
187 English if the applicant submits a request in writing by the
188 application deadline and if the applicant is otherwise eligible
189 under this section. To demonstrate the ability to communicate
190 orally in basic English, a passing score or grade is required,
191 as determined by the department or organization that developed
192 it, on the test for spoken English (TSE) by the Educational
193 Testing Service (ETS), the test of English as a foreign language
194 (TOEFL) by ETS, a high school or college level English course,

195 or the English examination for citizenship, Bureau of
196 Citizenship and Immigration Services. A notarized copy of an
197 Educational Commission for Foreign Medical Graduates (ECFMG)
198 certificate may also be used to demonstrate the ability to
199 communicate in basic English; and
200 b.(I) Is an unlicensed physician who graduated from a
201 foreign medical school listed with the World Health Organization
202 who has not previously taken and failed the examination of the
203 National Commission on Certification of Physician Assistants and
204 who has been certified by the Board of Medicine as having met
205 the requirements for licensure as a medical doctor by
206 examination as set forth in s. 458.311(1), (4) ~~(3)~~, (5) ~~(4)~~, and
207 (6) ~~(5)~~, with the exception that the applicant is not required
208 to have completed an approved residency of at least 1 year and
209 the applicant is not required to have passed the licensing
210 examination specified under s. 458.311 or hold a valid, active
211 certificate issued by the Educational Commission for Foreign
212 Medical Graduates; was eligible and made initial application for
213 certification as a physician assistant in this state between
214 July 1, 1990, and June 30, 1991; and was a resident of this
215 state on July 1, 1990, or was licensed or certified in any state
216 in the United States as a physician assistant on July 1, 1990;
217 or
218 (II) Completed all coursework requirements of the Master
219 of Medical Science Physician Assistant Program offered through
220 the Florida College of Physician's Assistants prior to its
221 closure in August of 1996. Prior to taking the examination, such
222 applicant must successfully complete any clinical rotations that

223 were not completed under such program prior to its termination
224 and any additional clinical rotations with an appropriate
225 physician assistant preceptor, not to exceed 6 months, that are
226 determined necessary by the council. The boards shall determine,
227 based on recommendations from the council, the facilities under
228 which such incomplete or additional clinical rotations may be
229 completed and shall also determine what constitutes successful
230 completion thereof, provided such requirements are comparable to
231 those established by accredited physician assistant programs.
232 This sub-sub-subparagraph is repealed July 1, 2001.
233 2. The department may grant temporary licensure to an
234 applicant who meets the requirements of subparagraph 1. Between
235 meetings of the council, the department may grant temporary
236 licensure to practice based on the completion of all temporary
237 licensure requirements. All such administratively issued
238 licenses shall be reviewed and acted on at the next regular
239 meeting of the council. A temporary license expires 30 days
240 after receipt and notice of scores to the licenseholder from the
241 first available examination specified in subparagraph 1.
242 following licensure by the department. An applicant who fails
243 the proficiency examination is no longer temporarily licensed,
244 but may apply for a one-time extension of temporary licensure
245 after reapplying for the next available examination. Extended
246 licensure shall expire upon failure of the licenseholder to sit
247 for the next available examination or upon receipt and notice of
248 scores to the licenseholder from such examination.
249 3. Notwithstanding any other provision of law, the
250 examination specified pursuant to subparagraph 1. shall be

251 administered by the department only five times. Applicants
252 certified by the board for examination shall receive at least 6
253 months' notice of eligibility prior to the administration of the
254 initial examination. Subsequent examinations shall be
255 administered at 1-year intervals following the reporting of the
256 scores of the first and subsequent examinations. For the
257 purposes of this paragraph, the department may develop, contract
258 for the development of, purchase, or approve an examination that
259 adequately measures an applicant's ability to practice with
260 reasonable skill and safety. The minimum passing score on the
261 examination shall be established by the department, with the
262 advice of the board. Those applicants failing to pass that
263 examination or any subsequent examination shall receive notice
264 of the administration of the next examination with the notice of
265 scores following such examination. Any applicant who passes the
266 examination and meets the requirements of this section shall be
267 licensed as a physician assistant with all rights defined
268 thereby.
269 Section 7. This act shall take effect July 1, 2006.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 7045 PCB GO 06-16 OGSR Supplemental Rebate Agreements
SPONSOR(S): Governmental Operations Committee, Rivera
TIED BILLS: None **IDEN./SIM. BILLS:** SB 516

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
Orig. Comm.: Governmental Operations Committee	5 Y, 0 N	Williamson	Williamson
1) Health Care Regulation Committee		Bell AJB	Mitchell
2) State Administration Council			
3)			
4)			
5)			

SUMMARY ANALYSIS

The Open Government Sunset Review Act requires the Legislature to review each public records and each public meetings exemption five years after enactment. If the Legislature does not reenact the exemption, it automatically repeals on October 2nd of the fifth year after enactment.

The bill reenacts the public records exemption relating to supplemental rebate agreements. It narrows the exemption by removing the public records exemption for trade secrets. The bill reenacts the public meetings exemption for the Medicaid Pharmaceutical and Therapeutics Committee. In addition, it requires that a record be made of each portion of an exempt meeting. The exemptions will repeal on October 2, 2006, if this bill does not become law.

This bill may have a fiscal impact on state government. It does not appear to have a fiscal impact on local governments.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Provide limited government – The bill narrows the public records exemption thereby increasing public access to government information. The bill requires the Medicaid Pharmaceutical and Therapeutics Committee to make a record of each portion of an exempt meeting.

B. EFFECT OF PROPOSED CHANGES:

Background

The 2001 Florida Legislature significantly expanded its efforts to control pharmaceutical costs in the state's Medicaid program by enacting a program called the preferred drug list (PDL).[1] Under this law, Medicaid prescribing practitioners are required to prescribe the medications on the PDL, or must obtain prior authorization from the Agency for Health Care Administration (AHCA) to prescribe a medication not on the PDL, in order for Medicaid to pay for the prescription.

In order for a drug manufacturer to have its medications considered for inclusion on the PDL, it must agree to provide the state both federally mandated rebates and state-mandated supplemental rebates. Since rebate negotiations involve disclosure by pharmaceutical manufacturers of proprietary information regarding the elements of their wholesale pricing, federal law prohibits disclosure of information received by Medicaid agencies from manufacturers that discloses identities of manufacturers or wholesalers or the prices charged by these manufacturers or wholesalers.[2] The federal prohibition applies to the U.S. Secretary of the Department of Health and Human Services, the U.S. Secretary of Veterans Affairs, or a state agency or contractor.

To address the federal confidentiality requirements and to ensure the use of this pricing information for negotiating state supplemental rebate agreements, the 2001 Legislature enacted a public records and public meetings exemption related to rebate negotiations.[3] Trade secrets, rebate amount, percent of rebate, manufacturer's pricing, and supplemental rebates with respect to supplemental rebate negotiations are confidential and exempt[4] from public records requirements.

According to Senate interim project report 2006-219, the state supplemental rebate negotiation process has been facilitated by this exemption and has been successful in benefiting the people of Florida. Since its implementation in 2002, the PDL program has generated over $262 million in state supplemental rebates, with $292 million in additional costs savings projected for Fiscal Year 2005-2006, a significant portion of which will be derived from supplemental rebate negotiations.

Current law also provides a public meetings exemption applicable in limited circumstances. Portions of meetings of the Medicaid Pharmaceutical and Therapeutics Committee are exempt from public meetings requirements if the aforementioned confidential and exempt records are discussed.[5]

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[1] Chapter 2001-104, L.O.F.
[2] 42 U.S.C. 1396r 8
[3] Chapter 2001 216, L.O.F.; codified in s. 409.91196, F.S.
[4] There is a difference between records that are exempt from public records requirements and those that are *confidential* and exempt. If the Legislature makes a record confidential and exempt, such record cannot be released by an agency to anyone other than to the persons or entities designated in the statute. *See* Attorney General Opinion 85-62. If a record is simply made exempt from disclosure requirements, an agency is not prohibited from disclosing the record in all circumstances. *See Williams v. City of Minneola*, 575 So.2d 683, 687 (Fla. 5th DCA), review denied, 589 So.2d 289 (Fla. 1991).
[5] Section 409.91196(2), F.S.

Pursuant to the Open Government Sunset Review Act,[6] the exemption will repeal on October 2, 2006, unless reenacted by the Legislature.[7] House staff reviewed the public records and public meetings exemption pursuant to the Open Government Sunset Review Act and determined that, with modification, the exemption meets the requirements for reenactment.[8] Based on AHCA's survey response, it appeared that the public records exemption for trade secrets was unnecessary because AHCA stated that rebate agreements and supplemental rebate amounts were trade secrets for purposes of the exemption. Such information is protected under the current public records exemption.

Effect of Bill

The bill removes the repeal date, thereby reenacting the public records and public meetings exemptions. It narrows the public records exemption by removing the exemption for trade secrets.

The bill requires the Medicaid Pharmaceutical and Therapeutics Committee, which is created within AHCA,[9] to make a record of each portion of an exempt meeting. The record must include the time of commencement and termination, all discussions and proceedings, the names of all persons present at any time, and the names of all persons speaking. The record of the exempt portion of a meeting is a public record; however, the rebate amount, percent of rebate, manufacturer's pricing, and supplemental rebate included in the record is confidential and exempt from public disclosure because of the public records exemption already afforded AHCA.[10]

Finally, the bill makes editorial changes and removes superfluous language.

C. SECTION DIRECTORY:

Section 1. - Amends s. 409.91196, F.S., to remove the repeal date.

Section 2. - Provides an effective date of October 1, 2006.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   The bill does not create, modify, amend, or eliminate a state revenue source.

2. Expenditures:

   [*See* FISCAL COMMENTS.]

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   The bill does not create, modify, amend, or eliminate a local revenue source.

2. Expenditures:

   The bill does not create, modify, amend, or eliminate local expenditures.

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[6] Section 119.15, F.S.
[7] Section 409.91196(3), F.S.
[8] Staff surveyed and interviewed AHCA staff.
[9] Section 409.91195, F.S.
[10] *See* s. 409.91196(1), F.S.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

The bill requires the Medicaid Pharmaceutical and Therapeutics Committee, which is a part of AHCA, to maintain a record of exempt portions of meetings. This could create a negative fiscal impact; however, the committee already hires a court reporter to keep a record of the open portion of the meeting. As such, additional expenditures should be avoided.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill does not require counties or municipalities to spend funds or to take an action requiring the expenditure of funds. This bill does not reduce the percentage of a state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenue.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

Open Government Sunset Review Act

The Open Government Sunset Review Act sets forth a legislative review process for newly created or substantially amended public records or public meetings exemptions. It requires an automatic repeal of the exemption on October 2nd of the fifth year after creation or substantial amendment, unless the Legislature reenacts the exemption.

The Act provides that a public records or public meetings exemption may be created or maintained only if it serves an identifiable public purpose, and may be no broader than is necessary to meet one of the following purposes:

- Allowing the state or its political subdivisions to effectively and efficiently administer a governmental program, which administration would be significantly impaired without the exemption;
- Protecting sensitive personal information that, if released, would be defamatory or would jeopardize an individual's safety. However, only the identity of an individual may be exempted under this provision; or,
- Protecting trade or business secrets.

If, and only if, in reenacting an exemption that will repeal, the exemption is expanded (essentially creating a new exemption), then a public necessity statement and a two-thirds vote for passage are required because of the requirements of Art. 1, s. 24(c), Florida Constitution. If the exemption is reenacted with grammatical or stylistic changes that do not expand the exemption, if the exemption is narrowed, or if an exception to the exemption is created (e.g., allowing another agency access to the confidential or exempt records), then a public necessity statement and a two-thirds vote for passage are not required.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

None.

1 A bill to be entitled
2 An act relating to a review under the Open Government
3 Sunset Review Act regarding supplemental rebate
4 agreements; amending s. 409.91196, F.S., which provides an
5 exemption from public records requirements for the rebate
6 amount, percent of rebate, manufacturer's pricing, and
7 supplemental rebate held by the Agency for Health Care
8 Administration relative to a preferred drug list
9 established by the agency and an exemption from public
10 meetings requirements for that portion of a meeting of the
11 Medicaid Pharmaceutical and Therapeutics Committee at
12 which such rebate amounts, percent of rebates,
13 manufacturer's pricing, and supplemental rebates are
14 discussed; making editorial changes; removing superfluous
15 language; requiring that a record of an exempt portion of
16 a meeting be made and maintained; removing the scheduled
17 repeal of the exemption; providing an effective date.
18
19 Be It Enacted by the Legislature of the State of Florida:
20
21 Section 1. Section 409.91196, Florida Statutes, is amended
22 to read:
23 409.91196 Supplemental rebate agreements; public
24 ~~confidentiality of~~ records and public meetings exemption.--
25 (1) The ~~Trade secrets,~~ rebate amount, percent of rebate,
26 manufacturer's pricing, and supplemental rebate held by ~~rebates~~
27 ~~which are contained in records of~~ the Agency for Health Care
28 Administration under s. 409.912(39)(a)7. ~~and its agents with~~

29 ~~respect to supplemental rebate negotiations and which are~~
30 ~~prepared pursuant to a supplemental rebate agreement under s.~~
31 ~~409.912(40)(a)7.~~ are confidential and exempt from s. 119.07(1)
32 and s. 24(a), Art. I of the State Constitution.
33 (2) That portion of a meeting ~~Those portions of meetings~~
34 of the Medicaid Pharmaceutical and Therapeutics Committee at
35 which the ~~trade secrets,~~ rebate amount, percent of rebate,
36 manufacturer's pricing, and supplemental rebate ~~rebates~~ are
37 discussed is ~~disclosed for discussion or negotiation of a~~
38 ~~supplemental rebate agreement under s. 409.912(40)(a)7. are~~
39 exempt from s. 286.011 and s. 24(b), Art. I of the State
40 Constitution. A record shall be made of each exempt portion of a
41 meeting. Such record must include the times of commencement and
42 termination, all discussions and proceedings, the names of all
43 persons present at any time, and the names of all persons
44 speaking. No exempt portion of a meeting may be held off the
45 record.
46 ~~(3) Subsections (1) and (2) are subject to the Open~~
47 ~~Government Sunset Review Act of 1995 in accordance with s.~~
48 ~~119.15, and shall stand repealed on October 2, 2006, unless~~
49 ~~reviewed and saved from repeal through reenactment by the~~
50 ~~Legislature.~~
51 Section 2. This act shall take effect October 1, 2006.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: PCB HCR 06-02 Licensure of Health Care Providers
SPONSOR(S): Health Care Regulation Committee
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
Orig. Comm.: Health Care Regulation Committee		Bell AJB	Mitchell
1)			
2)			
3)			
4)			
5)			

SUMMARY ANALYSIS

The Licensure of Health Care Providers Proposed Committee Bill (PCB) eliminates unnecessary duplication and variation of licensure requirements by health care providers licensed by the Agency for Health Care Administration (AHCA). The bill defines common terminology and consolidates core licensure requirements in newly created part II of chapter 408, F.S. The organization of core, uniform standards is similar to the regulatory scheme for health care practitioners by the Department of Health.

Standard minimum licensure requirements consolidated in the bill include: timeframes for the license application processing, two-year renewal cycle, definition of change of ownership, background screening, notice of exclusion from Medicare or Medicaid, notice of closure, inactive license, records retention, right of inspection, inspection reports, unlicensed activity, administrative fines, moratoriums, license denial, emergency suspension, and revocation.

The bill lists the facilities affected by the bill.

The effective date of the bill is October 1, 2006.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Provide Limited Government – The bill consolidates licensure standards and regulations of health care facilities into core licensure statutes. The bill streamlines current regulation and decreases unnecessary variations.

B. EFFECT OF PROPOSED CHANGES:

Present Situation

The licensure statutes for various health care providers regulated by AHCA contain duplication and variation of certain basic licensing standards. These standards include the application process, changes of ownership, licensure categories, background screenings, changes of administrator, right of inspection, inspection reports, unlicensed activity, administrative fines, moratoriums, and license denial and revocation. The majority of licenses are required to be renewed annually, although some programs call for biennial licensure. Each of these regulatory statutes has evolved independently and as such there is variation in the definitions of similar requirements. Licensure processing occurs within the broad requirements of licensure under the Administrative Procedures Act, s. 120.60, F.S., and many unique requirements within each specify authorizing statutes or rules.

Effect of Bill

The bill creates part II of chapter 408, F.S., by establishing a set of minimum core licensing requirements for all health care providers licensed by the Agency for Health Care Administration to eliminate unnecessary duplication and variation of licensure requirements among providers. This organization of core, uniform standards is similar to the regulatory scheme for health care practitioners within chapter 456, F.S., by the Department of Health. Common definitions of basic standards serve to eliminate confusion for operators of multiple provider types and streamline the licensure process. The bill creates streamlined and consistent licensing requirements for all providers regulated by AHCA, by standardizing terminology in basic licensure requirements.

The health care licensing programs subject to part II of Chapter 408, F.S. include:

- Drug Free Workplace Laboratories, as provided under ss. 112.0455 and 440.102;
- Birth Centers, as provided under chapter 383, F.S.;
- Abortion Clinics, as provided under chapter 390, F.S.;
- Crisis Stabilization Units, as provided under parts I and IV of chapter 394, F.S.;
- Short Term Residential Treatment Units, as provided under parts I and IV of chapter 394, F.S.; Residential Treatment Facilities, as provided under part IV of chapter 394, F.S.;
- Residential Treatment Centers for Children and Adolescents, as provided under part IV of chapter 394;
- Hospitals, as provided under part I of chapter 395, F.S.;
- Ambulatory Surgical Centers, as provided under part I of chapter 395, F.S.;
- Mobile Surgical Facilities, as provided under part I of chapter 395, F.S.;
- Private Review Agents, as provided under part I of chapter 395, F.S.;
- Health Care Risk Managers, as provided under part I of chapter 395, F.S.;
- Nursing Homes, as provided under part II of chapter 400, F.S.;
- Assisted Living Facilities, as provided under part III of chapter 400, F.S.;
- Home Health Agencies, as provided under part IV of chapter 400, F.S.;
- Nurse Registries, as provided under part IV of chapter 400, F.S.;

- Companion Services or Homemaker Services Providers, as provided under part IV of chapter 400, F.S.;
- Adult Day Care Centers, as provided under part V of chapter 400, F.S.;
- Hospices, as provided under part VI of chapter 400, F.S.;
- Adult Family-Care Homes, as provided under part VII of chapter 400, F.S.;
- Homes for Special Services as provided under part VIII of chapter 400, F.S.;
- Transitional Living Facilities, as provided under part VIII of chapter 400, F.S.;
- Prescribed Pediatric Extended Care Centers, as provided under part IX of chapter 400, F.S.;
- Home Medical Equipment Providers, as provided under part X of chapter 400, F.S.;
- Intermediate Care Facilities for the Developmentally Disabled, as provided under part XI of chapter 400, F.S.;
- Health Care Services Pools, as provided under part XII of chapter 400, F.S.;
- Health Care Clinics, as provided under part XIII of chapter 400, F.S.;
- Clinical Laboratories, as provided under part I of chapter 483, F.S.;
- Multiphasic Health Testing Centers, as provided under part II of chapter 483, F.S.; and
- Certification of Organizations Engaged in the Practice Of Cadaveric Organ and Tissue Procurement, Certification of Organ Procurement Organizations, Tissue Banks and Eye Banks as provided under chapter 765, F.S.

The bill creates licensing and regulatory standards for all of the above programs.

Licensure Requirements
The bill provides that it is unlawful to provide or offer services that require a license without first obtaining a license. Applicants must submit the appropriate application with license fee to the Agency for Health Care Administration (AHCA). The license fee cannot exceed the actual cost of regulation pursuant to part II of chapter 408. F.S., authorizing statutes, and administrative rules. Licensure fees may be adjusted annually based on the change in the consumer price index within existing maximum levels if increases are necessary to support the actual cost of regulation.

Inspection Fees
The bill provides for the assessment of inspection fees if required by authorizing statute and a fee assessment for license re-issuance due to a reported change by the provider.

Licensure Renewals
The bill mandates the timeframes for initial, renewal, and change of ownership application submission; the timeframe for AHCA review and approval or denial of applications; and the timeframe for applicant submission of omitted application information. These timeframes provide more specific direction than the broad licensing requirements of s. 120.60, F.S. The duration of a license is typically two years, but conditions of licensure category can shorten that period, such as the issuance of a provisional license. Change of ownership responsibilities of the transferor and transferee are specified in the bill.

Licensure Categories
The bill details the conditions for issuing a standard, provisional, or inactive license.

Background Check Requirements
Federal Bureau of Investigation (FBI) and Florida Department of Law Enforcement (FDLE) background screening is required for administrators, individual owners, and financial officers. A person with controlling interest is subject to background screening when there is reason to believe such person has a disqualifying offense. Notice of change of a person required to undergo background screening must be reported to AHCA, pursuant to the specific authorizing statute and rule requirements. New persons who are subject to the screening requirements must comply with background screening requirements; however, they may be employed pending FBI screening results if the state level (FDLE) screening is clear.

AHCA Right of Entry & Administrative Actions
The Agency for Health Care Administration (AHCA) has the right of entry and inspection of premises to determine compliance with part II of Chapter 408, F.S., authorizing statutes, and rules. AHCA may not enter into a premise, which AHCA believes is operating without a valid license unless permission is granted by the owner or a warrant is first obtained. The bill provides for administrative actions against unlicensed providers. The bill allows the agency to impose administrative fines, a moratorium on admissions, license denial, emergency suspension or revocation, or seek injunctive relief for regulatory violations affecting resident health, safety or welfare.

C. SECTION DIRECTORY:

Section 1. – Creates Part I of Chapter 408, F.S., consisting of sections 408.031, 408.032, 408.033, 408.034, 408.035, 408.036, 408.0361, 408.037, 408.038, 408.039, 408.040, 408.041, 408.042, 408.043, 408.044, 408.045, 408.0455, 408.05, 408.061, 408.062, 408.063, 408.07, 408.08, 408.09, 408.10, 408.15, 408.16, 408.18, 408.185, 408.20, 408.301, 408.302, 408.40, 408.50, 408.70, 408.7056, 408.7057, and 408.7071, F.S., entitled "Health Facility and Services Planning."

Section 2. – Creates Part II of Chapter 408, F.S., consisting of sections 408.801, 408.802, 408.803, 408.804, 408.805, 408.806, 408.807, 408.808, 408.809, 408.810, 408.811, 408.812, 408.813, 408.814, 408.815, 408.816, 408.817, 408.818, 408.819, 408.820, and 408.831, F.S., entitled "Health Care Licensing: General Provisions."

Section 3. – Creates Part III of Chapter 408, F.S., consisting of sections 408.90, 408.901, 408.902, 408.903, 408.904, 408.905, 408.906, 408.907, 408.908, and 408.909, F.S., entitled "Health Insurance Access."

Section 4. – Creates Part IV of Chapter 408, F.S., consisting of sections 408.911, 408.913, 408.914, 408.915, 408.916, 408.917, and 408.918, F.S., entitled "Health and Human Services Eligibility Access System."

Section 5. – Creates sections 408.801 – 408.820, F.S., to consolidate licensing requirements for facilities and services licensed by AHCA.

Section 6. – Amends s. 400.801, F.S., to redefine "home for special services" to mean a site licensed by AHCA prior to January 1, 2006.

Section 7. – Amends s. 408.831, F.S. to authorize AHCA to deny any application, or suspend or revoke any license when a licensee subject to part II of chapter 408, F.S., shares a common controlling interest with the applicant and has failed to pay all outstanding monies due to AHCA.

Section 8. - Specifies that the provisions of part II of chapter 408, F.S., prevail over provider authorizing statutes in case of a conflict.

Section 9. - The bill authorizes AHCA to double current annual licensure fees to provide for biennial licensure.

Section 10. – Directs the Division of Statutory Revision of the Office of Legislative Services to assist, substantive committees of the Senate and House of Representatives, in the preparation of draft legislation to conform the Florida Statutes and any legislation enacted during 2006 to the act.

Section 11. - The bill authorizes AHCA to issue any license for less than two years by charging a prorated licensure fee and specifying a different renewal date between October 1, 2006 and September 30, 2008. This will allow for staggering of expiration dates as providers change from annual to biennial licensure.

Section 12. - The effective date of the bill is October 1, 2006.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

In future years, licensure fees may be adjusted annually based on the change in the consumer price index within existing maximum levels if increases are necessary to support the actual cost of regulation.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   This bill does not require counties or municipalities to spend funds or take action requiring the expenditure of funds. This bill does not reduce the percentage of state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenue.

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

The bill authorizes rule making authority for the Agency for Health Care Administration to carry out provisions of the core licensing provisions. Some licensure requirements that are currently in rule will no longer be necessary if core licensure standards are implemented.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

1 A bill to be entitled
2 An act relating to the licensure of health care providers;
3 creating pts. I, II, III, and IV of ch. 408, F.S.;
4 creating s. 408.801, F.S.; providing a short title;
5 providing legislative findings and purpose; creating s.
6 408.802, F.S.; providing applicability; creating s.
7 408.803, F.S.; providing definitions; creating s. 408.804,
8 F.S.; requiring providers to have and display a license;
9 providing limitations; creating s. 408.805, F.S.;
10 establishing license fees and conditions for assessment
11 thereof; providing a method for calculating annual
12 adjustment of fees; providing for inspection fees;
13 providing that fees are nonrefundable; creating s.
14 408.806, F.S.; providing a license application process;
15 requiring specified information to be included on the
16 application; requiring payment of late fees under certain
17 circumstances; requiring inspections; providing an
18 exception; authorizing the Agency for Health Care
19 Administration to establish procedures and rules for
20 electronic transmission of required information; creating
21 s. 408.807, F.S.; providing procedures for change of
22 ownership; requiring the transferor to notify the agency
23 in writing within a specified time period; providing for
24 duties and liability of the transferor; providing for
25 maintenance of certain records; creating s. 408.808, F.S.;
26 providing license categories and requirements therefor;
27 creating s. 408.809, F.S.; requiring background screening
28 of specified employees; providing for submission of proof
29 of compliance, under certain circumstances; providing

30 conditions for granting provisional and standard licenses;
31 providing an exception to screening requirements; creating
32 s. 408.810, F.S.; providing minimum licensure
33 requirements; providing procedures for discontinuance of
34 operation and surrender of license; requiring forwarding
35 of client records; requiring publication of a notice of
36 discontinuance of operation of a provider; providing for
37 statewide toll-free telephone numbers for reporting
38 complaints and abusive, neglectful, and exploitative
39 practices; requiring proof of legal right to occupy
40 property, proof of insurance, and proof of financial
41 viability, under certain circumstances; requiring
42 disclosure of information relating to financial
43 instability; providing a penalty; prohibiting the agency
44 from licensing a health care provider that does not have a
45 certificate of need or an exemption; creating s. 408.811,
46 F.S.; providing for inspections and investigations to
47 determine compliance; providing that inspection reports
48 are public records; requiring retention of records for a
49 specified period of time; creating s. 408.812, F.S.;
50 prohibiting certain unlicensed activity by a provider;
51 requiring unlicensed providers to cease activity;
52 providing penalties; requiring reporting of unlicensed
53 providers; creating s. 408.813, F.S.; authorizing the
54 agency to impose administrative fines; creating s.
55 408.814, F.S.; providing conditions for the agency to
56 impose a moratorium or emergency suspension on a provider;
57 requiring notice; creating s. 408.815, F.S.; providing
58 grounds for denial or revocation of a license or change-

59 of-ownership application; providing conditions to continue
60 operation; exempting renewal applications from provisions
61 requiring the agency to approve or deny an application
62 within a specified period of time, under certain
63 circumstances; creating s. 408.816, F.S.; authorizing the
64 agency to institute injunction proceedings, under certain
65 circumstances; creating s. 408.817, F.S.; providing basis
66 for review of administrative proceedings challenging
67 agency licensure enforcement action; creating s. 408.818,
68 F.S.; requiring fees and fines related to health care
69 licensing to be deposited into the Health Care Trust Fund;
70 creating s. 408.819, F.S.; authorizing the agency to adopt
71 rules; providing a timeframe for compliance; creating s.
72 408.820, F.S.; providing exemptions from specified
73 requirements of pt. II of ch. 408, F.S.; amending s.
74 400.801, F.S.; providing that the definition of homes for
75 special services applies to sites licensed by the agency
76 after a certain date; amending s. 408.831, F.S.; revising
77 provisions relating to agency action to deny, suspend, or
78 revoke a license, registration, certificate, or
79 application; conforming cross-references; providing for
80 priority of application in case of conflict; authorizing
81 the agency to adjust annual licensure fees to provide
82 biennial licensure fees; requesting interim assistance of
83 the Division of Statutory Revision to prepare conforming
84 legislation for the 2007 Regular Session; authorizing the
85 agency to issue licenses for less than a specified time
86 period and providing conditions therefor; providing an
87 effective date.

88
89 Be It Enacted by the Legislature of the State of Florida:
90
91 Section 1. Part I of chapter 408, Florida Statutes,
92 consisting of sections 408.031, 408.032, 408.033, 408.034,
93 408.035, 408.036, 408.0361, 408.037, 408.038, 408.039, 408.040,
94 408.041, 408.042, 408.043, 408.044, 408.045, 408.0455, 408.05,
95 408.061, 408.062, 408.063, 408.07, 408.08, 408.09, 408.10,
96 408.15, 408.16, 408.18, 408.185, 408.20, 408.301, 408.302,
97 408.40, 408.50, 408.70, 408.7056, 408.7057, and 408.7071, Florida
98 Statutes, is created and entitled "Health Facility and Services
99 Planning."
100 Section 2. Part II of chapter 408, Florida Statutes,
101 consisting of sections 408.801, 408.802, 408.803, 408.804,
102 408.805, 408.806, 408.807, 408.808, 408.809, 408.810, 408.811,
103 408.812, 408.813, 408.814, 408.815, 408.816, 408.817, 408.818,
104 408.819, 408.820, and 408.831, Florida Statutes, is created and
105 entitled "Health Care Licensing: General Provisions."
106 Section 3. Part III of chapter 408, Florida Statutes,
107 consisting of sections 408.90, 408.901, 408.902, 408.903,
108 408.904, 408.905, 408.906, 408.907, 408.908, and 408.909, Florida
109 Statutes, is created and entitled "Health Insurance Access."
110 Section 4. Part IV of chapter 408, Florida Statutes,
111 consisting of sections 408.911, 408.913, 408.914, 408.915,
112 408.916, 408.917, and 408.918, Florida Statutes, is created and
113 entitled "Health and Human Services Eligibility Access System."
114 Section 5. Sections 408.801, 408.802, 408.803, 408.804,
115 408.805, 408.806, 408.807, 408.808, 408.809, 408.810, 408.811,
116 408.812, 408.813, 408.814, 408.815, 408.816, 408.817, 408.818,

117 408.819, and 408.820, Florida Statutes, are created to read:
118 408.801 Short title; purpose.--
119 (1) This part may be cited as the "Health Care Licensing
120 Procedures Act."
121 (2) The Legislature finds that there is unnecessary
122 duplication and variation in the requirements for licensure by
123 the agency. It is the intent of the Legislature to provide a
124 streamlined and consistent set of basic licensing requirements
125 for all such providers in order to minimize confusion,
126 standardize terminology, and include issues that are otherwise
127 not adequately addressed in the Florida Statutes pertaining to
128 specific providers.
129 408.802 Applicability.--The provisions of this part apply
130 to the provision of services that require licensure as defined in
131 this part and to the following entities licensed, registered, or
132 certified by the agency, as described in chapters 112, 383, 390,
133 394, 395, 400, 440, 483, and 765:
134 (1) Laboratories authorized to perform testing under the
135 Drug-Free Workplace Act, as provided under ss. 112.0455 and
136 440.102.
137 (2) Birth centers, as provided under chapter 383.
138 (3) Abortion clinics, as provided under chapter 390.
139 (4) Crisis stabilization units, as provided under parts I
140 and IV of chapter 394.
141 (5) Short-term residential treatment facilities, as
142 provided under parts I and IV of chapter 394.
143 (6) Residential treatment facilities, as provided under
144 part IV of chapter 394.
145 (7) Residential treatment centers for children and

146 adolescents, as provided under part IV of chapter 394.
147 (8) Hospitals, as provided under part I of chapter 395.
148 (9) Ambulatory surgical centers, as provided under part I
149 of chapter 395.
150 (10) Mobile surgical facilities, as provided under part I
151 of chapter 395.
152 (11) Private review agents, as provided under part I of
153 chapter 395.
154 (12) Health care risk managers, as provided under part I of
155 chapter 395.
156 (13) Nursing homes, as provided under part II of chapter
157 400.
158 (14) Assisted living facilities, as provided under part III
159 of chapter 400.
160 (15) Home health agencies, as provided under part IV of
161 chapter 400.
162 (16) Nurse registries, as provided under part IV of chapter
163 400.
164 (17) Companion services or homemaker services providers, as
165 provided under part IV of chapter 400.
166 (18) Adult day care centers, as provided under part V of
167 chapter 400.
168 (19) Hospices, as provided under part VI of chapter 400.
169 (20) Adult family-care homes, as provided under part VII of
170 chapter 400.
171 (21) Homes for special services, as provided under part
172 VIII of chapter 400.
173 (22) Transitional living facilities, as provided under part
174 VIII of chapter 400.

175 (23) Prescribed pediatric extended care centers, as
176 provided under part IX of chapter 400.
177 (24) Home medical equipment providers, as provided under
178 part X of chapter 400.
179 (25) Intermediate care facilities for persons with
180 developmental disabilities, as provided under part XI of chapter
181 400.
182 (26) Health care services pools, as provided under part XII
183 of chapter 400.
184 (27) Health care clinics, as provided under part XIII of
185 chapter 400.
186 (28) Clinical laboratories, as provided under part I of
187 chapter 483.
188 (29) Multiphasic health testing centers, as provided under
189 part II of chapter 483.
190 (30) Organ and tissue procurement agencies, as provided
191 under chapter 765.
192 408.803 Definitions.--As used in this part, the term:
193 (1) "Agency" means the Agency for Health Care
194 Administration, which is the licensing agency under this part.
195 (2) "Applicant" means an individual, corporation,
196 partnership, firm, association, or governmental entity that
197 submits an application for a license to the agency.
198 (3) "Authorizing statute" means the statute authorizing the
199 licensed operation of a provider listed in s. 408.802 and
200 includes chapters 112, 383, 390, 394, 395, 400, 440, 483, and
201 765.
202 (4) "Certification" means certification as a Medicare or
203 Medicaid provider of the services that require licensure, or

204 certification pursuant to the federal Clinical Laboratory
205 Improvement Amendment (CLIA).
206 (5) "Change of ownership" means an event in which the
207 licensee changes to a different legal entity or in which 45
208 percent or more of the ownership, voting shares, or controlling
209 interest in a corporation whose shares are not publicly traded on
210 a recognized stock exchange is transferred or assigned, including
211 the final transfer or assignment of multiple transfers or
212 assignments over a 2-year period that cumulatively total 45
213 percent or greater. A change solely in the management company or
214 board of directors is not a change of ownership.
215 (6) "Client" means any person receiving services from a
216 provider listed in s. 408.802.
217 (7) "Controlling interest" means:
218 (a) The applicant or licensee;
219 (b) A person or entity that serves as an officer of, is on
220 the board of directors of, or has a 5-percent or greater
221 ownership interest in the applicant or licensee; or
222 (c) A person or entity that serves as an officer of, is on
223 the board of directors of, or has a 5-percent or greater
224 ownership interest in the management company or other entity,
225 related or unrelated, with which the applicant or licensee
226 contracts to manage the provider.
227
228 The term does not include a voluntary board member.
229 (8) "License" means any permit, registration, certificate,
230 or license issued by the agency.
231 (9) "Licensee" means an individual, corporation,
232 partnership, firm, association, or governmental entity that is

233 issued a permit, registration, certificate, or license by the
234 agency. The licensee is legally responsible for all aspects of
235 the provider operation.
236 (10) "Moratorium" means a prohibition on the acceptance of
237 new clients.
238 (11) "Provider" means any activity, service, agency, or
239 facility regulated by the agency and listed in s. 408.802.
240 (12) "Services that require licensure" means those
241 services, including residential services, that require a valid
242 license before those services may be provided in accordance with
243 authorizing statutes and agency rules.
244 (13) "Voluntary board member" means a board member of a
245 not-for-profit corporation or organization who serves solely in a
246 voluntary capacity, does not receive any remuneration for his or
247 her services on the board of directors, and has no financial
248 interest in the corporation or organization. The agency shall
249 recognize a person as a voluntary board member following
250 submission of a statement to the agency by the board member and
251 the not-for-profit corporation or organization that affirms that
252 the board member conforms to this definition. The statement
253 affirming the status of the board member must be submitted to the
254 agency on a form provided by the agency.
255 408.804 License required; display.--
256 (1) It is unlawful to provide services that require
257 licensure, or operate or maintain a provider that offers or
258 provides services that require licensure, without first obtaining
259 from the agency a license authorizing the provision of such
260 services or the operation or maintenance of such provider.
261 (2) A license must be displayed in a conspicuous place

262 readily visible to clients who enter at the address that appears
263 on the license and is valid only in the hands of the licensee to
264 whom it is issued and may not be sold, assigned, or otherwise
265 transferred, voluntarily or involuntarily. The license is valid
266 only for the licensee, provider, and location for which the
267 license is issued.
268 408.805 Fees required; adjustments.--Unless otherwise
269 limited by authorizing statutes, license fees must be reasonably
270 calculated by the agency to cover its costs in carrying out its
271 responsibilities under this part, authorizing statutes, and
272 applicable rules, including the cost of licensure, inspection,
273 and regulation of providers.
274 (1) Licensure fees shall be adjusted to provide for
275 biennial licensure under agency rules.
276 (2) The agency shall annually adjust licensure fees,
277 including fees paid per bed, by not more than the change in the
278 Consumer Price Index based on the 12 months immediately preceding
279 the increase.
280 (3) The agency may, by rule, adjust licensure fees to cover
281 the cost of administering this part, authorizing statutes, and
282 applicable rules.
283 (4) An inspection fee must be paid as required in
284 authorizing statutes.
285 (5) Fees are nonrefundable.
286 (6) When a change is reported that requires issuance of a
287 license, a fee may be assessed. The fee must be based on the
288 actual cost of processing and issuing the license.
289 (7) A fee may be charged to a licensee requesting a
290 duplicate license. The fee may not exceed the actual cost of

291 duplication and postage.
292 (8) Total fees collected may not exceed the cost of
293 administering this part, authorizing statutes, and applicable
294 rules.
295 408.806 License application process.--
296 (1) An application for licensure must be made to the agency
297 on forms furnished by the agency, submitted under oath, and
298 accompanied by the appropriate fee in order to be accepted and
299 considered timely. The application must contain information
300 required by authorizing statutes and applicable rules and must
301 include:
302 (a) The name, address, and social security number of the
303 applicant and each controlling interest if the applicant or
304 controlling interest is an individual.
305 (b) The name, address, and federal employer identification
306 number or taxpayer identification number of the applicant and
307 each controlling interest if the applicant or controlling
308 interest is not an individual.
309 (c) The name by which the provider is to be known.
310 (d) The total number of beds or capacity requested, as
311 applicable.
312 (e) The name of the person or persons under whose
313 management or supervision the provider will operate and the name
314 of the administrator, if required.
315 (f) If the applicant offers continuing care agreements as
316 defined in chapter 651, proof shall be furnished that the
317 applicant has obtained a certificate of authority as required for
318 operation under chapter 651.
319 (g) Other information, including satisfactory inspection

320 results, that the agency finds necessary to determine the ability
321 of the applicant to carry out its responsibilities under this
322 part, authorizing statutes, and applicable rules.
323 (2)(a) The applicant for a renewal license must submit an
324 application that must be received by the agency at least 60 days
325 prior to the expiration of the current license.
326 (b) The applicant for initial licensure due to a change of
327 ownership must submit an application that must be received by the
328 agency at least 60 days prior to the date of change of ownership.
329 (c) For any other application or request, the applicant
330 must submit an application or request that must be received by
331 the agency at least 60 days prior to the requested effective
332 date, unless otherwise specified in authorizing statutes or
333 applicable rules.
334 (d) The agency shall notify the licensee by mail or
335 electronically at least 90 days prior to the expiration of a
336 license that a renewal license is necessary to continue
337 operation. The failure to timely submit an application and
338 license fee shall result in a late fee charged to the licensee by
339 the agency in an amount equal to 50 percent of the licensure fee,
340 but the aggregate amount of the fine may not exceed $5,000. If an
341 application is received after the required filing date and
342 exhibits a hand-canceled postmark obtained from a United States
343 post office dated on or before the required filing date, no fine
344 will be levied.
345 (3)(a) Upon receipt of an application for a license, the
346 agency shall examine the application and, within 30 days after
347 receipt, notify the applicant in writing of any apparent errors
348 or omissions and request any additional information required.

349 (b) Requested information omitted from an application for
350 licensure, license renewal, or change of ownership, other than an
351 inspection, must be filed with the agency within 21 days after
352 the agency's request for omitted information or the application
353 shall be deemed incomplete and shall be withdrawn from further
354 consideration and the fees shall be forfeited.
355 (c) Within 60 days after the receipt of a complete
356 application, the agency shall approve or deny the application.
357 (4)(a) Licensees subject to the provisions of this part
358 shall be issued biennial licenses unless conditions of the
359 license category specify a shorter license period.
360 (b) Each license issued shall indicate the name of the
361 licensee, the type of provider or service that the licensee is
362 required or authorized to operate or offer, the date the license
363 is effective, the expiration date of the license, the maximum
364 capacity of the licensed premises, if applicable, and any other
365 information required or deemed necessary by the agency.
366 (5) In accordance with authorizing statutes and applicable
367 rules, proof of compliance with s. 408.810 must be submitted with
368 an application for licensure.
369 (6) The agency may not issue an initial license to a health
370 care provider subject to the certificate-of-need provisions in
371 part I of this chapter if the licensee has not been issued a
372 certificate of need or certificate-of-need exemption, when
373 applicable. Failure to apply for the renewal of a license prior
374 to the expiration date renders the license void.
375 (7)(a) An applicant must demonstrate compliance with the
376 requirements in this part, authorizing statutes, and applicable
377 rules during an inspection pursuant to s. 408.811, as required by

378 authorizing statutes.
379 (b) An initial inspection is not required for companion
380 services or homemaker services providers, as provided under part
381 IV of chapter 400, or for health care services pools, as provided
382 under part XII of chapter 400.
383 (c) If an inspection is required by the authorizing statute
384 for a license application other than an initial application, the
385 inspection must be unannounced. This paragraph does not apply to
386 inspections required pursuant to ss. 383.324, 395.0161(4), and
387 483.061(2).
388 (d) If a provider is not available when an inspection is
389 attempted, the application shall be denied.
390 (8) The agency may establish procedures for the electronic
391 notification and submission of required information, including,
392 but not limited to:
393 (a) Licensure applications.
394 (b) Required signatures.
395 (c) Payment of fees.
396 (d) Notarization of applications.
397
398 Requirements for electronic submission of any documents required
399 by this part or authorizing statutes may be established by rule.
400 408.807 Change of ownership.--Whenever a change of
401 ownership occurs:
402 (1) The transferor shall notify the agency in writing at
403 least 60 days before the anticipated date of the change of
404 ownership.
405 (2) The transferee shall make application to the agency for
406 a license within the timeframes required in s. 408.806.

407 (3) The transferor shall be responsible and liable for:
408 (a) The lawful operation of the provider and the welfare of
409 the clients served until the date the transferee is licensed by
410 the agency.
411 (b) Any and all penalties imposed against the transferor
412 for violations occurring before the date of change of ownership.
413 (4) Any restriction on licensure, including a conditional
414 license existing at the time of a change of ownership, shall
415 remain in effect until removed by the agency.
416 (5) The transferee shall maintain records of the transferor
417 as required in this part, authorizing statutes, and applicable
418 rules, including:
419 (a) All client records.
420 (b) Inspection reports.
421 (c) All records required to be maintained pursuant to s.
422 409.913, if applicable.
423 408.808 License categories.--
424 (1) STANDARD LICENSE.--A standard license may be issued to
425 an applicant at the time of initial licensure, license renewal,
426 or change of ownership. A standard license shall be issued when
427 the applicant is in compliance with all statutory requirements
428 and agency rules. Unless sooner revoked, a standard license
429 expires 2 years after the date of issue.
430 (2) PROVISIONAL LICENSE.--A provisional license may be
431 issued to an applicant pursuant to s. 408.809(3). An applicant
432 against whom a proceeding denying or revoking a license is
433 pending at the time of license renewal may be issued a
434 provisional license effective until final action not subject to
435 further appeal.

436 (3) INACTIVE LICENSE.--An inactive license may be issued to
437 a health care provider subject to the certificate-of-need
438 provisions in part I of this chapter when the provider is
439 currently licensed, does not have a provisional license, and will
440 be temporarily unable to provide services but is reasonably
441 expected to resume services within 12 months. Such designation
442 may be made for a period not to exceed 12 months but may be
443 renewed by the agency for up to 12 additional months upon
444 demonstration by the licensee of the provider's progress toward
445 reopening. A request by a licensee for an inactive license or to
446 extend the previously approved inactive period must be submitted
447 to the agency and must include a written justification for the
448 inactive license with the beginning and ending dates of
449 inactivity specified, a plan for the transfer of any clients to
450 other providers, and the appropriate licensure fees. The agency
451 may not accept a request that is submitted after initiating
452 closure, after any suspension of service, or after notifying
453 clients of closure or suspension of service, unless the action is
454 a result of a natural disaster. Upon agency approval, the
455 provider shall notify clients of any necessary discharge or
456 transfer as required by authorizing statutes or applicable rules.
457 The beginning of the inactive license period is the date the
458 provider ceases operations. The end of the inactive license
459 period shall become the license expiration date. All licensure
460 fees must be current, must be paid in full, and may be prorated.
461 Reactivation of an inactive license requires the approval of a
462 renewal application, including payment of licensure fees and
463 agency inspections indicating compliance with all requirements of
464 this part, authorizing statutes, and applicable rules.

465 (4) OTHER LICENSES.--Other types of license categories may
466 be issued pursuant to authorizing statutes or applicable rules.
467 408.809 Background screening; prohibited offenses.--
468 (1) Level 2 background screening pursuant to chapter 435
469 must be conducted through the agency on each of the following
470 persons, who shall be considered an employee for the purposes of
471 conducting screening under chapter 435:
472 (a) The licensee, if an individual.
473 (b) The administrator or a similarly titled person who is
474 responsible for the day-to-day operation of the provider.
475 (c) The financial officer or similarly titled individual
476 who is responsible for the financial operation of the licensee or
477 provider.
478 (d) Any person who is a controlling interest if the agency
479 has reason to believe that such person has been convicted of any
480 offense prohibited by s. 435.04. For each controlling interest
481 who has been convicted of any such offense, the licensee shall
482 submit to the agency a description and explanation of the
483 conviction at the time of license application.
484 (2) Proof of compliance with level 2 screening standards
485 submitted within the previous 5 years to meet any provider or
486 professional licensure requirements of the agency, the Department
487 of Health, the Agency for Persons with Disabilities, or the
488 Department of Children and Family Services satisfies the
489 requirements of this section, provided that such proof is
490 accompanied, under penalty of perjury, by an affidavit of
491 compliance with the provisions of chapter 435 using forms
492 provided by the agency. Proof of compliance with the background
493 screening requirements of the Department of Financial Services

494 submitted within the previous 5 years for an applicant for a
495 certificate of authority to operate a continuing care retirement
496 community under chapter 651 satisfies the Department of Law
497 Enforcement and Federal Bureau of Investigation portions of a
498 level 2 background check.
499 (3) A provisional license may be granted to an applicant
500 when each individual required by this section to undergo
501 background screening has met the standards for the Department of
502 Law Enforcement background check but the agency has not yet
503 received background screening results from the Federal Bureau of
504 Investigation. A standard license may be granted to the licensee
505 upon the agency's receipt of a report of the results of the
506 Federal Bureau of Investigation background screening for each
507 individual required by this section to undergo background
508 screening that confirms that all standards have been met or upon
509 the granting of an exemption from disqualification by the agency
510 as set forth in chapter 435.
511 (4) When a person is newly employed in a capacity that
512 requires screening under this section, the licensee must notify
513 the agency of the change within the time period specified in the
514 authorizing statute or rules and must submit to the agency
515 information necessary to conduct level 2 screening or provide
516 evidence of compliance with background screening requirements of
517 this section. The person may serve in his or her capacity pending
518 the agency's receipt of the report from the Federal Bureau of
519 Investigation if he or she has met the standards for the
520 Department of Law Enforcement background check. However, the
521 person may not continue to serve in his or her capacity if the
522 report indicates any violation of background screening standards

523 unless an exemption from disqualification has been granted by the
524 agency as set forth in chapter 435.
525 (5) Background screening is not required to obtain a
526 certificate of exemption issued under s. 483.106.
527 408.810 Minimum licensure requirements.--In addition to the
528 licensure requirements specified in this part, authorizing
529 statutes, and applicable rules, each applicant and licensee must
530 comply with the requirements of this section in order to obtain
531 and maintain a license.
532 (1) An applicant for licensure must comply with the
533 background screening requirements of s. 408.809.
534 (2) An applicant for licensure must provide a description
535 and explanation of any exclusions, suspensions, or terminations
536 of the applicant from the Medicare, Medicaid, or federal Clinical
537 Laboratory Improvement Amendment (CLIA) programs.
538 (3) Unless otherwise specified in this part, authorizing
539 statutes, or applicable rules, any information required to be
540 reported to the agency must be submitted within 21 calendar days
541 after the report period or effective date of the information.
542 (4) Whenever a licensee discontinues operation of a
543 provider:
544 (a) The licensee must inform the agency not less than 30
545 days prior to the discontinuance of operation and inform clients
546 of such discontinuance as required by authorizing statutes.
547 Immediately upon discontinuance of operation by a provider, the
548 licensee shall surrender the license to the agency and the
549 license shall be canceled.
550 (b) The licensee shall remain responsible for retaining and
551 appropriately distributing all records within the timeframes

552 prescribed in authorizing statutes and applicable rules. In
553 addition, the licensee or, in the event of death or dissolution
554 of a licensee, the estate or agent of the licensee shall:
555 1. Make arrangements to forward records for each client to
556 one of the following, based upon the client's choice: the client
557 or the client's legal representative, the client's attending
558 physician, or the health care provider where the client currently
559 receives services; or
560 2. Cause a notice to be published in the newspaper of
561 greatest general circulation in the county in which the provider
562 was located that advises clients of the discontinuance of the
563 provider operation. The notice must inform clients that they may
564 obtain copies of their records and specify the name, address, and
565 telephone number of the person from whom the copies of records
566 may be obtained. The notice must appear at least once a week for
567 4 consecutive weeks.
568 (5)(a) On or before the first day services are provided to
569 a client, a licensee must inform the client and his or her
570 immediate family or representative, if appropriate, of the right
571 to report:
572 1. Complaints. The statewide toll-free telephone number for
573 reporting complaints to the agency must be provided to clients in
574 a manner that is clearly legible and must include the words: "To
575 report a complaint regarding the services you receive, please
576 call toll-free (phone number)."
577 2. Abusive, neglectful, or exploitative practices. The
578 statewide toll-free telephone number for the central abuse
579 hotline must be provided to clients in a manner that is clearly
580 legible and must include the words: "To report abuse, neglect, or

581 exploitation, please call toll-free (phone number)." The agency
582 shall publish a minimum of a 90-day advance notice of a change in
583 the toll-free telephone numbers.
584 (b) Each licensee shall establish appropriate policies and
585 procedures for providing such notice to clients.
586 (6) An applicant must provide the agency with proof of the
587 applicant's legal right to occupy the property before a license
588 may be issued. Proof may include, but need not be limited to,
589 copies of warranty deeds, lease or rental agreements, contracts
590 for deeds, quitclaim deeds, or other such documentation.
591 (7) If proof of insurance is required by the authorizing
592 statute, that insurance must be in compliance with chapter 624,
593 chapter 626, chapter 627, or chapter 628 and with agency rules.
594 (8) Upon application for initial licensure or change of
595 ownership licensure, the applicant shall furnish satisfactory
596 proof of the applicant's financial ability to operate in
597 accordance with the requirements of this part, authorizing
598 statutes, and applicable rules. The agency shall establish
599 standards for this purpose, including information concerning the
600 applicant's controlling interests. The agency shall also
601 establish documentation requirements, to be completed by each
602 applicant, that show anticipated provider revenues and
603 expenditures, the basis for financing the anticipated cash-flow
604 requirements of the provider, and an applicant's access to
605 contingency financing. A current certificate of authority,
606 pursuant to chapter 651, may be provided as proof of financial
607 ability to operate. The agency may require a licensee to provide
608 proof of financial ability to operate at any time if there is
609 evidence of financial instability, including, but not limited to,

610 unpaid expenses necessary for the basic operations of the
611 provider.
612 (9) A controlling interest may not withhold from the agency
613 any evidence of financial instability, including, but not limited
614 to, checks returned due to insufficient funds, delinquent
615 accounts, nonpayment of withholding taxes, unpaid utility
616 expenses, nonpayment for essential services, or adverse court
617 action concerning the financial viability of the provider or any
618 other provider licensed under this part that is under the control
619 of the controlling interest. Any person who violates this
620 subsection commits a misdemeanor of the second degree, punishable
621 as provided in s. 775.082 or s. 775.083. Each day of continuing
622 violation is a separate offense.
623 (10) The agency may not issue a license to a health care
624 provider subject to the certificate-of-need provisions in part I
625 of this chapter if the health care provider has not been issued a
626 certificate of need or an exemption. Upon initial licensure of
627 any such provider, the authorization contained in the certificate
628 of need shall be considered fully implemented and merged into the
629 license and shall have no force and effect upon termination of
630 the license for any reason.
631 408.811 Right of inspection; copies; inspection reports.--
632 (1) An authorized officer or employee of the agency may
633 make or cause to be made any inspection or investigation deemed
634 necessary by the agency to determine the state of compliance with
635 this part, authorizing statutes, and applicable rules. The right
636 of inspection extends to any business that the agency has reason
637 to believe is being operated as a provider without a license, but
638 inspection of any business suspected of being operated without

639 the appropriate license may not be made without the permission of
640 the owner or person in charge unless a warrant is first obtained
641 from a circuit court. Any application for a license issued under
642 this part, authorizing statutes, or applicable rules constitutes
643 permission for an appropriate inspection to verify the
644 information submitted on or in connection with the application.
645 (a) All inspections shall be unannounced, except as
646 specified in s. 408.806.
647 (b) Inspections for relicensure shall be conducted
648 biennially unless otherwise specified by authorizing statutes or
649 applicable rules.
650 (2) Inspections conducted in conjunction with certification
651 may be accepted in lieu of a complete licensure inspection.
652 However, a licensure inspection may also be conducted to review
653 any licensure requirements that are not also requirements for
654 certification.
655 (3) The agency shall have access to and the licensee shall
656 provide copies of all provider records required during an
657 inspection at no cost to the agency.
658 (4)(a) Each licensee shall maintain as public information,
659 available upon request, records of all inspection reports
660 pertaining to that provider that have been filed by the agency
661 unless those reports are exempt from or contain information that
662 is exempt from s. 119.07(1) and s. 24(a), Art. I of the State
663 Constitution or is otherwise made confidential by law. Effective
664 October 1, 2006, copies of such reports shall be retained in the
665 records of the provider for at least 3 years following the date
666 the reports are filed and issued, regardless of a change of
667 ownership.

668 (b) A licensee shall, upon the request of any person who
669 has completed a written application with intent to be admitted by
670 such provider, any person who is a client of such provider, or
671 any relative, spouse, or guardian of any such person, furnish to
672 the requester a copy of the last inspection report pertaining to
673 the licensed provider that was issued by the agency or by an
674 accrediting organization if such report is used in lieu of a
675 licensure inspection.
676 408.812 Unlicensed activity.--
677 (1) A person or entity may not offer or advertise services
678 that require licensure as defined by this part, authorizing
679 statutes, or applicable rules to the public without obtaining a
680 valid license from the agency. A licenseholder may not advertise
681 or hold out to the public that he or she holds a license for
682 other than that for which he or she actually holds the license.
683 (2) The operation or maintenance of an unlicensed provider
684 or the performance of any services that require licensure without
685 proper licensure is a violation of this part and authorizing
686 statutes. Unlicensed activity constitutes harm that materially
687 affects the health, safety, and welfare of clients. The agency or
688 any state attorney may, in addition to other remedies provided in
689 this part, bring an action for an injunction to restrain such
690 violation, or to enjoin the future operation or maintenance of
691 the unlicensed provider or the performance of any services in
692 violation of this part and authorizing statutes, until compliance
693 with this part, authorizing statutes, and agency rules has been
694 demonstrated to the satisfaction of the agency.
695 (3) It is unlawful for any person or entity to own,
696 operate, or maintain an unlicensed provider. If after receiving

697 notification from the agency, such person or entity fails to
698 cease operation and apply for a license under this part and
699 authorizing statutes, the person or entity shall be subject to
700 penalties as prescribed by authorizing statutes and applicable
701 rules. Each day of continued operation is a separate offense.
702 (4) Any person or entity that fails to cease operation
703 after agency notification may be fined $1,000 for each day of
704 noncompliance.
705 (5) When a controlling interest or licensee has an interest
706 in more than one provider and fails to license a provider
707 rendering services that require licensure, the agency may revoke
708 all licenses and impose actions under s. 408.814 and a fine of
709 $1,000 per day, unless otherwise specified by authorizing
710 statutes, against each licensee until such time as the
711 appropriate license is obtained for the unlicensed operation.
712 (6) In addition to granting injunctive relief pursuant to
713 subsection (2), if the agency determines that a person or entity
714 is operating or maintaining a provider without obtaining a
715 license and determines that a condition exists that poses a
716 threat to the health, safety, or welfare of a client of the
717 provider, the person or entity is subject to the same actions and
718 fines imposed against a licensee as specified in this part,
719 authorizing statutes, and agency rules.
720 (7) Any person aware of the operation of an unlicensed
721 provider must report that provider to the agency.
722 408.813 Administrative fines.--As a penalty for any
723 violation of this part, authorizing statutes, or applicable
724 rules, the agency may impose an administrative fine. Unless the
725 amount or aggregate limitation of the fine is prescribed by

726 authorizing statutes or applicable rules, the agency may
727 establish criteria by rule for the amount or aggregate limitation
728 of administrative fines applicable to this part, authorizing
729 statutes, and applicable rules. Each day of violation constitutes
730 a separate violation and is subject to a separate fine. For fines
731 imposed by final order of the agency and not subject to further
732 appeal, the violator shall pay the fine plus interest at the rate
733 specified in s. 55.03 for each day beyond the date set by the
734 agency for payment of the fine.
735 408.814 Moratorium; emergency suspension.--
736 (1) The agency may impose an immediate moratorium or
737 emergency suspension as defined in s. 120.60 on any provider if
738 the agency determines that any condition related to the provider
739 or licensee presents a threat to the health, safety, or welfare
740 of a client.
741 (2) A provider or licensee, the license of which is denied
742 or revoked, may be subject to immediate imposition of a
743 moratorium or emergency suspension to run concurrently with
744 licensure denial, revocation, or injunction.
745 (3) A moratorium or emergency suspension remains in effect
746 after a change of ownership, unless the agency has determined
747 that the conditions that created the moratorium, emergency
748 suspension, or denial of licensure have been corrected.
749 (4) When a moratorium or emergency suspension is placed on
750 a provider or licensee, notice of the action shall be posted and
751 visible to the public at the location of the provider until the
752 action is lifted.
753 408.815 License or application denial; revocation.--
754 (1) In addition to the grounds provided in authorizing

755 statutes, grounds that may be used by the agency for denying and
756 revoking a license or change of ownership application include any
757 of the following actions by a controlling interest:
758 (a) False representation of a material fact in the license
759 application or omission of any material fact from the
760 application.
761 (b) An intentional or negligent act materially affecting
762 the health or safety of a client of the provider.
763 (c) A violation of this part, authorizing statutes, or
764 applicable rules.
765 (d) A demonstrated pattern of deficient performance.
766 (e) The applicant, licensee, or controlling interest has
767 been or is currently excluded, suspended, or terminated from
768 participation in the state Medicaid program, the Medicaid program
769 of any other state, or the Medicare program.
770 (2) If a licensee lawfully continues to operate while a
771 denial or revocation is pending in litigation, the licensee must
772 continue to meet all other requirements of this part, authorizing
773 statutes, and applicable rules and must file subsequent renewal
774 applications for licensure and pay all licensure fees. The
775 provisions of ss. 120.60(1) and 408.806(3)(c) shall not apply to
776 renewal applications filed during the time period in which the
777 litigation of the denial or revocation is pending until that
778 litigation is final.
779 (3) An action under s. 408.814 or denial of the license of
780 the transferor may be grounds for denial of a change of ownership
781 application of the transferee.
782 408.816 Injunctions.--
783 (1) In addition to the other powers provided by this part,

784 authorizing statutes, and applicable rules, the agency may
785 institute injunction proceedings in a court of competent
786 jurisdiction to:
787 (a) Restrain or prevent the establishment or operation of a
788 provider that does not have a license or is in violation of any
789 provision of this part, authorizing statutes, or applicable
790 rules. The agency may also institute injunction proceedings in a
791 court of competent jurisdiction when a violation of this part,
792 authorizing statutes, or applicable rules constitutes an
793 emergency affecting the immediate health and safety of a client.
794 (b) Enforce the provisions of this part, authorizing
795 statutes, or any minimum standard, rule, or order issued or
796 entered into pursuant thereto when the attempt by the agency to
797 correct a violation through administrative sanctions has failed
798 or when the violation materially affects the health, safety, or
799 welfare of clients or involves any operation of an unlicensed
800 provider.
801 (c) Terminate the operation of a provider when a violation
802 of any provision of this part, authorizing statutes, or any
803 standard or rule adopted pursuant thereto exists that materially
804 affects the health, safety, or welfare of a client.
805
806 Such injunctive relief may be temporary or permanent.
807 (2) If action is necessary to protect clients of providers
808 from immediate, life-threatening situations, the court may allow
809 a temporary injunction without bond upon proper proofs being
810 made. If it appears by competent evidence or a sworn,
811 substantiated affidavit that a temporary injunction should be
812 issued, the court, pending the determination on final hearing,

813 shall enjoin the operation of the provider.
814 408.817 Administrative proceedings.--Administrative
815 proceedings challenging agency licensure enforcement action shall
816 be reviewed on the basis of the facts and conditions that
817 resulted in the agency action.
818 408.818 Health Care Trust Fund.--Unless otherwise
819 prescribed by authorizing statutes, all fees and fines collected
820 under this part, authorizing statutes, and applicable rules shall
821 be deposited into the Health Care Trust Fund, created in s.
822 408.16, and used to pay the costs of the agency in administering
823 the provider program paying the fees or fines.
824 408.819 Rules.--The agency is authorized to adopt rules as
825 necessary to administer this part. Any licensed provider that is
826 in operation at the time of adoption of any applicable rule under
827 this part or authorizing statutes shall be given a reasonable
828 time under the particular circumstances, not to exceed 6 months
829 after the date of such adoption, within which to comply with such
830 rule, unless otherwise specified by rule.
831 408.820 Exemptions.--Except as prescribed in authorizing
832 statutes, the following exemptions shall apply to specified
833 requirements of this part:
834 (1) Laboratories authorized to perform testing under the
835 Drug-Free Workplace Act, as provided under ss. 112.0455 and
836 440.102, are exempt from s. 408.810(5)-(10).
837 (2) Birth centers, as provided under chapter 383, are
838 exempt from s. 408.810(7)-(10).
839 (3) Abortion clinics, as provided under chapter 390, are
840 exempt from s. 408.810(7)-(10).
841 (4) Crisis stabilization units, as provided under parts I

842 and IV of chapter 394, are exempt from s. 408.810(8)-(10).
843 (5) Short-term residential treatment facilities, as
844 provided under parts I and IV of chapter 394, are exempt from s.
845 408.810(8)-(10).
846 (6) Residential treatment facilities, as provided under
847 part IV of chapter 394, are exempt from s. 408.810(8)-(10).
848 (7) Residential treatment centers for children and
849 adolescents, as provided under part IV of chapter 394, are exempt
850 from s. 408.810(8)-(10).
851 (8) Hospitals, as provided under part I of chapter 395, are
852 exempt from s. 408.810(7)-(9).
853 (9) Ambulatory surgical centers, as provided under part I
854 of chapter 395, are exempt from s. 408.810(7)-(10).
855 (10) Mobile surgical facilities, as provided under part I
856 of chapter 395, are exempt from s. 408.810(7)-(10).
857 (11) Private review agents, as provided under part I of
858 chapter 395, are exempt from ss. 408.806(7), 408.810, and
859 408.811.
860 (12) Health care risk managers, as provided under part I of
861 chapter 395, are exempt from ss. 408.806(7), 408.810, and
862 408.811.
863 (13) Nursing homes, as provided under part II of chapter
864 400, are exempt from s. 408.810(7).
865 (14) Assisted living facilities, as provided under part III
866 of chapter 400, are exempt from s. 408.810(10).
867 (15) Home health agencies, as provided under part IV of
868 chapter 400, are exempt from s. 408.810(10).
869 (16) Nurse registries, as provided under part IV of chapter
870 400, are exempt from s. 408.810(6) and (10).

871 (17) Companion services or homemaker services providers, as
872 provided under part IV of chapter 400, are exempt from s.
873 408.810(6)-(10).
874 (18) Adult day care centers, as provided under part V of
875 chapter 400, are exempt from s. 408.810(10).
876 (19) Adult family-care homes, as provided under part VII of
877 chapter 400, are exempt from s. 408.810(7)-(10).
878 (20) Homes for special services, as provided under part
879 VIII of chapter 400, are exempt from s. 408.810(7)-(10).
880 (21) Transitional living facilities, as provided under part
881 VIII of chapter 400, are exempt from s. 408.810(7)-(10).
882 (22) Prescribed pediatric extended care centers, as
883 provided under part IX of chapter 400, are exempt from s.
884 408.810(10).
885 (23) Home medical equipment providers, as provided under
886 part X of chapter 400, are exempt from s. 408.810(10).
887 (24) Intermediate care facilities for persons with
888 developmental disabilities, as provided under part XI of chapter
889 400, are exempt from s. 408.810(7).
890 (25) Health care services pools, as provided under part XII
891 of chapter 400, are exempt from s. 408.810(6)-(10).
892 (26) Health care clinics, as provided under part XIII of
893 chapter 400, are exempt from ss. 408.809 and 408.810(1), (6),
894 (7), and (10).
895 (27) Clinical laboratories, as provided under part I of
896 chapter 483, are exempt from s. 408.810(5)-(10).
897 (28) Multiphasic health testing centers, as provided under
898 part II of chapter 483, are exempt from s. 408.810(5)-(10).
899 (29) Organ and tissue procurement agencies, as provided

900 under chapter 765, are exempt from s. 408.810(5)-(10).
901 Section 6. Paragraph (b) of subsection (1) of section
902 400.801, Florida Statutes, is amended to read:
903 400.801 Homes for special services.--
904 (1) As used in this section, the term:
905 (b) "Home for special services" means a site licensed by
906 the agency prior to January 1, 2006, where specialized health
907 care services are provided, including personal and custodial
908 care, but not continuous nursing services.
909 Section 7. Subsections (1) and (3) of section 408.831,
910 Florida Statutes, are amended to read:
911 408.831 Denial, suspension, or revocation of a license,
912 registration, certificate, or application.--
913 (1) In addition to any other remedies provided by law, the
914 agency may deny each application or suspend or revoke each
915 license, registration, or certificate of entities regulated or
916 licensed by it:
917 (a) If the applicant, licensee, or a licensee subject to
918 this part which shares a common controlling interest with the
919 applicant ~~registrant, or certificateholder, or, in the case of a~~
920 ~~corporation, partnership, or other business entity, if any~~
921 ~~officer, director, agent, or managing employee of that business~~
922 ~~entity or any affiliated person, partner, or shareholder having~~
923 ~~an ownership interest equal to 5 percent or greater in that~~
924 ~~business entity,~~ has failed to pay all outstanding fines, liens,
925 or overpayments assessed by final order of the agency or final
926 order of the Centers for Medicare and Medicaid Services, not
927 subject to further appeal, unless a repayment plan is approved by
928 the agency; or

929 (b) For failure to comply with any repayment plan.
930 (3) This section provides standards of enforcement
931 applicable to all entities licensed or regulated by the Agency
932 for Health Care Administration. This section controls over any
933 conflicting provisions of chapters 39, ~~381,~~ 383, 390, 391, ~~393,~~
934 394, 395, 400, 408, 468, 483, and 765 ~~641~~ or rules adopted
935 pursuant to those chapters.
936 Section 8. In case of conflict between the provisions of
937 part II of chapter 408, Florida Statutes, and the authorizing
938 statutes governing the licensure of health care providers by the
939 Agency for Health Care Administration found in s. 112.0455 and
940 chapters 383, 390, 394, 395, 400, 440, 483, and 765, Florida
941 Statutes, the provisions of part II of chapter 408, Florida
942 Statutes, shall prevail.
943 Section 9. All provisions that apply to the entities
944 specified in s. 408.802, Florida Statutes, as created by this
945 act, in effect on October 1, 2006, that provide for annual
946 licensure fees are hereby adjusted to provide for biennial
947 licensure fees with a corresponding doubling of the amount.
948 Section 10. The Legislature recognizes that there is a need
949 to conform the Florida Statutes to the policy decisions reflected
950 in this act and that there may be a need to resolve apparent
951 conflicts between any changes or additions to the authorizing
952 statutes, as defined in s. 408.803, Florida Statutes, or any
953 other legislation that has been or may be enacted during 2006 and
954 this chapter 408, Florida Statutes, as amended by this act.
955 Therefore, in the interim between this act becoming a law and the
956 2007 Regular Session of the Legislature or an earlier special
957 session addressing this issue, the Division of Statutory Revision

958 shall provide the relevant substantive committees of the Senate
959 and the House of Representatives with assistance, upon request,
960 to enable such committees to prepare draft legislation to conform
961 the Florida Statutes and any legislation enacted during 2006 to
962 the provisions of this act.
963 Section 11. For the purpose of staggering license
964 expiration dates, the Agency for Health Care Administration may
965 issue a license for less than a 2-year period to those providers
966 making the transition from annual to biennial licensure as
967 authorized in this act. The agency shall charge a prorated
968 licensure fee for this shortened period. This authority shall
969 expire September 30, 2008.
970 Section 12. This act shall take effect October 1, 2006.

PCB HCR 06-04

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: PCB HCR 06-04 Electronic Prescribing
SPONSOR(S): Health Care Regulation Committee
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
Orig. Comm.: Health Care Regulation Committee		Bell AJB	Mitchell
1)			
2)			
3)			
4)			
5)			

SUMMARY ANALYSIS

With rapid change in new information technologies the development of electronic prescribing practices is integral to the achievement of state and national goals for electronic medical records. Current regulations regarding written prescriptions are problematic for prescriptions electronically generated.

The Proposed Committee Bill (PCB) on Electronic Prescribing allows for the development and regulation of electronic prescribing practices and provides protections for consumers. It creates one new provision in state statute and amends four others.

The bill defines "records custodians" and provides that all those with access to medical or prescription records abide by confidentiality and disclosure requirements. The bill establishes information that must be contained in electronic prescriptions. The bill regulates the use of electronic prescribing software and forbids that such software interfere with prescribing decisions at the point of care, or direct practitioners toward choosing particular pharmacies. Finally, the bill provides mechanisms to ensure that patients receive brand name drugs, when such drugs are medically necessary, and not substitutes, when prescribed electronically.

According to the Department of Health, there is no fiscal impact to implement the provisions in this bill.

The effective date of the bill is upon becoming law.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Provide Limited Government – The bill removes regulatory barriers to streamline the process of prescribing prescription drugs electronically.

Safeguard Individual Liberty – The bill protects the rights of consumers and their health care providers to determine appropriate pharmaceuticals and purchase from pharmacies of their choice; and to guarantee the confidentiality of medical records and prescriptions.

B. EFFECT OF PROPOSED CHANGES:

PRESENT SITUATION

Florida law permits electronic prescriptions under chapter 456, F.S., and authorizes the regulation of the practice of pharmacy by the Florida Board of Pharmacy. Section 465.003(14), F.S., further defines "prescription" to be any order for drugs or medicinal supplies written or transmitted by any means of communication by a licensed practitioner and intended to be dispensed by a pharmacist. Prescriptions may be transmitted from practitioners to pharmacies orally or through writing; and pharmacies may transfer prescriptions by any means, including electronic, under specified conditions.

Medical Records

Currently only certain health care practitioners and their employers (if agreed by contract) are considered records owners and subject to limitations on the handling of patient medical records under s. 456.072, F.S. Other individuals who later come into possession of patient medical records are not subject to these limitations.

Legible Prescribing Law

The Legible Prescribing Law, codified in s. 456.42, F.S, requires that all written prescription drugs must:

- Be legibly printed or typed;
- Contain the name of the prescribing practitioner;
- Contain the name and strength of the drug, the quantity of the drug in both textual and numerical formats;
- Contain directions for use;
- Be dated and signed with the month written in textual letters; and
- Be signed by the prescribing practitioner on the day when issued.

In order to fill a written prescription, Florida law requires that the prescription be signed by the prescribing practitioner. This poses a problem for electronically generated prescriptions.

Generic Substitution

Currently, under s. 456.025, F.S., a pharmacist may substitute a generic drug for a brand name drug when any written prescription does not include the words, "MEDICALLY NECESSARY" written by the prescribing practitioner. It is technically difficult for the prescribing practitioner to write on electronically generated prescriptions.

Electronic prescribing is integral to the achievement of state and national goals for integrated electronic medical records. The bill creates one and amends four provisions in state statute for the development of electronic prescribing practices, the regulation of electronic prescribing software, and the protection of patient rights.

EFFECTS OF THE BILL

Definition of Records Custodian

The bill amends s. 456.057, F.S., to define "records custodian" and to require records custodians and records owners to maintain records and documents as provided under the confidentiality and disclosure requirements of this section. The bill provides that all those with access to medical or prescription records abide by confidentiality and disclosure requirements. According to the Department of Health (DOH), this helps address confidentiality concerns when patient medical records are abandoned by the practitioner. This provision is subject to enforcement by the Office of Attorney General through injunctive relief and fines of up to $5,000 per violation.

Requirements for Electronic Prescriptions

The bill amends s. 456.42, F.S., to provide requirements for prescriptions that are electronically generated and transmitted. The bill requires that the electronic prescription contain the name of the prescribing practitioner, name and strength of the drug prescribed, quantity of the drug prescribed in numerical format (in contrast to handwritten prescriptions that require both textual and numerical format), directions for use of the drug, date, and signature by practitioner only on the day issued. The signature may be in an electronic format as defined by s. 668.003(4).

Consumer Choice of Pharmacy

The bill creates s. 456.43, F.S., to regulate electronic prescribing software for the protection of consumers and patient's rights. As electronic prescribing becomes more prevalent it is necessary to protect consumer choice when choosing a pharmacy.This section provides restrictions and establishes that electronic prescribing software:

- Shall not interfere with patient's freedom to choose a pharmacy;
- Shall not attempt to influence, through economic incentives or otherwise, the prescribing decision of a physician at the "point of care"—the time that the practitioner or agent is in the act of prescribing a certain pharmaceutical or directing a patient to a certain pharmacy.
- Shall be permitted to show information regarding a payor's formulary as long as nothing is designed to preclude or make more difficult the act of the patient or physician selecting any particular pharmacy or pharmaceutical.

Protections against Generic Substitution of Brand Name Drugs

The bill amends s. 456.025, F.S., to provide mechanisms to ensure that patients receive brand name drugs and not generic substitutes, when brand name drugs are medically necessary. The bill ensures that a pharmacist may fill electronically generated prescriptions with the brand name drug if the prescription reflects that it is medically necessary without requiring the prescribing practitioner to write the words, "MEDICALLY NECESSARY."

The effective date of the bill is July 1, 2006.

BACKGROUND

Electronic prescribing (e-prescribing) utilizes computers and automated data systems rather than handwritten communications to generate prescriptions, and is the future standard practice in prescription writing. Although e-prescribing rates today vary between 5 percent and 18 percent for

physicians, usage is increasing[1] due to initiatives at the national and state levels, and because of independent efforts by health care providers and pharmacists. In June 2005, President Bush called for most Americans to have electronic health records[2] within ten years. The Florida Health Information Network was developed by the Agency for Health Care Administration (AHCA) to facilitate the development of a statewide privacy-protected health information infrastructure network as recommended by the Governor's Health Information Infrastructure Advisory Board. The program has received funding from the Florida Legislature to support personnel and grant programs aimed at developing regional health information exchanges and to encourage the use of electronic health records.[3] Electronic prescribing is an integral component in the fulfillment of these national and state goals.

Concerns with patient safety, the efficiency of care, and integrated medical records are the key objectives driving efforts for electronic prescribing. More than 4 billion prescriptions are written each year[4] and therefore even small improvements in the prescribing process will translate into significant healthcare cost and safety benefits. Studies suggest that the national savings from universal adoption of electronic prescribing systems could be as high as $27 billion, due to a combination of injury prevention, better utilization of drugs[5], and efficiency both at the point of care and subsequent to treatment.

Security Measures Used by Electronic Prescribing Networks

Currently, there are a number of methods through which electronic networks secure confidentiality and data integrity. These features include credentialing, where prescribers and pharmacies are enrolled in a network through access authorization; user ID and password for authentication and access to electronic prescribing software; the use of network-assigned electronic signatures; and the transmission of prescription messages through a private leased line or through the Internet using a virtual private network connection or protocol.[6]

Benefits of Electronic Prescribing

Reduction of potential errors of handwriting and transcription

The prescribing process is error-prone. Adverse drug events (ADE) are the 4th leading cause of death[7] and cost as much as $136 billion a year[8]. Among ADE's, 7,000 deaths a year are attributed to prescription error[9]. Causes of errors include illegible handwriting, wrong dosage, and the overlooking of dangerous drug-drug or drug-allergy interactions. Medication errors further account for 1 out of 131 ambulatory care deaths.[10] As a solution for a portion of these errors, computer-assisted prescriptions have been shown to cut errors by 70% over handwritten prescriptions.[11] In addition to improving the readability of scripts and the accuracy of transcription from the prescription to the pharmacy, a reduction in errors accomplished by electronic prescribing is due to information made available to doctors about the correct dosage, use instructions, and other aspects of the prescription. At the point of care, electronic prescribing systems can provide an overall medication management process by

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[1] Ferris, Nancy. 11/2/05. "CMS finalizes e-prescribing rules." *Government Health.* www.govhealthit.com/article91285-11-02-05-Web.
[2] According to the Florida Senate Interim Project 2006-135, "An electronic health record is a digital collection of information from a patient's medical history that may include diagnoses, prescribed medications, vital signs, immunizations, and personal characteristics."
[3] Agency for Health Care Administration press release, January 6, 2006; http://www.fdhc.state.fl.us/dhit/press_release.shtml.
[4] AllScripts analysis of e-prescribing at http://www.allscripts.com/slnsClnclnfo.aspx
[5] Agency for Healthcare Research and Quality. MEPS Highlights #11: Distribution of health care expenses, 1999.
[6] National Committee on Vital and Health Statistics. http://www.cdc.gov/nchs/data/ncvhs/nchvs50th.pdf
[7] Committee on Quality of Health Care in America: Institute of Medicine. "To err is human: building a safer health system." Washington, D.C.: National Academy Press, 2000.
[8] Lazarou, J., Pomeranz, B., Corey, PN. "Incidence of adverse drug reactions in hospitalized patients: a meta-analysis of prospective studies. *JAMA*. 1998; 279:1200-1205.
[9] Johnson, JA., Bootman, JL. "Drug-related morbidity and mortality: a cost-of-illness model." *Arch Intern Med.* 1995; 155:1949-1956.
[10] "Electronic Prescribing: Toward Maximum Value and Rapid Adoption." A report of the *Electronic Prescribing Initiative.* Washington, D.C., April 14, 2004.
[11] "HHS Accelerates Use of E-Prescribing and Electronic Health Records." *Press Release from the US Department of Health and Human Services.* 11/5/2005. http://biz.yahoo.com/prnews/051005/dcw035.html?.v=29&printer=1.

performing checks against the patient's current medications, duplicate therapies, medical history, diagnoses, body weight, age, and more. The system then alerts the physician if problems are found.

Integration of prescription information into the electronic medical record

Electronic prescribing can further contribute to the integration of the prescription into a patient's consolidated medical record. Access to information about a patient's formulary can guide physicians to consider formulary-based drug coverage, including on-formulary alternatives and co-pay information. By checking with healthcare formularies at point-of-care, generic substitutions and generic first-line therapy choices are encouraged, thus reducing patient costs.

Efficiency

Electronic prescribing increases efficiency for physicians, patients, and pharmacists. At the point-of-care, electronic prescribing saves time for the physician's staff. For many practitioners, it is quicker to e-prescribe than to have a nurse spend time calling in a refill for the drug.[12] Physicians can expect fewer callbacks from pharmacies to clarify prescription details and refill renewal authorizations that are completed in a fraction of the time, so that more time can be dedicated to patient care and other activities.[13] A 2003 survey of Boston area physicians found that 88 percent of those surveyed reported that they and their staff spend almost one-third of their time responding to phone calls from pharmacies regarding prescriptions, and that these call-backs interrupt office flow and reduce productivity related to chart-pulls, re-filing charts, faxing prescriptions, and so on.[14] For patients, electronic prescribing means eliminated or significantly reduced waiting times at pharmacies.[15] Benefits in efficiency for pharmacists are also significant. Because all necessary prescription information is transmitted and received, more time can be spent with customers. Electronic prescribing improves record keeping, reduces phone calls and faxes, and more readily alerts pharmacists to possible drug contraindications within a patient's file. Approximately 900 million prescription-related calls are made annually, for refills, questions and clarifications; and electronic prescribing reduces the expense of this for all parties.[16]

Protecting Against Abuses of Electronic Prescribing

Although electronic prescribing does have the demonstrated potential to save lives, time, and money, unsecured systems could lead to forgery, fraud, unfair trade practices, or the loss of patient confidentiality. In developing electronic programs it is critical that precautions be taken to expand consumer protection. Among these measures, the patient's right to choose medications and pharmacies should be protected; and therefore, software used in electronic prescribing should be prevented from directing the practitioner toward specific medications or pharmacies through pop-up ads or marketing of any other kind. Patient confidentiality must also be protected; and therefore, electronic data services ("records custodians") should be bound by the same specified requirements for confidentiality and disclosure as pharmacies and physicians already are. It is also important that electronic prescriptions include the same level of information as paper prescriptions; detailing patient and physician names, drug name and strength, quantity and directions for use of the drug, date, electronic signature, and an option to prevent automatic substitution of brand name drugs with generic drugs in cases where the brand name drug is medically necessary for the patient.

Expansion of Electronic Prescribing in Medicare and Florida Medicaid

Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, electronic-prescribing is optional for physicians and pharmacies. However, starting on January 1, 2006, drugs

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[12] Baldwin, Gary. 10/17/2005. "E-prescribing eliminates wait." *Health Leaders.* http://www..healthleaders.com/news/print.php?contentid=73529.

[13] Institute of Medicine, Center for Information Technology Leadership, in Walgreens presentation on e-prescribing.

[14] "Boston Area Physicians Embrace E-Prescribing Technology as a Tool To Improve Healthcare". Medco Health Solutions, Inc. – News and Pressroom article on 2/7/2003. http://www.corporate-ir.net/ireye/ir_site.zhtml?ticker=MHS&script=410&layout=-6&item_id=442064

[15] Baldwin, Gary. 10/17/2005. "E-prescribing eliminates wait." *Health Leaders.* http://www..healthleaders.com/news/print.php?contentid=73529.

[16] Healthcare Information and Management Systems Society at http://www.himss.org/ASP/topics_eprescribing.asp.

covered under Medicare Part D are required to support electronic prescribing.[17] The Act has also called for the creation of a grant program that supports the implementation and adoption of electronic prescribing technology beginning in 2007.

The Florida Medicaid program has used an electronic prescribing system since the summer of 2002. Three thousand of the state's highest prescribing (by volume) physicians were given interactive handheld computers that load information on drugs, formularies, and the previous 100 days of prescription history. This represents physicians writing 80 percent of all Medicaid prescriptions in FL, which involves approximately 25 million transactions per year.[18] Florida Medicaid program staff estimate that about $2 million is saved each month by the use of the electronic prescribing system, and that the program has demonstrated the potential for electronic prescribing to save lives as well.[19]

C. SECTION DIRECTORY:

Section 1. – Amends s. 456.057, F.S., to provide definitions for "records custodian" and to require records custodians and records owners to maintain records and documents as provided under the confidentiality and disclosure requirements of the section.

Section 2. – Amends s. 456.42, F.S., to provide requirements for prescriptions that are electronically generated and transmitted.

Section 3. – Creates s. 456.43, F.S., to regulate electronic prescribing software for the protection of consumers and patient's rights.

Section 4. – Amends s. 456.025, F.S., to prevent the substitution of generic drugs when brand name drugs are medically necessary, when a prescription is electronically transmitted and generated.

Section 5. – Provides an effective date of July 1, 2006.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

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[17] For complete standards see "Government announces ePRESCRIPTION standards for drug plans" by Caroline Broder, Healthcare IT News. 11/2/2005. www.healthcareitnews.com/NewsArticleView.aspz?ContentID=3940.
[18] Roop, Liz. 2005. "State by state programs" eMPOWEPrescription. www.gsm.com, or 813-258-4747.
[19] The Florida Senate Interim Project Report 2006-135.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   This bill does not require counties or municipalities to spend funds or take action requiring the expenditure of funds. This bill does not reduce the percentage of state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenue.

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

The Department of Health has sufficient rulemaking authority to implement the provisions in the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

1 A bill to be entitled
2 An act relating to medical records; amending s. 456.057,
3 F.S.; providing definitions; requiring a health care
4 practitioner's employer who is a records owner and a
5 records custodian to comply with specified requirements
6 for confidentiality and disclosure; amending s. 456.42,
7 F.S.; providing requirements for prescriptions of
8 medicinal drugs by health care practitioners that are
9 electronically generated and transmitted; creating s.
10 456.43, F.S.; regulating electronic prescribing for
11 medicinal drugs; providing restrictions for electronic
12 prescribing software; providing definitions; authorizing
13 electronic prescribing software to show information
14 regarding a payor's formulary under certain circumstances;
15 amending s. 465.025, F.S.; specifying requirements for a
16 prescriber to prevent generic substitution for brand name
17 drugs when a prescription is electronically transmitted
18 and generated; amending s. 381.028, F.S.; correcting a
19 cross-reference; providing an effective date.
20
21 Be It Enacted by the Legislature of the State of Florida:
22
23 Section 1. Present subsections (3) through (19) of section
24 456.057, Florida Statutes, are renumbered as subsections (5)
25 through (21), respectively, and new subsections (3) and (4) are
26 added to that section to read:
27 456.057 .Ownership and control of patient records; report or
28 copies of records to be furnished.--
29 (3) As used in this section, the term "records custodian"

30 means any person or entity that:
31 (a) Maintains documents that are authorized in subsection
32 (2); or
33 (b) Obtains medical records from a records owner.
34 (4) Any health care practitioner's employer who is a
35 records owner and any records custodian shall maintain records or
36 documents as provided under the confidentiality and disclosure
37 requirements of this section.
38 Section 2. Section 456.42, Florida Statutes, is amended to
39 read:
40 456.42 Written prescriptions for medicinal drugs.--A
41 written prescription for a medicinal drug issued by a health care
42 practitioner licensed by law to prescribe such drug must be
43 legibly printed or typed so as to be capable of being understood
44 by the pharmacist filling the prescription; must contain the name
45 of the prescribing practitioner, the name and strength of the
46 drug prescribed, the quantity of the drug prescribed in both
47 textual and numerical formats, and the directions for use of the
48 drug; must be dated with the month written out in textual
49 letters; and must be signed by the prescribing practitioner on
50 the day when issued. However, a prescription that is
51 electronically generated and transmitted must contain the name of
52 the prescribing practitioner, the name and strength of the drug
53 prescribed, the quantity of the drug prescribed in numerical
54 format, and the directions for use of the drug and must be dated
55 and signed by the prescribing practitioner only on the day
56 issued, which signature may be in an electronic format as defined
57 by s. 668.003(4).
58 Section 3. Section 456.43, Florida Statutes, is created to

59 read:
60 456.43 Electronic prescribing for medicinal drugs.--
61 (1) Electronic prescribing shall not interfere with a
62 patient's freedom to choose a pharmacy.
63 (2) Electronic prescribing software shall not use any means
64 or permit any other person to use any means, including, but not
65 limited to, advertising, instant messaging, and pop-up ads, to
66 influence or attempt to influence, through economic incentives or
67 otherwise, the prescribing decision of a physician at the point
68 of care. Such means shall not be triggered or in specific
69 response to the input, selection, or act of a physician or his or
70 her agent in prescribing a certain pharmaceutical or directing a
71 patient to a certain pharmacy.
72 (a) The term "prescribing decision" means a physician's
73 decision to prescribe a certain pharmaceutical or direct a
74 patient to a certain pharmacy.
75 (b) The term "point of care" means the time that a
76 physician or his or her agent is in the act of prescribing a
77 certain pharmaceutical or directing a patient to a certain
78 pharmacy.
79 (3) Electronic prescribing software may show information
80 regarding a payor's formulary as long as nothing is designed to
81 preclude or make more difficult the act of a physician or patient
82 selecting any particular pharmacy or pharmaceutical.
83 Section 4. Subsection (2) of section 465.025, Florida
84 Statutes, is amended to read:
85 465.025 Substitution of drugs.--
86 (2) A pharmacist who receives a prescription for a brand
87 name drug shall, unless requested otherwise by the purchaser,

88 substitute a less expensive, generically equivalent drug product
89 that is:
90 (a) Distributed by a business entity doing business, and
91 subject to suit and service of legal process, in the United
92 States; and
93 (b) Listed in the formulary of generic and brand name drug
94 products as provided in subsection (5) for the brand name drug
95 prescribed,
96
97 unless the prescriber writes the words "MEDICALLY NECESSARY," in
98 her or his own handwriting, on the face of a written
99 prescription; ~~or~~ unless, in the case of an oral prescription, the
100 prescriber expressly indicates to the pharmacist that the brand
101 name drug prescribed is medically necessary; or unless, in the
102 case of a prescription that is electronically generated and
103 transmitted, the prescriber makes an overt act when transmitting
104 the prescription to indicate that the brand name drug prescribed
105 is medically necessary. When done in conjunction with the
106 electronic transmission of the prescription, the prescriber's
107 overt act indicates to the pharmacist that the brand name drug
108 prescribed is medically necessary.
109 Section 5. Paragraph (c) of subsection (7) of section
110 381.028, Florida Statutes, is amended to read:
111 381.028 Adverse medical incidents.--
112 (7) PRODUCTION OF RECORDS.--
113 (c)1. Fees charged by a health care facility for copies of
114 records requested by a patient under s. 25, Art. X of the State
115 Constitution may not exceed the reasonable and actual cost of
116 complying with the request, including a reasonable charge for the

117 staff time necessary to search for records and prevent the
118 disclosure of the identity of any patient involved in the adverse
119 medical incident through redaction or other means as required by
120 the Health Insurance Portability and Accountability Act of 1996
121 or its implementing regulations. The health care facility may
122 require payment, in full or in part, before acting on the records
123 request.
124 2. Fees charged by a health care provider for copies of
125 records requested by a patient under s. 25, Art. X of the State
126 Constitution may not exceed the amount established under s.
127 456.057(18) ~~(16)~~, which may include a reasonable charge for the
128 staff time necessary to prevent the disclosure of the identity of
129 any patient involved in the adverse medical incident through
130 redaction or other means as required by the Health Insurance
131 Portability and Accountability Act of 1996 or its implementing
132 regulations. The health care provider may require payment, in
133 full or in part, before acting on the records request.
134 Section 6. This act shall take effect July 1, 2006.

Addendum

Health Care Regulation Committee

Wednesday, March 15, 2006
8:45 AM - 11:00 AM
212 Knott Building

Allan G. Bense
Speaker

Rene Garcia
Chair

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1A (for drafter's use only)

Bill No. **HB 181**

COUNCIL/COMMITTEE ACTION

ADOPTED	__	(Y/N)
ADOPTED AS AMENDED	__	(Y/N)
ADOPTED W/O OBJECTION	__	(Y/N)
FAILED TO ADOPT	__	(Y/N)
WITHDRAWN	__	(Y/N)
OTHER	____	

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1 Council/Committee hearing bill: Health Care Regulation
2 Representative(s) Hays offered the following:
3
4 **Amendment to Amendment (1) by Representative Hays (with**
5 **directory and title amendments)**
6 Remove line(s) 47 and insert:
7
8 nurse licensed pursuant to chapter 464 or a physician licensed
9 pursuant to chapter 458 or chapter 459.

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1 (for drafter's use only)

Bill No. **HB 881**

COUNCIL/COMMITTEE ACTION

ADOPTED	__	(Y/N)
ADOPTED AS AMENDED	__	(Y/N)
ADOPTED W/O OBJECTION	__	(Y/N)
FAILED TO ADOPT	__	(Y/N)
WITHDRAWN	__	(Y/N)
OTHER	____	

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1 Council/Committee hearing bill: Health Care Regulation
2 Representative(s) Flores offered the following:
3
4 **Amendment (with directory and title amendments)**
5 Remove everything after the enacting clause and insert:
6
7 Section 1. Section 458.3124, Florida Statutes, is amended
8 to read:
9 458.3124 Restricted license; certain experienced foreign-
10 trained physicians.--
11 (1) A person who was trained in a medical school that is
12 listed in the World Directory of Medical Schools published by
13 the World Health Organization and is located in a country other
14 than the United States, Canada, or Puerto Rico may apply to take
15 Step III of the United States Medical Licensing Examination, if
16 the person:
17 (a) Legally practiced medicine for at least 5 years in the
18 country in which the school is located;
19 (b) Has passed Steps I and II <u>to include the clinical</u>
20 <u>knowledge and clinical skills components</u> of the United States
21 Medical Licensing Examination;

22 (c) Is certified by the Educational Commission for Foreign
23 Medical Graduates as qualified for a restricted license to
24 practice medicine;
25 (d) Is not subject to discipline, investigation, or
26 prosecution in any jurisdiction for acts that threaten the
27 public health, safety, or welfare or violate chapter 456 or this
28 chapter; and
29 (e) Has been a resident of this state at least 5 years
30 ~~since July 1, 1996~~.
31 (2) A person applying for licensure under this section
32 must submit to the Department of Health ~~on or before December~~
33 ~~31, 2000:~~
34 ~~(a) A~~ a completed application and documentation required
35 by the Board of Medicine to prove compliance with subsection
36 (1)~~; and~~.
37 ~~(b) A nonrefundable application fee not to exceed $500 and~~
38 ~~a nonrefundable examination fee not to exceed $300 plus the~~
39 ~~actual cost to purchase and administer the examination.~~
40 ~~(3) A person applying under this section may take the~~
41 ~~examination a maximum of 5 times within 5 years.~~
42 (3)~~(4)~~ A restricted licensee under this section must
43 practice under the supervision of a licensee approved by the
44 board, with the first year of licensure under direct supervision
45 and the second year in community service under indirect
46 supervision, including practicing with organizations that serve
47 indigent populations, such as s. 501(c)(3) agencies, public
48 health units, prisons, or other organizations approved by the
49 board.
50 (4)~~(5)~~ Notwithstanding s. 458.311(1)(f), a person who
51 successfully meets the requirements of this section and who

52 successfully passes Step III of the United States Medical
53 Licensing Examination is eligible for full licensure as a
54 physician.
55 (5) ~~(6)~~ The board shall adopt rules to implement this
56 section.
57 Section 2. Section 458.3126, Florida Statutes, is created
58 to read:
59 458.3126 International Medical Graduates.—
60 (1) International medical graduates, also referred to as
61 foreign trained physicians, are individuals who have trained in
62 an allopathic foreign medical school that is listed in the
63 International Medical Education Directory and is located outside
64 the United States, Canada, or Puerto Rico. Pursuant to s.
65 456.021(1), it is the intent to use foreign-speaking Florida
66 residents that are duly qualified to become actively qualified
67 in their profession so that all people of this state may receive
68 better services. There are several avenues for international
69 medical graduates to practice medicine in the state.
70 (2) The intent of this section is to provide a summary of
71 the different avenues available for international medical
72 graduates, these are not inclusive. It is recommended that
73 individuals read the entire referenced section of statute to
74 assure full compliance.
75 (a) FULL LICENSURE.--An international medical graduate
76 must have a valid Educational Commission for Foreign Medical
77 Graduates (ECFMG) certificate; complete a 2-year approved
78 residency in one specialty area and obtain a passing score on
79 all parts of the licensure examination of the United States
80 Medical Licensing Examination (USMLE), pursuant to s. 458.311.

81 (b) RESTRICTED LICENSURE.--An international medical
82 graduate may receive a restricted license and sit for Part III
83 of the USMLE examination if they have passed Part I and II of
84 the USMLE; is certified by the ECFMG; a resident of the state
85 for 5 years; practiced under the direct supervision of a board
86 approved licensed physician for the first year and the second
87 year under the indirect supervision of a physician in a
88 community service setting that serves the indigent population.
89 If the person passes Part III of the USMLE they are eligible for
90 full licensure, pursuant to s. 458.3124.
91 (c) Graduates of an international allopathic medical
92 school may practice in a hospital or teaching hospital as a
93 house physician. The registration application is renewable every
94 two years pursuant to s. 458.345.
95 (d) Visiting physicians may be issued a temporary
96 certificate under the following ss. 458.3135, 458.3137, and
97 458.3145.
98 Section 3. This act shall take effect July 1, 2006.
99
100
101 ========== T I T L E A M E N D M E N T ==========
102 Remove line(s) and insert:
103

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1 (for drafter's use only)

Bill No. **PCB HCR 06-02**

COUNCIL/COMMITTEE ACTION

ADOPTED	__	(Y/N)
ADOPTED AS AMENDED	__	(Y/N)
ADOPTED W/O OBJECTION	__	(Y/N)
FAILED TO ADOPT	__	(Y/N)
WITHDRAWN	__	(Y/N)
OTHER	____	

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1 Council/Committee hearing bill: Health Care Regulation
2 Representative(s) Garcia offered the following:
3
4 **Amendment (with directory and title amendments)**
5 Remove line(s) 325 and insert:
6
7 prior to the expiration of the current license. If the renewal
8 application and fee are received prior to license expiration,
9 the license shall not be deemed to have expired if the
10 expiration date of the license occurs during the agency's review
11 of the renewal application.

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HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 2 (for drafter's use only)

Bill No. **PCB HCR 06-02**

COUNCIL/COMMITTEE ACTION

ADOPTED	__	(Y/N)
ADOPTED AS AMENDED	__	(Y/N)
ADOPTED W/O OBJECTION	__	(Y/N)
FAILED TO ADOPT	__	(Y/N)
WITHDRAWN	__	(Y/N)
OTHER	____	

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1 Council/Committee hearing bill: Health Care Regulation
2 Representative(s) Garcia offered the following:
3
4 **Amendment (with directory and title amendments)**
5 Remove line(s) 415 and insert:
6
7 remain in effect until the agency determines that the grounds
8 for the restriction are corrected.

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HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 3 (for drafter's use only)

Bill No. **PCB HCR 06-02**

COUNCIL/COMMITTEE ACTION

ADOPTED	__	(Y/N)
ADOPTED AS AMENDED	__	(Y/N)
ADOPTED W/O OBJECTION	__	(Y/N)
FAILED TO ADOPT	__	(Y/N)
WITHDRAWN	__	(Y/N)
OTHER	____	

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1 Council/Committee hearing bill: Health Care Regulation
2 Representative(s) Garcia offered the following:
3
4 **Amendment (with directory and title amendments)**
5 Remove line(s) 454 and insert:
6
7 a result of a natural or manmade disaster. Upon agency approval,
8 the

000000