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HOUSE OF REPRESENTATIVES
COMMITTEE ON
HEALTH REGULATION
ANALYSIS

BILL #: HB 1873 (PCB HR 01-05)

RELATING TO: Health Care/Prevention of Medical Errors

SPONSOR(S): Committee on Health Regulation, Representative Farkas, and others

TIED BILL(S): HB 1871 (PCB HR 01-11)

ORIGINATING COMMITTEE(S)/COUNCIL(S)/COMMITTEE(S) OF REFERENCE:

(1) HEALTH REGULATION YEAS 10 NAYS 0
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I. SUMMARY:

This bill incorporates many of the recommendations of the Florida Commission on Excellence in Health Care relating to preventing medical errors through education of health care practitioners, facility personnel, and the public. It is a comprehensive bill that addresses all facets of health care delivery systems that could prevent errors as well as providing deterrents through enhanced penalties.

There is no fiscal impact to the state.

II. SUBSTANTIVE ANALYSIS:

A. DOES THE BILL SUPPORT THE FOLLOWING PRINCIPLES:

1.	Less Government	Yes [x]	No []	N/A []
2.	Lower Taxes	Yes []	No []	N/A [x]
3.	Individual Freedom	Yes []	No []	N/A [x]
4.	Personal Responsibility	Yes [x]	No []	N/A []
5.	Family Empowerment	Yes [x]	No []	N/A []

For any principle that received a "no" above, please explain:

B. PRESENT SITUATION:

The 2000 Legislature created the Florida Commission on Excellence in Health Care to facilitate the development of a comprehensive statewide strategy for improving the health care delivery system through meaningful reporting standards, data collection and review, and quality measurement.

The Legislature directed the commission to:

1. Identify existing data sources that evaluate the quality of care in Florida and collect, analyze, and evaluate this data.
2. Establish guidelines for data sharing and coordination.
3. Identify core sets of quality measures for standardized reporting by appropriate components of the health care continuum.
4. Recommend a framework for quality measurement and outcome reporting.
5. Develop quality measures that enhance and improve the ability to evaluate and improve care.
6. Make recommendations regarding research and development needed to advance quality measurement and reporting.
7. Evaluate regulatory issues relating to the pharmacy profession and recommend changes necessary to optimize patient safety.
8. Facilitate open discussion of a process to ensure that comparative information on health care quality is valid, reliable, comprehensive, understandable, and widely available in the public domain.
9. Sponsor public hearings to share information and expertise, identify "best practices," and recommend methods to promote their acceptance.

10. Evaluate current regulatory programs to determine what changes, if any, need to be made to facilitate patient safety.

11. Review public and private health care purchasing systems to determine if there are sufficient mandates and incentives to facilitate continuous improvement in patient safety.

12. Analyze how effective existing regulatory systems are in ensuring continuous competence and knowledge of effective safety practices.

13. Develop a framework for organizations that license, accredit, or credential health care practitioners and health care providers to more quickly and effectively identify unsafe practitioners and providers and to take action necessary to remove the unsafe practitioner or provider from practice or operation until such time as the practitioner or provider has proven safe to practice or operate.

14. Recommend procedures for development of a curriculum on patient safety and methods of incorporating such curriculum into training, licensure, and certification requirements.

15. Develop a framework for regulatory bodies to disseminate information on patient safety to health care practitioners, health care providers, and consumers through conferences, journal articles and editorials, newsletters, publications, and Internet websites.

16. Recommend procedures to incorporate recognized patient safety considerations into practice guidelines and into standards related to the introduction and diffusion of new technologies, therapies, and drugs.

17. Recommend a framework for development of community-based collaborative initiatives for error reporting and analysis and implementation of patient safety improvements.

18. Evaluate the role of advertising in promoting or adversely affecting patient safety.

19. Evaluate and make recommendations regarding the need for licensure of additional persons who participate in the delivery of health care to Floridians, including, but not limited to, surgical technologists and pharmacy technicians.

20. Evaluate the benefits and problems of the current disciplinary systems and make recommendations regarding alternatives and improvements.

The Legislature specified that the commission shall consist of the following membership: the secretary of the Department of Health, the secretary of the Agency for Health Care Administration, one representative each from the Board of Medicine, the Board of Osteopathic Medicine, the Board of Pharmacy, the Board of Dentistry, the Board of Nursing, the Florida Dental Association, the Florida Medical Association, the Florida Osteopathic Medical Association, the Florida Academy of Physician Assistants, the Florida Chiropractic Association, the Florida Chiropractic Society, the Florida Podiatric Medical Association, the Florida Society of Ambulatory Surgical Centers, the Florida Nurses Association, the Florida Organization of Nursing Executives, the Florida Pharmacy Association, the Florida Society of Health System Pharmacists, Inc., the Florida Hospital Association, the Association of Community Hospitals and Health Systems of Florida, Inc., the Florida League of Health Systems, the Florida Health Care Risk Management Advisory Council, the Florida Health Care Association, the Florida Statutory Teaching Hospital Council, Inc., the Florida Statutory Rural Hospital Council, the Florida Association of Homes for the Aging, the Florida Society for Respiratory Care; one licensed clinical laboratory director, two health lawyers, one representative of the medical malpractice professional liability insurance industry, two

representatives of the health insurance industry, five consumer advocates, two legislators, and one representative of a Florida medical school.

The Legislature further specified that:

1. The commission membership must reflect the geographic and demographic diversity of the state;

2. The secretaries of the Department of Health and the Agency for Health Care Administration shall jointly chair the commission;

3. Subcommittees shall be formed by the joint chairs, as needed, to make recommendations to the full commission;

4. All votes on work products of the commission shall be at the full commission level; and

5. All recommendations to the Governor, the President of the Senate, and the Speaker of the House of Representatives must pass by a two-thirds vote of the full commission.

The Legislature directed that a report be submitted to the Governor, the President of the Senate, and the Speaker of the House of Representatives no later than February 1, 2001. The report contained a summary of the commission's recommendations. Further information can be found at myflorida.com@doh.state.fl.us. Copies of the Report are available on line at http://www.floridahealthstat.com.

The Introduction to the Commission on Excellence in Health Care Report states:

> "Building a safer health care system means designing processes of care to ensure that patients are safe from preventable injury. Once agreement has been reached on a particular course of treatment, patients should have the reasonable assurance that it will proceed correctly and safely so they have the best chance possible of achieving the desired outcome. As health care and the system that delivers it become more complex, the opportunity for errors increases. Establishing systems that will promote patient safety and error reduction will require a concerted effort by all components of the health care delivery system, including practitioners and providers, health care entities, purchasers, consumers, regulators, and policy-makers. Traditional clinical boundaries and a culture of blame must be changed so that all members of the health care team are encouraged and supported in reporting and correcting problems. But more importantly, safety systems must be systematically integrated throughout the health care delivery system.
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> "This report describes the efforts of the members of the legislatively appointed Florida Commission on Excellence in Health Care to examine the quality of Florida's health care delivery system. The commission focused its attention on quality of health care issues, patient safety and the reduction of health care errors, as directed by the 2000 Legislature. The Legislature recognized that Florida's health care delivery system is one of the largest and most complex industries in the state, and that additional focus on strengthening it by eliminating avoidable mistakes in the diagnosis and treatment of patients holds tremendous promise to increase the quality of health care services available to residents and visitors.
>
> "This report proposes a comprehensive strategy for addressing broad issues of quality health care including reducing health care errors and improving patient safety. The strategy includes market and regulatory initiatives as well as public and private efforts, including enhanced

consumer involvement. To address the issue of additional marketplace incentives, the commission proposed that quality performance be recognized and rewarded. Both health care facilities and practitioners would be recognized publicly as quality providers.

"Commission members opined that the increased publication of performance data would allow consumers to use the information to make health care decisions based on records of quality. The commission agreed that a basic level of safety should be assured for all health care consumers, and that an efficient and effective regulatory component is critical to accomplishing this goal. However, the commission also recognized that regulation alone would not be sufficient to reduce health care errors and improve patient safety. The commission indicated strongly that in addition to the existing mandatory reporting system, a voluntary, incentive-driven, non-punitive system, for quality improvement purposes should be created to encourage reporting of errors that could result in injury. Moreover, these records should be redacted of names and used as a learning tool by health care practitioners, providers, and the public.

The commission made an attempt to address all aspects of the health care continuum to ensure that, in the future, health care performance is measured and monitored with a focus on the patient rather than the setting within which treatment occurs. Throughout their deliberations, commission members remained singularly focused on developing a patient-centered health care improvement plan that relies on valid, reliable, and accurate data to establish short-term as well as longer-term goals and objectives. The commission held a total of seven meetings, during which fourteen hours of public testimony was heard. Three subcommittees were formed to address the areas of:

- Regulation
- Education/Best Practices
- Quality Measurement/Data Collection and Reporting"

The Commission made a lot of recommendations for the Department of Health and the Agency for Health Care Administration to implement, as well as to the Legislature for those issues requiring statutory change. Among the findings and recommendations of the Commission Report are several statutory changes, including the following proposals to:

- "Expand the content of periodic regulatory board newsletters to include articles on disciplinary cases resulting from health care errors." (p. 13 and 21, unanimous).
- "Compile and integrate data on health care errors." (p. 14 and 25, unanimous).
- "Identify statutes that require revisions." (p. 14).
- "Corrective actions taken following adverse incidents should be disseminated in a periodic advisory to reporting entities so loss preventions systems can be implemented that will result in improved patient care." (p. 14 and 21, unanimous).
- "Enhance timely resolution of disciplinary cases." (p. 16).
- "Periodically publish information for the medical community regarding best practices of prevention strategies." (p. 16 and 21, 2/3 majority).
- "…[P]rovide meaningful status updates regarding the investigation and prosecution of the complaint to the person who filed the complaint and/or the patient or the patient's legal representative."(p. 16 and 19, unanimous).
- "Publish, no less than quarterly, a summary of adverse incident reports, which shall not include information that would identify the reporting facility or health care practitioner involved. The purpose of the publication of such summaries is to promote the rapid dissemination of information relating to incidents to assist in the avoidance of similar incidents and reduce morbidity and mortality. (NOTE: A public records exemption will be necessary, as is currently provided for annual hospital reports). The quarterly report should replace the current annual reporting requirements."(p. 17 and 21, 2/3 majority).

- "Seek statutory authority to extend the current protections of peer review, relating to quality improvement functions, for institutional pharmacists to community pharmacists." (p. 17 and 22, 2/3 majority).
- "Create…new language to allow, upon request, the complaint(s) and defendant/practitioner to receive a copy of the expert report, with the identity of the expert witness redacted, when said report is the basis for closure." (p. 19, 2/3 majority).
- "Amend s. 395.1072, F.S., to change the Health Care Risk Manager Advisory Council to be a seven (7) member-group." (p. 20, unanimous).
- "Create a new statutory section in Chapter 395 to provide immunity from civil liability to risk managers and licensed facilities for reporting only." (p. 20, 2/3 majority).
- "Report every allegation of sexual misconduct…" (See p. 20, unanimous).
- "Create a new statutory provision to specify that: <u>It shall be unlawful for any person to coerce, intimidate, or preclude a risk manager from lawfully executing his or her reporting obligations pursuant to Chapter 395, F.S. Such unlawful action shall be subject to civil monetary penalties not to exceed $10,000 per violation."</u> (pp. 20-21, unanimous).
- "Ensure that regulatory rules for any practice setting in which surgical procedures are performed require that the practice setting establish minimum training and education requirements for all operating personnel." (p. 16 and 22, unanimous).
- "Legislation should be proposed requiring a course in medical errors and patient safety, including root cause analysis, error reduction, error prevention and patient safety practices as a requirement for initial and re-licensing of appropriate health care professionals. The course will be included in the existing number of required hours." (p. 24, unanimous).
- "Require each nursing home to implement a quality assurance program directed by an interdisciplinary team that meets at least every other month." (p. 28, unanimous).

C. EFFECT OF PROPOSED CHANGES:

Please see Section-By-Section Analysis.

D. SECTION-BY-SECTION ANALYSIS:

<u>Section 1.</u> Amends s. 395.0197, F.S., to require annual one-hour risk management course for all personnel of a licensed facility except licensed health care practitioners who are required to complete continuing education coursework for licensure purposes; requires facility internal risk management programs to include a prohibition against unlicensed personnel from assisting in surgical procedures unless the facility has conducted a competency assessment of the person and authorized the person specifically to participate, such assistance or participation is done only under the direct and immediate supervision of a licensed physician, and is not otherwise an activity that may only be performed by a licensed health care practitioner; amends cross-references; requires agency to publish quarterly on the Internet, a summary and trend analysis of adverse incidents which shall not include information that would identify the patient, the reporting facility, or the health care practitioners involved; requires agency to publish annually on the Internet, a summary and trend analysis of all adverse incidents and malpractice claims which shall not include information that would identify the patient, the reporting facility, or the health care practitioners involved; provides legislative intent for published adverse incident report summaries; mandates that every allegation of sexual misconduct by a licensed health care practitioner be reported to the department; creates privilege against civil liability for risk managers and facilities who report information pursuant to Chapter 395, F.S., unless the risk manager or facility acted in bad faith or with malice; and provides that it is unlawful for any person to coerce, intimidate, or preclude a risk manager from lawfully executing the reporting requirements of Chapter 395, F.S., and sets a civil penalty for doing so.

Section 2. Amends s. 395.10972, F.S., to change Health Care Risk Manager Advisory Council from a five-member council to a seven-member council, adding two licensed health care practitioners of whom one shall be a licensed physician. Also, provides that one of the risk managers shall be recommended by and a member of the Florida Society of Healthcare Risk Management.

Section 3. Amends s. 395.701, F.S., to provide certain documents to be used for purposes of determining the proper public medical assistance assessment.

Section 4. Amends s. 456.013, F.S., to require boards, or the department when there is no board, to implement a 2-hour continuing education course requirement as part of the licensure and renewal process for all health care practitioners. Provides that the two hours shall count toward the total number of continuing education hours required, not in addition to. Requires the courses to be approved by the board and to include a study of root cause analysis, error reduction and prevention, and patient safety. Allows facility-provided course which focuses on prevention of errors in that particular facility to count for one of two hours to meet this requirement.

Section 5. Amends s. 456.063, F.S., to require licensed health care practitioners to report allegations of sexual misconduct to the department regardless of the practice setting in which the alleged sexual misconduct occurred.

Section 6. Amends s. 456.072, F.S., to add two new grounds for discipline and to modify one ground for discipline for all health care practitioners, including providing health care services to the wrong patient/wrong-site/wrong-procedure and leaving a foreign body in a patient such as a sponge, clamp, forceps, or surgical needle. Also, clarifies what "restriction of practice or license" means, adds three penalties which are currently in some, but not all practice acts, relating to refunds of fees, issuance of a letter of concern, and remedial education, and requires boards to assess costs of the case against the licensee at the time disciplinary action is imposed.

Section 7. Amends s. 456.073, F.S., to require the department to notify the patient or patient's legal representative, in addition to the complainant, of the current status of the case. Also, allows the complainant to receive a copy of the expert report, if one was obtained by the department and used as the basis for closing a case. Requires that the identity of the expert be kept confidential since the case is not public until 10 days after a finding of probable cause.

Section 8. Amends s. 456.077, F.S., to designate additional grounds for discipline, which shall be handled by citation.

Section 9. Amends s. 456.081, F.S., to require additional information relating to adverse incidents, error prevention and safety strategies, and best practices information to be posted on the department's website. Requires summaries of final orders entered after July 1, 2001, to be available on the website. Provides legislative intent.

Section 10. Amends s. 458.331, F.S., to conform to cross-references in s. 395.0197, F.S.

Section 11. Amends s. 459.015, F.S., to conform to cross-references in s. 395.0197, F.S.

Section 12. Amends s. 465.019, F.S., to require institutional pharmacies which employ pharmacy technicians to maintain a policy and procedure manual specifying those tasks which a pharmacy technician is allowed to perform.

Section 13. Amends s. 465.0196, F.S., to require special pharmacies which employ pharmacy technicians to maintain a policy and procedure manual specifying those tasks which a pharmacy technician is allowed to perform.

Section 14. Requires the Department of Health and the Agency for Health Care Administration to conduct a review of all statutorily reporting requirements for health care practitioners and facilities; requires report to Legislature on or before November 1, 2001, with recommendations and suggested statutory changes to streamline reporting requirements to avoid duplicative, overlapping, and unnecessary reports or data elements.

Section 15. Amends s. 468.1755, F.S., to create new ground for discipline for a nursing home administrator who fails to implement an ongoing quality assurance program directed by an interdisciplinary team which meets at least every other month.

Section 16. Reenacts ss. 468.1695 and 468.1735, F.S., relating to nursing home administration.

Section 17. Reenacts s. 484.056, F.S., relating to hearing aid specialists.

Section 18. Amends s. 766.101, F.S., to include a continuous quality improvement committee of a licensed pharmacy to the definition of "medical review committee."

Section 19. Reenacts ss. 440.105 and 626.989, F.S., relating to medical review committees.

Section 20. Amends s. 766.1115, F.S., to conform cross-reference.

Section 21. Provides an effective date of July 1, 2001.

III. 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:

None.

IV. CONSEQUENCES OF ARTICLE VII, SECTION 18 OF THE FLORIDA CONSTITUTION:

A. APPLICABILITY OF THE MANDATES PROVISION:

The bill does not require a city or county to expend funds or to take any action requiring the expenditure of funds.

B. REDUCTION OF REVENUE RAISING AUTHORITY:

This bill does not reduce the authority that municipalities or counties have to raise revenues in the aggregate.

C. REDUCTION OF STATE TAX SHARED WITH COUNTIES AND MUNICIPALITIES:

This bill does not reduce the percentage of state tax shared with counties or municipalities.

V. COMMENTS:

A. CONSTITUTIONAL ISSUES:

None.

B. RULE-MAKING AUTHORITY:

The boards, or the department when there is no board, shall require the completion of a 2-hour course relating to prevention of medical errors as part of the licensure and renewal process. The course shall be approved by the board. Each board already has existing rulemaking authority to require continuing education and to approve providers and/or course content. No new rulemaking authority is necessary.

The boards, or the department when there is no board, already has statutory authority to designate certain violations for which a citation may be issued in lieu of the case proceeding through the full prosecutorial route. This bill specifies additional grounds that shall be handled by citation. The boards and the department might need to amend their rules to include these additional grounds. However, this bill does not bestow any new rulemaking authority upon the boards or department since they already have sufficient rulemaking authority in this regard.

There are two new grounds for discipline added to Chapter 456, F.S., which apply to all health care practitioners. The boards, and the department for those professions which do not have a board, would need to set disciplinary guidelines for violating these provisions. Since the boards and the department already have rulemaking authority to set disciplinary guidelines, no new rulemaking authority is needed. Likewise, one new ground for discipline is added to the nursing home administrator's practice act that will need guidelines for penalties to be set by the board. The board already has sufficient rulemaking authority to do so.

There is no new rulemaking authority provided in this bill.

C. OTHER COMMENTS:

None.

VI. AMENDMENTS OR COMMITTEE SUBSTITUTE CHANGES:

None.

VII. SIGNATURES:

COMMITTEE ON HEALTH REGULATION:

Prepared by:	Staff Director:
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