SENATE STAFF ANALYSIS AND ECONOMIC IMPACT STATEMENT

(This document is based only on the provisions contained in the legislation as of the latest date listed below.)

BILL: CS/SB 2344

SPONSOR: Health, Aging and Long-Term Care Committee and Senator Diaz-Balart

SUBJECT: Florida Commission on Excellence in Health Care

DATE: April 6, 2000 REVISED: _____ _____ _____ _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Carter	Wilson	HC	Favorable/CS
2.			GO	
3.				
4.				
5.				

I. Summary:

Committee Substitute for Senate Bill 2344 creates the Florida Commission on Excellence in Health Care and designates the Secretary of Health and the Director of Health Care Administration as co-chairs. The purpose of the Commission is to develop a comprehensive statewide strategy for improving health care delivery systems through meaningful reporting standards, data collection and review, and quality measurement. In carrying out its various assigned responsibilities, the Commission is required to sponsor public hearings. The bill explicitly prohibits use of information generated through the Commission's work to be used for evidentiary purposes in legal or administrative proceedings. Membership and appointment to the 36-member Commission is specified in the bill. The Commission is required to submit a report of its findings and recommendations to the Governor, the President of the Senate, and the Speaker of the House of Representatives by February 1, 2001; but, is to continue to exist until its termination date of June 1, 2001, for purposes of assisting the Department of Health, the Agency for Health Care Administration, and the regulatory boards in their drafting of proposed legislation and rules to implement the Commission's recommendations and for purposes of providing information to the health care industry about its recommendations. An appropriation of $91,000 is made to the Department of Health from the General Revenue Fund to cover costs of travel and related expenses of staff and consumer members and for copying and distributing Commission documents.

This bill creates two undesignated sections of law.

II. Present Situation:

INSTITUTE OF MEDICINE REPORT ON AVOIDABLE MEDICAL ERRORS

The Institute of Medicine, in 1999, published its widely acclaimed book entitled *To Err is Human: Building a Safer Health System* in which it reports extensively on errors in America's health care

system, especially in hospitals. The following overview, as stated in the opening lines of its Executive Summary, provides a good summation of the problems highlighted in the book:

> The knowledgeable health reporter for the *Boston Globe*, Betsy Lehman died from an overdose during chemotherapy. Willie King had the wrong leg amputated. Ben Kolb was eight years old when he died during 'minor' surgery due to a drug mix-up.[1] [These] horrific cases that make the headlines are just the tip of the iceberg. Two large studies, one conducted in Colorado and Utah and the other in New York, found that adverse events occurred in 2.9 and 3.7 percent of hospitalizations, respectively.[2] In Colorado and Utah hospitals, 8.8 percent of adverse events led to death, as compared with 13.6 percent in New York hospitals. In both of these studies, over half of these adverse events resulted from medical error and could have been prevented. [When] extrapolated to the over 33.6 million admissions to U.S. hospitals in 1997, the results of the study in Colorado and Utah imply that at least 44,000 Americans die each year as a result of medical errors. The results of the New York Study suggest the number may be as high as 98,000.[3]

The book contains a detailed discussion of medical errors and offers numerous recommendations for actions that could be taken to improve safety in the nation's health care delivery system.

STATE REGULATION OF HEALTH QUALITY ASSURANCE

Department of Health

The Department of Health was created in 1996 to promote and protect the health of all residents and visitors in the state through organized state and community efforts as provided in s. 20.43, F.S. The duties and responsibilities delegated to the department by the Legislature include: disease and disability prevention; health program design; study of disease causes and formulation of preventive strategies; development of working associations with all agencies and organizations involved in health and health care delivery; analyzing trends in the evolution of health systems and identifying and promoting the use of innovative, cost-effective health delivery systems; serving as the statewide repository of all aggregate data accumulated by state agencies related to health care, analyzing that data and issuing periodic reports and policy statements; requiring that all aggregate data be kept in a manner that promotes easy utilization by the public, state agencies, and all other interested parties; biennially publishing and annually updating a state health plan that assesses current health programs, systems, and costs; making projections of future problems and

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[1] *A Tale of Two Stories: Contrasting Views of Patient Safety* by Richard Cook, David Woods, and Charlotte Miller, Chicago, Illinois: National Patient Safety Foundation, 1998.

[2] *Citing* "Incidence of Adverse Events and Negligence in Hospitalized Patients: Results of the Harvard Medical Practice Study I," by Brennan, Troyen A. et al, *New England Journal of Medicine*, 324:370-376, 1991; Leape, Lucian L. et al, "The Nature of Adverse Events in Hospitalized Patients: Results of the Harvard Medical Practice Study II," *New England Journal of Medicine*, 324(6):377-384, 1991; Thomas, Eric J. et al., "Incidence and Types of Adverse Events and Negligent Care in Utah and Colorado," [forthcoming Spring 2000].

[3] *Citing* American Hospital Association, Hospital Statistics, Chicago, IL, 1999.

opportunities; and recommending changes needed in the health care system to improve the public health.

As set forth in s. 20.43, F.S., the Department of Health and its 26 boards and councils are charged with regulating health care practitioners who provide health care services to the people of Florida in accordance with chapters 455-491, F.S., as necessary for the preservation of the health, safety, and welfare of the public. The department also regulates emergency medical service providers pursuant to chapter 401, F.S., such as paramedics and emergency medical technicians.

Agency for Health Care Administration

The Agency for Health Care Administration (AHCA or agency) was created in 1992 by enactment of section 1 of chapter 92-33, *Laws of Florida*. That provision of law was codified in statute as s. 20.42, F.S., which establishes AHCA and provides its organizational structure. The mission of the agency is to work to ensure that all Floridians have access to affordable, quality health care. The agency is located within the Department of Business and Professional Regulation, but is essentially independent of that department. Under its current statutory authority, the agency contains four divisions. The agency regulates health care facilities and managed care organizations which provide delivery mechanisms for health care in Florida in accordance with chapters 395, 400, 636, and 641, F.S. Section 20.42, F.S., sets forth the organizational structure of the agency and lists the responsibilities of each division, two of which will be affected by this bill. The Division of Health Quality Assurance is responsible for the licensure and inspection of health facilities. The Division of Health Policy and Cost Control is responsible for health policy, the State Center for Health Statistics, the development of The Florida Health Plan, certificate of need, state and local health planning pursuant to s. 408.033, F.S., and research and analysis.

The Statutory Regulation of Hospital Quality Control and Quality Assurance

The regulation of hospital quality control and quality assurance is used in this analysis for illustrative purposes because of the extensive breadth of hospital regulation in this area. Also, statutory regulation of hospital quality control and quality assurance specifies regulatory roles for the Agency for Health Care Administration and the Department of Health.

Currently, primary responsibility for ensuring the integrity of the state's health care delivery system rests jointly with the Department of Health and AHCA. Both agencies have a number of regulatory responsibilities that charge them with ensuring that consumers who access the health care delivery system are afforded quality care. The Department of Health and the Agency for Health Care Administration both have powers and duties relating to health policy and researching and analyzing health-related data. The department and the agency share regulatory responsibilities pertaining to licensure and regulation of health care practitioners. Although the statutory responsibility to license and discipline practitioners has been delegated to the Department of Health, the law also provides in s. 20.43(3), F.S., that the *department may contract with the Agency for Health Care Administration who shall provide consumer complaint, investigative, and prosecutorial services required by the Division of Medical Quality Assurance, councils, or boards, as appropriate*. Despite the permissive language used in s. 20.43(3), F.S., approximately $18 million, annually, in funding is appropriated directly to the agency for complaint, investigative, and prosecutorial services.

Hospital Risk Management and Adverse Incidents

Chapter 395, F.S., provides for the regulation of certain facilities by the Agency for Health Care Administration (AHCA or agency). Under s. 395.002, F.S., a "licensed facility" is defined to mean a hospital, ambulatory surgical center, or mobile surgical facility licensed in accordance with the chapter. "Medical staff" is defined to mean licensed medical physicians or osteopathic physicians with privileges in a licensed facility, as well as other licensed health care practitioners with clinical privileges as approved by a licensed facility's governing board.

Section 395.0193, F.S., requires each licensed facility, as a condition of licensure, to provide for peer review of physicians who deliver health care services at the facility. Each licensed facility must develop written, binding procedures by which such peer review must be conducted. Such procedures must include: a mechanism for choosing the membership of the body or bodies that conduct peer review; adoption of rules of order for the peer review process; a fair review of the case with the physician involved; a mechanism to identify and avoid conflict of interest on the part of the peer review panel members; and recording of agendas and minutes which do not contain confidential material, for review by the agency.

Section 395.0197, F.S., sets forth the requirements for all licensed facilities to establish an internal risk management program, to report and investigate adverse incidents that occur within the facility, and to implement a plan of corrective action following an adverse incident. That section also requires AHCA to compile annual reports summarizing adverse incidents, types of malpractice claims, and disciplinary actions taken against professionals in the aggregate. Section 395.0197, F.S., requires each licensed facility, as a part of its administrative functions, to establish an internal risk management program that includes all of the following components: the investigation and analysis of the frequency and causes of general categories and specific types of adverse incidents to patients; the development of appropriate measures to minimize the risk of adverse incidents to patients; the analysis of patient grievances that relate to patient care and the quality of medical services; and the development and implementation of an incident reporting system. The internal risk management program is the responsibility of the governing board of the health care facility. The section encourages the use of other innovative approaches to reduce the frequency and severity of medical malpractice and patient injury claims, including extending internal risk management programs to health care providers' offices and the assuming of provider liability by a licensed health care facility for acts or omissions occurring within the licensed facility. Section 395.0197(2), F.S., requires each facility to hire a licensed risk manager who is responsible for implementation and oversight of such facility's internal risk management program.

Section 395.0197(5), F.S., defines "adverse incident," for purposes of reporting to AHCA, as an event over which the health care personnel could exercise control and which is associated in whole or in part with medical intervention rather than the condition for which such intervention occurred. In order to meet the requirements for reporting, the adverse incident must also have:

- resulted in death, brain or spinal damage; permanent disfigurement; fracture or dislocation of bones or joints; limitation of neurological, physical, or sensory function which continues after discharge from the facility; any condition that required specialized medical attention or surgical intervention; or any condition requiring the transfer of the patient to a unit providing more acute care;

- involved the performance of a surgical procedure on the wrong patient, a wrong surgical procedure, or a surgical procedure otherwise unrelated to the patient's diagnosis or medical condition;
- required the surgical repair of damage resulting to a patient from a planned surgical procedure where the damage was not a recognized specific risk and disclosed to the patient and documented through the informed-consent process; or
- required a surgical procedure to remove unplanned foreign objects remaining from a surgical procedure.

Section 395.0197(7), F.S., requires the facility to notify AHCA by no later than one day following the risk manager's receipt of an adverse incident report of an incident which occurred in the licensed facility or prior to admission to the facility which involved the death of a patient, brain or spinal damage to a patient, the performance of a surgical procedure on the wrong patient, the performance of a wrong-site surgical procedure, or the performance of a wrong surgical procedure. Section 395.0197(8), F.S., requires the facility to submit a report to AHCA, within 15 calendar days from the date of occurrence, adverse incidents arising within the facility or prior to admission to the facility which involved the death of a patient, brain or spinal damage to a patient, the performance of a surgical procedure on the wrong patient, the performance of a wrong-site surgical procedure, the performance of a wrong surgical procedure, the performance of a medically unnecessary procedure, the surgical repair of damage resulting from a planned surgical procedure which is not a recognized specific risk disclosed to the patient as part of the informed-consent process, or the performance of procedures to remove unplanned foreign objects remaining from a surgical procedure.

In addition to the required adverse incident reports, a licensed facility is required under subsection 395.0197(6), F.S., to file with AHCA an annual report summarizing data regarding adverse incidents. The licensed facility's annual report must include the total number of adverse incidents; a listing by category of the types of operations, diagnostic or treatment procedures, or other actions causing the injuries, and the number of incidents occurring within each category; a listing by category of the types of injuries caused and the number of incidents occurring within each category; a code number using the health care professional's license number and a separate code number identifying all other individuals directly involved, the relationship of the individuals to the facility, and the number of incidents in which each individual has been involved; and a description of all malpractice claims filed against the facility including pending and closed claims, the nature of the incident and the persons involved, and the status and disposition of each claim.

Section 395.0198, F.S., provides a public records exemption for information contained in the notification of an adverse incident required by s. 395.0197(7), F.S. Adverse incident reports are not discoverable or admissible in a civil or administrative action, except that such information may be used in disciplinary proceedings by AHCA against the facility or by the regulatory boards against the health care practitioners involved. The public records exemption also precludes public access to adverse incident information used as part of the investigation or prosecution of the disciplinary case. Moreover, the records obtained by the agency in enforcing this section are not available to the public, nor discoverable or admissible in any civil or administrative action, except that the records may be used in disciplinary proceedings by the agency or appropriate regulatory board in actions against the license of the facility or health care practitioner. Sections

395.0197(6)(c) and (8), F.S., have additional exemptions from the public records law for adverse incident reports and the annual report to the agency regarding adverse incidents.

Pursuant to s. 395.0197(18), F.S., the Agency for Health Care Administration uses the information reported by the facility relating to adverse incidents and disciplinary action to compile a statewide aggregate report which summarizes adverse incident reports by category of reported incident and type of professional involved, types of malpractice claims filed by type of professional involved, and disciplinary actions taken against professionals, by type of professional involved. This annual statistical report is not required to be broken down by county, city, or facility. The annual report does not contain specific names of practitioners or facilities which might undermine the process of self-reporting.

III. Effect of Proposed Changes:

Section 1. Committee Substitute for Senate Bill 2344:

- Provides legislative findings that the health care delivery industry is one of the largest and most complex industries in Florida and that by eliminating avoidable mistakes in the diagnosis and treatment of Floridians, through additional focus on strengthening health care delivery systems, tremendous promise is recognized for increasing the quality of health care services available to Floridians.

- Provides legislative intent to create the Florida Commission on Excellence in Health Care to facilitate development of a comprehensive statewide strategy for improving health care delivery systems through meaningful reporting standards, data collection, data review, and quality measurement.

- Defines the terms, as used in the bill: “agency,” “commission,” “department,” “error,” “health care practitioner,” and “health care provider.”

- Creates the Florida Commission on Excellence in Health Care.

- Specifies duties and responsibilities for the Commission, which include: (1) identifying existing data sources that evaluate quality of care in Florida and collect, analyze, and evaluate the data; (2) establishing guidelines for data sharing and coordination; (3) identifying core sets of quality measures for standardized reporting by appropriate components of the health care continuum; (4) recommending a framework for quality measurement and outcome reporting; (5) developing quality measures that enhance and improve the ability to evaluate and improve care; (6) making recommendations regarding research and development needed to advance quality measurement and reporting; (7) evaluating regulatory issues relating to the pharmacy profession and recommending changes necessary to optimize patient safety; (8) facilitating 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) sponsoring public hearings to share information and expertise, identifying “best practices,” and recommending methods to promote their acceptance; (10) evaluating current regulatory programs to determine what changes, if any, need to be made to facilitate patient safety; (11) reviewing public and private health care purchasing systems to determine

if there are sufficient mandates and incentives to facilitate continuous improvement in patient safety; (12) analyzing how effective existing regulatory systems are in ensuring continuous competence and knowledge of effective safety practices; (13) developing a framework that would allow certain regulatory and credentialing organizations to more quickly and effectively identify unsafe health care providers and health care practitioners and to take action necessary to remove such providers and practitioners from operation or practice until the provider or practitioner can demonstrate that it is safe for the provider or practitioner to resume operating or practicing; (14) recommending procedures for development of a curriculum on patient safety and methods of incorporating such curriculum into training, licensure, and certification requirements; (15) developing a framework for regulatory bodies to disseminate information on patient safety to health care practitioners, health care providers, consumers through conferences, journal articles and editorials, newsletters, publications, and Internet websites; (16) recommending 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) recommending a framework for development of community-based collaborative initiatives for error reporting and analysis and implementation of patient safety improvements; and (18) evaluating the role of advertising in promoting or adversely affecting patient safety.

- Specifies the Commission must reflect the geographic and demographic diversity of the state and provides for membership, structure, staffing, and certain administrative and procedural requirements of the Commission:
  * *Commission Membership*--(1) Secretary of Health, (2) Director of AHCA, one representative each from the (3) Board of Medicine, (4) Board of Osteopathic Medicine, (5) Board of Pharmacy, (6) Board of Dentistry, (7) Board of Nursing, (8) Florida Dental Association, (9) Florida Medical Association, (10) Florida Osteopathic Medical Association, (11) Florida Chiropractic Association, (12) Florida Podiatric Medical Association, (13) Florida Nurses Association, (14) Florida Organization of Nursing Executives, (15) Florida Pharmacy Association, (16) Florida Society of Health System Pharmacists, Inc., (17) Florida Hospital Association, (18) Association of Community Hospitals and Health Systems of Florida, Inc., (19) Florida League of Health Systems, (20) Florida Health Care Risk Management Advisory Council, (21) Florida Health Care Association, (22) Florida Statutory Teaching Hospital Council, Inc., (23) Florida Statutory Rural Hospital Council, (24) Florida Association of Homes for the Aging, (25) a health lawyer who is a member of the Health Law Section of the Florida Bar and who defends physicians, appointed by the Secretary of Health, (26) a health lawyer who is a member of the Academy of Florida Trial Lawyers, appointed by the Secretary of Health, (27) a health insurance industry representative, appointed by the Director of Health Care Administration, representing indemnity plans, (28) a health insurance industry representative, appointed by the Director of Health Care Administration, representing managed care, (29) a consumer advocate representing the Association for Responsible Medicine, (30) a consumer representative the first of two appointed by the Governor, (31) a consumer representative the second of two appointed by the Governor, (32) a consumer member appointed by the President of the Senate, (33) a consumer member appointed by the Speaker of the House of Representatives, (34) a legislator appointed by the President of the Senate, (35) a legislator appointed by the Speaker of the House of

Representatives, and (36) one representative of a Florida medical school appointed by the Secretary of Health.

* *Commission Administration, Structure, and Staffing*--The Commission must hold its first meeting by July 15, 2000, and will to be jointly chaired by the Secretary of Health and the Director of Health Care Administration who may form subcommittees, as needed to make recommendations to the full Commission; the full Commission is required to vote on all work products of the Commission; recommendations submitted to the Governor, President of the Senate, and Speaker of the House of Representatives must be adopted by a vote of two-thirds of the Commission membership; agencies and organizations represented on the Commission may appoint alternate members to attend and vote in the place of members unable to attend a Commission or subcommittee meeting and must absorb all costs of travel and expenses related to their participation on the Commission; the state is required to reimburse, as provided by state law, the costs of travel and expenses for consumer members on the Commission; and the Commission will be staffed by employees of the Department of Health and AHCA.

- *Evidentiary Prohibitions*--Subsection (5) of the bill makes the Commission's findings, recommendations, evaluations, opinions, investigations, proceedings, records, reports, minutes, testimony, correspondence, work product, and actions available to the public but shields such activities, actions, information, documents, records, and members of the Commission from introduction into evidence at any civil, criminal, special, or administrative proceedings against a health care practitioner or health care provider that arise from matters which are the subject of the findings of the Commission. This subsection also provides language clarifying that information, documents, records which are otherwise available and that may be obtained from original sources are not immunized from discovery or use in any civil, criminal, special, or administrative proceeding, nor is a person testifying before the Commission or a member of the Commission prohibited from testifying as to matters within his or her knowledge.

  * Clarifying language provides that the findings, recommendations, evaluations, opinions, investigations, proceedings, records, reports, minutes, testimony, correspondence, work product, and actions of the Commission may be used as a guide and resource but may not be construed as establishing or advocating the standard of care for health care practitioners or health care providers unless subsequently enacted into law or adopted in rule. Furthermore, such documents, activities, actions, and work product of the Commission shall not be admissible as evidence by introduction of documents or as a basis of an expert opinion as to the standard of care applicable to health care practitioners or health care providers in legal or administrative proceedings unless later enacted into law or adopted in rule.

  * The bill prohibits persons who testify before the Commission or who are Commission members from identifying any patient, health care practitioner, or health care provider by name and prohibits naming any person in Commission findings, recommendations, evaluations, opinions, investigations, proceedings, records, reports, minutes, testimony, correspondence, work product, and actions of the Commission.

- The Commission is required to submit a report of its findings and recommendations to the Governor, the President of the Senate, and the Speaker of the House of Representatives by February 1, 2001. Following submission of the report, the Commission is to continue in existence until June 1, 2001, at which time it is abolished, and is to assist the Department of Health, the Agency for Health Care Administration, and the regulatory boards in their drafting of proposed legislation and rules implementing the Commission's recommendations and for the purpose of providing information to the health care industry on its recommendations.

Section 2. Appropriates $91,000 in nonrecurring general revenue from the General Revenue Fund to the Department of Health to cover the Commission's costs relating to travel and related expenses of staff and consumer members and the reproduction and dissemination of documents.

Section 3. Provides for the bill to take effect upon becoming a law.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The provisions of this bill have no impact on public records or open meetings issues under the requirements of Article I, Subsections 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

V. Economic Impact and Fiscal Note:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Private sector Commission members will incur costs associated with travel to Commission meetings.

C. Government Sector Impact:

There is a $91,000 appropriation to the Department of Health from the General Revenue Fund to cover costs relating to travel and other related expenses for the Commission on

Excellence in Health Care staff and consumer members and to cover the costs of copying and distributing Commission documents.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Amendments:

None.