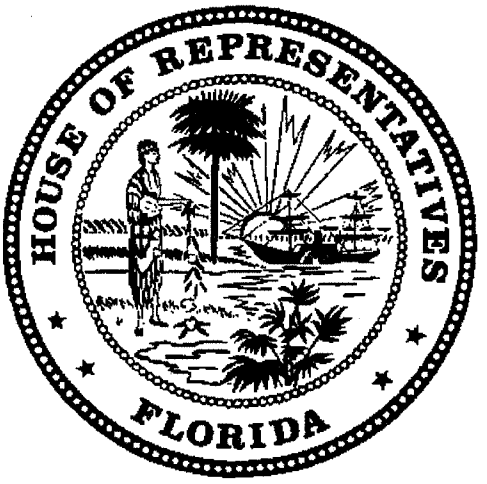

Committee on Health Quality

Tuesday, February 19, 2008
8:00 AM – 10:15 AM
306 HOB

COMMITTEE MEETING PACKET

Marco Rubio
Speaker

Gayle Harrell
Chair

House of Representatives

Committee on Health Quality

AGENDA

February 19, 2008
8:00 AM – 10:15 AM
(306 HOB)

I. Opening Remarks

II. Consideration of HB 275 by Garcia, R. -- Pharmacy

III. Consideration of HB 567 by Poppell -- Onsite Sewage Treatment and Disposal Systems

IV. Workshop relating to proposed revisions to the hospital Code 15 reporting system

V. Workshop relating to the Cancer Drug Donation Program

VI. Presentation by the Area Health Education Centers regarding the status of tobacco cessation and prevention training of health professionals

VII. Presentation by the Department of Health regarding the status of the Physician Workforce Assessment and Development Program

VIII. Presentation of the 2008 committee interim projects

IX. Closing Remarks & Adjournment

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 275 Pharmacy

SPONSOR(S): Garcia and others

TIED BILLS: **IDEN./SIM. BILLS:** SB 334

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Committee on Health Quality		Owen	Lowell
2) Healthcare Council			
3) Policy & Budget Council			
4)			
5)			

SUMMARY ANALYSIS

The bill broadens licensure by endorsement for pharmacists by deleting the requirement that an applicant for licensure must have obtained a passing score on the licensure examination not more than 12 years prior to application.

Effective January 1, 2010, the bill increases the number of pharmacy technicians a pharmacist may supervise from three to four under guidelines approved by the Board of Pharmacy (board).

In addition, effective January 1, 2010, the bill requires pharmacy technicians to register with the board; applicants must be at least 16 years of age. A person whose license to practice pharmacy has been suspended, denied, or restricted is prohibited from registering as a pharmacy technician. The bill specifies registration renewal requirements for pharmacy technicians and grounds for discipline against a registered pharmacy technician and the denial of registration as a pharmacy technician. A pharmacy technician must complete biennially complete 20 hours of continuing education as a condition of registration renewal. The bill exempts from the registration requirements pharmacy technician students obtaining practical training required by a pharmacy technician-training program and persons licensed as pharmacy interns. The bill requires the board to maintain a directory of registered pharmacy technicians indicating their place of employment and publish the directory on the Internet.

According to the Department of Health, they will need eight full-time equivalent positions to implement the provisions of the bill. If the number of registrants does not produce sufficient revenue to support the program costs, there will be a negative fiscal impact on the Medical Quality Assurance Trust Fund (see fiscal impact).

The bill is effective upon becoming law, except as specified in the bill.

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Provide limited government - The bill proposes the new regulation of a profession--pharmacy technicians--through registration with the Department of Health.

B. EFFECT OF PROPOSED CHANGES:

Present Situation

Pharmacists

Chapter 465, F.S., governs the practice of pharmacy, creating the Board of Pharmacy (board) within the Department of Health (department) to regulate the profession. According to the department, there are approximately 17,000 licensed pharmacists in Florida.

An individual seeking to be licensed as a pharmacist in Florida has two paths to licensure: licensure by examination and licensure by endorsement. Section 465.007, F.S. sets out the requirements for licensure by examination, allowing an applicant to sit for the examination[1] if the board certifies the applicant:

- Has completed the application form and submitted an examination fee no greater than $100 plus the actual cost to the department for purchase of portions of the examination from the National Association of Boards of Pharmacy or a similar national organization.
- Is 18 years of age or older.
- Has received a degree from a school or college of pharmacy accredited by an accrediting agency recognized and approved by the United States Office of Education or has graduated from a four-year undergraduate pharmacy program of a school or college of pharmacy located outside the United States and has demonstrated proficiency in English by passing both the Test of English as a Foreign Language and the Test of Spoken English.
- Has completed an internship program approved by the board.

In addition, the board must certify that a graduate of a foreign school or college of pharmacy has also completed a minimum of 500 hours of supervised work in Florida under a licensed pharmacist and has passed the board-approved Foreign Pharmacy Graduate Equivalency Examination.

Licensure by endorsement is a licensing procedure that allows an out-of-state practitioner who holds an active license in a state that has licensing requirements substantially equivalent to, or more stringent than, those in the state in which the practitioner is seeking licensure to obtain a license without meeting all of the licensure requirements for a person who is obtaining licensure for the first time. Section 465.0075, F.S., sets out the requirements for licensure by endorsement for pharmacists, requiring the applicant to have:

- Successfully met the age and educational requirements listed above for licensure by examination.[2]
- Obtained a passing score on the licensure examination of the National Association of Boards of Pharmacy or a similar nationally recognized examination, if the board certifies the applicant has taken the examination not more than 12 years prior to application.
- Submitted evidence of the active licensed practice of pharmacy in another jurisdiction for two of the immediately preceding five years or evidence of successful completion of board-approved

[1] The examination is comprised of two parts: Part A is the North American Pharmacist Licensure Examination (NAPLEX); Part B is the Multistate Pharmacy Jurisprudence Examination (Florida Version).

[2] Section 465.0075(1)(b) and (c), F.S.

postgraduate training, a board-approved clinical competency examination within one year immediately preceding application for licensure, or completion of an internship within two years immediately preceding application.
- Obtained a passing score on the pharmacy jurisprudence portions of the licensure examination.

Pharmacy Technicians

A pharmacy technician assists the pharmacist in performing a number of routine and administrative tasks, including:
- Counting tablets.
- Labeling bottles.
- Stocking shelves.
- Verifying prescriptions.[3]

A pharmacy technician may work in a variety of settings, such as hospitals and mail-order pharmacies, although most work within a retail pharmacy.[4] While a majority of pharmacy technicians receive training on-the-job, numerous educational institutions throughout the country offer a pharmacy technician training program.[5] In addition, the Pharmacy Technician Certification Board and the Institute for the Certification of Pharmacy Technicians offer certification exams that test the knowledge and skills of the technician across multiple practice settings.[6] The minimum educational qualification to sit for either certification exam is a GED or high school diploma.

Nationwide, there are approximately 285,000 pharmacy technicians[7]; in Florida, the number may range from approximately 19,000[8] to as high as 51,000 (registration applications estimated to be received by the department in the first four years after the bill is enacted). According to the Institute for the Certification of Pharmacy Technicians, 39 states require registration or licensure of pharmacy technicians. The requirements range from simple registration to full licensure with continuing education requirements.

Section 465.014, F.S., specifies the tasks and functions of pharmacy technicians. A person other than a pharmacist or pharmacy intern may not engage in the practice of pharmacy, except that a pharmacist may delegate to a pharmacy technician those duties, tasks, and functions that do not fall within the definition of the practice of the profession of pharmacy. The acts delegated to a pharmacy technician by a pharmacist must be performed under the direct supervision of a licensed pharmacist who is responsible for all such acts performed by persons under the pharmacist's supervision. Under the supervision of a pharmacist, a pharmacy technician may initiate or receive communications with a practitioner or his or her agent on behalf of a patient regarding prescription refill authorization requests.

A pharmacist may not supervise more than one pharmacy technician unless permitted by the board.[9] The board has determined that the following tasks may be performed by a pharmacy technician under a supervisory ration of 2:1 or 3:1:
- Community pharmacies may have a pharmacy technician enter prescription information into a computer.
- Community pharmacies servicing nursing homes and community or special pharmacies providing parenteral and/or enteral services may allow a pharmacy technician to:
    - Enter prescription information into a computer.
    - Prepackage and label unit dose medication.

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[3] http://www.bls.gov/oco/ocos252.htm (viewed February 11, 2008).
[4] *Id.*
[5] http://www.ashp.org/s_ashp/technician_index.asp?CID=3494&DID=5428 (viewed February 13, 2008).
[6] *See* https://www.ptcb.org/AM/Template.cfm?Section=Guidebook_to_Certification (viewed February 13, 2008) (providing a link to a certification exam guidebook that discusses the material tested in detail).
[7] *Id.*
[8] http://flahec.org/hlthcareers/PHARMTEC.HTM (viewed February 13, 2008).
[9] Rule 64B16-27.420, F.A.C.

- Reconstitute bulk parenteral/enteral preparations to be sorted for dispensing at a later date.
- Refill unit dose mobile transport systems (carts).
- Distribute bulk medicinal drugs, appliances and other auxiliary health care products to other departments.

- Institutional pharmacies and nuclear pharmacies may allow a pharmacy technician to:
  - Enter prescription information into a computer.
  - Prepackage and label unit dose medication.
  - Reconstitute bulk parenteral/enteral preparations to be sorted for dispensing at a later date.
  - Refill unit dose mobile transport systems (carts).
  - Distribute bulk medicinal drugs, appliances and other auxiliary health care products to other departments.
- Nuclear pharmacy permits allow the pharmacy technician to receive diagnostic orders only. Therapy or blood product procedure orders must be received by a pharmacist.

The Sunrise Act

Section 11.62, F.S., the "Sunrise Act," (the act) states that it is the intent of the Legislature that:

- No profession or occupation is subject to regulation by the state unless the regulation is necessary to protect the public health, safety, or welfare from significant and discernible harm or damage and that the police power of the state be exercised only to the extent necessary for that purpose; and
- No profession or occupation is regulated by the state in a manner that unnecessarily restricts entry into the practice of the profession or occupation or adversely affects the availability of the professional or occupational services to the public.

In determining whether to regulate a profession or occupation, the act requires the Legislature to consider the following:

- Whether the unregulated practice of the profession or occupation will substantially harm or endanger the public health, safety, or welfare, and whether the potential for harm is recognizable and not remote.
- Whether the practice of the profession or occupation requires specialized skill or training, and whether that skill or training is readily measurable or quantifiable so that examination or training requirements would reasonably assure initial and continuing professional or occupational ability.
- Whether the regulation will have an unreasonable effect on job creation or job retention in the state or will place unreasonable restrictions on the ability of individuals who seek to practice or who are practicing a given profession or occupation to find employment.
- Whether the public is or can be effectively protected by other means.
- Whether the overall cost-effectiveness and economic impact of the proposed regulation, including the indirect costs to consumers, will be favorable.

The act requires the proponents of the proposed regulation to submit information documenting how the regulation meets specific criteria outlined in the act. These criteria include:

- Documentation of the nature and extent of the harm to the public caused by the unregulated practice of the profession or occupation, including a description of any complaints that have been lodged against persons who have practiced the profession or occupation in this state during the preceding 3 years.
- An explanation of the reasons why other types of less restrictive regulation would not effectively protect the public.
- A description of the voluntary efforts made by members of the profession or occupation to protect the public and a statement of the reasons why these efforts are not adequate to protect the public.

This bill proposes the new regulation of a profession. However, the information required to be submitted by the act has not been provided to the committee.

Effect of Proposed Changes

The bill broadens the licensure by endorsement provision by deleting the requirement that an applicant for licensure as a pharmacist must have obtained a passing score on the licensure examination not more than 12 years prior to application.

Effective January 1, 2010, the bill expands the number of pharmacy technicians a pharmacist may supervise from three to four under board-approved guidelines. When a pharmacist supervises four pharmacy technicians, at least one of the four technicians must be certified by the Pharmacy Technician Certification Board or any other nationally accredited certifying body approved by the board.

The bill requires a person seeking to work as a pharmacy technician in Florida to register with the board by filing an application form furnished by the board. The bill requires the board to register an applicant who has remitted a registration fee no greater than $50 every two years as set by the board, completed the application form, and remitted a nonrefundable application fee no greater than $50 as set by the board. Pharmacy technician applicants must be at least 16 years of age. A person whose license to practice pharmacy has been denied, suspended, or restricted for disciplinary purposes is not eligible to be registered as a pharmacy technician.

The bill exempts from the pharmacy technician registration requirements:

- A pharmacy technician student who may be placed in a pharmacy for the purpose of obtaining practical training required by the body accrediting the pharmacy technician training program. The bill requires the pharmacy technician student to wear identification that indicates his or her student status when performing pharmacy technician functions.
- A person licensed by Florida as a pharmacy intern.

The bill requires a pharmacy technician, as a condition of registration renewal, to complete 20 hours of continuing education courses approved by the board or the Accreditation Council for Pharmaceutical Education. Four hours of the continuing education must be via live presentation and two hours must be related to the prevention of medication errors and pharmacy law.

The bill requires the board to adopt rules that require a registration issued to a pharmacy technician by the board to be displayed so that it is available to the public and to facilitate inspection by the department. The board is authorized to adopt other rules to administer the pharmacy technician requirements.

The bill authorizes the board to deny registration, or take disciplinary action, as applicable, against an applicant for registration as a pharmacy technician or registered pharmacy technician who has committed an act that constitutes a substantial violation of the general regulatory provisions of Chapter 456, F.S., or the pharmacy practice act, which occurred before the applicant or registrant was registered as a pharmacy technician.

The board must adopt rules requiring and specifying the manner in which a pharmacy must notify the board when a registered technician is employed or ceases employment with the pharmacy. The board must maintain a current directory of registered pharmacy technicians indicating their place of employment and the directory must be published on the Internet.

Effective January 1, 2010, the bill imposes a first degree misdemeanor for a person who is not registered as a pharmacy technician, or who is not otherwise exempt from the requirement to register, to perform the functions of a registered pharmacy technician or to otherwise hold himself or herself out to others as a person who is registered to perform the functions of a registered pharmacy technician in Florida.

C. SECTION DIRECTORY:

Section 1: Amends s. 465.0075, F.S., revising provisions governing licensure by endorsement.

Section 2: Amends s. 465.014, F.S., providing for the registration of pharmacy technicians, effective January 1, 2010.

Section 3: Amends s. 465.015, F.S., prohibiting unauthorized activity as an unregistered pharmacy technician, providing penalties, effective January 1, 2010.

Section 4: Amends s. 465.019, F.S., conforming references relating to use of pharmacy technicians in institutional pharmacies, effective January 1, 2010.

Section 5: Provides an effective date of upon becoming law, except as otherwise expressly provided.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

Currently, there are 17,000 licensed pharmacists in the state. Based on the provisions in this bill, a pharmacist could supervise up to four pharmacy technicians. So, there are 68,000 registered pharmacy technician slots available. However, it is very unlikely that every pharmacist would supervise the maximum number of technicians.

The department has projected that within the next four years a total of 51,000 persons will seek registration as a pharmacy technician. The initial and renewal fee is $50 per application and will result in revenue of $4.6 million in the first four years. Registration is renewable biannually so the revenue collected to support regulation will fluctuate.

Depending upon the number of persons seeking registration as a Pharmacy Technician, the revenue may not cover the cost of the regulatory requirements, per s. 216.0236, F.S. To meet the projected expenditures in the first year, the minimum number of persons to seek registration is 15,000 persons.

Estimated Revenue	1st Year	2nd Year	2nd Year	4th Year
Number of persons seeking registration	30,000 persons x $50	10,000 persons x $50	10,000 persons x $50	1,000 persons X $50
Initial Registration Fee	$1,500,000	$ 500,000	$ 500,000	$ 50,000
Renewal Fee			1,500,000	500,000
Total	$1,500,000	$500,000	$2,000,000	$550,000

2. Expenditures:

The department estimates that they will need eight full-time equivalent positions to implement the provisions of the bill. Three of the positions will be located in the Board of Pharmacy Office to support the registration application process. One position will be located in Consumer Services Unit to receive and process complaints. Two positions will be located in the Investigative Services Unit to investigate all legally sufficient complaints received. Two positions will be for the Prosecution Services Unit to respond to all legally sufficient complaints to determine probable cause. Currently, the department contracts with a vendor to process initial and renewal applications and related fees at a rate of $7.89 per application.

The total projected expenditures are $2.1 million in the first four years.

Estimated Expenditures	1st Year	2nd Year	3rd Year	4th Year
Salaries				
1- Regulatory Supervisor, PG 420 (Pharmacy)	46,397	46,397	46,397	46,397
1 – Regulatory Spec II, PG 17 (Pharmacy)	39,627	39,627	39,627	39,627
1 – Regulatory Spec I, PG 15 (Pharmacy)	36,155	36,155	36,155	36,155
1 - Government Analyst, PG 22 (CSU)	51,748	51,748	51,748	51,748
2 - Investigator Spec II, PG 20 (ISU)	92,794	92,794	92,794	92,794
1 - Senior Attorney, PG 230 (PSU)	73,259	73,259	73,259	73,259
1- Reg Spec II, PG 17 (PSU)	39,627	39,627	39,627	39,627
Expense				
Non-Recurring Exp Pkg 7 professional staff	23,716			
Non-Recurring Exp Pkg 1 support staff	2,947			
Rec exp, Max Travel - 2 FTE	40,424	40,424	40,424	40,424
Rec exp, Lmt Travel - 3 FTE	36,804	36,804	36,804	36,804
Rec exp, No Travel - 2 FTE	13,400	13,400	13,400	13,400
Rec exp, spt staff - 1 FTE	5,426	5,426	5,426	5,426
Operating Capital Outlay				
8 FTE OCO Pkg	8,000			
Contracted Services				
Initial & Renewal processing	236,700	$ 78,900	$ 315,600	86,790
Human Resources Services				
8 FTE HR	3,184	3,184	3,184	3,184
Total	$ 750,207	$ 557,744	$ 794,444	$ 565,634

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:
   None.

2. Expenditures:
   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Pharmacy technicians currently working in the state will incur costs associated with the registration and continuing education requirements.

Pharmacies that employ pharmacy technicians may indirectly incur higher costs to ensure compliance with the regulatory requirements of the bill.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable because the bill does not appear to require counties or cities to spend funds or take action requiring the expenditure of funds; reduce the authority that cities or counties have to raise revenues in the aggregate; or reduce the percentage of a state tax shared with cities or counties.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

No additional rulemaking authority is required as a result of this bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

On line 87, "board" should be replaced with "department". Professional licensure applicants apply to the department and the applicable board adopts the licensure application form by rule.

On line 158, "pharmacy technician" should be replaced with "registered pharmacy technician" to reflect the required registration of pharmacy technicians.

Section 465.0197(1), F.S., should be similarly amended the replace "pharmacy technician" with "registered pharmacy technician."

D. STATEMENT OF THE SPONSOR

No statement submitted.

IV. AMENDMENTS/COUNCIL SUBSTITUTE CHANGES

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. (for drafter's use only)

Bill No. **0275**

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	_____

Council/Committee hearing bill: Committee on Health Quality

Representative Robaina offered the following:

Amendment (with title amendment)

Remove lines 58-170 and insert:

Section 2. This act shall take effect upon becoming a law.

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

Remove lines 5-25 and insert:

nationally recognized examination; providing an effective date.

A bill to be entitled

An act relating to pharmacy; amending s. 465.0075, F.S.; revising provisions governing licensure by endorsement to remove the timeframe requirement for passage of a nationally recognized examination; amending s. 465.014, F.S.; providing for the registration of pharmacy technicians; requiring the Board of Pharmacy to set fees and rules to register pharmacy technicians; providing qualification requirements; providing a limitation; exempting pharmacy technician students and licensed pharmacy interns from certain registration requirements; providing continuing education requirements for registration renewal; providing grounds for denial, suspension, or revocation of registration or other disciplinary action; authorizing the board to impose certain penalties; requiring the board to adopt rules; requiring the board to maintain a directory of registered pharmacy technicians and publish the directory on the Internet; amending s. 465.015, F.S.; prohibiting a person who is not registered as a pharmacy technician from performing certain functions or holding himself or herself out to others as a pharmacy technician; providing penalties; amending s. 465.019, F.S.; conforming references relating to use of pharmacy technicians in institutional pharmacies; providing effective dates.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Subsection (1) of section 465.0075, Florida Statutes, is amended to read:

465.0075 Licensure by endorsement; requirements; fee.--

(1) The department shall issue a license by endorsement to any applicant who applies to the department and remits a nonrefundable fee of not more than $100, as set by the board, and whom the board certifies:

(a) Has met the qualifications for licensure in s. 465.007(1)(b) and (c);

(b) Has obtained a passing score, as established by rule of the board, on the licensure examination of the National Association of Boards of Pharmacy or a similar nationally recognized examination, if the board certifies that the applicant has taken the required examination ~~not more than 12 years prior to application~~;

(c)1. Has submitted evidence of the active licensed practice of pharmacy, including practice in community or public health by persons employed by a governmental entity, in another jurisdiction for at least 2 of the immediately preceding 5 years or evidence of successful completion of board-approved postgraduate training or a board-approved clinical competency examination within the year immediately preceding application for licensure; or

2. Has completed an internship meeting the requirements of s. 465.007(1)(c) within the 2 years immediately preceding application; and

(d) Has obtained a passing score on the pharmacy jurisprudence portions of the licensure examination, as required by board rule.

Section 2. Effective January 1, 2010, section 465.014, Florida Statutes, is amended to read:

465.014 Pharmacy technician.--

(1) A ~~No~~ person other than a licensed pharmacist or pharmacy intern may not engage in the practice of the profession of pharmacy, except that a licensed pharmacist may delegate to ~~nonlicensed~~ pharmacy technicians registered pursuant to this section those duties, tasks, and functions which do not fall within the purview of s. 465.003(13). All such delegated acts shall be performed under the direct supervision of a licensed pharmacist who shall be responsible for all such acts performed by persons under his or her supervision. A registered pharmacy technician, under the supervision of a pharmacist, may initiate or receive communications with a practitioner or his or her agent, on behalf of a patient, regarding refill authorization requests. A ~~No~~ licensed pharmacist may not ~~shall~~ supervise more than one registered pharmacy technician unless otherwise permitted by the guidelines adopted by the board. The board shall establish guidelines to be followed by licensees or permittees in determining the circumstances under which a licensed pharmacist may supervise up to four registered ~~more than one but not more than three~~ pharmacy technicians. When a pharmacist supervises four registered pharmacy technicians under the guidelines of the board, at least one of the four must be certified by the Pharmacy Technician Certification Board or any

other nationally accredited certifying body approved by the board.

(2) Any person who wishes to work as a pharmacy technician in this state must register by filing an application with the board on a form adopted by rule of the board. The board shall register each applicant who has remitted a registration fee set by the board, not to exceed $50 biennially; has completed the application form and remitted a nonrefundable application fee set by the board, not to exceed $50; and is at least 16 years of age.

(3) A person whose license to practice pharmacy has been denied, suspended, or restricted for disciplinary purposes is not eligible to be registered as a pharmacy technician.

(4) Notwithstanding the requirements of this section or any other provision of law, a pharmacy technician student may be placed in a pharmacy for the purpose of obtaining practical training required by the body accrediting the pharmacy technician training program. A pharmacy technician student shall wear identification that indicates his or her student status when performing the functions of a pharmacy technician, and registration under this section is not required.

(5) Notwithstanding the requirements of this section or any other provision of law, a person licensed by the state as a pharmacy intern may be employed as a registered pharmacy technician without paying a registration fee or filing an application with the board to register as a pharmacy technician.

(6) As a condition of registration renewal, a pharmacy technician must complete 20 hours biennially of continuing

education courses approved by the board or the Accreditation Council for Pharmaceutical Education, of which 4 hours must be via live presentation and 2 hours must be related to the prevention of medication errors and pharmacy law.

(7) If the board finds that an applicant for registration as a pharmacy technician or that a registered pharmacy technician has committed an act that constitutes grounds for discipline as set forth in s. 456.072(1) or has committed an act that constitutes grounds for denial of a license or disciplinary action as set forth in this chapter, including an act that constitutes a substantial violation of s. 456.072(1) or a violation of this chapter which occurred before the applicant or registrant was registered as a pharmacy technician, the board may enter an order imposing any of the penalties specified in s. 456.072(2) against the applicant or registrant.

(8) The board shall adopt rules that require each registration issued by the board under this section to be displayed in such a manner as to make it available to the public and to facilitate inspection by the department, rules that require and specify the manner in which a pharmacy shall notify the board when a registered pharmacy technician is employed or ceases employment with the pharmacy, and such other rules as necessary to administer the provisions of this section.

(9) The board shall maintain a current directory of registered pharmacy technicians indicating their place of employment and publish the directory on the Internet.

Section 3. Effective January 1, 2010, paragraph (d) is added to subsection (3) of section 465.015, Florida Statutes, to read:

465.015 Violations and penalties.--

(3)

(d) It is unlawful for a person who is not registered as a pharmacy technician under this chapter, or who is not otherwise exempt from the requirement to register as a pharmacy technician, to perform the functions of a registered pharmacy technician or hold himself or herself out to others as a person who is registered to perform the functions of a registered pharmacy technician in this state.

(4) Any person who violates any provision of subsection (1) or subsection (3) commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083. Any person who violates any provision of subsection (2) commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084. In any warrant, information, or indictment, it shall not be necessary to negative any exceptions, and the burden of any exception shall be upon the defendant.

Section 4. Effective January 1, 2010, subsection (5) of section 465.019, Florida Statutes, is amended to read:

465.019 Institutional pharmacies; permits.--

(5) All institutional pharmacies shall be under the professional supervision of a consultant pharmacist, and the compounding and dispensing of medicinal drugs shall be done only by a licensed pharmacist. Every institutional pharmacy that

employs or otherwise utilizes registered pharmacy technicians shall have a written policy and procedures manual specifying those duties, tasks, and functions which a registered pharmacy technician is allowed to perform.

Section 5. Except as otherwise expressly provided in this act, this act shall take effect upon becoming a law.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 567 Onsite Sewage Treatment and Disposal Systems

SPONSOR(S): Poppell

TIED BILLS: **IDEN./SIM. BILLS:** SB 1318

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Committee on Health Quality		Owen	Lowell
2) Healthcare Council			
3)			
4)			
5)			

SUMMARY ANALYSIS

House Bill 567 adds a local government representative to the Research Review and Advisory Committee and the Technical Review Advisory Panel, which advise the Department of Health on issues relating to onsite sewage treatment and disposal systems.

The bill appears to have an insignificant fiscal impact to the state on the state or local government.

The bill is effective July 1, 2008.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

The bill does not appear to implicate any of the House principles.

B. EFFECT OF PROPOSED CHANGES:

Present Situation

The Research Review and Advisory Committee

The Research Review and Advisory Committee (committee) is created in statute to advise the Department of Health (department). The committee is directed "to advise the department on directions for new research, review and rank proposals for research contracts, and review draft research reports and make comments."[1] Currently, the committee is comprised of the following nine members:[2]

- A representative of the Division of Environmental Health of the department
- A representative from the septic tank industry
- A representative from the home building industry
- A representative from an environmental interest group
- A representative from the State University System, from a department knowledgeable about onsite sewage treatment and disposal systems
- A professional engineer registered in this state who has work experience in onsite sewage treatment and disposal systems
- A representative from the real estate profession
- A representative from the restaurant industry
- A consumer

According to the department, the committee has identified the following research priorities for 2008:[3]

- Restoration of the University of South Florida Lysimeter Station ($20,000 to $50,000 approximate cost)
- Phase II of the Florida Passive Nitrogen Removal Project ($200,000 approximate cost)
- Wekiva Onsite Sewage Treatment and Disposal System Seasonal Variability Assessment ($200,000 approximate cost)
- Alternative Drainfield Product Assessment ($300,000 approximate cost)
- Long-term Deformation of Tanks on Different Materials ($20,000 approximate cost)

[1] Section 381.0065(4)(o), F.S.
[2] *Id.*
[3] http://floridashealth.com/Environment/ostds/research/Research_Priorities_2008.pdf (visited February 8, 2008).

The Technical Review and Advisory Panel

The Technical Review and Advisory Panel (panel) is created in statute "to assist the department in rulemaking and decision making by drawing on the expertise of representatives from several groups that are affected by onsite sewage treatment and disposal systems. The panel may also review and comment on any legislation or any existing or proposed state policy or issue related to onsite sewage treatment and disposal systems."[4] Currently, the committee is comprised of the following ten members:[5]

- A soil scientist
- A professional engineer, recommended by the Florida Engineering Society
- Two representatives from the home building industry, recommended by the Florida Home Builders Association, including one who is a developer who develops lots using onsite sewage treatment and disposal systems
- A representative from the county health departments who has experience permitting and inspecting the installation of onsite sewage treatment and disposal systems
- A representative from the real estate industry, recommended by the Florida Association of Realtors
- A consumer with a science background
- Two representatives of the septic tank industry, recommended by the Florida Onsite Wastewater Association, including one who is a manufacturer of onsite sewage treatment and disposal systems
- A representative from the environmental health profession, recommended by the Florida Environmental Health Association, who is not employed by a county health department

At their most recent meeting (January 2008), the panel discussed several issues, which included:[6]

- Septic tank lids, Rule 64E-6.013, F.A.C., requiring all treatment receptacles to have a watertight lid.
- Mound stabilization, Rule 64E-6.009, F.A.C., allowing mounds to be hydro seeded.
- Alternative Systems, Rule 64E-6.009, F.A.C., removing the requirement that the county health department (CHD) require an engineer to design a system having a total absorption area greater than 1,000 square feet and removing the requirement that the CHD require the design engineer to certify that the installed system complies with the approved design and installation requirements.
- Septic tank installation, Rule 64E-6.013, F.A.C., removing the requirement that the access manhole over the inlet and outlet extend within eight inches and requiring the manhole to be exposed at the ground surface. Also requiring all fiberglass tanks to be covered with a minimum of four inches of soil, with the exception of the exposed hatch or riser covers.

Members of both the committee and panel receive reimbursement for per diem and travel expenses.

Section 381.0065(3)(j), F.S., specifies that "research projects shall not be awarded to firms or entities that employ or are associated with persons who serve on either the technical review and advisory panel or the research review and advisory committee."

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[4] Section 381.0068(2), F.S.
[5] *Id.*
[6] http://www.doh.state.fl.us/environment/ostds/trap/agenda/Ag20080124.pdf (visited February 8, 2008).

Effect of Proposed Changes

The bill adds a representative from local government who is knowledgeable about domestic wastewater treatment to the research review and advisory committee. The membership of the committee is increased to a total of ten members.

The bill adds a representative from local government who is knowledgeable about domestic wastewater treatment and who is recommended by the Florida Association of Counties and the Florida League of Cities to the technical review and advisory panel. The membership of the panel is increased to a total of eleven members.

C. SECTION DIRECTORY:

Section 1: Amends s. 381.0065, F.S., revising the membership of the research review and advisory committee.

Section 2: Amends s. 381.0068, F.S., revising the membership of the technical review and advisory panel.

Section 3: Provides an effective date of July 1, 2008.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

Estimated Recurring Expenditures	**1st Year**	**2nd Year**
Travel and per diem for two new members estimated at four meetings each year at $500 per meeting	$4,000	$4,000
Total Estimated Trust Fund Expenditures	$4,000	$4,000

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

The department may incur a nominal increase in Trust Fund expenditures for travel and per diem expenses associated with the two new members.

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 a state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenues

2. Other:

None.

B. RULE-MAKING AUTHORITY:

No additional rulemaking authority is required as a result of this bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

D. STATEMENT OF THE SPONSOR

No statement submitted.

IV. AMENDMENTS/COUNCIL SUBSTITUTE CHANGES

A bill to be entitled

An act relating to onsite sewage treatment and disposal systems; amending ss. 381.0065 and 381.0068, F.S.; providing that a member of local government who is knowledgeable about domestic wastewater treatment be added to the research review and advisory committee and the technical review and advisory panel established by the Department of Health for purposes of onsite sewage treatment & disposal system regulation; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Paragraph (o) of subsection (4) of section 381.0065, Florida Statutes, is amended to read:

381.0065 Onsite sewage treatment and disposal systems; regulation.--

(4) PERMITS; INSTALLATION; AND CONDITIONS.--A person may not construct, repair, modify, abandon, or operate an onsite sewage treatment and disposal system without first obtaining a permit approved by the department. The department may issue permits to carry out this section, but shall not make the issuance of such permits contingent upon prior approval by the Department of Environmental Protection, except that the issuance of a permit for work seaward of the coastal construction control line established under s. 161.053 shall be contingent upon receipt of any required coastal construction control line permit from the Department of Environmental Protection. A construction

permit is valid for 18 months from the issuance date and may be extended by the department for one 90-day period under rules adopted by the department. A repair permit is valid for 90 days from the date of issuance. An operating permit must be obtained prior to the use of any aerobic treatment unit or if the establishment generates commercial waste. Buildings or establishments that use an aerobic treatment unit or generate commercial waste shall be inspected by the department at least annually to assure compliance with the terms of the operating permit. The operating permit for a commercial wastewater system is valid for 1 year from the date of issuance and must be renewed annually. The operating permit for an aerobic treatment unit is valid for 2 years from the date of issuance and must be renewed every 2 years. If all information pertaining to the siting, location, and installation conditions or repair of an onsite sewage treatment and disposal system remains the same, a construction or repair permit for the onsite sewage treatment and disposal system may be transferred to another person, if the transferee files, within 60 days after the transfer of ownership, an amended application providing all corrected information and proof of ownership of the property. There is no fee associated with the processing of this supplemental information. A person may not contract to construct, modify, alter, repair, service, abandon, or maintain any portion of an onsite sewage treatment and disposal system without being registered under part III of chapter 489. A property owner who personally performs construction, maintenance, or repairs to a system serving his or her own owner-occupied single-family

residence is exempt from registration requirements for performing such construction, maintenance, or repairs on that residence, but is subject to all permitting requirements. A municipality or political subdivision of the state may not issue a building or plumbing permit for any building that requires the use of an onsite sewage treatment and disposal system unless the owner or builder has received a construction permit for such system from the department. A building or structure may not be occupied and a municipality, political subdivision, or any state or federal agency may not authorize occupancy until the department approves the final installation of the onsite sewage treatment and disposal system. A municipality or political subdivision of the state may not approve any change in occupancy or tenancy of a building that uses an onsite sewage treatment and disposal system until the department has reviewed the use of the system with the proposed change, approved the change, and amended the operating permit.

(o) The department shall appoint a research review and advisory committee, which shall meet at least semiannually. The committee shall advise the department on directions for new research, review and rank proposals for research contracts, and review draft research reports and make comments. The committee is comprised of:

1. A representative of the Division of Environmental Health of the Department of Health.

2. A representative from the septic tank industry.

3. A representative from the home building industry.

4. A representative from an environmental interest group.

5. A representative from the State University System, from a department knowledgeable about onsite sewage treatment and disposal systems.

6. A professional engineer registered in this state who has work experience in onsite sewage treatment and disposal systems.

7. A representative from local government who is knowledgeable about domestic wastewater treatment.

8.~~7.~~ A representative from the real estate profession.

9.~~8.~~ A representative from the restaurant industry.

10.~~9.~~ A consumer.

Members shall be appointed for a term of 3 years, with the appointments being staggered so that the terms of no more than four members expire in any one year. Members shall serve without remuneration, but are entitled to reimbursement for per diem and travel expenses as provided in s. 112.061.

Section 2. Subsection (2) of section 381.0068, Florida Statutes, is amended to read:

381.0068 Technical review and advisory panel.--

(2) The primary purpose of the panel is to assist the department in rulemaking and decisionmaking by drawing on the expertise of representatives from several groups that are affected by onsite sewage treatment and disposal systems. The panel may also review and comment on any legislation or any existing or proposed state policy or issue related to onsite sewage treatment and disposal systems. If requested by the panel, the chair will advise any affected person or member of

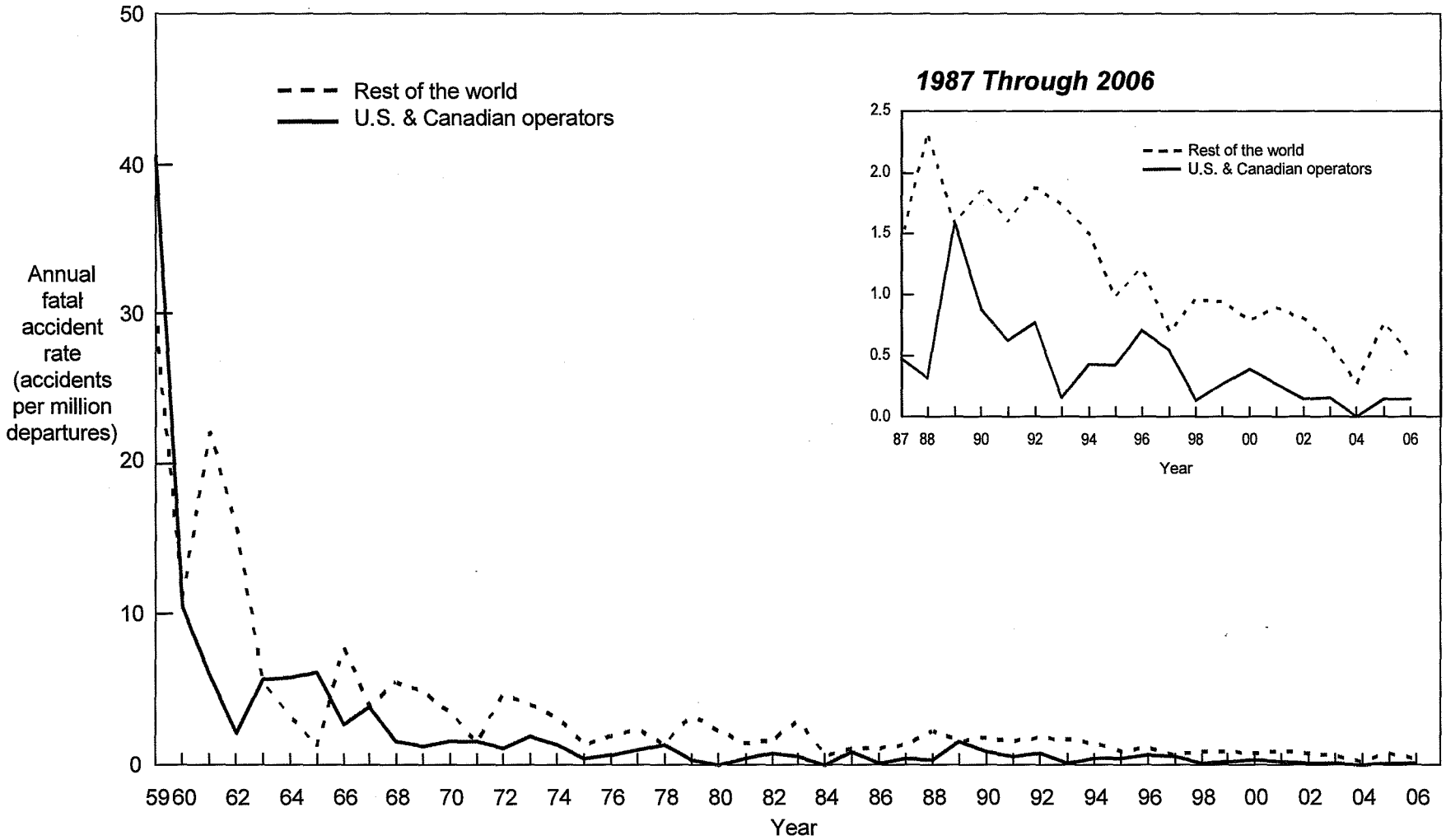
the Legislature of the panel's position on the legislation or any existing or proposed state policy or issue. The chair may also take such other action as is appropriate to allow the panel to function. At a minimum, the panel shall consist of a soil scientist; a professional engineer registered in this state who is recommended by the Florida Engineering Society and who has work experience in onsite sewage treatment and disposal systems; two representatives from the home-building industry recommended by the Florida Home Builders Association, including one who is a developer in this state who develops lots using onsite sewage treatment and disposal systems; a representative from the county health departments who has experience permitting and inspecting the installation of onsite sewage treatment and disposal systems in this state; a representative from the real estate industry who is recommended by the Florida Association of Realtors; a consumer representative with a science background; two representatives of the septic tank industry recommended by the Florida Onsite Wastewater Association, including one who is a manufacturer of onsite sewage treatment and disposal systems; a representative from local government who is knowledgeable about domestic wastewater treatment and who is recommended by the Florida Association of Counties and the Florida League of Cities; and a representative from the environmental health profession who is recommended by the Florida Environmental Health Association and who is not employed by a county health department. Members are to be appointed for a term of 2 years. The panel may also, as needed, be expanded to include ad hoc, nonvoting representatives who have topic-specific expertise. All

rules proposed by the department which relate to onsite sewage treatment and disposal systems must be presented to the panel for review and comment prior to adoption. The panel's position on proposed rules shall be made a part of the rulemaking record that is maintained by the agency. The panel shall select a chair, who shall serve for a period of 1 year and who shall direct, coordinate, and execute the duties of the panel. The panel shall also solicit input from the department's variance review and advisory committee before submitting any comments to the department concerning proposed rules. The panel's comments must include any dissenting points of view concerning proposed rules. The panel shall hold meetings as it determines necessary to conduct its business, except that the chair, a quorum of the voting members of the panel, or the department may call meetings. The department shall keep minutes of all meetings of the panel. Panel members shall serve without remuneration, but, if requested, shall be reimbursed for per diem and travel expenses as provided in s. 112.061.

Section 3. This act shall take effect July 1, 2008.

U.S. and Canadian Operators Accident Rates by Year

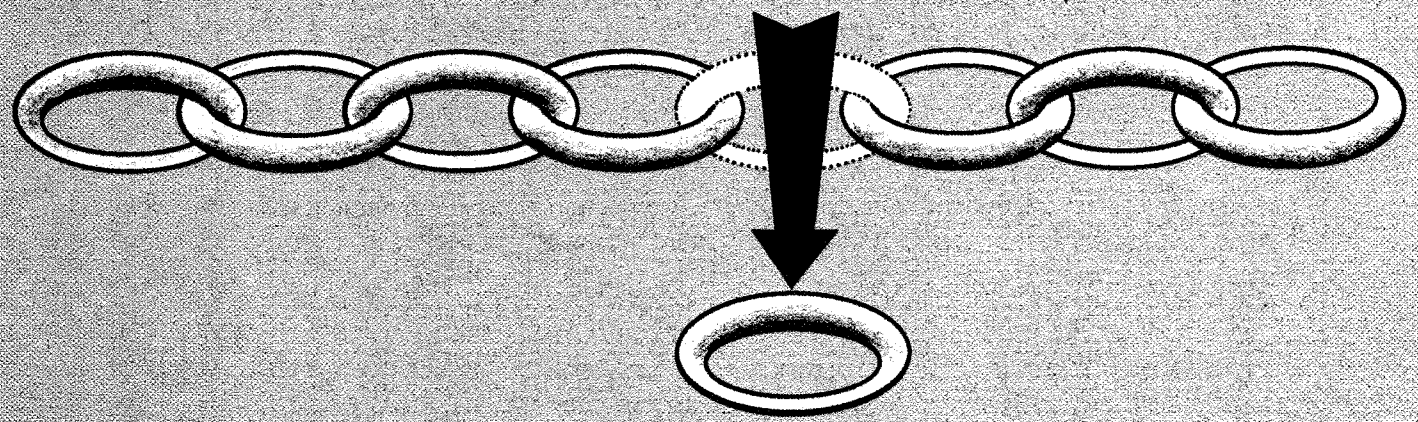
Fatal Accidents – Worldwide Commercial Jet Fleet – 1959 Through 2006



BOEING

Accident Prevention Strategies

"Removing Links in the Accident Chain"



Commercial Jet Aircraft Accidents

World Wide Operations

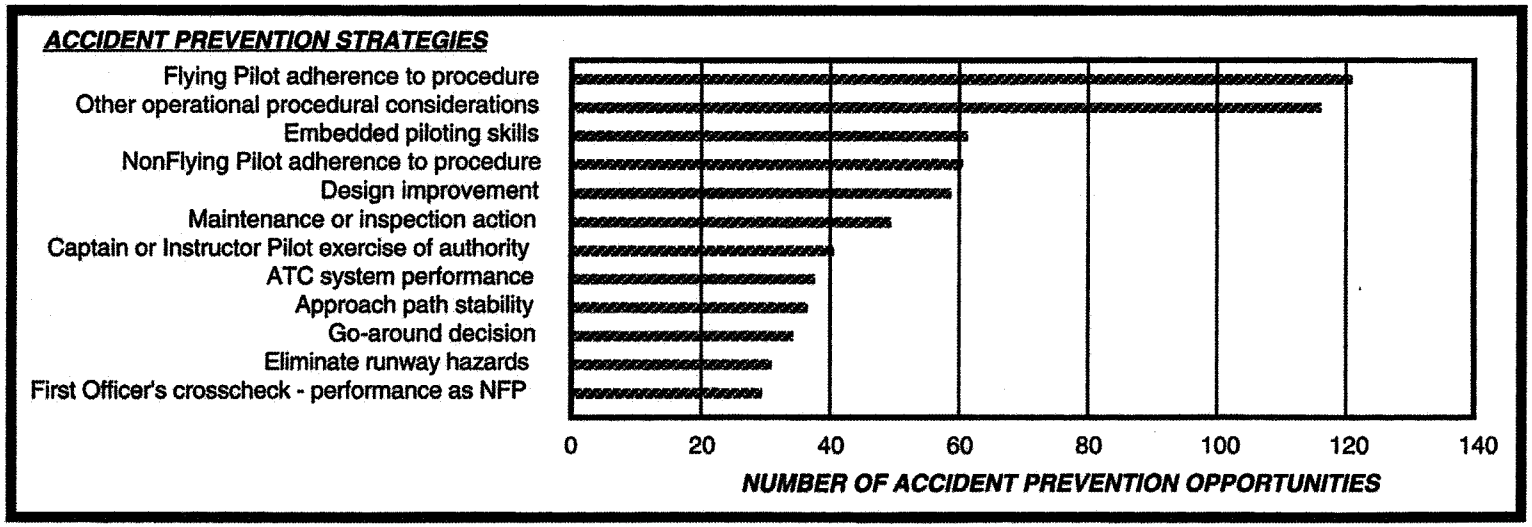
1982-1991

EXECUTIVE SUMMARY

This document represents an ongoing process of developing lessons learned from past events to identify strategies for preventing future accidents. 232 commercial jet aircraft accidents over a 10-year period (1982 - 1991) were examined to develop recommendations for Accident Prevention Strategies. The sequence of events was established for each accident, and events were grouped using 37 categories of Accident Prevention Strategies. An Accident Prevention Strategy is defined as an action which, had it been utilized, would have broken the chain of events and prevented the accident. The number of strategies identified for a given accident varied from only one (in 39 accidents) to 20 (in one accident) with an average of just under 4 strategies per accident. 193 accidents had two or more opportunities to stop the progression of events, and thus prevent the accident.

The following chart shows the top 12, out of the 37, strategies listed by their number of occurrences. The most common strategy was "Flying Pilot adherence to procedure", which was a factor 122 times in 97 accidents (it occurred more than one time in 14 accidents). Detailed definitions of the Strategies are shown on the following pages.

ACCIDENT PREVENTION OPPORTUNITIES - 232 ACCIDENTS (1982 - 1991)

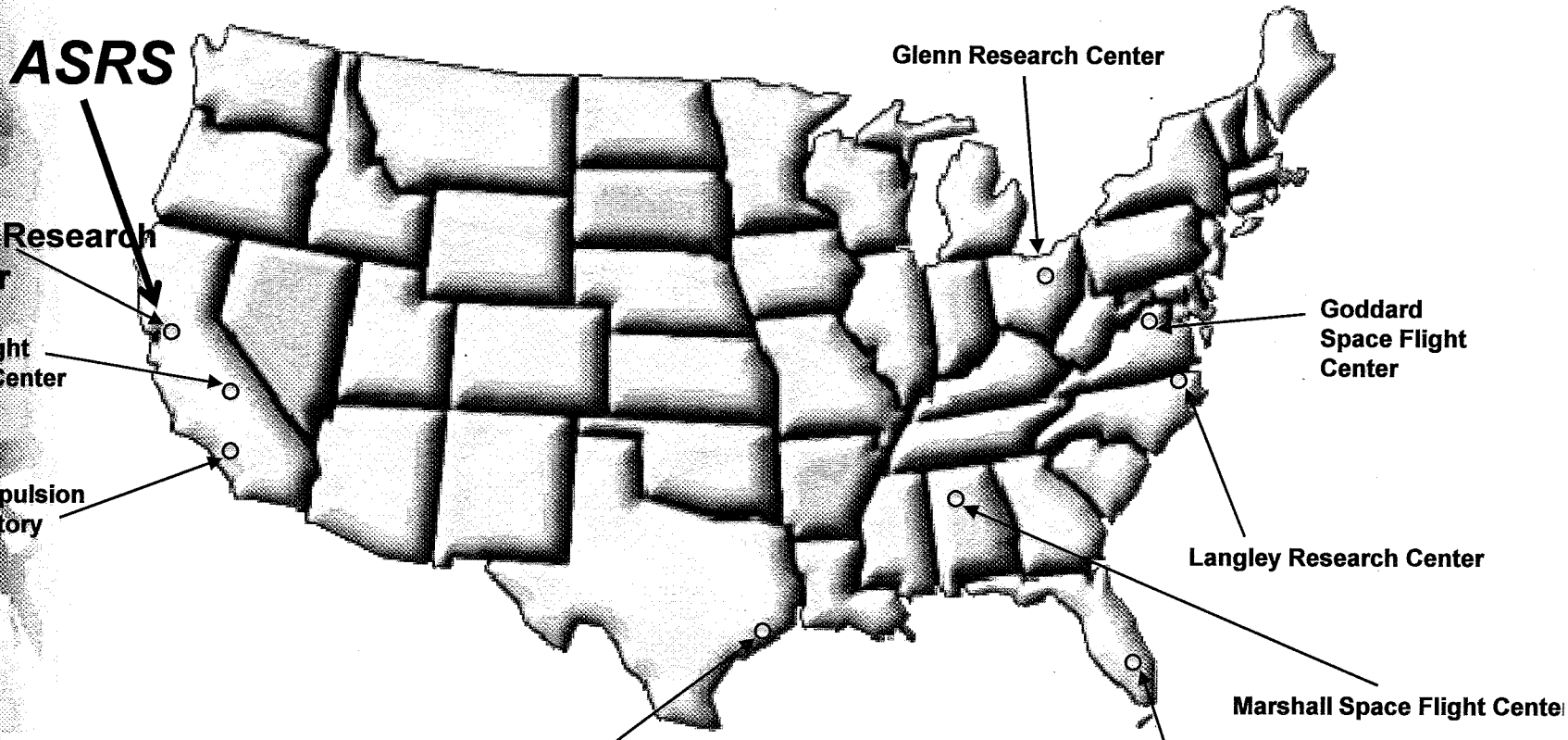


ASRS
Aviation Safety Reporting System

Florida House of Representatives
Health Quality Committee
and
Florida Hospital Association
Tallahassee, FL
February 19, 2008

Linda Connell, Director
NASA ASRS

NASA Centers



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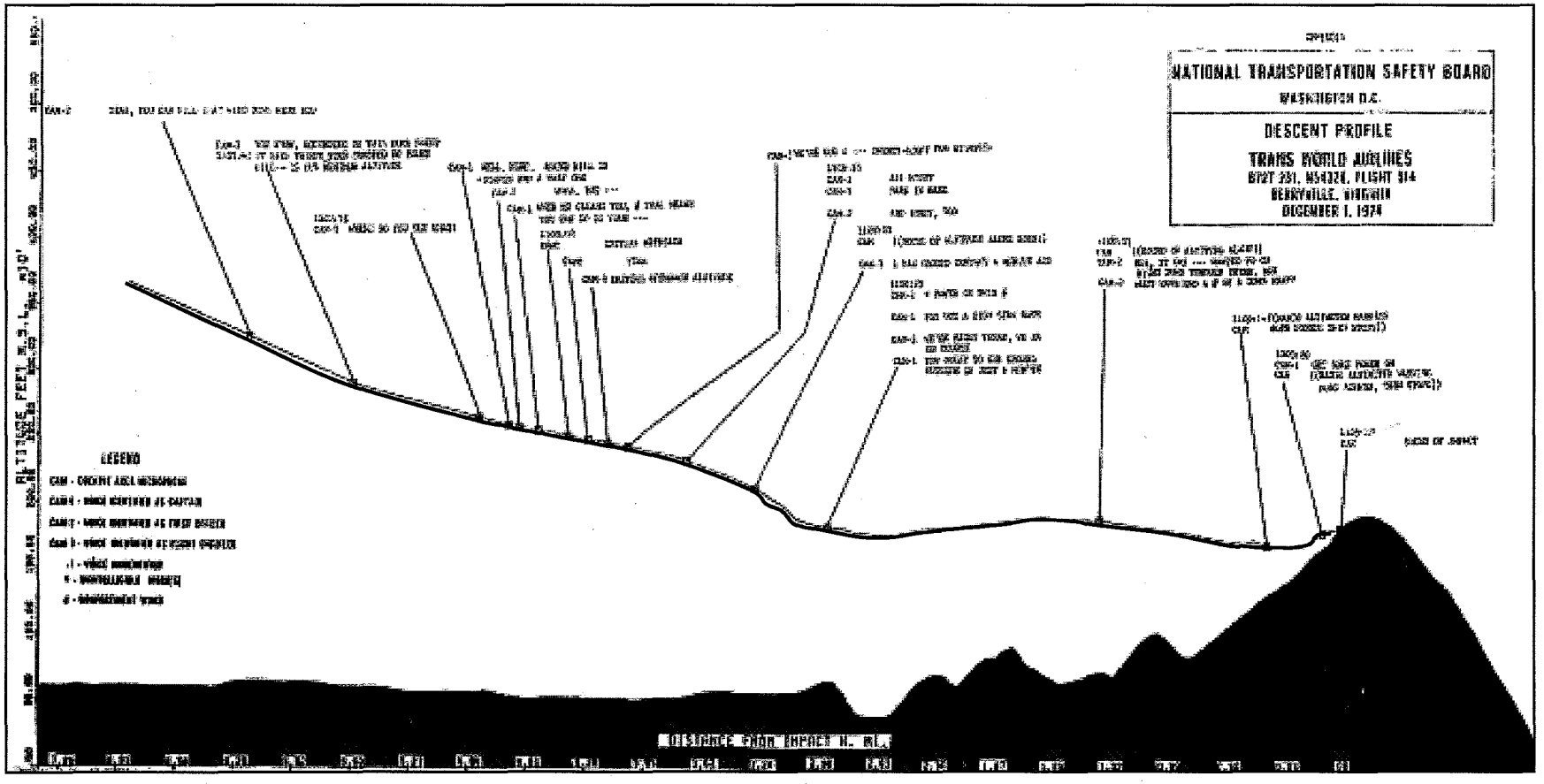
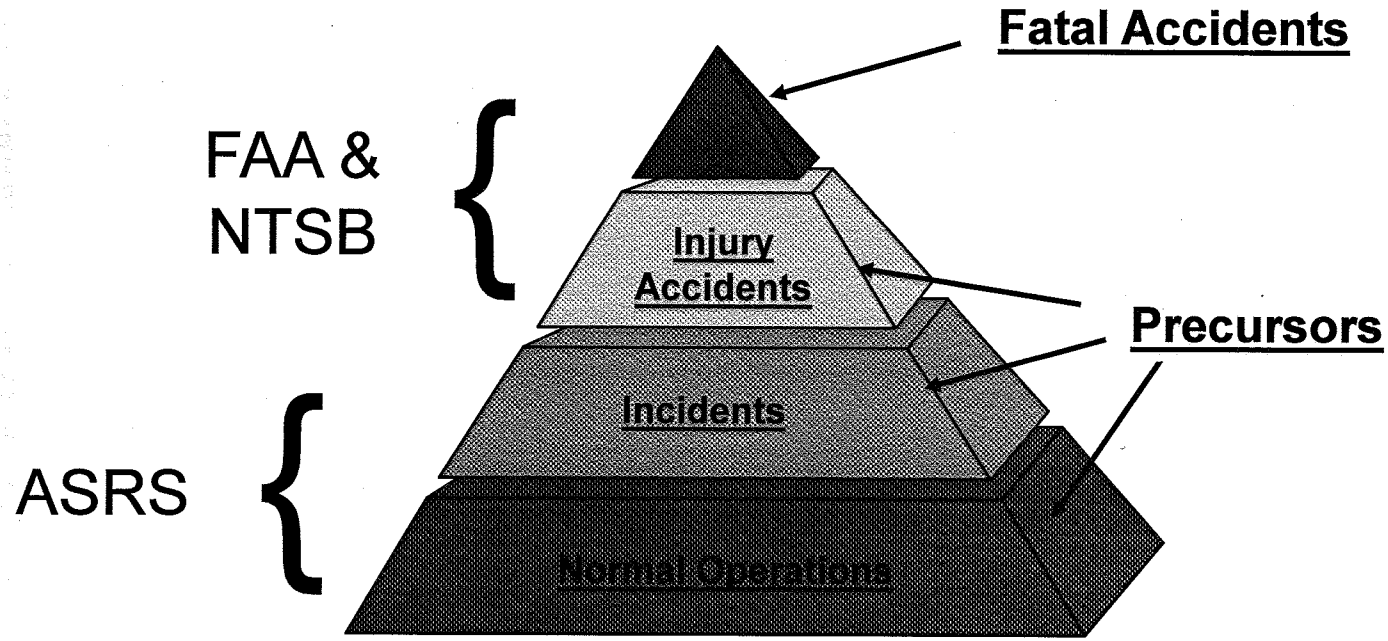


TWA 514, December 1, 1974

Event Occurrences



ASRS is Complementary to Other Systems of Reporting

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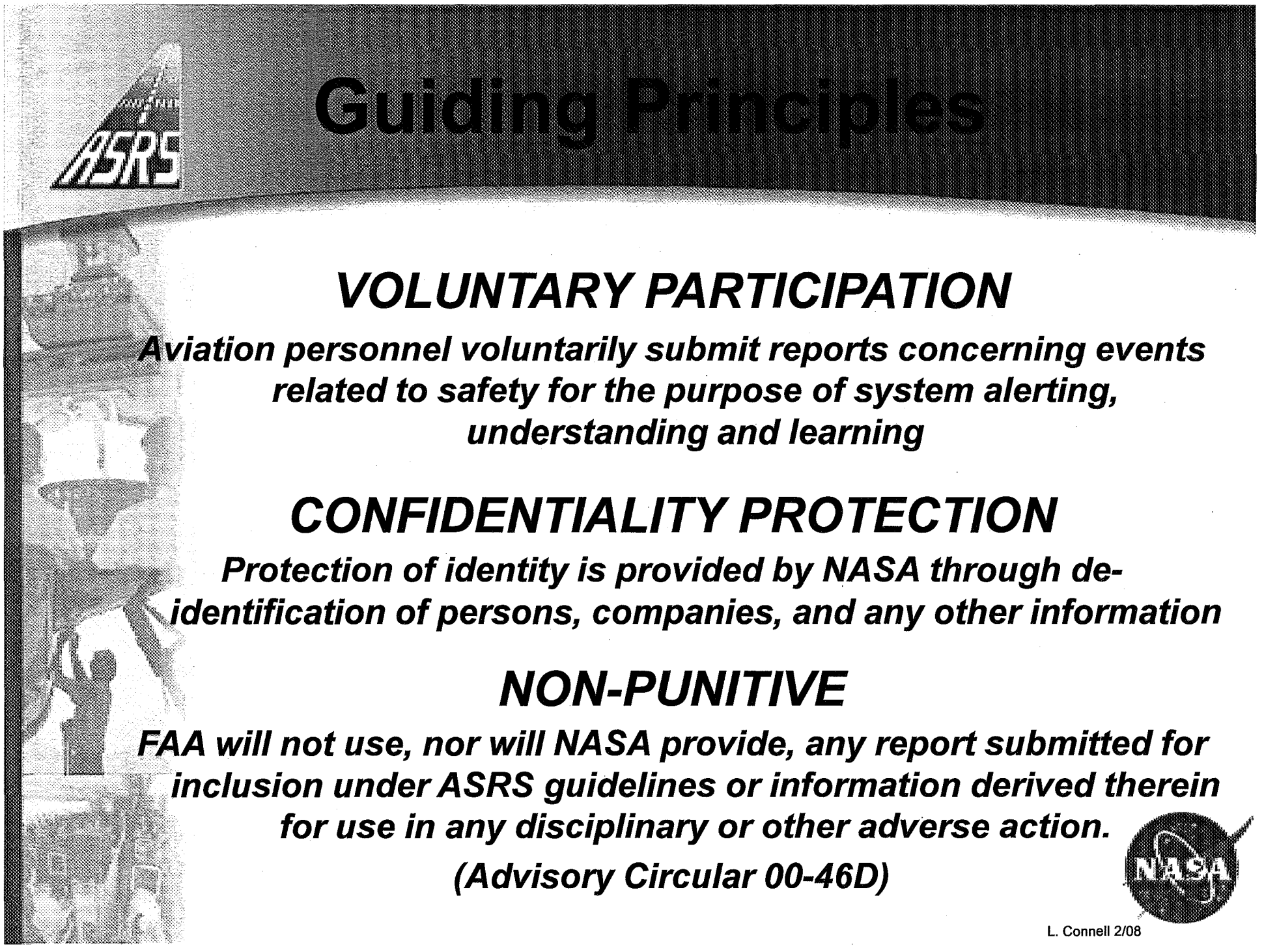

Guiding Principles

VOLUNTARY PARTICIPATION

Aviation personnel voluntarily submit reports concerning events related to safety for the purpose of system alerting, understanding and learning

CONFIDENTIALITY PROTECTION

Protection of identity is provided by NASA through de-identification of persons, companies, and any other information

NON-PUNITIVE

FAA will not use, nor will NASA provide, any report submitted for inclusion under ASRS guidelines or information derived therein for use in any disciplinary or other adverse action.

(Advisory Circular 00-46D)

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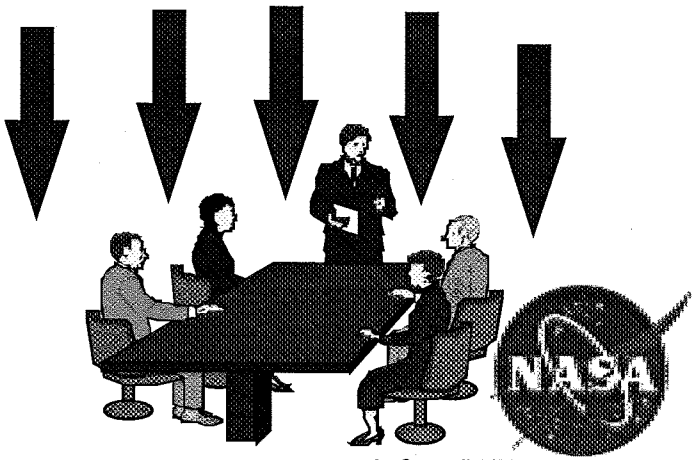
ASRS PURPOSE

ALERTS

Identify Deficiencies and Discrepancies

PRODUCTS

Provide Data for Planning and Improvements



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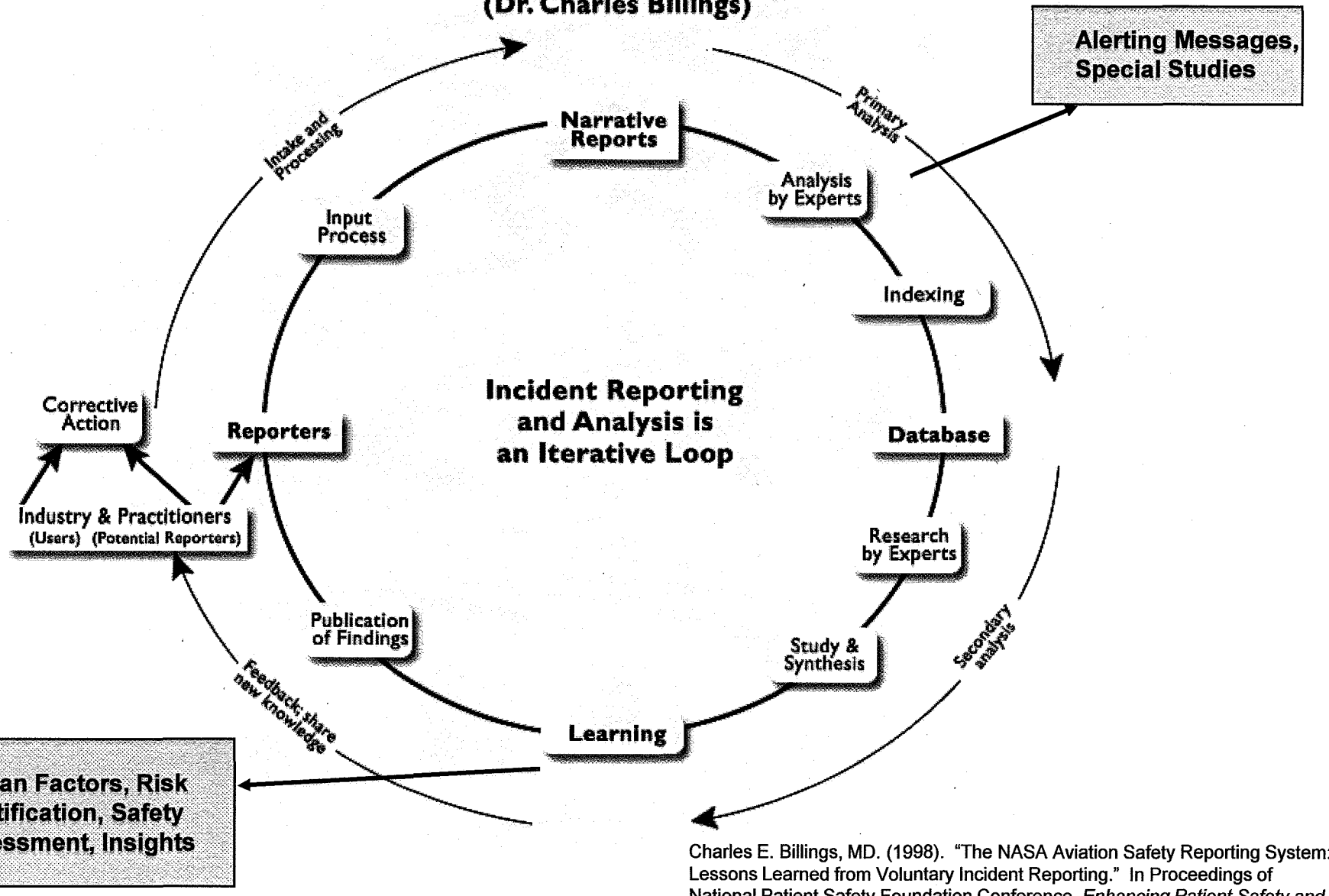
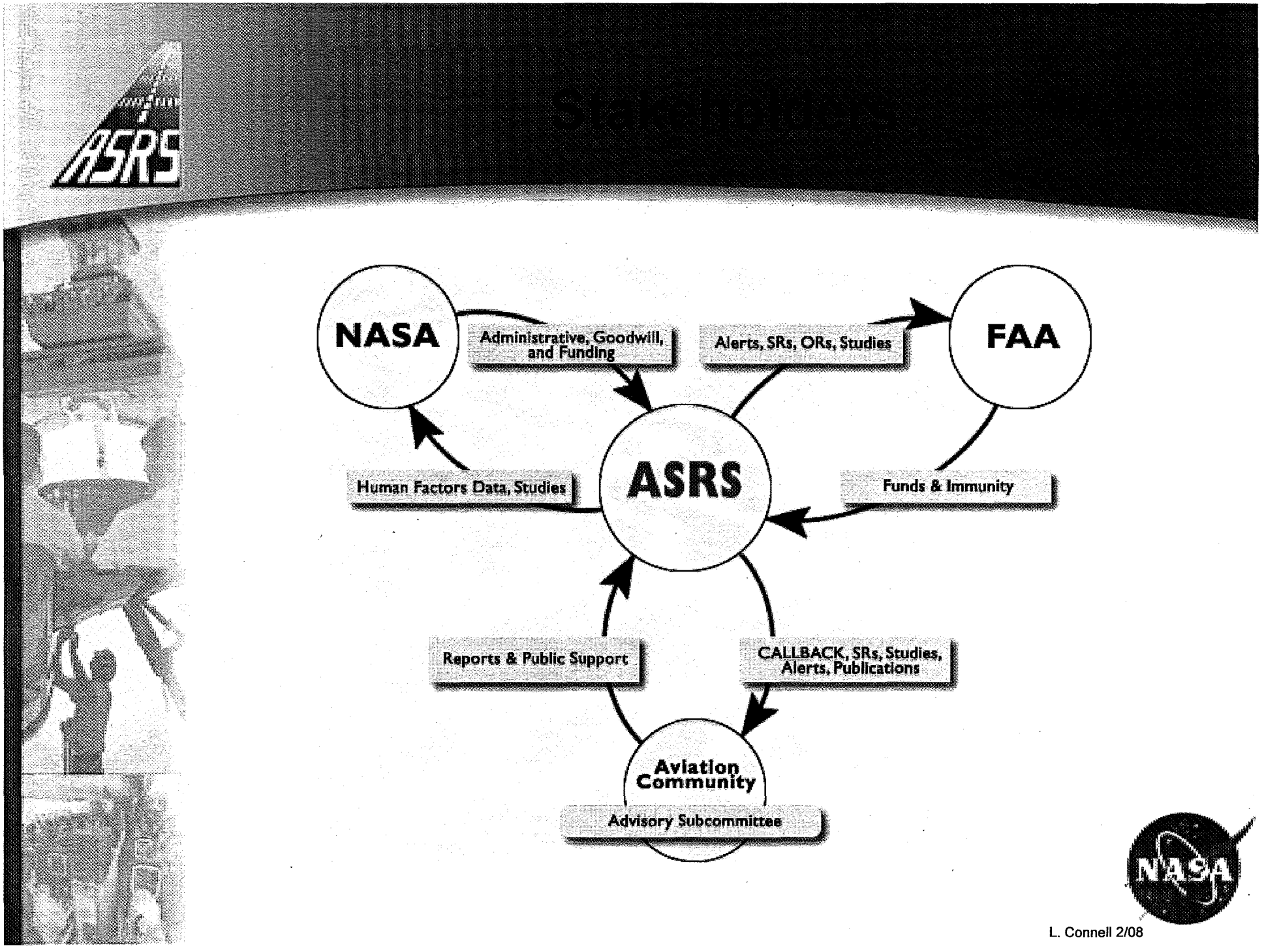
The Incident Reporting Model

(Dr. Charles Billings)



Charles E. Billings, MD. (1998). "The NASA Aviation Safety Reporting System: Lessons Learned from Voluntary Incident Reporting." In Proceedings of National Patient Safety Foundation Conference, *Enhancing Patient Safety and Reducing Errors in Health Care*, Chicago (pp. 97-100).



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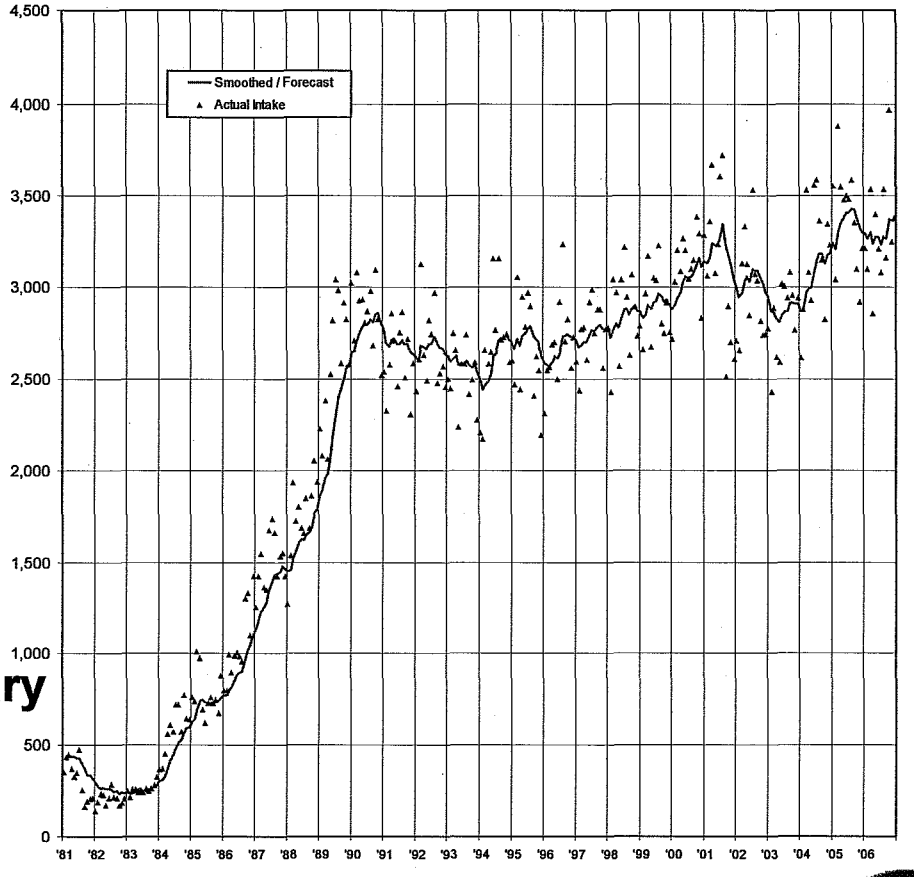
ASRS Report Intake

- An increase (CY07) of better that 100% since 1988
- Averaging 3,700 Reports Per Month
  - 185+ per working day
- Total Intake for 2007 > 44,000
- Record Intake for February 2008 – 4,425 reports
- Projected Intake for 2008 45,000



Annual ASRS Monthly Report Intake 1981 – 2006

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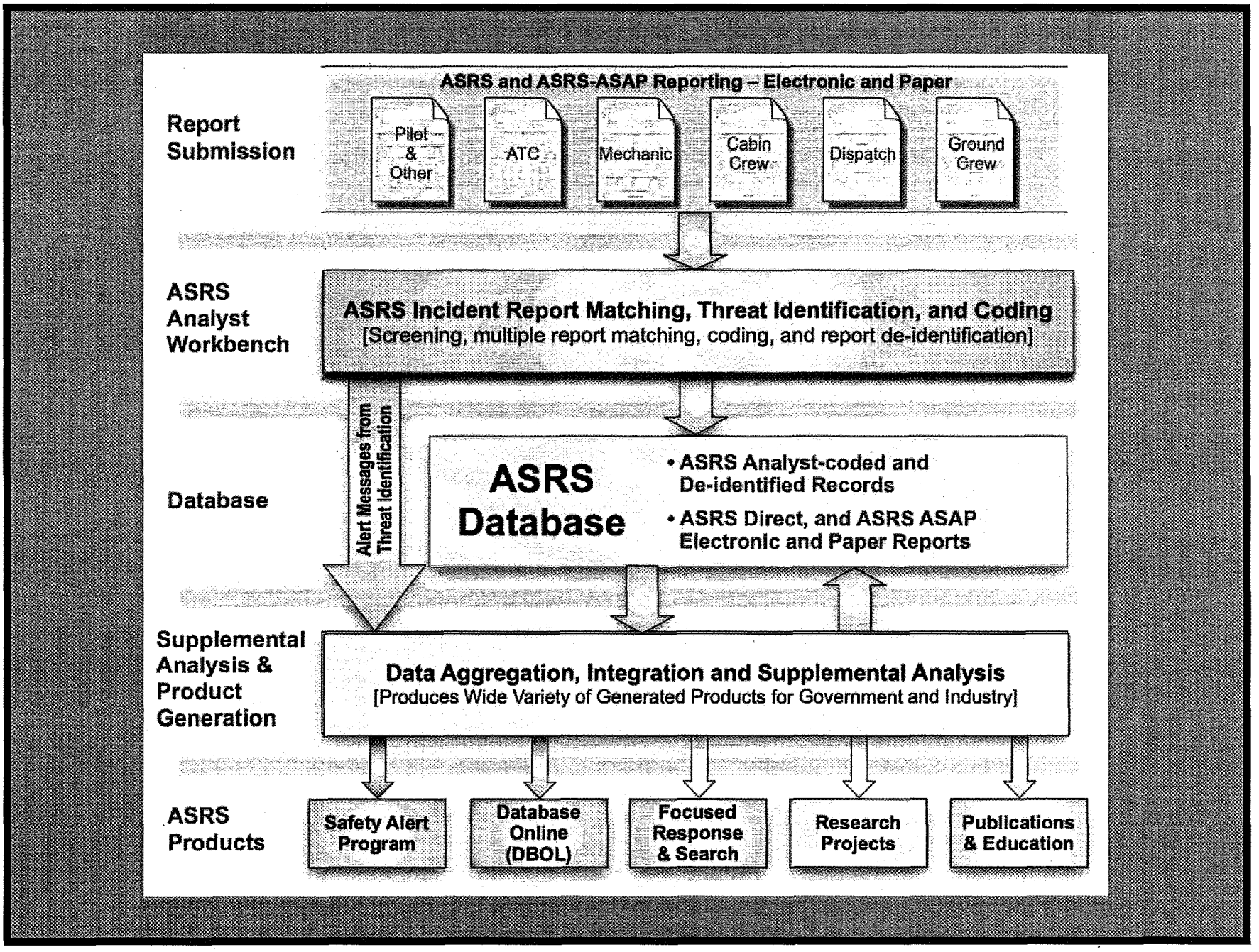
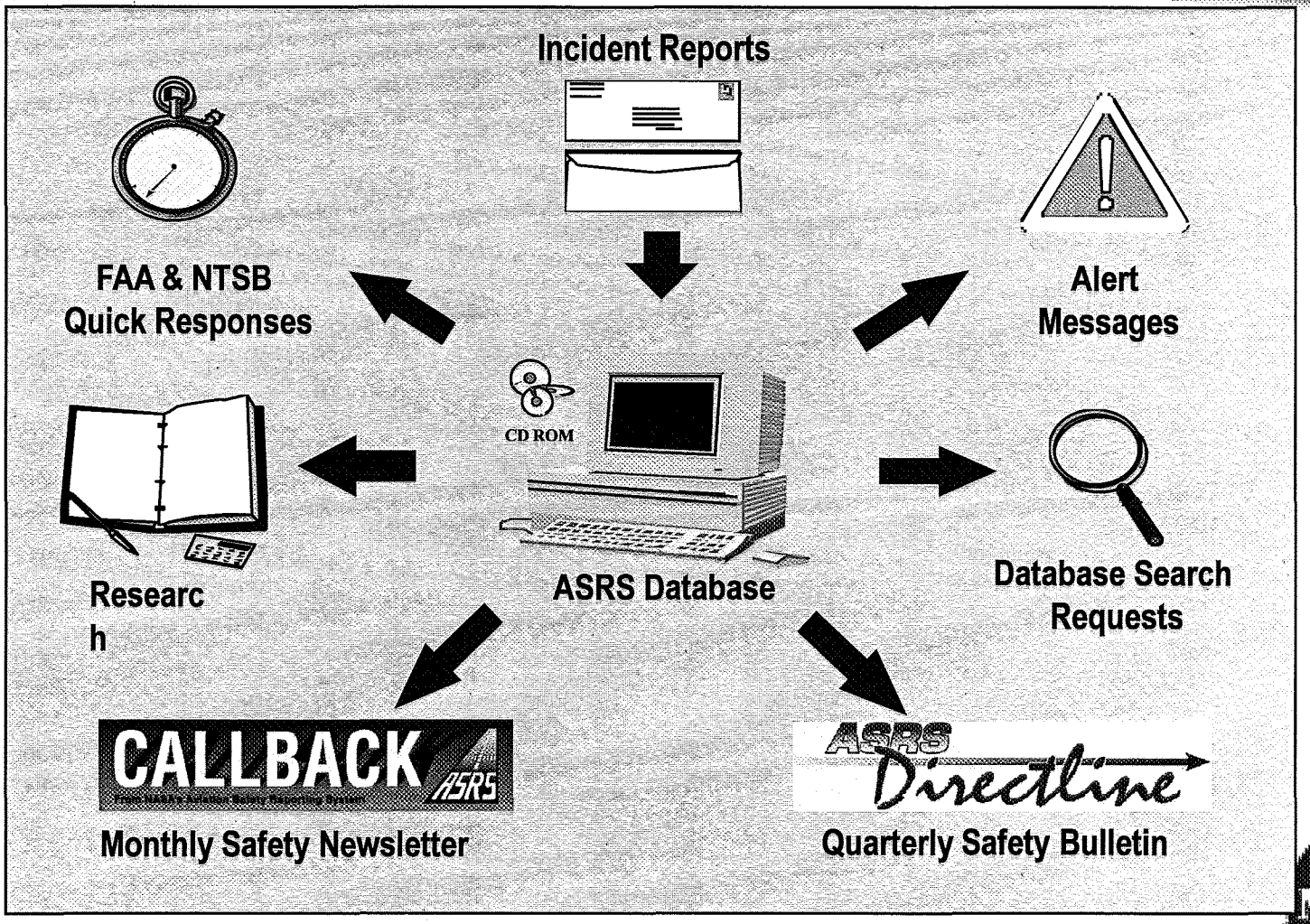

Report Submission
ASRS and ASRS-ASAP Reporting – Electronic and Paper
Pilot & Other
ATC
Mechanic
Cabin Crew
Dispatch
Ground Crew
ASRS Analyst Workbench
ASRS Incident Report Matching, Threat Identification, and Coding
[Screening, multiple report matching, coding, and report de-identification]
Alert Messages from Threat Identification
Database
ASRS Database
• ASRS Analyst-coded and De-identified Records
• ASRS Direct, and ASRS ASAP Electronic and Paper Reports
Supplemental Analysis & Product Generation
Data Aggregation, Integration and Supplemental Analysis
[Produces Wide Variety of Generated Products for Government and Industry]
ASRS Products
Safety Alert Program
Database Online (DBOL)
Focused Response & Search
Research Projects
Publications & Education

ASRS PRODUCTS & SERVICES FOR THE AVIATION COMMUNITY



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ASRS Model Applied to Aviation & Other Domains

National and International Reputation

ASRS Recognized Model for Proactive Contribution to Safety & Risk Management Process

- **Int'l Confidential Aviation Safety Systems (ICASS)**
  - **Includes 11 countries modeled after ASRS**
- **Patient Safety Reporting System (PSRS)**
  - **Dept of Veterans Affairs requested NASA to develop medical reporting system with external, independent, voluntary, confidential, & non-punitive features**
  - **FAA and NASA highlighted in chapter of Institute of Medicine (IOM) report, "To Err is Human" which has launched nationwide patient safety efforts.**
- **Fire Fighters Near Miss Reporting System**
  - **Launched August, 2005 was modeled after ASRS**
  - **Development Task Force included FAA and NASA ASRS**

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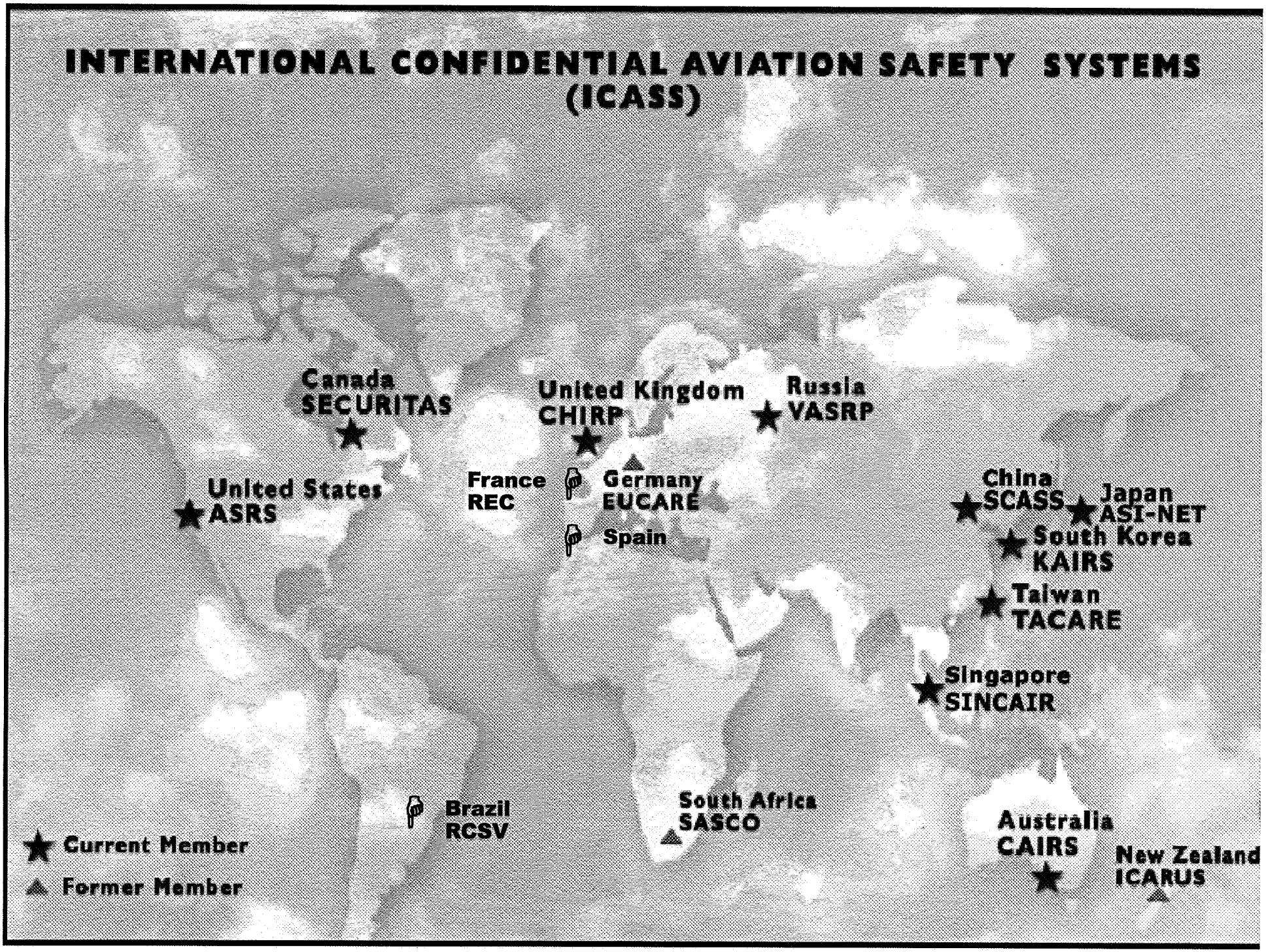
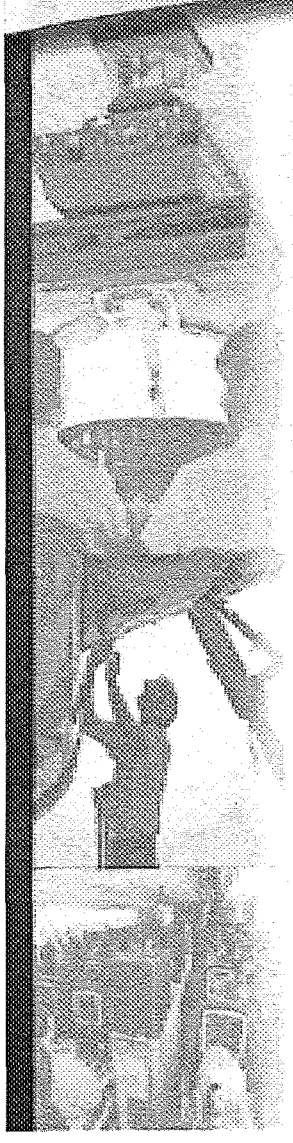

INTERNATIONAL CONFIDENTIAL AVIATION SAFETY SYSTEMS
(ICASS)
Canada
SECURITAS
United States
ASRS
United Kingdom
CHIRP
Russia
VASRP
France
REC
Germany
EUCARE
Spain
China
SCASS
Japan
ASI-NET
South Korea
KAIRS
Taiwan
TACARE
Singapore
SINCAIR
Brazil
RCSV
South Africa
SASCO
Australia
CAIRS
New Zealand
ICARUS
Current Member
Former Member

See It. Report It.
Make a Difference.

Lessons learned. Lessons shared.
Near-real-time support for our war fighters

Unique Aspects of ASRS



System-Wide Perspective - capability to identify hazards identified by aviation personnel and match reports from all segments of aviation community

- ASRS was catalyst for recent FAA focus on Teterboro Departures

System-Wide Alerting - both national and international capability to provide ASRS Alert Messages to industry and government

Data Processing through Aviation Expert Analysts

- ASRS Office staff include Aviation Expert Analysts with a combined total of 380 years of experience in aviation (air carrier pilots, corporate pilots, general aviation pilots, air traffic control, and maintenance)
- Experts read and review 100% of reports and reliably code information to databases

Comprehensive and Time Tested Coding Taxonomy

- Fixed Field Codes combined with Narrative Text yields qualitative data for further secondary analysis techniques (Perilog, special studies, focused analytic techniques, etc)

Unique Aspects of ASRS

Strong Immunity and Legal Provisions

- Federal Law specifically addressing ASRS (14 CFR 91.25)
- FAA Advisory Circular 00-46D
- ASRS Mandated by Congress in 1980's

Information Sharing on Safety/Security

- Database Search Requests, Database Shared with FAA NASDAC, Topical Studies, Structured Telephone Callback Studies, Collaborations with Industry and Gov't (FAA, NTSB, NASA, TSA, etc.)
- Largest source of ASAP data collected in central location

National and International Reputation

- ASRS Recognized Model for Proactive Contribution to Safety Process
- Int'l Confidential Aviation Safety Systems (ICASS)
- ASRS Model Being Utilized by Other Domains for Safety Improvements

SUMMARY

WHY CONFIDENTIAL REPORTING WORKS

- When organizations want to learn more about the occurrence of events, the best approach is simply to ask those involved.
- People are generally willing to share their knowledge if they are assured:
  - Their identities will remain protected
  - There is no disciplinary or legal consequences

SUMMARY

- A properly constructed ***confidential***, ***voluntary***, ***non-punitive*** reporting system can be used by any person to safely share information
- Confidential reporting systems have the means to answer the question ***why*** - why a system failed, why a human erred
- Incident/event data is complementary to the data gathered by other monitoring systems

Select Year: 2007 Go

The 2007 Florida Statutes

Title XXXIII	Chapter 499	View Entire Chapter
REGULATION OF TRADE, COMMERCE, INVESTMENTS, AND SOLICITATIONS	DRUG, COSMETIC, AND HOUSEHOLD PRODUCTS	

499.029 Cancer Drug Donation Program.--

(1) This section may be cited as the "Cancer Drug Donation Program Act."

(2) There is created a Cancer Drug Donation Program within the Department of Health for the purpose of authorizing and facilitating the donation of cancer drugs and supplies to eligible patients.

(3) As used in this section:

(a) "Cancer drug" means a prescription drug that has been approved under s. 505 of the federal Food, Drug, and Cosmetic Act and is used to treat cancer or its side effects or is used to treat the side effects of a prescription drug used to treat cancer or its side effects. "Cancer drug" does not include a substance listed in Schedule II, Schedule III, Schedule IV, or Schedule V of s. 893.03.

(b) "Closed drug delivery system" means a system in which the actual control of the unit-dose medication package is maintained by the facility rather than by the individual patient.

(c) "Department" means the Department of Health.

(d) "Donor" means a patient or patient representative who donates cancer drugs or supplies needed to administer cancer drugs that have been maintained within a closed drug delivery system; health care facilities, nursing homes, hospices, or hospitals with closed drug delivery systems; or pharmacies, drug manufacturers, medical device manufacturers or suppliers, or wholesalers of drugs or supplies, in accordance with this section. "Donor" includes a physician licensed under chapter 458 or chapter 459 who receives cancer drugs or supplies directly from a drug manufacturer, drug wholesaler, or pharmacy.

(e) "Eligible patient" means a person who the department determines is eligible to receive cancer drugs from the program.

(f) "Health care facility" means a health care facility licensed under chapter 395.

(g) "Health care clinic" means a health care clinic licensed under part X of chapter 400.

(h) "Hospice" means a corporation licensed under part IV of chapter 400.

(i) "Hospital" means a facility as defined in s. 395.002 and licensed under chapter 395.

(j) "Nursing home" means a facility licensed under part II of chapter 400.

(k) "Participant facility" means a class II hospital pharmacy that has elected to participate in the program and that accepts donated cancer drugs and supplies under the rules adopted by the department for the program.

(l) "Pharmacist" means a person licensed under chapter 465.

(m) "Pharmacy" means an entity licensed under chapter 465.

(n) "Prescribing practitioner" means a physician licensed under chapter 458 or any other medical professional with authority under state law to prescribe cancer medication.

(o) "Prescription drug" means a drug as defined in s. 465.003(8).

(p) "Program" means the Cancer Drug Donation Program created by this section.

(q) "Supplies" means any supplies used in the administration of a cancer drug.

(4) Any donor may donate cancer drugs or supplies to a participant facility that elects to participate in the program and meets criteria established by the department for such participation. Cancer drugs or supplies may not be donated to a specific cancer patient, and donated drugs or supplies may not be resold by the program. Cancer drugs billed to and paid for by Medicaid in long-term care facilities that are eligible for return to stock under federal Medicaid regulations shall be credited to Medicaid and are not eligible for donation under the program. A participant facility may provide dispensing and consulting services to individuals who are not patients of the hospital.

(5) The cancer drugs or supplies donated to the program may be prescribed only by a prescribing practitioner for use by an eligible patient and may be dispensed only by a pharmacist.

(6)(a) A cancer drug may only be accepted or dispensed under the program if the drug is in its original, unopened, sealed container, or in a tamper-evident unit-dose packaging, except that a cancer drug packaged in single-unit doses may be accepted and dispensed if the outside packaging is opened but the single-unit-dose packaging is unopened with tamper-resistant packaging intact.

(b) A cancer drug may not be accepted or dispensed under the program if the drug bears an expiration date that is less than 6 months after the date the drug was donated or if the drug appears to have been tampered with or mislabeled as determined in paragraph (c).

(c) Prior to being dispensed to an eligible patient, the cancer drug or supplies donated under the program shall be inspected by a pharmacist to determine that the drug and supplies do not appear to have been tampered with or mislabeled.

(d) A dispenser of donated cancer drugs or supplies may not submit a claim or otherwise seek reimbursement from any public or private third-party payor for donated cancer drugs or supplies dispensed to any patient under the program, and a public or private third-party payor is not required to provide reimbursement to a dispenser for donated cancer drugs or supplies dispensed to any patient under the program.

(7)(a) A donation of cancer drugs or supplies shall be made only at a participant facility. A participant facility may decline to accept a donation. A participant facility that accepts donated cancer drugs or supplies under the program shall comply with all applicable provisions of state and federal law relating to the storage and dispensing of the donated cancer drugs or supplies.

(b) A participant facility that voluntarily takes part in the program may charge a handling fee sufficient to cover the cost of preparation and dispensing of cancer drugs or supplies under the program. The fee shall be established in rules adopted by the department.

(8) The department, upon the recommendation of the Board of Pharmacy, shall adopt rules to carry out the provisions of this section. Initial rules under this section shall be adopted no later than 90 days after the effective date of this act. The rules shall include, but not be limited to:

(a) Eligibility criteria, including a method to determine priority of eligible patients under the program.

(b) Standards and procedures for participant facilities that accept, store, distribute, or dispense donated cancer drugs or supplies.

(c) Necessary forms for administration of the program, including, but not limited to, forms for use by entities that donate, accept, distribute, or dispense cancer drugs or supplies under the program.

(d) The maximum handling fee that may be charged by a participant facility that accepts and distributes or dispenses donated cancer drugs or supplies.

(e) Categories of cancer drugs and supplies that the program will accept for dispensing; however, the department may exclude any drug based on its therapeutic effectiveness or high potential for abuse or diversion.

(f) Maintenance and distribution of the participant facility registry established in subsection (10).

(9) A person who is eligible to receive cancer drugs or supplies under the state Medicaid program or under any other prescription drug program funded in whole or in part by the state, by any other prescription drug program funded in whole or in part by the Federal Government, or by any other prescription drug program offered by a third-party insurer, unless benefits have been exhausted, or a certain cancer drug or supply is not covered by the prescription drug program, is ineligible to participate in the program created under this section.

(10) The department shall establish and maintain a participant facility registry for the program. The participant facility registry shall include the participant facility's name, address, and telephone number. The department shall make the participant facility registry available on the department's website to any donor wishing to donate cancer drugs or supplies to the program. The department's website shall also contain links to cancer drug manufacturers that offer drug assistance programs or free medication.

(11) Any donor of cancer drugs or supplies, or any participant in the program, who exercises reasonable care in donating, accepting, distributing, or dispensing cancer drugs or supplies under the program and the rules adopted under this section shall be immune from civil or criminal liability and from professional disciplinary action of any kind for any injury, death, or loss to person or property relating to such activities.

(12) A pharmaceutical manufacturer is not liable for any claim or injury arising from the transfer of any cancer drug under this section, including, but not limited to, liability for failure to transfer or communicate product or consumer information regarding the transferred drug, as well as the expiration date of the transferred drug.

(13) If any conflict exists between the provisions in this section and the provisions in this chapter or chapter 465, the provisions in this section shall control the operation of the Cancer Drug Donation Program.

History.--s. 1, ch. 2006-310; s. 122, ch. 2007-5.

64F-12.026 Cancer Drug Donation Program.

The purpose of this section is to establish and maintain a cancer drug donation program under which unused cancer prescription drugs and cancer supplies may be donated and dispensed to eligible individuals who are diagnosed with cancer. This rule applies to the department or any person who donates, receives, dispenses or otherwise participates or wishes to participate in the cancer drug donation program.

(1) Recipient Eligibility Requirements.

(a) A Florida resident who is diagnosed with cancer is eligible to receive drugs or supplies under the cancer drug donation program unless the person falls under paragraph 64F-12.026(1)(b), F.A.C.

(b) A Florida resident is ineligible to participate in the cancer drug donation program if the person is eligible to receive cancer drugs or supplies through the Medicaid program, third-party insurer or any other prescription drug program funded in whole or in part by the Federal Government, unless these benefits have been exhausted, or a certain cancer drug or supply need by the patient is not covered by the prescription drug program as stated in Section 499.029(9), F.S.

(2) Donor Eligibility Requirements. Any person defined as a donor in Section 499.029(3), F.S., is determined to be eligible to be a donor.

(3) Participant Facility Requirements.

(a) Eligibility: Only a Class II Institutional Pharmacy, permitted under Chapter 465, F.S., that accepts, stores and dispenses donated cancer drugs and supplies may participate in the cancer drug donation program.

(b) Notice of Participation: Participation in the cancer drug donation program is voluntary. To be eligible for participation in the cancer drug donation program, a Class II Institutional Pharmacy must elect to participate and provide the department with all of the following as set forth in Form DH-MQA 1100, 2/07, incorporated by reference in subsection (4):

1. The name, permit number, street address, and telephone number of the pharmacy;

2. The name and telephone number of a pharmacist or another contact as determined by the pharmacist who is employed by or under contract with the pharmacy;

3. A statement indicating the pharmacy meets the eligibility requirements under paragraph (3)(a) herein.

(c) Withdrawal from participation: A pharmacy may withdraw from participation in the cancer drug donation program upon at least 10 days written notification to the department as set forth in Form DH-MQA 1100, 2/07, incorporated by reference in subsection (4).

(d) Storage: Cancer drugs and supplies donated under the cancer drug donation program shall be stored in a secure storage area under environmental conditions appropriate for the cancer drugs or supplies being stored. Donated cancer drugs and supplies may not be stored with non-donated inventory.

(e) Dispensing:

1. Cancer drugs and supplies shall be dispensed by a licensed pharmacist, whether or not employed by or under contract with a participant facility, pursuant to the requirements in Chapter 465, F.S.;

2. The pharmacist shall inspect the donated cancer drugs and supplies for adulteration, misbranding, mislabeling, and the date of expiration before dispensing. Cancer drugs or supplies that are tampered with, expired, adulterated, mislabeled or misbranded may not be dispensed;

3. Before a cancer drug or supply may be dispensed to a recipient, the recipient shall sign a cancer drug donation program Recipient Record, Form DH-MQA 1098, 2/07, incorporated by reference in subsection (4), and shall be notified, both orally and in writing, that the cancer drug or supply may have been previously dispensed;

4. Cancer drugs and supplies shall be dispensed only to recipients who meet the following eligibility requirements:

a. Individuals who are uninsured;

b. All other individuals who are otherwise eligible under subsection (1) herein to receive cancer drugs or supplies from the cancer drug donation program.

5. Cancer drugs or supplies may not be donated to a specific cancer patient.

(f) Recordkeeping requirements:

1. Donor and Recipient Records as reflected in Forms DH-MQA 1099, 2/07 and 1098, 2/07, incorporated by reference in subsection (4) shall be maintained at least 3 years by the participant facility.

2. Destruction Records for donated drugs or supplies as reflected in Form DH-MQA 1099, 2/07, incorporated by reference in subsection (4) shall be maintained at least 3 years by the participant facility. For each drug or supply destroyed the record shall include all of the following information:

a. The date of destruction;

b. The name, strength and quantity of the cancer drug destroyed;

c. The name of the person or firm that destroyed the drug;

d. The source of the drugs or supplies destroyed.

(4) Required Forms for Program Participants.

(a) Cancer Drug Donation Program Recipient Record, DOH form_DH-MQA 1098, effective February 2007 and incorporated herein by reference.

(b) Cancer Drug Donation Program Donation and Destruction Record, DOH Form DH-MQA 1099, effective February 2007, and incorporated herein by reference.

(c) Cancer Drug Donation Program Notice of Participation or Withdrawal, DOH Form DH-MQA 1100, effective February 2007, and incorporated herein by reference.

The above referenced required forms are available by contacting the Department of Health, Drugs, Devices and Cosmetics Program, 4052 Bald Cypress Way, Bin C-04, Tallahassee, Florida 32399-3255, or by downloading them from the program's website.

(5) Dispensing Fees. A cancer drug donation program participant facility may charge the recipient of the drug or supply a handling fee of no more than 300% of the Medicaid dispensing fee or no more than $15.00, whichever is less, for each cancer drug or supply dispensed.

(6) Categories of drugs and supplies eligible for donation.

(a) Cancer drugs. A cancer drug is eligible for donation under the cancer drug donation program only if all the following requirements are met:

1. The donation is accompanied by a completed cancer drug donation program Donation Record that is signed by the person making the donation or that person's authorized representative;

2. The drug's expiration date is at least 6 months later than the date that the drug was donated and its tamper resistant packaging is intact;

3. The drug is in its original, unopened, sealed, tamper-evident unit dose packaging that includes the drug's lot number and expiration date. Single-unit dose drugs may be accepted if the single-unit dose packaging is unopened;

4. Cancer drugs billed to and paid for by Medicaid in long-term care facilities are not eligible for donation unless not reimbursable by Medicaid.

(b) Cancer supplies. Cancer supplies are eligible for donation under the cancer drug donation program only if the supplies meet all the following requirements:

1. The supplies have not been tampered with or mislabeled; the supplies are in their original, unopened, sealed packaging;

2. The donation is accompanied by a completed cancer drug donation program Donation Record that is signed by the person making the donation or that person's authorized representative.

(c) Drugs and supplies not eligible for donation. All of the following drugs are ineligible for donation or acceptance under the cancer drug donation program.

1. Substances listed in Schedule II, Schedule III, Schedule IV or Schedule V of Section 893.03, F.S.;

2. Drugs and supplies that do not meet the criteria under paragraphs (6)(a) and (b), herein;

3. Drugs that expire less than 6 months after the date of donation.

(7) The Department shall establish a website at www.doh.state.fl.us/mqa/DDC/Cancer/index.html to maintain the registry of participant facilities. The website shall also contain links to cancer drug manufacturers that offer drug assistance programs or free medication.

Specific Authority 499.029(8) FS. Law Implemented 499.029 FS. History–New 8-6-07.

Cancer Drug Donation Program Overview

House Committee on Health Quality

February 19, 2008

Erika L. Lilja

Program Operations Administrator

§ 499.029, *Florida Statutes*

- Creates the Cancer Drug Donation Program to authorize and facilitate the donation of cancer drugs and supplies to eligible cancer patients.
- Establishes requirements for participant facilities, eligible patients, donated drugs, records keeping, handling fees, and the participant facility registry.
- Provides rulemaking authority to administer the program.

64F-12.026, *Florida Administrative Code*

8/4/06:	Notice of Rule Development published.
8/25/06:	Rule Development Workshop.
1/19/07:	Notice of Proposed Rulemaking published.
3/9/07:	Notice of Withdrawal published for non-technical changes.
3/30/07:	Revised Notice of Proposed Rulemaking published.
6/22/07:	Notice of Change published in response to JAPCs concerns.
8/6/07:	Rule effective date.

Cancer Drug Donation Program

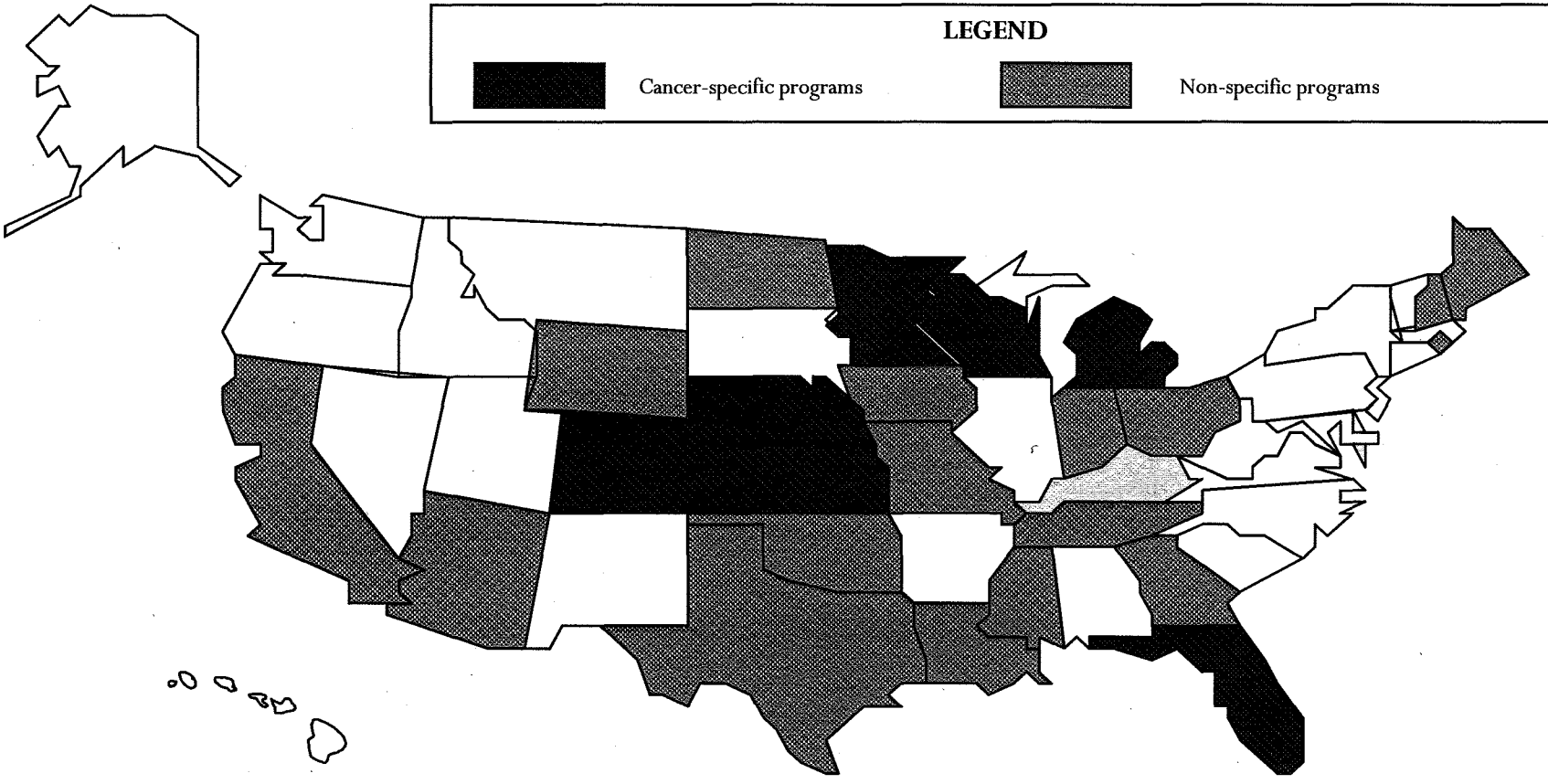
- Implementation on 8/6/07.
- Outreach
- Current participation
- Challenges

Program Participation Report

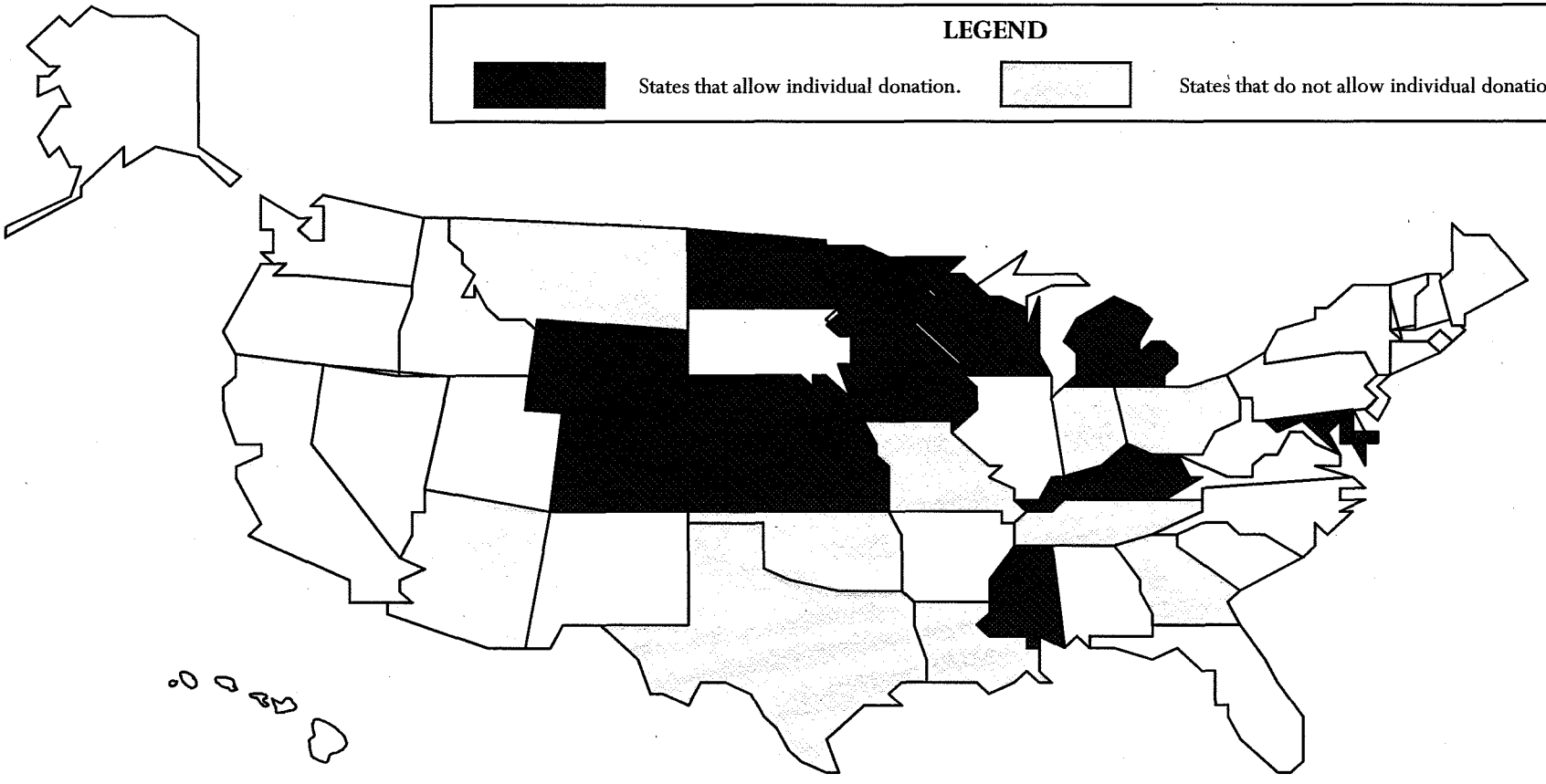
Hospital Participant	Date Hospital Approved	Contact	Phone	Total # of Donations	Total # of Drugs Donated	# of Patients Currently Receiving Drugs	Total # of Recipients	Information Received
Lee Memorial Hospital Inc	11/5/2007	Tina Gegeckas	239-334-5636	4	4	0	0	1/18/2008
Halifax Medical Center	11/13/2007	Jim Shepherd	386-254-4193	3	3	1	1	1/17/2008
Total				7	7	1	1	

Note: approximately 10-15 donations have been referred to a Nebraska facility where patient-possessed donations are accepted.

Other States



Other States



Q &A

Program Contact Information:

Dinah Skrnich

Cancer Drug Donation Program Manager

(850) 245-4735

Dinah_skrnich@doh.state.fl.us

www.doh.state.fl.us/ddc/cancer

Florida AHEC Network Tobacco Training & Cessation Project

Progress From

October 1, 2007 to January 1, 2008

FLORIDA AHEC NETWORK
TOBACCO TRAINING PROGRAM
2007-2008

Health Professions Schools Participating in Clinical Training

- University of Miami School of Medicine, Undergraduate and Residency Programs in Family Medicine, OB/GYN and Internal Medicine
- Miami-Dade College Health Professions Division (Nursing and Respiratory Therapy)
- Florida Keys Community College Nursing
- Brevard Community College Nursing
- Florida Southern College - Nursing
- University of Central Florida - Nursing

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FLORIDA AHEC NETWORK
TOBACCO TRAINING PROGRAM
2007-2008

Health Professions Schools Participating in Clinical Training, cont'd

- Nova Southeastern University - Medical, Nursing, Pharmacy, Dental
- Indian River Community College - Nursing
- Palm Beach Community College - Nursing
- Barry University
- Central Florida Community College
- Edison College
- Florida A & M University
- Hillsborough Community College

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AREA HEALTH EDUCATION CENTERS

FLORIDA AHEC NETWORK
TOBACCO TRAINING PROGRAM
2007-2008

Health Professions Schools Participating in Clinical Training, cont'd

- Keiser University
- Lake Erie College of Osteopathic Medicine
- Manatee Community College
- Manatee County Technical Institute
- Pasco Hernando Community College
- St. Petersburg College
- South Florida Community College
- University of South Florida

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FLORIDA AHEC NETWORK
TOBACCO TRAINING PROGRAM
2007-2008

Health Professions Schools Participating in Clinical Training, cont'd

- Withlacoochee Technical Institute
- Florida State University College of Medicine
- Chipola College – Nursing
- Okaloosa Walton College – Nursing
- University of Florida College of Dentistry
- University of Florida College of Medicine
- University of Florida College of Nursing
- University of Florida College of Pharmacy
- University of Florida College of Public Health and Health Professions
- University of West Florida – Nursing

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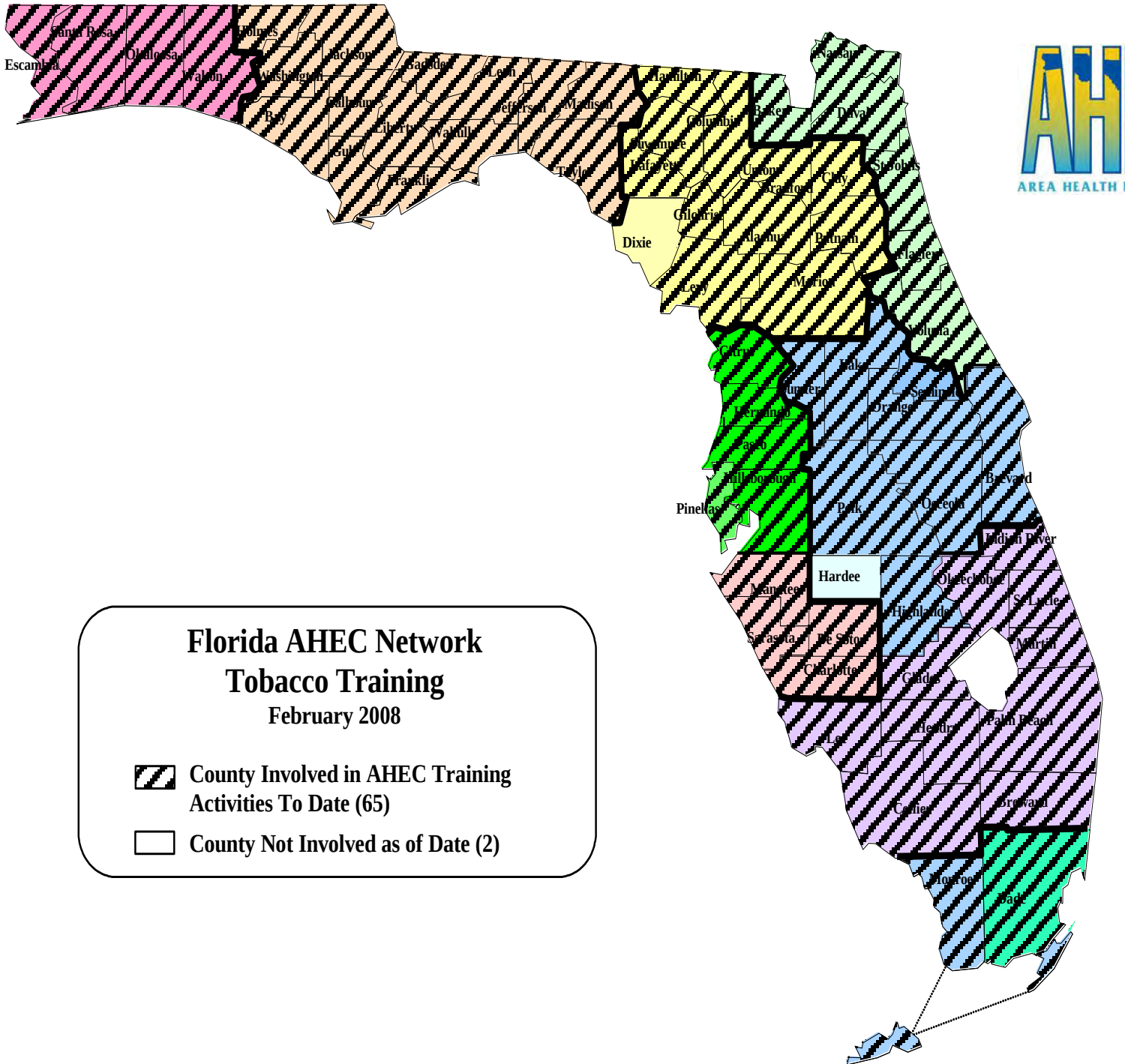

Florida AHEC Network
Tobacco Training
February 2008

County Involved in AHEC Training Activities To Date (65)

County Not Involved as of Date (2)

FLORIDA AHEC NETWORK
TOBACCO TRAINING PROGRAM
2007-2008

Number of Health Professions Students/Residents Trained by Discipline

• Medicine:	934
• Nursing:	423
• Residents:	33
• Dentistry:	213
• Dental Hygiene:	18
• Pharmacy:	358
• Allied Health:	175
• Physical Therapy:	8
• Others:	4
Total Number Trained:	**2,166**

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FLORIDA AHEC NETWORK
TOBACCO TRAINING PROGRAM
2007-2008

Number of Health Care Providers Trained

- Physicians: 125
- Nurses/NPs: 190
- Dentist: 6
- Others: 282

Total Trained: 603

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FLORIDA AHEC NETWORK
TOBACCO TRAINING PROGRAM
2007-2008

Total # of hours of Continuing Education to Date

1,341 Hours

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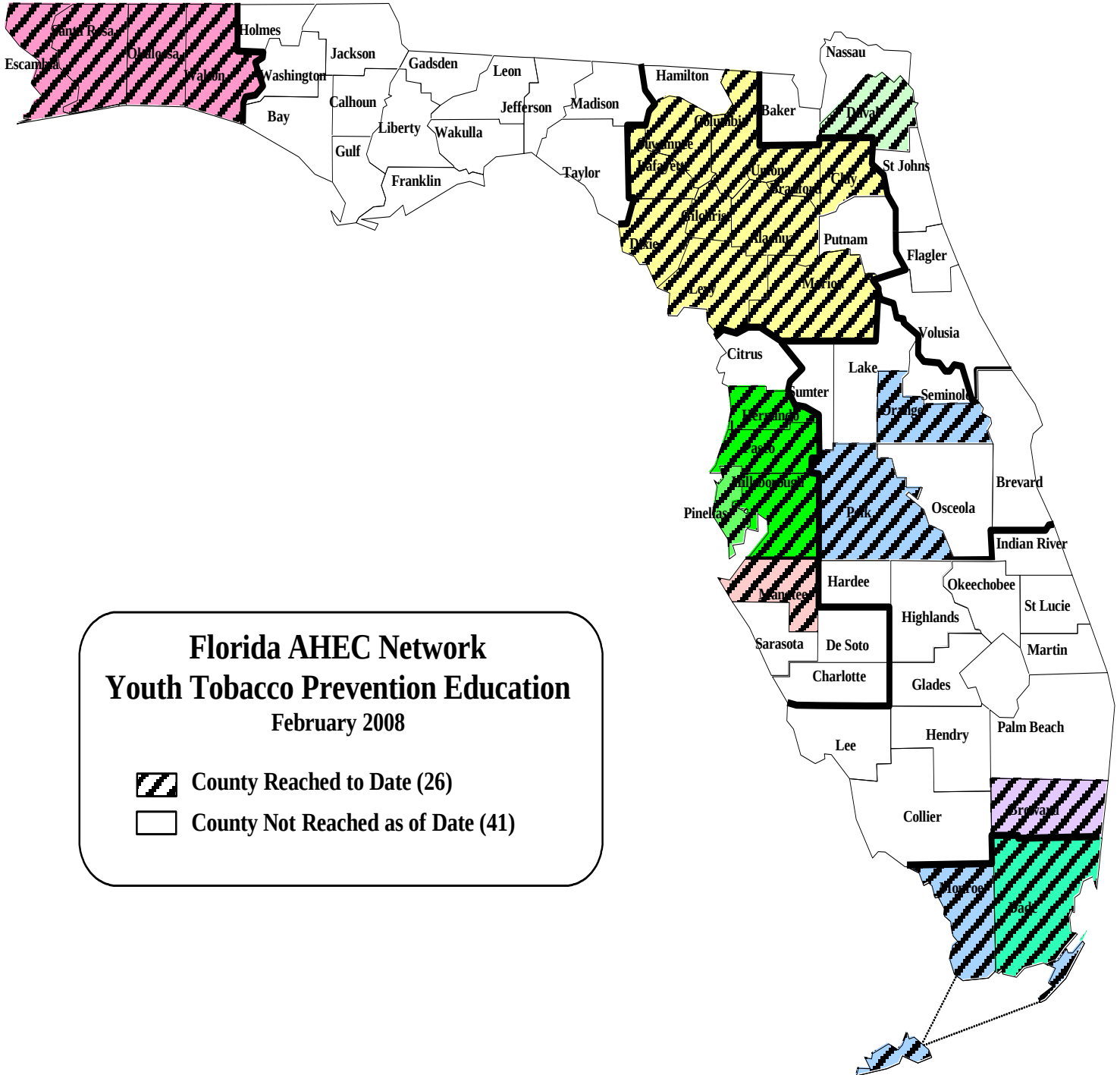
AREA HEALTH EDUCATION CENTERS


Escambia
Santa Rosa
Okaloosa
Walton
Holmes
Washington
Bay
Jackson
Calhoun
Gulf
Liberty
Gadsden
Wakulla
Franklin
Leon
Jefferson
Madison
Taylor
Hamilton
Suwannee
Lafayette
Dixie
Columbia
Baker
Union
Bradford
Alachua
Gilchrist
Levy
Nassau
Duval
St Johns
Clay
Putnam
Flagler
Marion
Volusia
Citrus
Lake
Sumter
Hernando
Pasco
Pinellas
Seminole
Orange
Osceola
Brevard
Indian River
Polk
Hardee
Manatee
Sarasota
De Soto
Charlotte
Okeechobee
Highlands
St Lucie
Martin
Glades
Lee
Hendry
Palm Beach
Collier
Broward
Monroe
Florida AHEC Network
Youth Tobacco Prevention Education
February 2008
County Reached to Date (26)
County Not Reached as of Date (41)

FLORIDA AHEC NETWORK
TOBACCO TRAINING PROGRAM
2007-2008

Number of Elementary through High Schools receiving prevention training:	**142**
Number of Counties Reached:	**26**
Number of school-age youth trained on tobacco prevention:	**46,743**

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FLORIDA AHEC NETWORK
TOBACCO TRAINING PROGRAM
2007-2008

Number of persons receiving cessation services:	**839**
Number of persons referred to the Quitline:	**1,581**
Number of collaborating agencies:	**228**
Number of tobacco information materials disseminated:	**In excess of 16,568**

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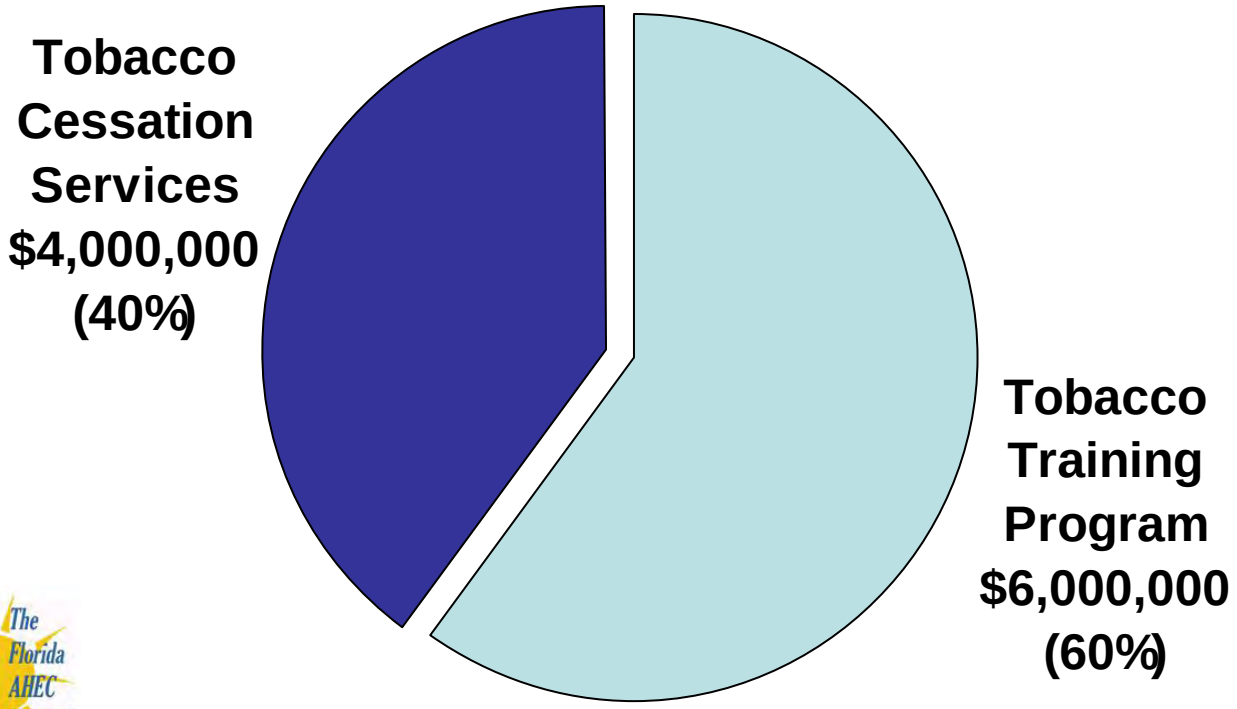
FLORIDA AHEC NETWORK
TOBACCO TRAINING AND CESSATION INITIATIVE
DISTRIBUTION OF APPROPRIATED FUNDS
2007-2008



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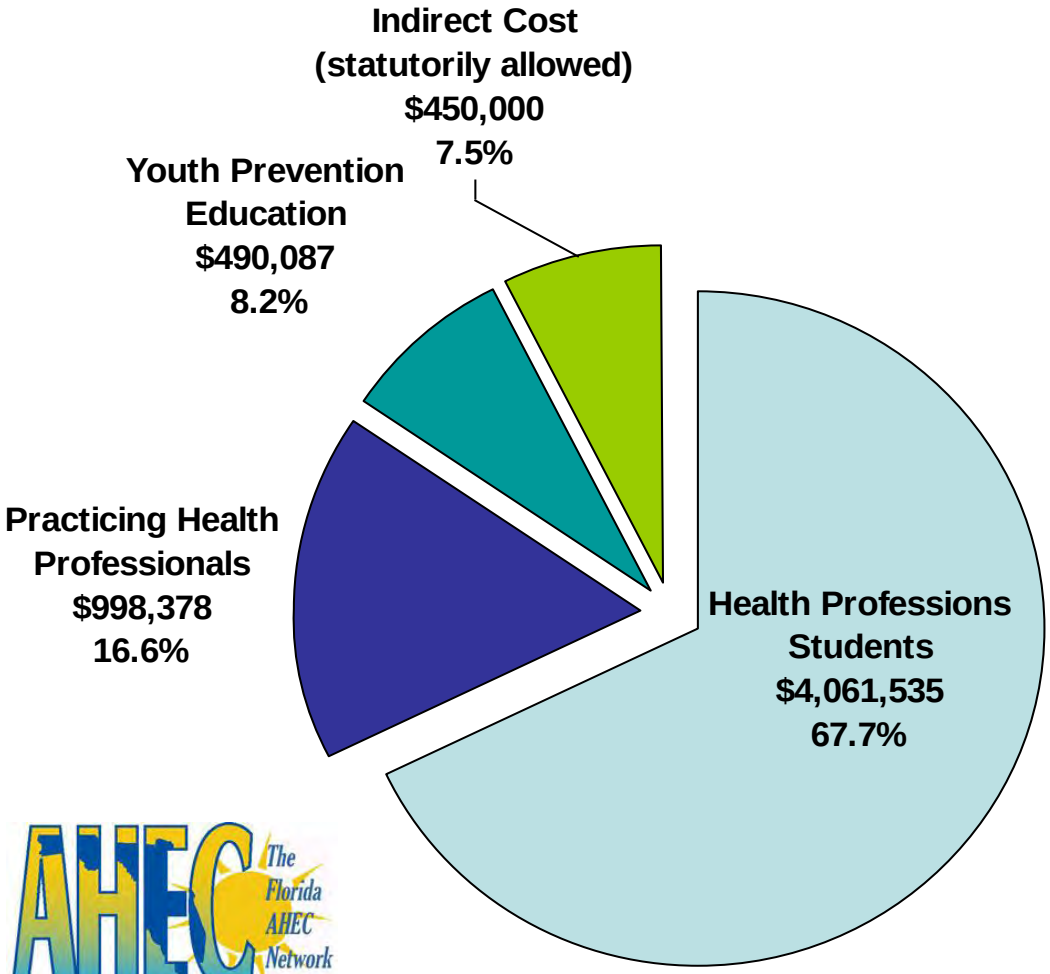
AREA HEALTH EDUCATION CENTERS

FLORIDA AHEC NETWORK
TOBACCO TRAINING PROGRAM
2007-2008



AHEC The Florida AHEC Network
AREA HEALTH EDUCATION CENTERS

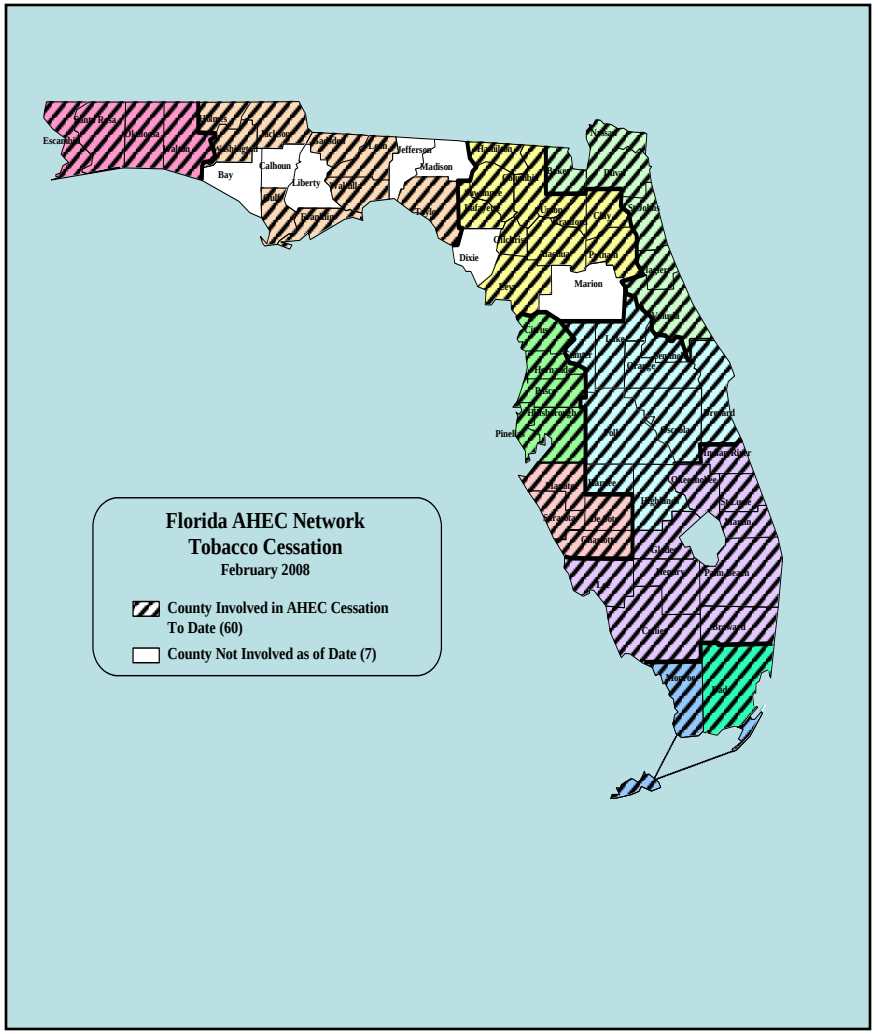
- Over **4,500** health professions students to be trained at approximately **$ 125** per student training hour.

- Over **3,000** practicing health professionals to be trained at approximately **$ 175** per professional training hour.

- Nearly **60,000** youth to receive tobacco prevention education at under **$ 10** per child.

FLORIDA AHEC NETWORK
TOBACCO CESSATION SERVICES
2007-2008

- Total funding for cessation program **$3.7 million** ($4 million minus 7.5% Indirect Cost)
- Developing nearly **200** tobacco cessation service sites in **60** Florida counties.



The Florida AHEC Network
AREA HEALTH EDUCATION CENTERS

PHYSICIAN WORKFORCE ASSESSMENT
AND DEVELOPMENT PROGRAM

Section 381.4018, F.S.

Physician Workforce

Assessment and Development

Select Year: 2007 Go

The 2007 Florida Statutes

Title XXIX PUBLIC HEALTH | Chapter 381 PUBLIC HEALTH: GENERAL PROVISIONS | View Entire Chapter

381.4018 Physician workforce assessment and development.--

(1) LEGISLATIVE INTENT.--The Legislature recognizes that physician workforce planning is an essential component of ensuring that there is an adequate and appropriate supply of well-trained physicians to meet this state's future health care service needs as the general population and elderly population of the state increase. The Legislature finds that items to consider relative to assessing the physician workforce may include physician practice status; specialty mix; geographic distribution; demographic information, including, but not limited to, age, gender, race, and cultural considerations; and needs of current or projected medically underserved areas in the state. Long-term strategic planning is essential as the period from the time a medical student enters medical school to completion of graduate medical education may range from 7 to 10 years or longer. The Legislature recognizes that strategies to provide for a well-trained supply of physicians must include ensuring the availability and capacity of quality graduate medical schools in this state, as well as using new or existing state and federal programs providing incentives for physicians to practice in needed specialties and in underserved areas in a manner that addresses projected needs for physician manpower.

(2) PURPOSE.--The Department of Health shall serve as a coordinating and strategic planning body to actively assess the state's current and future physician workforce needs and work with multiple stakeholders to develop strategies and alternatives to address current and projected physician workforce needs.

(3) GENERAL FUNCTIONS.--The department shall maximize the use of existing programs under the jurisdiction of the department and other state agencies and coordinate governmental and nongovernmental stakeholders and resources in order to develop a state strategic plan and assess the implementation of such strategic plan. In developing the state strategic plan, the department shall:

(a) Monitor, evaluate, and report on the supply and distribution of physicians licensed under chapter 458 or chapter 459. The department shall maintain a database to serve as a statewide source of data concerning the physician workforce.

(b) Develop a model and quantify, on an ongoing basis, the adequacy of the state's current and future physician workforce as reliable data becomes available. Such model must take into account demographics, physician practice status, place of education and training, generational changes, population growth, economic indicators, and issues concerning the "pipeline" into medical education.

(c) Develop and recommend strategies to determine whether the number of qualified medical school applicants who might become competent, practicing physicians in this state will be sufficient to meet the capacity of the state's medical schools. If appropriate, the department shall, working with representatives of appropriate governmental and nongovernmental entities, develop strategies and recommendations and identify best practice programs that introduce health care as a profession and strengthen skills needed for medical school admission for elementary, middle, and high school students, and improve premedical education at the precollege and college level in order to increase this state's potential pool of medical students.

(d) Develop strategies to ensure that the number of graduates from the state's public and private allopathic and osteopathic medical schools are adequate to meet physician workforce needs, based on the analysis of the physician workforce data, so as to provide a high-quality medical education to students in a manner that recognizes the uniqueness of each new and existing medical school in

this state.

(e) Pursue strategies and policies to create, expand, and maintain graduate medical education positions in the state based on the analysis of the physician workforce data. Such strategies and policies must take into account the effect of federal funding limitations on the expansion and creation of positions in graduate medical education. The department shall develop options to address such federal funding limitations. The department shall consider options to provide direct state funding for graduate medical education positions in a manner that addresses requirements and needs relative to accreditation of graduate medical education programs. The department shall consider funding residency positions as a means of addressing needed physician specialty areas, rural areas having a shortage of physicians, and areas of ongoing critical need, and as a means of addressing the state's physician workforce needs based on an ongoing analysis of physician workforce data.

(f) Develop strategies to maximize federal and state programs that provide for the use of incentives to attract physicians to this state or retain physicians within the state. Such strategies should explore and maximize federal-state partnerships that provide incentives for physicians to practice in federally designated shortage areas. Strategies shall also consider the use of state programs, such as the Florida Health Service Corps established pursuant to s. 381.0302 and the Medical Education Reimbursement and Loan Repayment Program pursuant to s. 1009.65, which provide for education loan repayment or loan forgiveness and provide monetary incentives for physicians to relocate to underserved areas of the state.

(g) Coordinate and enhance activities relative to physician workforce needs, undergraduate medical education, and graduate medical education provided by the Division of Medical Quality Assurance, the Community Hospital Education Program and the Graduate Medical Education Committee established pursuant to s. 381.0403, area health education center networks established pursuant to s. 381.0402, and other offices and programs within the Department of Health as designated by the [1]State Surgeon General.

(h) Work in conjunction with and act as a coordinating body for governmental and nongovernmental stakeholders to address matters relating to the state's physician workforce assessment and development for the purpose of ensuring an adequate supply of well-trained physicians to meet the state's future needs. Such governmental stakeholders shall include, but need not be limited to, the [1]State Surgeon General or his or her designee, the Commissioner of Education or his or her designee, the Secretary of Health Care Administration or his or her designee, and the Chancellor of the State University System or his or her designee from the Board of Governors of the State University System, and, at the discretion of the department, other representatives of state and local agencies that are involved in assessing, educating, or training the state's current or future physicians. Other stakeholders shall include, but need not be limited to, organizations representing the state's public and private allopathic and osteopathic medical schools; organizations representing hospitals and other institutions providing health care, particularly those that have an interest in providing accredited medical education and graduate medical education to medical students and medical residents; organizations representing allopathic and osteopathic practicing physicians; and, at the discretion of the department, representatives of other organizations or entities involved in assessing, educating, or training the state's current or future physicians.

(i) Serve as a liaison with other states and federal agencies and programs in order to enhance resources available to the state's physician workforce and medical education continuum.

(j) Act as a clearinghouse for collecting and disseminating information concerning the physician workforce and medical education continuum in this state.

History.--s. 1, ch. 2007-172.

[1]**Note.**--Chapter 2007-40 redesignated the Secretary of Health as the State Surgeon General.

The Physician Workforce Voluntary Survey

PHYSICIAN WORKFORCE QUESTIONNAIRE

The items below relate to very important questions regarding Florida's current and future physician workforce. Your responses will be instrumental in shaping Florida's health care and physician workforce policies. Secretary of the Department of Health, M. Rony François, M.D., M.S.P.H., Ph.D., and the Council of Florida Medical School Deans, Florida Graduate Medical Education Committee, Florida Medical Association and Florida Osteopathic Medical Association appreciate your time and effort in responding to the eight questions below.

Name: *FirstName MI. LastName* **License Number:** *ME 123456789*

1. Do you practice medicine at any time during the year in Florida?

   Note: If you check 'No' then please stop here. ◯ Yes ◯ No

2. How many months/year do you practice medicine in Florida?

   ◯ 1-4 Months ◯ 5-8 Months ◯ 9-12 Months

3. In what Florida counties do you practice?(may select up to 5 counties)
   Please note - County Names and Numeric Codes are listed on the **back side of the form.**
   Please print or type County Names and Numeric Codes below.

	County Name	Numeric Code	1-20 Hrs/Wk	21-40 Hrs/Wk	More than 40 Hrs/Wk
a.			◯	◯	◯
b.			◯	◯	◯
c.			◯	◯	◯
d.			◯	◯	◯
e.			◯	◯	◯

4. Is more than twenty percent (20%) of your practice non-clinical? (i.e. research, teaching, administration)

   ◯ Yes ◯ No

5. Are you a resident or fellow?

   ◯ Yes ◯ No

6. What is the primary specialty area(s) of your current clinical practice?(may select up to 5 different areas)
   Please note - Specialty Areas and Numeric Codes are listed on the **back side of the form.**
   Please print or type Specialty Areas and Numeric Codes below.

	Specialty Area	Numeric Code	1-20%	21-40%	41-60%	61-80%	81-100%
a.			◯	◯	◯	◯	◯
b.			◯	◯	◯	◯	◯
c.			◯	◯	◯	◯	◯
d.			◯	◯	◯	◯	◯
e.			◯	◯	◯	◯	◯

7. Do you plan to retire, relocate outside of the state of Florida, or significantly reduce the scope of your practice within the next five years?

   ◯ Yes ◯ No

8. Do you currently take emergency call or otherwise work clinically in a hospital emergency department or provide for the immediate, acute care of trauma patients?

   ◯ Yes ◯ No

ME0123456789

County Names and Numeric Codes (Reference for question # 3)

11 ALACHUA	25 DIXIE	39 HILLSBOROUGH	53 MARTIN	67 SANTA ROSA
12 BAKER	26 DUVAL	40 HOLMES	54 MONROE	68 SARASOTA
13 BAY	27 ESCAMBIA	41 INDIAN RIVER	55 NASSAU	69 SEMINOLE
14 BRADFORD	28 FLAGLER	42 JACKSON	56 OKALOOSA	70 SUMTER
15 BREVARD	29 FRANKLIN	43 JEFFERSON	57 OKEECHOBEE	71 SUWANNEE
16 BROWARD	30 GADSDEN	44 LAFAYETTE	58 ORANGE	72 TAYLOR
17 CALHOUN	31 GILCHRIST	45 LAKE	59 OSCEOLA	73 UNION
18 CHARLOTTE	32 GLADES	46 LEE	60 PALM BEACH	74 VOLUSIA
19 CITRUS	33 GULF	47 LEON	61 PASCO	75 WAKULLA
20 CLAY	34 HAMILTON	48 LEVY	62 PINELLAS	76 WALTON
21 COLLIER	35 HARDEE	49 LIBERTY	63 POLK	77 WASHINGTON
22 COLUMBIA	36 HENDRY	50 MADISON	64 PUTNAM	78 UNKNOWN
23 DADE	37 HERNANDO	51 MANATEE	65 ST.JOHNS	79 OUT OF STATE
24 DESOTO	38 HIGHLANDS	52 MARION	66 ST.LUCIE	80 FOREIGN

Specialty Areas and Numeric Codes (Reference for question # 6)

000 NO CLINICAL PRACTICE
020 ALLERGY AND IMMUNOLOGY
040 ANESTHESIOLOGY
045 CRITICAL CARE MEDICINE
048 PAIN MEDICINE
042 PEDIATRIC ANESTHESIOLOGY
060 COLON AND RECTAL SURGERY
080 DERMATOLOGY
100 DERMATOPATHOLOGY
081 PROCEDURAL DERMATOLOGY
110 EMERGENCY MEDICINE
118 MEDICAL TOXICOLOGY
114 PEDIATRIC EMERGENCY MEDICINE
116 SPORTS MEDICINE
119 UNDERSEA AND HYPERBARIC MEDICINE
120 FAMILY MEDICINE
125 GERIATRIC MEDICINE
127 SPORTS MEDICINE
140 INTERNAL MEDICINE
141 CARDIOVASCULAR DISEASE
154 CLINICAL CARDIAC ELECTROPHYSIOLOGY
142 CRITICAL CARE MEDICINE
143 ENDOCRINOLOGY, DIABETES, AND METABOLISM
144 GASTROENTEROLOGY
151 GERIATRIC MEDICINE
145 HEMATOLOGY
155 HEMATOLOGY AND ONCOLOGY
146 INFECTIOUS DISEASE
152 INTERVENTIONAL CARDIOLOGY
148 NEPHROLOGY
147 ONCOLOGY
149 PULMONARY DISEASE
156 PULMONARY DISEASE AND CRITICAL CARE MEDICINE
150 RHEUMATOLOGY
157 SPORTS MEDICINE
130 MEDICAL GENETICS
190 MOLECULAR GENETIC PATHOLOGY
160 NEUROLOGICAL SURGERY
180 NEUROLOGY
185 CHILD NEUROLOGY
187 CLINICAL NEUROPHYSIOLOGY
183 NEUROMUSCULAR MEDICINE
186 NEURODEVELOPMENTAL DISABILITIES
181 PAIN MEDICINE
188 VASCULAR NEUROLOGY
200 NUCLEAR MEDICINE
220 OBSTETRICS AND GYNECOLOGY
240 OPHTHALMOLOGY
260 ORTHOPAEDIC SURGERY
261 ADULT RECONSTRUCTIVE ORTHOPAEDICS
262 FOOT AND ANKLE ORTHOPAEDICS
263 HAND SURGERY
270 MUSCULOSKELETAL ONCOLOGY
268 ORTHOPAEDIC SPORTS MEDICINE
267 ORTHOPAEDIC SURGERY OF THE SPINE
269 ORTHOPAEDIC TRAUMA
265 PEDIATRIC ORTHOPAEDICS
280 OTOLARYNGOLOGY
286 NEUROTOLOGY
288 PEDIATRIC OTOLARYNGOLOGY
300 PATHOLOGY-ANATOMIC AND CLINICAL
305 BLOOD BANKING/TRANSFUSION MEDICINE
306 CHEMICAL PATHOLOGY
307 CYTOPATHOLOGY
310 FORENSIC PATHOLOGY
311 HEMATOLOGY
314 MEDICAL MICROBIOLOGY
315 NEUROPATHOLOGY
316 PEDIATRIC PATHOLOGY
301 SELECTIVE PATHOLOGY
320 PEDIATRICS
321 ADOLESCENT MEDICINE
329 NEONATAL-PERINATAL MEDICINE
325 PEDIATRIC CARDIOLOGY
323 PEDIATRIC CRITICAL CARE MEDICINE
324 PEDIATRIC EMERGENCY MEDICINE
326 PEDIATRIC ENDOCRINOLOGY
332 PEDIATRIC GASTROENTEROLOGY
327 PEDIATRIC HEMATOLOGY/ONCOLOGY
335 PEDIATRIC INFECTIOUS DISEASES
328 PEDIATRIC NEPHROLOGY
330 PEDIATRIC PULMONOLOGY
331 PEDIATRIC RHEUMATOLOGY
333 PEDIATRIC SPORTS MEDICINE
336 DEVELOPMENTAL-BEHAVIORAL PEDIATRICS
340 PHYSICAL MEDICINE AND REHABILITATION
341 PAIN MEDICINE
346 PEDIATRIC REHABILITATION
345 SPINAL CORD INJURY MEDICINE
360 PLASTIC SURGERY
361 CRANIOFACIAL CURGERY
363 HAND SURGERY
380 PREVENTIVE MEDICINE
399 MEDICAL TOXICOLOGY
398 UNDERSEA AND HYPERBARIC MEDICINE
400 PSYCHIATRY
401 ADDICTION PSYCHIATRY
405 CHILD AND ADOLESCENT PSYCHIATRY
406 FORENSIC PSYCHIATRY
407 GERIATRIC PSYCHIATRY
402 PAIN MEDICINE
409 PSYCHOSOMATIC MEDICINE
420 RADIOLOGY DIAGNOSTIC
421 ABDOMINAL RADIOLOGY
429 CARDIOTHORACIC RADIOLOGY
422 ENDOVASCULAR SURGICAL NEURORADIOLOGY
426 MUSCULOSKELETAL RADIOLOGY
423 NEURORADIOLOGY
425 NUCLEAR RADIOLOGY
424 PEDIATRIC RADIOLOGY
427 VASCULAR AND INTERVENTIONAL RADIOLOGY
430 RADIATION ONCOLOGY
520 SLEEP MEDICINE
440 SURGERY-GENERAL
443 HAND SURGERY
445 PEDIATRIC SURGERY
442 SURGICAL CRITICAL CARE
450 VASCULAR SURGERY
460 THORACIC SURGERY
480 UROLOGY
485 PEDIATRIC UROLOGY
999 OTHER

The Physician Workforce Mandatory Survey

PHYSICIAN WORKFORCE SURVEY

Governor Charlie Crist, State Surgeon General Ana Viamonte Ros and the Florida Legislature recognize the importance of assessing Florida's current and future physician workforce. Critical legislation was passed last year that requires the Department of Health to evaluate the geographic distribution and specialty mix of active Florida physicians. Please refer to F.S. 381.4018 Physician workforce assessment and development. The questions in this physician workforce survey will be instrumental in shaping Florida's health care and physician workforce policies. Your time and effort in responding to the questions below is appreciated.

Instructions for completing the survey:

- Questions 1 - 12 apply to all physicians
- If you are an on-call specialist taking emergency call in an emergency department, please also answer questions 13 - 16
- If you provide only radiological services, please also answer questions 17 - 25
- If you provide obstetric services, please also answer questions 26 - 32

1. **Do you practice medicine at any time during the year in Florida?**
   - ○ Yes.
   - ○ No. Please stop here and review the Affirmation Statement on page 5.

2. **How many months per year do you practice in Florida?**
   - ○ 1-4 Months
   - ○ 5-8 Months
   - ○ 9-12 Months

3. **In what Florida County(ies) is your medical practice located? (May select up to 5 counties - See p. 5 for county codes) For each county selected: How many hours per week do you practice in each setting?**

County Name	Numeric Code	1-20 Hrs/Wk	21-40 Hrs/Wk	> 40 Hrs/Wk
		○	○	○
		○	○	○
		○	○	○
		○	○	○
		○	○	○

4. **Are you in a solo practice?**
   - ○ Yes
   - ○ No

5. **Which practice setting best describes where the majority of your time is spent? (Choose Only One)**
   - ○ Private Office Setting
   - ○ Federally Qualified Health Center
   - ○ Governmental Clinical Setting (for example: County Health Department)
   - ○ Federal Healthcare Facility (for example: military or VA)
   - ○ Hospital-Outpatient Department/Service
   - ○ Hospital-Inpatient
   - ○ Hospital Emergency Department
   - ○ Hospital Other (for example: hospital-based radiologist, pathologist, anesthesiologist or medical director)
   - ○ Nursing Home/Extended Care Facility
   - ○ Ambulatory Surgery Center/Free-Standing Imaging Diagnostic Center
   - ○ Other Setting

*TST-000000101

6. **Are you currently enrolled in an internship, residency program or fellowship program?**
   - ○ Yes
   - ○ No

7. **Does more than 20 percent of your practice include non clinical work (research, teaching, administration)?**
   - ○ Yes
   - ○ No

8. **List your primary specialty area, and any additional specialties, of your current clinical practice and the percentage of time you spend working in that area: (Select up to 5 Areas - See p. 6 for specialty codes)**

Specialty Area	Numeric Code	1-20%	21-40%	41-60%	61-80%	81-100%
		○	○	○	○	○
		○	○	○	○	○
		○	○	○	○	○
		○	○	○	○	○
		○	○	○	○	○

9. **Do you plan to retire, relocate outside of the State of Florida, or significantly reduce the scope of your practice within the next five years?**
   - ○ Yes
   - ○ No

10. **If you have changed the scope of your practice in the last two years, what are the reasons for the change (Choose All That Apply)?**
    - ○ Liability
    - ○ Reimbursement
    - ○ Regulatory and Administrative Burden
    - ○ Retirement
    - ○ Lifestyle Considerations, Other than Retirement
    - ○ Other

11. **Do you currently take emergency call or otherwise work clinically in a hospital emergency department or provide for the immediate, acute care of trauma patients?**
    - ○ Yes
    - ○ No
    - ○ Exempt Due to Medical Staff Bylaws

12. **If you take emergency call or otherwise work clinically in a hospital emergency department, are you**
    - ○ Full Time
    - ○ On-Call Specialty

For on-call specialists taking emergency call in an emergency department please answer questions 13 - 16

13. **At how many hospitals do you currently take emergency call?**
    - ○ One
    - ○ Two
    - ○ Three or greater

14. **How many days per month do you take call?**
    - ○ 1-4
    - ○ 5-9
    - ○ 10 or greater

15. **If you have taken hospital emergency department call during the past 2 years, has the number of emergency on-call hours that you work:**
    - ○ Increased
    - ○ Decreased
    - ○ Stayed the Same

16. **If you have decreased or plan to decrease or stop taking emergency department call, please check any reason that applies**
    - ○ Liability
    - ○ Reimbursement
    - ○ Lifestyle Considerations
    - ○ Impact to Private Practice
    - ○ Changing Practice Patterns
    - ○ Exemption
    - ○ Other

For physicians that provide only radiological services, please answer questions 17 - 25

17. **Do you read mammograms or other breast imaging exams?**
    - ○ Yes
    - ○ No

18. **If you do not read mammograms or other breast imaging exams, please choose the most important reason why:**
    - ○ Liability
    - ○ Reimbursement
    - ○ Uninteresting Field
    - ○ Too Stressful
    - ○ Too Much Regulation
    - ○ Other

If you read mammograms, please continue.
If you do not read mammograms, please skip to question 26.

19. **Do you read screening mammograms?**
    - ○ Yes
    - ○ No

20. **Do you read diagnostic mammograms and sonograms?**
    - ○ Yes
    - ○ No

21. **Do you perform BOTH ultrasound and stereotactic guided core biopsies?**
    - ○ Yes
    - ○ No

22. **Do you read breast MRIs?**
    - ○ Yes
    - ○ No

23. **Do you read breast MRIs AND perform MRI guided core biopsies?**
    - ○ Yes
    - ○ No

24. **In the next two years, will the number of mammograms you read change for any reason, including retirement:**
    - ○ Increase
    - ○ Decrease
    - ○ Stay the Same
    - ○ Discontinue

25. **Have you done a 6-month or greater breast imaging fellowship?**
    - ○ Yes
    - ○ No

For physicians that provide obstetric services only, please answer questions 26 - 32

26. **Do you deliver babies?**
    - ○ Yes
    - ○ No. Thank you for taking this survey. Please review the Affirmation Statement on page 5.

27. **How many routine deliveries per month?**
    - ○ None
    - ○ Low, < 10 per month
    - ○ Medium, 10-30 per month
    - ○ High, >30 per month

28. **How many high risk deliveries per month?**
    - ○ None
    - ○ Low, < 10 per month
    - ○ Medium, 10-30 per month
    - ○ High, >30 per month

29. **How many c-sections per month?**
    - ○ None
    - ○ Low, < 10 per month
    - ○ Medium, 10-30 per month
    - ○ High, >30 per month

30. **How many emergency room deliveries per month for patients having minimal or no "known" prenatal care?**
    - ○ None
    - ○ Low, < 10 per month
    - ○ Medium, 10-30 per month
    - ○ High, >30 per month

31. **How many assists or consultative services per month?**
    - ○ None
    - ○ Low, < 10 per month
    - ○ Medium, 10-30 per month
    - ○ High, >30 per month

32. **Are you planning to discontinue doing obstetric care for any reason, including retirement, in the next two years?**
    - ○ Yes
    - ○ No

AFFIRMATION STATEMENT:

I affirm that I have completed the survey to the extent that it is applicable to me. This information provided is true and accurate to the best of my knowledge and the submission does not contain any knowingly false information.

County Names and Numeric Codes (Reference for question # 3)

11	ALACHUA	25	DIXIE	39	HILLSBOROUGH	53	MARTIN	67	SANTA ROSA
12	BAKER	26	DUVAL	40	HOLMES	54	MONROE	68	SARASOTA
13	BAY	27	ESCAMBIA	41	INDIAN RIVER	55	NASSAU	69	SEMINOLE
14	BRADFORD	28	FLAGLER	42	JACKSON	56	OKALOOSA	70	SUMTER
15	BREVARD	29	FRANKLIN	43	JEFFERSON	57	OKEECHOBEE	71	SUWANNEE
16	BROWARD	30	GADSDEN	44	LAFAYETTE	58	ORANGE	72	TAYLOR
17	CALHOUN	31	GILCHRIST	45	LAKE	59	OSCEOLA	73	UNION
18	CHARLOTTE	32	GLADES	46	LEE	60	PALM BEACH	74	VOLUSIA
19	CITRUS	33	GULF	47	LEON	61	PASCO	75	WAKULLA
20	CLAY	34	HAMILTON	48	LEVY	62	PINELLAS	76	WALTON
21	COLLIER	35	HARDEE	49	LIBERTY	63	POLK	77	WASHINGTON
22	COLUMBIA	36	HENDRY	50	MADISON	64	PUTNAM	78	UNKNOWN
23	DADE	37	HERNANDO	51	MANATEE	65	ST.JOHNS	79	OUT OF STATE
24	DESOTO	38	HIGHLANDS	52	MARION	66	ST.LUCIE	80	FOREIGN

See reverse side for specialty codes.

Specialty Areas and Numeric Codes (Reference for question # 8)

000	**NO CLINICAL PRACTICE**
020	**ALLERGY AND IMMUNOLOGY**
040	**ANESTHESIOLOGY**
045	CRITICAL CARE MEDICINE
048	PAIN MEDICINE
042	PEDIATRIC ANESTHESIOLOGY
060	**COLON AND RECTAL SURGERY**
080	**DERMATOLOGY**
100	DERMATOPATHOLOGY
081	PROCEDURAL DERMATOLOGY
110	**EMERGENCY MEDICINE**
118	MEDICAL TOXICOLOGY
114	PEDIATRIC EMERGENCY MEDICINE
116	SPORTS MEDICINE
119	UNDERSEA AND HYPERBARIC MEDICINE
120	**FAMILY MEDICINE**
125	GERIATRIC MEDICINE
127	SPORTS MEDICINE
140	**INTERNAL MEDICINE**
141	CARDIOVASCULAR DISEASE
154	CLINICAL CARDIAC ELECTROPHYSIOLOGY
142	CRITICAL CARE MEDICINE
143	ENDOCRINOLOGY, DIABETES, AND METABOLISM
144	GASTROENTEROLOGY
151	GERIATRIC MEDICINE
145	HEMATOLOGY
155	HEMATOLOGY AND ONCOLOGY
146	INFECTIOUS DISEASE
152	INTERVENTIONAL CARDIOLOGY
148	NEPHROLOGY
147	ONCOLOGY
149	PULMONARY DISEASE
156	PULMONARY DISEASE AND CRITICAL CARE MEDICINE
150	RHEUMATOLOGY
157	SPORTS MEDICINE
130	**MEDICAL GENETICS**
190	MOLECULAR GENETIC PATHOLOGY
160	**NEUROLOGICAL SURGERY**
180	**NEUROLOGY**
185	CHILD NEUROLOGY
187	CLINICAL NEUROPHYSIOLOGY
183	NEUROMUSCULAR MEDICINE
186	NEURODEVELOPMENTAL DISABILITIES
181	PAIN MEDICINE
188	VASCULAR NEUROLOGY
200	**NUCLEAR MEDICINE**
220	**OBSTETRICS AND GYNECOLOGY**
240	**OPHTHALMOLOGY**
260	**ORTHOPAEDIC SURGERY**
261	ADULT RECONSTRUCTIVE ORTHOPAEDICS
262	FOOT AND ANKLE ORTHOPAEDICS
263	HAND SURGERY
270	MUSCULOSKELETAL ONCOLOGY
268	ORTHOPAEDIC SPORTS MEDICINE
267	ORTHOPAEDIC SURGERY OF THE SPINE
269	ORTHOPAEDIC TRAUMA
265	PEDIATRIC ORTHOPAEDICS
280	**OTOLARYNGOLOGY**
286	NEUROTOLOGY
288	PEDIATRIC OTOLARYNGOLOGY
300	**PATHOLOGY-ANATOMIC AND CLINICAL**
305	BLOOD BANKING/TRANSFUSION MEDICINE
306	CHEMICAL PATHOLOGY
307	CYTOPATHOLOGY
310	FORENSIC PATHOLOGY
311	HEMATOLOGY
314	MEDICAL MICROBIOLOGY
315	NEUROPATHOLOGY
316	PEDIATRIC PATHOLOGY
301	SELECTIVE PATHOLOGY
320	**PEDIATRICS**
321	ADOLESCENT MEDICINE
329	NEONATAL-PERINATAL MEDICINE
325	PEDIATRIC CARDIOLOGY
323	PEDIATRIC CRITICAL CARE MEDICINE
324	PEDIATRIC EMERGENCY MEDICINE
326	PEDIATRIC ENDOCRINOLOGY
332	PEDIATRIC GASTROENTEROLOGY
327	PEDIATRIC HEMATOLOGY/ONCOLOGY
335	PEDIATRIC INFECTIOUS DISEASES
328	PEDIATRIC NEPHROLOGY
330	PEDIATRIC PULMONOLOGY
331	PEDIATRIC RHEUMATOLOGY
333	PEDIATRIC SPORTS MEDICINE
336	DEVELOPMENTAL-BEHAVIORAL PEDIATRICS
340	**PHYSICAL MEDICINE AND REHABILITATION**
341	PAIN MEDICINE
346	PEDIATRIC REHABILITATION
345	SPINAL CORD INJURY MEDICINE
360	**PLASTIC SURGERY**
361	CRANIOFACIAL CURGERY
363	HAND SURGERY
380	**PREVENTIVE MEDICINE**
399	MEDICAL TOXICOLOGY
398	UNDERSEA AND HYPERBARIC MEDICINE
400	**PSYCHIATRY**
401	ADDICTION PSYCHIATRY
405	CHILD AND ADOLESCENT PSYCHIATRY
406	FORENSIC PSYCHIATRY
407	GERIATRIC PSYCHIATRY
402	PAIN MEDICINE
409	PSYCHOSOMATIC MEDICINE
420	**RADIOLOGY DIAGNOSTIC**
421	ABDOMINAL RADIOLOGY
429	CARDIOTHORACIC RADIOLOGY
422	ENDOVASCULAR SURGICAL NEURORADIOLOGY
426	MUSCULOSKELETAL RADIOLOGY
423	NEURORADIOLOGY
425	NUCLEAR RADIOLOGY
424	PEDIATRIC RADIOLOGY
427	VASCULAR AND INTERVENTIONAL RADIOLOGY
430	**RADIATION ONCOLOGY**
520	**SLEEP MEDICINE**
440	**SURGERY-GENERAL**
443	HAND SURGERY
445	PEDIATRIC SURGERY
442	SURGICAL CRITICAL CARE
450	VASCULAR SURGERY
460	**THORACIC SURGERY**
480	**UROLOGY**
485	PEDIATRIC UROLOGY
999	**OTHER**

Workforce Surveys: Project Status Update

Reported on
January 23, 2008
Florida Department of Health

Workforce Surveys Available

- Physician Workforce
  - Offered to both allopathic and osteopathic physicians
  - Used to assess Florida's current and future physician workforce
  - Required by SB770; must complete prior to next renewal
  - Included paper survey insert in the renewal notices
  - Offered online and incorporated into the renewal process
  - Provide survey response data to DHAT for analysis and reporting
- Nursing Workforce
  - Developed by the Florida Center for Nursing (FCN) as a voluntary survey
  - Available to RNs, LPNs, and ARNPs
  - Offered online only and incorporated into the renewal process
  - Replaced previous survey that was external to the DOH website and had a response rate of less than 6%
  - Provide survey response data to FCN for analysis and reporting

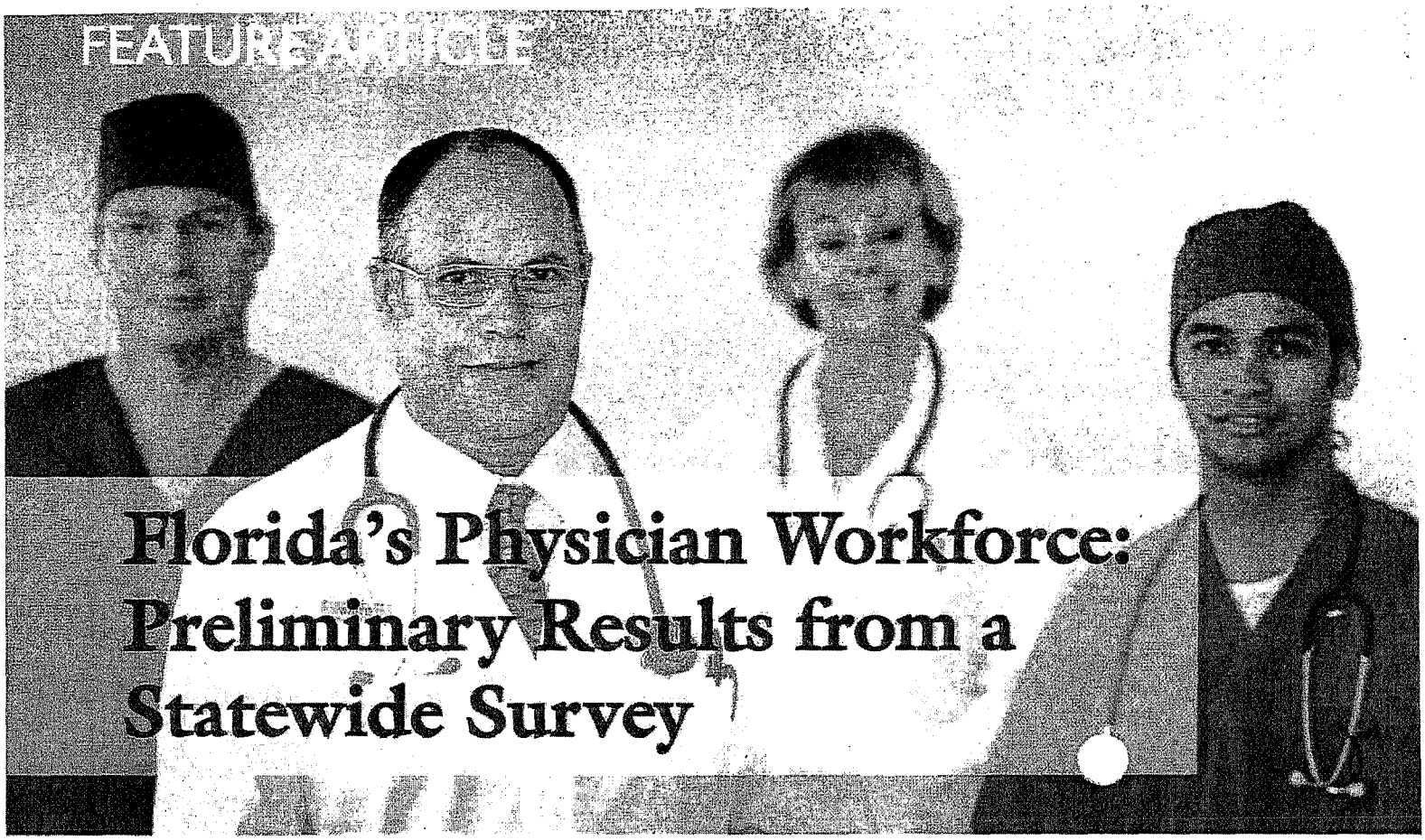
Project Status

Survey Type	Survey Released	Survey End Date	Current Response*	Data Provided
Allopathic Physicians (27,000)	10/15/07	9/30/08	91%	2/28/08 and as requested
Osteopathic Physicians (5,150)	12/03/07	11/30/08	78%	4/30/08 and as requested
Nurses (133,200)	12/19/07	12/31/08	92%	Monthly

*Percent of practitioners who renewed and completed the survey.

Non-Disciplinary Citations

- Mail non-disciplinary citation notices 90 days after expiration date.
  - April 30, 2008 - Allopathic Physicians
  - June 30, 2008 - Osteopathic Physicians
- Mail non-renewal notification letter 150 days prior to next renewal cycle



Florida's Physician Workforce: Preliminary Results from a Statewide Survey

Robert G. Brooks, MD, MBA
Nir Menachemi, PhD, MPH

As each practicing physician knows, quality of care for patients includes the need for well-trained physicians who are available to meet the unique medical requirements of patients in their local communities. Similarly, from the patient's standpoint, the availability of qualified doctors, who can meet their needs in a timely way, is crucial to their success in the maintenance of a healthy life and in receipt of excellent care when disease occurs. Despite the obvious need for access to physician services, national predictions about the current and future physician workforce suggest that an actual net decrease in the number of practicing medical doctors may occur over the next 10 years unless changes are made in policies at the medical school, residency, and practice levels.

The medical workforce in Florida is challenged by a unique situation where mounting pressures on physicians is occurring as a result of multiple factors. With major concerns about medical liability, new constitutional amendments that threaten the fabric of the physician-patient relationship, and declining financial incentives, the current situation in our state requires timely action by policy makers. Unfortunately, Florida has not traditionally had an accurate picture of its physician workforce because data has been scarce. At times this has been noted as a glaring gap in critical information such as during the legislative and social debates surrounding medical liability and, more recently, during the discussions about adding two new medical schools to the state's educational landscape.

Fortunately, the lack of information on the Florida physician workforce is about to change for two reasons. First, in 2006, the Florida Department of Health (FDOH), with the urging of then-Governor Jeb Bush, developed a voluntary survey of physicians which was included in the re-licensure application materials sent to physicians for their January, 2007 renewal. In Florida, approximately one-half of all Florida allopathic physicians renew their licenses in any given year. >>>

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Thus, the data collected in early 2007 represents the largest set of information about the Florida physician workforce collected in our state's history. Secondly, in the Spring of 2007, the Florida Legislature passed legislation which will require the FDOH to develop, in conjunction with input from health care groups (including the Florida Medical Association), a formal, mandatory survey of Florida's physicians beginning with the 2008 renewal cycle. Both of these new changes will be of help in analyzing the composition, practice patterns, and services of currently practicing doctors. In this paper, we will present and discuss some of the early results from the voluntary survey collected from physicians renewing their licenses in January of 2007.

Methods

The survey instrument was included in the mailing for licensure renewal to the approximately 50 percent of Florida allopathic physicians who were required to renew their license by January 31, 2007. Physician participants could respond through a Web site or by return mail. The survey process did not include physicians applying for initial licensure.

The survey itself was developed by the FDOH it conjunction with multiple partners including the Florida Medical Association, medical specialty societies, the Council of Medical School Deans, the Graduate Medical Education Committee, and other health care groups. The survey consisted of eight questions that inquired about the physician's duration of practice in a given year, their county of practice, medical specialty, level of training (resident, fellow, practicing), coverage of emergency departments, and plans to retire, relocate, or reduce their work within the next five years.

In our current analysis, we excluded physicians who did not have a practice address within Florida, those whose answer to the question on specialty-type suggested they were not in clinical practice, and those who were currently in a residency or fellowship program. Physicians who did not answer the question about training (n=313 or 2.1 percent), however, were retained since it is possible they are currently in practice. Since more than one specialty could be chosen by physician respondents, for purposes of this study, we used the specialty marked which had the highest allotment of time (usually 81-100 percent, but occasionally 61-80 percent). Using this method, we also categorized all medical specialists, all pediatric subspecialists, and all surgical specialists into unique groups. Lastly, since less than three percent of physicians answered they only worked 1 – 4 months per year in Florida the analysis includes physicians who indicated they worked in Florida for any length of time (1 – 4, 5 – 8, or 9 – 12 months).

Results

The overall response rate was 22,035 of 24,840 physicians (88.7 percent). Exclusions included: practice address not in Florida - 5,151 (23.4 percent), residents or fellows – 664 (4.1percent), and specialty code indicating no clinical practice – 70 (<1 percent). The remaining 15,518 physicians are included in the following analyses.

Table 1 *(See Tables at end of article)* shows the overall characteristics of the physician respondents. By frequency, medical specialists (14.2 percent) were the largest represented group, followed by general internal medicine (14.1 percent), surgical specialists (13.8 percent), and family medicine (11.5 percent) physicians. Overall, the mean age of respondents was 51.43 years. Approximately 78 percent were male, and the majority were White (64.6 percent). Of note, only 4.6 percent of respondents were Black, 10.9 percent Asian, and 15.0 percent indicated Hispanic ethnicity. The majority of physicians (55.5 percent) worked more than 40 hours per week in clinical care. In addition, 30.4 percent worked from 21 – 40 hours per week, and 14.1 percent worked 20 or fewer hours in their medical practice (data not shown).

Table 2 *(See Tables at end of article)* displays the number of physician respondents in medical, pediatric, and surgical specialties. As with all numbers presented in this article, it should be noted that this number represents an 88.7 percent response for one-half of the total number of licensed physicians. It is therefore difficult to extrapolate the numbers, particularly where a specialty has only a few respondents, to calculate the total number of physicians in that specialty in the state.

Table 3 *(See Tables at end of article)* shows the distribution of Florida physicians by county for the 10 largest counties (by population) in Florida. The data in this table is particularly useful when examining the relative distribution of each specialty and how it differs around the state. For example, whereas family physicians make-up 5.9 percent of doctors in Palm Beach county, there are proportionately twice as many (12.7 percent) family physicians in Miami-Dade county.

Coverage of emergency departments by physicians, by clinical specialty, is shown in Table 4. *(See Tables at end of article)* As expected, the highest percent is noted for emergency medicine physicians (88.9 percent). Of interest, among 10 clinical groups that typically take emergency calls, pediatrics (13.3 percent), and family medicine (13.5 percent) had the lowest coverage rates statewide. In the 10 large counties displayed in Table 4, the rates of emergency room coverage ranged from zero percent (0/6) for pediatric specialists in Brevard, to 100 percent (21/21) for emergency medicine doctors in Polk county. From the county standpoint, rates for emergency room coverage for these 10 clinical groups ranged from 24.9 percent in Miami-Dade, to 43.6 percent in Brevard.

Lastly, we reviewed the percent of physicians planning to leave, or significantly reduce, practice within five years (Table 5). *(See Tables at end of article)* When looking at state level data, the rates ranged from 8.4 percent for pediatric sub-specialists, >>>

to 17.8 percent for general surgeons. From a county standpoint, rates varied from 10.6 percent for Hillsborough, to 14.6 percent for Pinellas county. Individual specialty groups varied widely by county with certain specialties having no physicians indicating an intention to leave practice within five years (e.g., general surgery in Lee – 0/6; pediatric sub-specialists in Palm Beach – 0/23, Duval – 0/39, Polk – 0/6, Brevard – 0/6, and Lee – 0/6), while in other areas more than 25 percent of physicians responding to the survey suggested they will be leaving practice within five years (e.g., general surgery in Broward – 9/36, Orange - 5/20; emergency medicine in Palm Beach - 10/39, Hillsborough - 11/40).

Discussion

Information about the physician workforce is important if we, as a state, are to maximally cover the multitude of patients and their medical conditions requiring timely and complete attention. Florida has been handicapped by not having current data about the nature of the physicians practicing in the state including where they are located, what their practice type entails, the services they offer, and their future plans (e.g. retirement or decrease in clinical activity). With the passing of new legislation, this information will now be accessible in the years to come. In the interim, the voluntary physician survey that targeted those getting re-licensed in 2007 provides a glimpse into some of these important practice patterns.

Although an almost 90 percent response rate to this voluntary survey is excellent, it must be noted that the data represent an approximate 50 percent sample, not the entire population of Florida physicians. While we believe the survey provides valuable information, not previously available, we would also caution about its uses, particularly where the number of physicians in a given specialty or geographic area are small. In these cases, one cannot assume that one-half of that population was sampled. However, for larger groups and for an overall view of the physician workforce in the state several trends can be observed.

For example, the data suggest the total number of allopathic physicians who are actively practicing clinical medicine in the state is probably in the range of 34,000. This number excludes the many physicians who hold a Florida license, but do not appear to have a practice address in the state. It also excludes residents and fellows in training programs.

The mean age of the respondent physician was slightly greater than 51 years. This important demographic characteristic should be tracked over time. Over 78 percent of the practicing physicians in the study were male, a number which will likely be changing given the fact the majority of entering students in many medical schools are now female. Also noteworthy is the fact that in this study 15 percent of physicians were of Hispanic origin, but only 4.6 percent were Black physicians. Asian physicians made up almost 11 percent of the study respondents.

Much discussion has occurred around the question as to whether Florida has an adequate number of a variety of specialist physicians to meet its needs. This has been particularly true of "high-risk" specialties such as neurosurgery, trauma surgery, obstetrics, etc., since the 2003 debate on medical malpractice. Given the nature of the sampling it is difficult to know if the respondents in these specific specialties represent one-half of the total number of these much-needed specialties in Florida, and whether the estimated total number would be adequate to meet patient needs. When a similar survey is administered in the 2008 re-licensure cycle, those data can be combined with the current data to help resolve the issue about total numbers, hours worked per week in clinical practice, etc.

The same issue holds true when trying to assess the basic medical coverage needs in smaller counties and emergency rooms. While these figures show larger counties where very few physicians in particular specialties are covering emergency departments, it is hard to know whether that equates to gaps in coverage in those geographic areas. As the mandatory survey data begin to be collected yearly beginning in 2008, however, we should be able to better answer this question more accurately.

Similarly, it will be important to follow the trends related to future plans to leave or reduce practice as noted in this study. Physician respondents in certain specialties (e.g., general surgery, obstetrics/gynecology) were more than twice as likely to say they were likely to retire (or leave practice for other reasons) within five years, than others such as medical or pediatric specialists. Tracking these trends over time will be valuable to policymakers and educational leaders, particularly given the length of time, often eight or more years, needed in training to replace these physicians.

In summary, we believe the findings from this voluntary survey of Florida's physician workforce offers valuable new information that will assist leaders in the state to better plan for the needs of patients and doctors. When combined with the mandatory survey which is being planned for implementation in 2008 and beyond, these data will provide a framework upon which policymakers, educators, and professional societies such as the Florida Medical Association, can work to maximize quality care for patients.●

Table: 1 Descriptive characteristics of physicians responding to the survey

				Race/Ethnicity					
	Frequency (%)	Mean Age	% male	% White	% Hispanic	% Asian	% Black	% Native Am.	% Other
Medical specialties	2,197 (14.2%)	51.05	87.9	61.2	17.0	13.6	1.8	0.2	6.3
Internal Medicine	2,185 (14.1%)	49.57	75.6	49.1	18.5	17.4	6.3	0.1	8.5
Surgical specialties	2,162 (13.9%)	52.57	93.0	82.1	7.7	5.0	2.8	0	2.4
Family Medicine	1,779 (11.5%)	53.86	72.7	58.6	18.5	12.9	6.3	0.2	8.5
Pediatrics	1,002 (6.5%)	49.20	49.6	51.1	21.8	14.2	8.0	0.1	4.7
Anesthesiology	898 (5.8%)	49.32	79.6	66.9	14.0	9.6	4.1	0.2	5.2
Radiology	775 (5.0%)	50.96	79.7	78.3	9.9	6.6	2.1	0	3.2
Psychiatry	732 (4.7%)	55.81	71.5	60.3	17.8	13.8	3.8	0	4.4
Obstetrics/ Gynecology	720 (4.6%)	51.71	71.2	68.9	13.1	4.9	9.7	0.3	3.7
Emergency Medicine	731 (4.7%)	47.42	82.6	70.4	11.5	6.4	7.8	0.3	3.6
General Surgery	377 (2.4%)	53.78	90.4	68.9	16.9	8.3	3.1	0	2.8
Pathology	364 (2.3%)	52.91	70.5	71.9	12.6	9.3	3.1	0.3	2.8
Pediatric sub-specialty	362 (2.3%)	50.03	69.0	53.3	24.4	11.6	4.5	0	6.2
Neurology	309 (2.0%)	52.72	83.0	66.6	14.7	11.4	1.7	0.3	5.4
Dermatology	275 (1.8%)	48.96	67.8	86.6	5.2	4.4	1.8	0.4	1.8
Other	650 (4.2%)	53.84	77.3	70.7	11.4	9.5	4.3	0.3	3.8
Total	**15,518 (100%)**	**51.43**	**78.3**	**64.6**	**15.0**	**10.9**	**4.6**	**0.2**	**4.7**

Eponym trivia provided by funtrivia.com. Answers: 1. Brucellosis 2. hygiene 3. insomnia 4. arachnophobia 5. Apgar score

Table: 2 Numbers of select medical, pediatric, and surgical specialists who responded to the survey

Medical Specialty	Survey (N=)
Cardiology	
General	621
Interventional	40
Electrophsiology	18
Gastroenterology	350
Pulmonary Diseases & critical care medicine	154
Pulmonary Medicine	81
Critical Care Medicine	43
Hematology and Oncology	188
Oncology only	47
Hematology only	23
Nephrology	159
Infectious Diseases	146
Endocrine	116
Geriatrics	101
Rheumatology	95

Pediatric Specialty	Survey (N=)
Neonatalogy	94
Adolescent Med.	38
Endocrine	35
Cardiology	34
Critical Care	34
Hematology and Oncology	29
Neurology	20
Gastroenterology	19
Nephrology	15
Infectious Diseases	13
Pulmonary	12
Developmental/ Behavioral	9
Rheumatology	3

Surgical Specialty	Survey (N=)
Opthalmology	508
Orthopedics	310
Sports Medicine	54
Adult reconst.	40
Spine	34
Hand	31
Pediatric	18
Trauma	14
Foot and ankle	5
Musculoskeletal	2
Urology	278
Plastics	249
Hand	9
Craniofacial	5
Otolaryngology	196
Neurosurgery	126
Thoracic	107
Vascular	78
Colon and rectal	33
Pediatric	24
Critical Care	12
Hand	7

Table: 3 | Distribution of Florida physician respondents by county

	Top 10 Florida counties by population									
	Miami Dade	Broward	Palm Beach	Hills-borough	Pinellas	Orange	Duval	Polk	Brevard	Lee
Medical specialties	341 (13.8%)	218 (13.6%)	200 (17.0%)	160 (13.8%)	142 (16.5%)	121 (13.9%)	145 (17.7%)	38 (12.4%)	49 (11.7%)	41 (10.9%)
Internal Medicine	345 (14.0%)	237 (14.8%)	197 (16.7%)	168 (14.5%)	136 (15.8%)	108 (12.4%)	89 (10.5%)	48 (15.6%)	73 (17.4%)	61 (16.3%)
Surgical specialties	305 (12.4%)	238 (14.9%)	181 (15.4%)	157 (13.5%)	121 (14.0%)	141 (16.2%)	108 (12.7%)	37 (21.1%)	63 (15.0%)	59 (15.7%)
Family Medicine	314 (12.7%)	123 (7.7%)	69 (5.9%)	95 (8.2%)	86 (10.0%)	109 (12.5%)	103 (12.1%)	32 (10.4%)	51 (12.2%)	35 (9.3%)
Pediatrics	190 (7.7%)	99 (6.2%)	62 (5.3%)	79 (6.8%)	51 (5.9%)	66 (7.6%)	67 (7.9%)	19 (6.2%)	15 (3.6%)	26 (6.9%)
Anesthesiology	150 (6.1%)	111 (6.9%)	64 (5.4%)	83 (7.2%)	46 (5.3%)	23 (2.6%)	45 (5.3%)	19 (16.2%)	25 (6.0%)	25 (6.7%)
Radiology	100 (4.1%)	84 (5.3%)	70 (5.9%)	39 (3.4%)	49 (5.7%)	22 (2.5%)	47 (5.5%)	14 (4.6%)	19 (4.5%)	15 (4.0%)
Psychiatry	130 (5.3%)	70 (4.4%)	53 (4.5%)	65 (5.6%)	32 (3.7%)	36 (4.1%)	20 (2.4%)	17 (5.5%)	16 (3.8%)	15 (4.0%)
Obstetrics/ Gynecology	112 (4.5%)	79 (4.9%)	66 (5.6%)	63 (5.4%)	35 (4.1%)	55 (6.3%)	46 (5.4%)	12 (3.9%)	16 (3.8%)	16 (4.3%)
Emergency Medicine	86 (3.5%)	65 (4.1%)	42 (3.6%)	44 (3.8%)	44 (5.1%)	49 (5.6%)	44 (5.2%)	22 (7.2%)	25 (6.0%)	25 (6.7%)
Pediatric sub-specialty	82 (3.3%)	63 (3.9%)	20 (1.7%)	37 (3.2%)	14 (1.6%)	34 (3.9%)	23 (2.7%)	5 (1.6%)	6 (1.4%)	5 (1.3%)
General Surgery	71 (2.9%)	36 (2.3%)	24 (2.0%)	35 (3.0%)	15 (1.7%)	21 (2.4%)	15 (1.8%)	10 (3.3%)	8 (1.9%)	6 (1.6%)
Pathology	39 (1.6%)	45 (2.8%)	20 (1.7%)	45 (3.9%)	24 (2.8%)	21 (2.4%)	21 (2.5%)	8 (2.6%)	8 (1.9%)	7 (1.9%)
Neurology	48 (1.9%)	34 (2.1%)	23 (2.0%)	26 (2.2%)	17 (2.0%)	14 (1.6%)	27 (3.2%)	6 (2.0%)	9 (2.1%)	5 (1.3%)
Dermatology	40 (1.6%)	22 (1.4%)	39 (3.3%)	20 (1.7%)	17 (2.0%)	9 (1.0%)	15 (1.8%)	6 (2.0%)	6 (1.4%)	13 (3.5%)
Other	112 (4.5%)	76 (4.8%)	48 (4.1%)	44 (3.8%)	34 (3.9%)	41 (4.7%)	33 (3.9%)	14 (4.6%)	30 (7.2%)	21 (5.6%)
Total	**2465 (100%)**	**1600 (100%)**	**1178 (100%)**	**1160 (100%)**	**863 (100%)**	**870 (100%)**	**848 (100%)**	**307 (100%)**	**419 (100%)**	**375 (100%)**

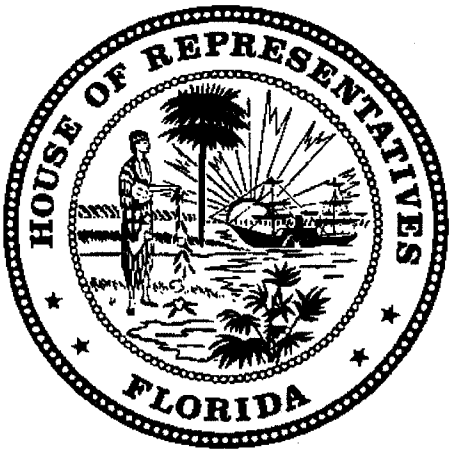
Table: 4 | Percent of physician respondents who indicated they cover an emergency department

	Top 10 Florida counties by population										
	Miami Dade	Broward	Palm Beach	Hills-borough	Pinellas	Orange	Duval	Polk	Brevard	Lee	State Total
Emergency Medicine	80.2%	87.7%	73.8%	90.9%	86.4%	91.7%	95.5%	100%	96.0%	92.0%	88.9
General Surgery	37.1%	58.3%	45.8%	57.1%	53.3%	65.0%	60.0%	50.0%	87.5%	66.7%	57.2
Surgical specialties	47.0%	54.4%	56.4%	59.2%	54.2%	61.0%	61.8%	59.5%	61.9%	50.0%	56.5
Medical specialties	19.4%	18.9%	17.6%	19.1%	33.3%	25.6%	28.7%	35.1%	53.1%	30.0%	25.7
Obstetrics/Gynecology	25.2%	24.1%	34.8%	19.0%	42.9%	21.8%	47.8%	33.3%	37.5%	43.8%	34.1
Pediatric sub-specialty	28.4%	33.3%	50.0%	32.4%	35.7%	31.3%	21.7%	40.0%	0	60.0%	29.5
Internal Medicine	15.2%	16.6%	19.3%	16.7%	21.3%	17.0%	23.0%	20.8%	30.6%	13.3%	20.3
Psychiatry	14.0%	14.3%	15.1%	18.5%	28.1%	8.3%	20.0%	18.8%	12.5%	6.7%	14.5
Family Medicine	13.7%	10.6%	8.7%	9.5%	5.8%	13.8%	12.6%	15.6%	15.7%	11.4%	13.5
Pediatrics	10.1%	14.1%	12.9%	6.3%	7.8%	14.1%	9.0%	21.1%	40.0%	19.2%	13.3
Average for above	**24.8%**	**29.7%**	**29.8%**	**29.0%**	**33.5%**	**32.9%**	**34.6%**	**37.8%**	**43.6%**	**33.6%**	--

Table: 5 | Percent of physician respondents planning to leave or significantly reduce practice within next five years

	Top 10 Florida counties by population										
	Miami Dade	Broward	Palm Beach	Hills-borough	Pinellas	Orange	Duval	Polk	Brevard	Lee	State Total
General Surgery	7.1	25.0	20.8	8.6	13.3	25.0	13.3	22.2	12.5	0	17.8
Obstetrics/Gynecology	15.3	15.2	21.2	21.0	17.1	11.3	13.0	8.3	6.3	12.5	16.9
Psychiatry	17.7	18.6	13.2	9.2	18.8	8.3	5.0	5.9	31.3	26.7	16.7
Emergency Medicine	9.5	17.5	24.4	29.5	11.4	8.3	14.0	4.5	12.0	12.0	15.7
Pathology	18.4	11.1	10.0	11.1	25.0	20.0	4.8	25.0	12.5	14.3	15.5
Family Medicine	14.3	20.8	7.2	12.6	14.0	13.9	13.6	12.5	14.0	20.0	14.9
Surgical specialties	18.1	11.3	15.5	6.4	14.3	18.4	17.0	22.9	13.1	12.3	14.2
Radiology	17.3	8.5	10.1	12.8	14.6	0	14.9	7.1	15.8	26.7	14.2
Neurology	10.4	8.8	18.2	3.8	17.6	7.1	18.5	16.7	0	0	13.3
Anesthesiology	11.4	8.3	12.5	15.7	22.2	4.3	13.3	21.1	20.0	12.0	13.1
Dermatology	10.0	27.7	10.3	25.0	17.6	11.1	20.0	16.7	16.7	0	11.3
Internal Medicine	13.4	14.0	8.6	8.9	15.6	7.4	8.0	2.1	5.5	8.3	10.4
Pediatrics	13.8	8.1	8.1	6.3	5.9	9.4	11.9	5.3	6.7	3.8	10.0
Medical specialties	9.7	8.8	9.0	3.8	13.5	9.1	6.2	5.3	10.2	10.0	8.8
Pediatric sub-specialty	9.9	4.8	0	13.5	14.3	3.0	0	0	0	0	8.1
Other	13.5	18.7	20.8	13.6	8.8	15.0	12.1	28.6	10.3	9.5	15.8
Total % per column	**13.5**	**12.8**	**12.3**	**10.6**	**14.6**	**11.4**	**11.5**	**11.2**	**11.6**	**11.6**	**12.9**

2008 INTERIM PROJECTS



Building Florida's Health Information Network

February 13, 2008

Marco Rubio
Speaker

Gayle Harrell
Chair
Health Quality Committee

I. Executive Summary

Information technology (IT) has transformed the financial, retail, and telecommunications industries by enabling greater efficiency, better quality, and more consumer choice. The potential benefits of IT have yet to be fully realized in the U.S. health care sector.[1] Widespread adoption of IT in the health care sector, such as interoperable electronic medical records, holds the promise of improving patient safety and reducing the cost of healthcare by preventing unnecessary procedures.

The state of Florida has taken a leading role in the national movement toward creating interoperable health information exchanges. Over the course of the previous three years, the state has invested $5.5 million in a grants program to establish regional health information organizations (RHIOs) as the basis for a statewide health information exchange (HIE) known as the Florida Health Information Network (FHIN). In addition, Governor Jeb Bush created the Governor's Health Information Infrastructure Advisory Board in May 2004 to advise the Agency for Health Care Administration as it develops a strategy to develop a Florida health information infrastructure.[2] The Board produced a whitepaper, "Florida Health Information Network, Architectural Considerations for State Infrastructure", which outlines their vision for the FHIN.[3]

The role of a RHIO is to work at the local level to bring together healthcare providers in the community for the purpose of sharing healthcare data and integrating their different computer systems into a health care data network that can exchange medical records among all participants.[4] There is no single model for a RHIO to follow. Most RHIOs vary in their size, member organizations, amount and nature of data collected and shared, and delivery method.[5] One of the major challenges facing RHIOs across the nation is the ability to maintain sustainable funding. The first phase of development for RHIOs is usually provided by grant funding. However, the second phase of development generally involves maintaining and improving systems, requiring some type of sustainable funding.[6]

The intended purpose of the FHIN is to connect the RHIOs and serve as an advisory body to help manage the growth and operation of the entire network. Despite the state's investment through the FHIN grants program, the Legislature has not created the FHIN;

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[1] Castro, Daniel, "Improving Health Care: Why a Dose of IT May Be Just What the Doctor Ordered," The Information Technology and Innovation Foundation (October 2007).
[2] Executive Order Number 04-93 (2004), available at http://www.fdhc.state.fl.us/dhit/Board/executive_order.pdf. (visited December 17, 2007).
[3] Governor's Health Information Infrastructure Advisory Board, "Florida Health Information Network, Architectural Considerations for State Infrastructure," Version 6.2, April 19, 2007.
[4] *Id.* at iv.
[5] E-HIM Work Group on Patient Identification in RHIOs. "Surveying the RHIO Landscape: A Description of Current RHIO Models, with a Focus on Patient Identification." *Journal of AHIMA 77*, no.1 (January 2006): 64A-D. http://library.ahima.org/xpedio/groups/public/documents/ahima/bok1_028980.hcsp?dDocName=bok1_028980 (visited December 19, 2007).
[6] *Id.*

consequently, the RHIOs are developing locally in the absence of guiding principles from a statewide perspective.

During the same time period, other states and the federal government have initiated efforts to create health information exchanges. Based on a review of these efforts and the efforts within Florida, there are three prominent options that the Legislature may consider to foster the development of a statewide HIE.

One option available to the state is to build and operate the Florida Health Information Network (FHIN) as outlined in the Governor's Health Information Infrastructure Advisory Board's (GHIIAB) published white paper.[7] This model relies heavily on the participation of regional health information organizations (RHIOs) to provide the body of data necessary to exchange over the internet-based, statewide network. Also a key feature of this model is the creation of a not-for-profit corporation to oversee the creation of the FHIN. The state has the option of either directing the Agency for Health Care Administration (agency) to build the technical elements of the FHIN or directing the corporation to contract with vendors to build the technical elements of the FHIN. With this model, the state maintains ownership of the technology and is responsible for the technical and oversight functions of the network. The total budget for the first fiscal year, as outlined in the GHIIAB's white paper, is $9,400,000.

A second option is to direct the agency to issue an invitation to negotiate (ITN) to explore the different models the statewide network could adopt to maximize the state's investment before building the network. This option differs slightly from the FHIN model discussed above in that the state has the ability to pursue ideas that may not have been previously considered--ideas for a statewide network model that will provide the best value to the state. With this option, the state maintains ownership of the technology and is responsible for oversight of the operation. The funding portion of this model is similar to the FHIN model. The vendor chosen through the ITN process is paid by the agency to complete the deliverables outlined in the contract.

A third option is to continue funding the development of RHIOs through the grants program administered by the agency and to create an incentive program to encourage physician adoption of electronic medical records (EMR). This option avoids a substantial up-front investment, while continuing to incubate the development of RHIOs and encourage the adoption of EMR systems by physicians--both of which are the most basic and essential elements of a statewide infrastructure. As discussed later in this project, many states across the nation are choosing this measured, deliberate approach to achieving statewide health information exchange.

If the state of Florida is dedicated to pursuing a statewide health information exchange, whether this year or in the future, one common element across all three options that must be established is an advisory body. An advisory body at the state level will provide the guidance that is necessary to protect the state's best interest. Currently,

[7] Governor's Health Information Infrastructure Advisory Board, "Florida Health Information Network, Architectural Considerations for State Infrastructure," Version 6.2, April 19, 2007.

each RHIO in Florida, which acts as the governing body in its respective region, is developing to best serve the population within its region. There is no statutorily created statewide advisory body to bring together these multiple interests for the benefit of the state and the state's financial investment.

II. Definitions

Currently, there are multiple competing definitions surrounding key health care IT terms, with terms often used interchangeably. For purposes of this project, the following terms and definitions will be utilized:

- Interoperable: the ability of different information technology systems and software applications to communicate, to exchange data accurately, effectively, and consistently, and to use the information that has been exchanged.[8]
- Electronic Medical Record: a record of a person's medical treatment that is created by a licensed health care provider and that is stored in an interoperable and accessible digital format.
- Electronic Health Record: a record of a person's health information, collected over a period of time, generated by one or more encounters in any care delivery setting.
- Personal Health Record: an Internet-based set of tools that allow individuals to access and coordinate their lifelong health information and make appropriate parts of it available to those who need it.[9]
- Health Information Exchange: an electronic system used to acquire, process, and transmit electronic medical records, which can be shared in real-time among authorized health care providers, health care facilities, health insurers, and other recipients as authorized by law, to facilitate provision of health care services.
- Regional Health Information Organization: a neutral organization with a defined governance structure which is composed of and facilitates collaboration among its stakeholders in a given medical trading area, community, or region through secure electronic health information exchange to advance the effective and efficient delivery of healthcare for individuals and communities. The geographic footprint of a RHIO can range from a local community to a large multi-state region.

III. Health Information Exchange

A. Federal Efforts

On April 27, 2004, President George W. Bush issued an Executive Order[10] in order to encourage the development of a nationwide interoperable health information technology

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[8] The National Alliance for Health Information Technology, "What is interoperability?" http://www.nahit.org/cms/index.php?option=com_content&task=view&id=186&Itemid=195 (visited January 21, 2008).

[9] The Markle Foundation, http://www.connectingforhealth.org/resources/final_phwg_report1.pdf (visited January 21, 2008).

infrastructure. The Executive Order directed the Secretary of Health and Human Services to establish within the Office of the Secretary the position of National Health Information Technology Coordinator. The Office of the National Coordinator (ONC) is tasked with developing, maintaining, and implementing a strategic plan to guide the nationwide implementation of interoperable health information technology in both the public and private health care sectors in order to reduce medical errors, improve quality, and produce greater value for health care expenditures.

In 2004 President Bush also set the goal for most Americans to have access to an interoperable electronic medical record by the year 2014. In order to accomplish this goal, the United States Department of Health and Human Services (HHS) created a "Strategic Framework",[11] which outlines the vision and goals of HHS' health information technology initiative. The plan of action consists of four sequential main goals; each goal is supported by three major strategies. The four goals are diagramed in Figure 1.[12]

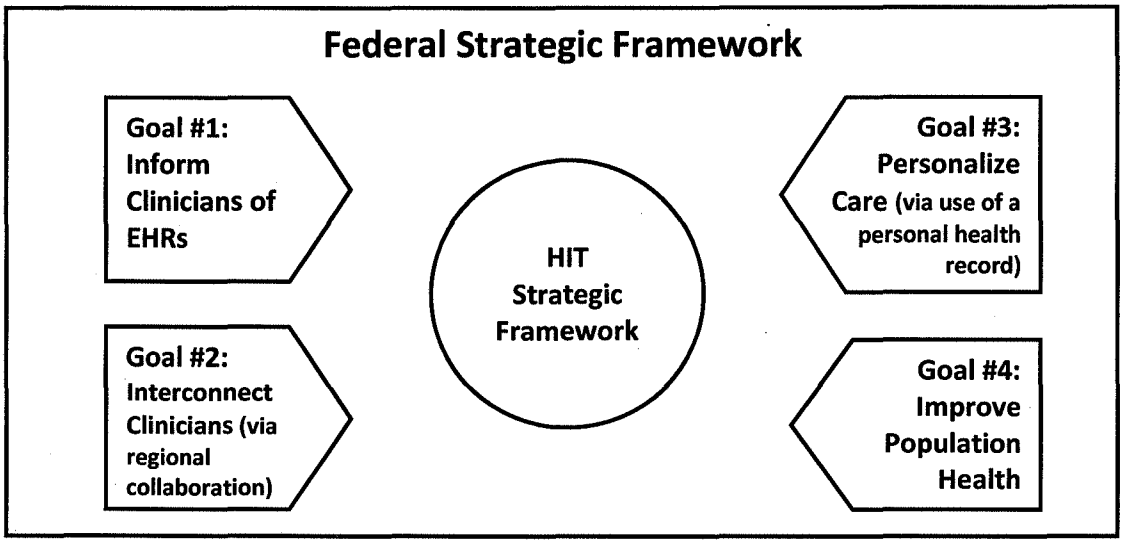

Figure 1

The federal government has taken an active role in ensuring the necessary steps are taken to achieve the outlined goals. The ONC awarded multiple contracts in 2005 to entities conducting work in the field of health information technology (HIT). Project goals included:

- Identifying interoperability standards (such as to facilitate the exchange of patient health data, through a contract with the Healthcare Information Technology Standards Panel (HITSP);

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[10] *Executive Order: Incentives for the Use of Health Information Technology and Establishing the Position of the National Health Information Technology Coordinator* (visited December 4, 2007) http://www.whitehouse.gov/news/releases/2004/04/20040427-4.html

[11] U.S. Department of Health and Human Services, "Summary of Strategic Framework," (visited December 13, 2007) www.hhs.gov/healthit/framework.html.

[12] *Id.*

- Defining a certification process for health IT products, through a contract with the Certification Commission for Healthcare Information Technology (CCHIT); and
- Designing and evaluating standards-based prototype architectures for the Nationwide Health Information Network (NHIN).

State and federal governments are both actively working to set technical interoperability standards, though for different purposes. Technical interoperability standards are important to state governments to enable the multiple participating entities to connect to each other, whether through a statewide HIE or other means. The federal government is pursuing technical interoperability standards to enable states to communicate with each other through the NHIN. Both state and federal government technical standards are equally important to overall HIE and should complement each other.

The federal government has also created a program aimed at increasing the adoption of electronic health records (EHR) among physician practices. The five-year project, which will begin in the spring of 2008, will provide annual bonuses to physician groups using nationally certified EHR systems to meet clinically qualified measures. During the five year project, it is estimated that 3.6 million consumers will be directly affected as their primary care physician adopts certified EHRs in their practices.[13]

B. Efforts In Other States

States across the nation have recognized the potential benefit of HIT and many are moving forward with HIT efforts. However, states differ in their vision of incorporating HIT into their healthcare system and the roadmap to achieve their vision. Smaller states are better positioned to participate in statewide health information exchange (HIE), due to the fact that they have smaller, centrally-located populations and fewer healthcare stakeholders to coordinate, while larger states tend to have a greater number of stakeholders and a larger, more diverse population.[14] Regional health information organizations (RHIOs) across states are many and varied, with minimal inter-RHIO connection. Many states have multiple RHIOs, but their participants, organization, structure, and activities are as varied as the communities they represent.[15]

The state plays a variety of roles in statewide HIE projects across the nation, which include: the main cross-stakeholder facilitator, a primary driver of the project, a funding resource, and a data resource.[16] Some states have partnered in creating a legal entity, such as a 501(c)(3) to implement a roadmap to statewide HIE; while others have formed a steering committee, advisory council or task force to continue to research the process by which statewide interoperability should be achieved. One commonality across states is the presence of a statewide advisory body to oversee the process by which a state

[13] U.S. Department of Health and Human Services, "HHS Announces Project to Help 3.6 Million Consumers Reap Benefits of Electronic Health Records," October 30, 2007.
[14] Avalere Health, "Evolution of State Health Information Exchange, A Study of Vision, Strategy, and Progress, as prepared for the Agency for Healthcare Research and Quality," AHRQ Publication No. 06-0057, January 2006, 5.
[15] *Id.*
[16] Avalere Health, "Evolution of State Health Information Exchange, A Study of Vision, Strategy, and Progress, as prepared for the Agency for Healthcare Research and Quality," AHRQ Publication No. 06-0057, January 2006, 7.

reaches interoperability. Figure 2 illustrates the varied level of HIE adoption across the nation.[17]

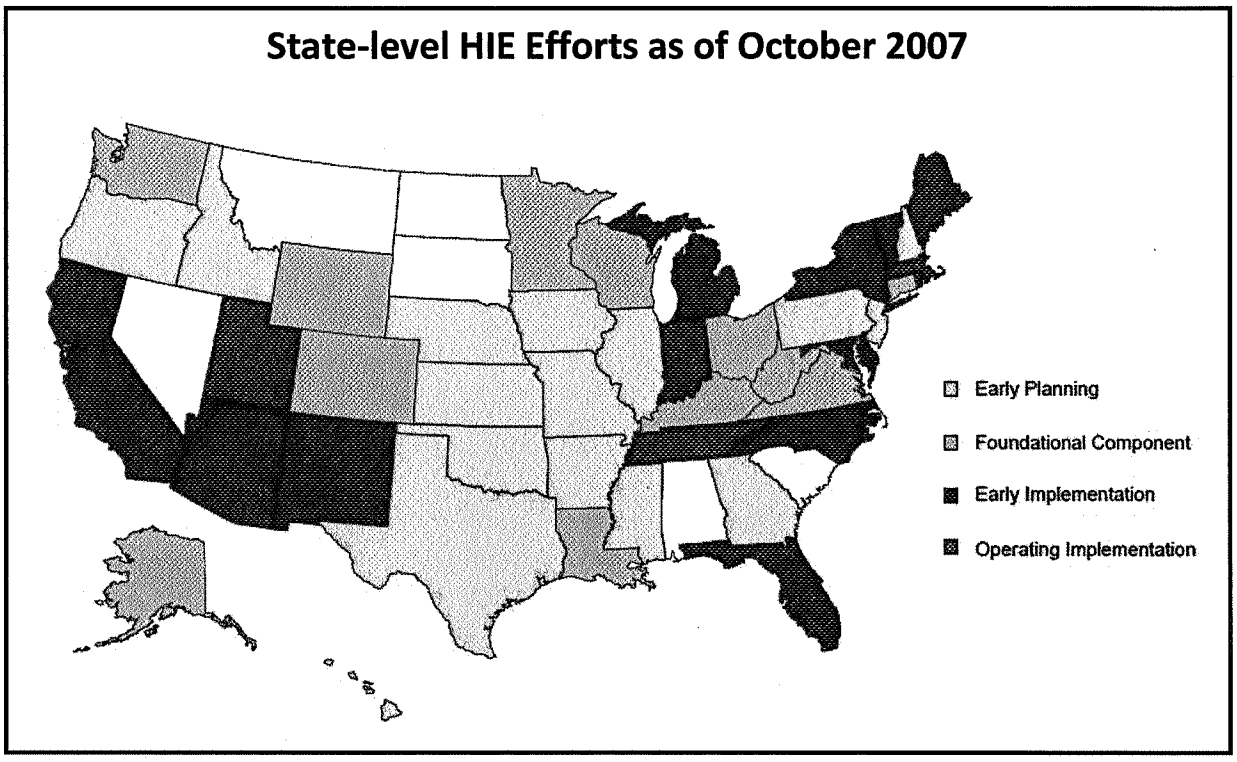

Figure 2

For example, the state of Georgia has formed an advisory board to advise the Department of Community Health in establishing a statewide strategy that will enable health information to be available across the full continuum of care.[18] Georgia also administers a grants program to foster health information exchange, which awarded $853,088 in grants in 2007.[19] The state of Minnesota has formed a public-private collaborative to enhance the statewide HIE infrastructure, which is scheduled to go live in early 2008.[20] Minnesota also operates an EHR adoption grant program aimed at supporting the adoption and use of EHRs by healthcare providers in rural and underserved areas of the state.[21]

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[17] American Health Information Management Association's Foundation of Research and Education, "Building Sustainable Health Information Exchange: Roles for State Level Public-Private Partnerships," State-Level HIE Consensus Project, Consensus Conference, November 5-6, 2007, 15.

[18] Executive Order of Georgia Governor Sonny Perdue, October 17, 2006.

[19] Press release, Georgia Department of Community Health, "Four Georgia Health Partnerships Receive $853,088 in Grants," November 5, 2007.

[20] Press release, Minnesota Office of the Governor, "Minnesota Health Information Exchange to be among largest 'e-initiatives' in the nation," September 10, 2007.

[21] Minnesota Department of Health, "Minnesota e-Health Initiative Funding Opportunities," http://www.health.state.mn.us/e-health/funding.html (visited January 5, 2008).

The state of Kentucky's roadmap to statewide HIE is very similar to the previously proposed Florida Health Information Network. The state approved the creation of the Kentucky e-Health Corporation which is an independent public-private entity responsible for managing the development and operations of the statewide Kentucky e-Health Network currently under development.

According to the e-Health Initiative, the top sources of upfront funding in the United States for health information exchange initiatives in 2007 were hospitals (53%), federal government grants and contracts (44%), state government grants and contracts (43%), private payers (32%), and philanthropic sources (31%).[22]

C. Florida Efforts

In Florida, the development of a statewide HIE began on May 4, 2004, when Governor Jeb Bush created the Governor's Health Information Infrastructure Advisory Board (Board) by executive order.[23] The executive order required the Board to "advise and support the Agency for Health Care Administration as it develops and implements a strategy for the adoption and use of electronic health records and creates a plan to promote the development and implementation of a Florida health information infrastructure." In addition, the 2004 Affordable Health Care for Floridians Act complemented the executive order by directing the agency to "develop and implement a strategy for the adoption and use of electronic health records."[24]

The board issued an interim report to Governor Bush in 2005 that called for, among other recommendations, the immediate development of the Florida Health Information Network (FHIN) in order to encourage the adoption of electronic health records.[25] The vision for the FHIN is outlined in the board's white paper, "Florida Health Information Network, Architectural Considerations for State Infrastructure".[26] The model outlined by the board relies heavily on the RHIO as the vehicle for statewide HIE. The FHIN will act as the conductor of health information among healthcare providers and can be described as having two main components: regional HIE, through RHIOs, and a statewide infrastructure that will connect the RHIOs to enable statewide HIE.[27] The report also recognized two main obstacles facing the development of the FHIN: the low number of healthcare providers who have adopted electronic health record systems, and the lack of an infrastructure to share health information effectively.

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[22] e-Health Initiative, "Fourth Annual Survey of Health Information Exchange at the State, Regional, and Community Levels," December 19, 2007, http://www.ehealthinitiative.org/2007HIESurvey/Financing.asp (visited January 5, 2008).

[23] Executive Order Number 04-93 (2004), available at http://www.fdhc.state.fl.us/dhit/Board/executive_order.pdf. (visited December 17, 2007).

[24] Chapter 2004-297, L.O.F., s. 408.062(5), F.S.

[25] Governor's Health Information Infrastructure Advisory Board, "First Interim Report to Governor Jeb Bush," http://ahca.myflorida.com/dhit/Board/interim_rept_gov.pdf (visited December 17, 2007).

[26] Governor's Health Information Infrastructure Advisory Board, "Florida Health Information Network, Architectural Considerations for State Infrastructure," Version 6.2, April 19, 2007.

[27] Florida Health Policy Center, "Florida's Health Information Network: What will it cost to develop?," February 2007, http://www.floridahealthpolicycenter.org/research/pdfs/FHIN%20brief.pdf (visited December 19, 2007).

Over the course of three years, the board and the agency worked together to implement recommendations related to advancing the adoption and utilization of EHRs and establishing RHIOs and locally-based HIE.[28] The board published its final report to Governor Charlie Crist on July 6, 2007.[29] The report said that the foundation for a statewide network is in place and recommended the following actions to Governor Crist to implement the FHIN:

- Promote and support the continuing development of the state's local health information exchanges.
- Establish a new advisory board as soon as possible to guide the direction and development of the FHIN.
- Require action on specific steps to assist in developing the network from Florida Medicaid, the Department of Health, and the Department of Management Services, and possibly other state agencies.
- Insist on a "bias in favor of action" on this initiative by members of the administration, placing an emphasis on data exchange operations over the occasional government tendency to conduct further studies before taking substantive action.

The board was not extended by Executive Order and ceased to operate on June 30, 2007. In January 2008, agency Secretary Andrew Agwunobi appointed a 14-member Health Information Exchange Coordinating Committee. The committee is organized "to advise and support the agency in developing and implementing a strategy to establish a privacy-protected, secure and integrated statewide network for the exchange of electronic health records among authorized physicians."[30]

FHIN Grants Program

In 2006, the Legislature authorized the agency to administer a grants program to advance the development of a health information network.[31] According to the agency, grants are currently awarded in three categories:[32]

- Assessment and planning grants - Support engaging appropriate healthcare stakeholders to develop a strategic plan for health information exchange in their communities.
- Operations and evaluation grants - Support projects that demonstrate health information exchange among two or more competing provider organizations.

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[28] Florida Center for Health Information and Policy Analysis, "Privacy and Security Solutions for Interoperable Health Information Exchange, Florida Implementation and Impact Report," December 3, 2007, 4.
[29] Governor's Health Information Infrastructure Advisory Board, "Final Report of the Governor's Health Information Infrastructure Advisory Board," July 6, 2007, http://ahca.myflorida.com/dhit/Board/Brdmtg63007.pdf (visited December 19, 2007).
[30] Agency for Health Care Administration, http://ahca.myflorida.com/dhit/Governance/HIECCIndex.shtml (visited January 21, 2008).
[31] Section 408.05(4)(b), F.S.
[32] Agency for Health Care Administration, "FY 2007-2008 Grants Program Requirements," http://ahca.myflorida.com/dhit/FHINgrantsProgram/FGPSched0708.pdf (visited January 21, 2008).

- Training and technical assistance grants - Support practitioner training and technical assistance activities designed to increase physician and dentist use of electronic health record systems.

From Fiscal Year 2005-2006 through Fiscal Year 2007-2008, a total of $5.5 million has been appropriated by the legislature to fund the grants program.

About half of the RHIOs that have received state grants are operational in exchanging data within their region, but on a very limited basis. The scope of the exchange and number of users participating in the exchange is still relatively small. The remaining RHIOs that have received state grants are pre-operational and continuing to develop and test various elements of their HIE. Figure 3 depicts the location of the RHIOs that received a FHIN grant in Fiscal Year 2005-2006 through Fiscal Year 2007-2008, in addition to one independent RHIO which has not received funding.

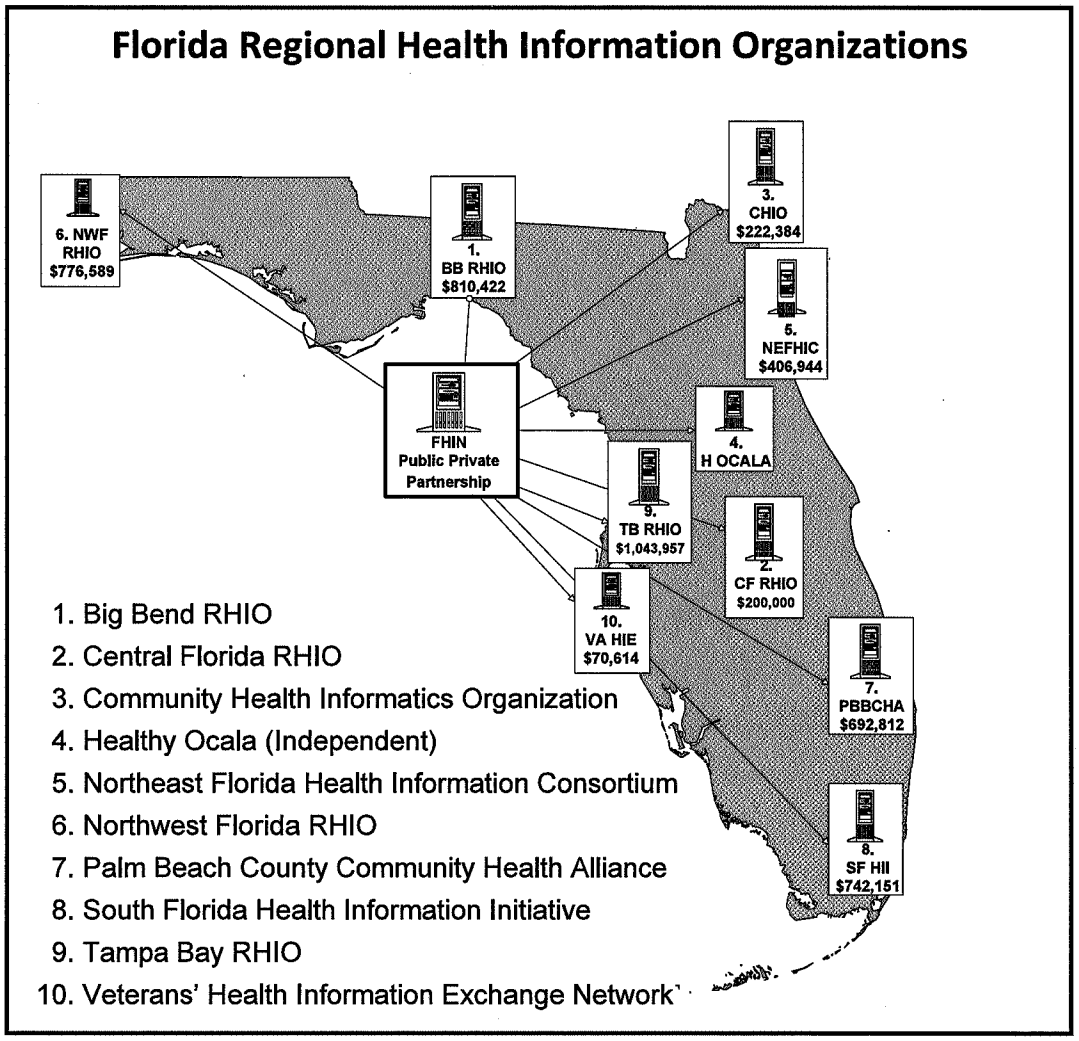

Figure 3

Potential Models for Statewide Health Information Exchange

There are several structural and funding options for creating a statewide health information exchange. The degree of state involvement in the HIE can vary with each model. A number of states are moving forward in parallel with federal efforts to develop and implement policies and plans that promote HIT and HIE.[33] As of December 19, 2007, 30 different pieces of legislation passed in 19 different states focusing on building the capacity for HIT.[34] Many states have passed legislation that applies to HIE on a statewide basis. They differ in their approach--some authorize a statewide entity to facilitate the development of a statewide system, while others focus on the need to set technical standards.

Fifty-seven bills were proposed in 2007 which authorize the establishment of a committee, taskforce, commission or working group.[35] The goals of these groups vary by state--some are directed to create a specific long-range plan for statewide HIE, while others are tasked with developing recommendations for financial incentives for EHR adoption.[36] Eighty-two bills were proposed in 2007 which include direct funding appropriations and/or loan programs or tax credits for the purchasing of various HIT tools.[37]

The rate of EHR adoption amongst physicians across the nation is low, although exact figures vary depending on the individual survey's definition of EHR. Consequently, some argue that the body of clinical data to be shared over a statewide network is too low to consider building the infrastructure at the present time. However, there are valuable data sets in electronic form available today that could be integrated into a single report and made available to authorized providers through a statewide network. As physician adoption of EHR systems increases, additional information could be added to the statewide network. The data sources available in electronic format include:[38]

- Claims form filed by providers with payors, which may include claims information such as: patient name, treating and referring physician, dates of service, diagnoses, and treatment procedures performed.
- Medication prescriptions stored by the pharmacy benefit managers.
- Test results maintained by laboratories.

For purposes of this project, three options for Florida government involvement in a statewide HIE are considered and discussed below.

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[33] eHealth Initiative, "Fourth Annual Survey of Health Information Exchange at the State, Regional and Community Levels," December 19, 2007,
[34] *Id.*
[35] *Id.*
[36] *Id.*
[37] *Id.*
[38] Governor's Health Information Infrastructure Advisory Board, "First Interim Report to Governor Jeb Bush," http://ahca.myflorida.com/dhit/Board/interim_rept_gov.pdf (visited December 21, 2007).

Florida Health Information Network (FHIN) Model

The FHIN model has been debated in Florida in recent years. The Governor's Health Information Infrastructure Advisory Board (GHIIAB) outlined the need for the FHIN in their published white paper[39] and legislation has been filed that would create the FHIN corporation to oversee the creation of the statewide network.[40] In its first year of operation, the FHIN would develop its organizational structure and build the physical components of the statewide network. In its second year, the FHIN would begin connecting RHIOs and exchanging health data.[41]

The technical model for FHIN is outlined in a white paper published by the GHIIAB.[42] The FHIN model relies heavily on the participation of regional health information organizations (RHIOs) to accomplish statewide HIE. The state has the option of directing the agency to build the technical elements of the FHIN or directing the corporation to contract with vendors to build the technical elements of the FHIN. Either way, the state is still responsible for the oversight of the technical functions of the FHIN and maintains ownership of all elements of the FHIN. The FHIN would:

- Serve as an Internet-based, statewide network that will integrate communications and data transfer among local health information networks and RHIOs.[43] No patient records are stored by the FHIN. The server sends a data request to all connected databases in the network to pull together pertinent records on a patient and send them to the requesting healthcare provider.[44]
- Utilize a state-level server which will maintain an Enterprise Master Patient Index of all patients receiving medical care and operate a Record Locator Service that will use the listing of patient identifiers contained in the EMPI to query health care providers in each RHIO in order to collect the appropriate patient records.[45]
- Authenticate users and RHIOs to determine if they are authorized to access patient records via the FHIN.[46]
- Function as the major portal for integrating state agency health care datasets, such as the State Health Online Tracking System (SHOTS) immunization data from the Department of Health and Medicaid data from the Agency for Health Care Administration (agency).[47]

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[39] Governor's Health Information Infrastructure Advisory Board, "Florida Health Information Network, Architectural Considerations for State Infrastructure," Version 6.2, April 19, 2007.
[40] See HB 1409, 2006, http://www.myfloridahouse.gov/Sections/Bills/billsdetail.aspx?BillId=33643&SessionId=42 and HB 1121, 2007, http://www.myfloridahouse.gov/Sections/Bills/billsdetail.aspx?BillId=36128&SessionId=54.
[41] Governor's Health Information Infrastructure Advisory Board, "Florida Health Information Network, Architectural Considerations for State Infrastructure," Version 6.2, April 19, 2007, 47.
[42] Governor's Health Information Infrastructure Advisory Board, "Florida Health Information Network, Architectural Considerations for State Infrastructure," Version 6.2, April 19, 2007.
[43] *Id.* at 4.
[44] *Id.* at 7.
[45] *Id.* at 5.
[46] *Id.* at 6.
[47] *Id.* at 6.

The GHIIAB also outlined the need for the state to create an independent, not-for-profit organization to oversee the creation of the FHIN with management by an uncompensated, appointed board of directors.[48] The potential roles of the FHIN corporation are outlined in legislation filed in 2006[49] and 2007[50] and include:

- Setting technical standards for RHIOs where networks need to employ identical technical specifications to connect to FHIN. [51]
- Implementing a marketing program to promote widespread use of the network.
- Developing and implementing specific programs or strategies that address the creation, development, and expansion of RHIOs and the recruitment of participants in the network.
- Developing an annual budget that includes funding from public and private entities, including user fees.
- Developing and enforcing privacy and security standards for participation in the network.
- Recommending reform of state law to reduce barriers to participation in the network.

The GHIIAB's white paper outlined the operational budget for the FHIN's operations and administration, core functions, core services provided to participating RHIOs, and communication and training. The budget for the first fiscal year is higher than the budget for the later years due to start-up costs, which may be one-time expenses. Regardless of whether the FHIN is built by the state or built by contracted vendors, the budget would be approximately the same.[52] The total budget for the first fiscal year is $9,400,000.

In the FHIN's business plan,[53] it is assumed that the RHIO is the customer and will purchase technology and business services from the FHIN. The business plan accounts for state funding for the first three years of operation.

Agency-Issued Invitation to Negotiate (ITN)

A second option the state could pursue to create a statewide HIE is to direct the agency to issue an invitation to negotiate (ITN).[54] An ITN offers the state the ability to explore what each respondent proposes before determining what the statewide HIE

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[48] *Id.* at 42.
[49] See HB 1409, 2006, http://www.myfloridahouse.gov/Sections/Bills/billsdetail.aspx?BillId=33643&SessionId=42
[50] See HB 1121, 2007, http://www.myfloridahouse.gov/Sections/Bills/billsdetail.aspx?BillId=36128&SessionId=54
[51] Governor's Health Information Infrastructure Advisory Board, "Florida Health Information Network, Architectural Considerations for State Infrastructure," Version 6.2, April 19, 2007, 5.
[52] Telephone interview with Christopher Sullivan, Agency for Health Care Administration, December 21, 2007.
[53] Florida Center for Health Information and Policy Analysis, "Florida Health Information Network Business Plan, Version 1," March 2007.
[54] *See* s. 287.012(17), F.S., "*Invitation to negotiate* means a written solicitation for competitive sealed replies to select one or more vendors with which to commence negotiations for the procurement of commodities or contractual services. The invitation to negotiate is used when the agency determines that negotiations may be necessary for the state to receive the best value. A written solicitation includes a solicitation that is electronically posted."

infrastructure will look like. The outcome of the negotiation process may be a model that looks like the proposed FHIN, but the model may take a different shape. It is possible for new technical models to emerge as technology advances and information sharing capabilities mature.[55] Therefore, the advantage to the agency issuing an ITN is that the state could receive the most up-to-date statewide model options from vendors.

The ITN should request proposals that address both the physical infrastructure of the network and also the day-to-day operational structure of the network. The vendor may also be tasked with seeking additional funding for the project.

With this option, the state appropriates money to the agency for the contract. The funding portion of this model is similar to the FHIN model discussed above. The vendor chosen by the agency in the ITN process is paid by the agency to complete the deliverables outlined in the contract. However, the state maintains ownership of the technology and is responsible for oversight of the operation.

Funding of the FHIN Grants Program and an EMR Adoption Loan Program

A third option the state may consider to create a statewide HIE is to continue funding the development of RHIOs through the grants program administered by the agency and to create an incentive program to encourage physician adoption of EMRs. This option allows the building of a statewide HIE from a grassroots level, beginning with the most basic and essential infrastructure -- an EMR system for physicians. By providing funding to local entities, the base level of HIE is strengthened. While allowing RHIOs to become financially and socially viable and encouraging the adoption of EMRs at the physician level will not produce statewide HIE immediately, it could be considered a measured, deliberate method of achieving the same goal. Also, this option avoids an enormous up-front investment by the state and allows for technology to evolve further, as it does so rapidly in the healthcare arena, before the state chooses a statewide solution.

This option would consist of the following elements:

- FHIN Grants Program
  The language in current statute directing the agency to administer a grants program is broad and lacks specified deliverables required of the grantees.[56] To strengthen the grants program, specific criteria for grant applications should be added into statute, with an emphasis on the ability of the local exchange to demonstrate interoperability and HIE. Limiting the number of years an entity is eligible to receive a state grant will encourage the grantee to maximize grant dollars and build a sustainable business model.

- Physician EMR Adoption Loan Program

[55] National Governor's Association Center for Best Practices, "Request for Proposals, An Examination of Financing, Accountability, and Oversight Models to Sustain Electronic Health Information Exchange," Version 12.20.07, 3.
[56] See s. 408.05(4)(b), F.S.

Many single and small practice physician offices cite cost as a key barrier to adoption of an EMR system. The state should offer a no-interest loan to physicians to purchase hardware, software, subscription services and training necessary to implement an EMR system in their office. The loan program would recycle the appropriated money by funding new loans as initial loans are repaid. This program encourages HIE at the very base level- the physician who creates the EMR for his or her patient.[57]

- Statewide HIE Advisory Council
  A statewide HIE advisory council is beneficial to the advancing of a statewide HIE initiative.[58] The council serves as a body to provide leadership for the development and implementation of the future HIE infrastructure. Duties may include researching privacy and security standards for HIE, identifying barriers to participation in an HIE, recommending incentive programs to encourage participation in HIE, and creating a long-range plan that identifies options for achieving statewide HIE. Absent the physical infrastructure for HIE, an advisory council should remain in place to ensure the state remains focused on the goal of statewide HIE.

If the state of Florida is dedicated to pursuing a statewide health information exchange, whether this year or in the future, one common element across all three options that must be established is a statutorily-created advisory body. An advisory body at the state level will do what is necessary to protect the state's best interest. Currently, each RHIO in Florida is developing to best serve the population within its region. There is no statutorily created statewide advisory body to bring together these multiple interests for the benefit of the state and the state's financial investment. It is essential that a state level advisory body work to ensure the state's developing RHIOs are able to exchange data when the state is ready to participate in a statewide health information exchange.

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[57] The state of Minnesota currently operates a similar program entitled the "Minnesota Interconnected Electronic Health Record Grant Program." See s. 144.3345, Minnesota Statutes 2006, http://www.revisor.leg.state.mn.us/bin/getpub.php?pubtype=STAT_CHAP_SEC&year=2006&section=144.3345.

[58] States such as Georgia (see http://dch.georgia.gov/00/channel_title/0,2094,31446711_74254445,00.html), Kansas (see http://www.governor.ks.gov/news/NewsRelease/2007/nr-07-0207a.htm), and Michigan (see http://www.michigan.gov/mdch/0,1607,7-132-2946_44257---,00.html), have a statewide HIE Advisory Council.

Appendix A: Federal Efforts

The American Health Information Community

In order to further the President's initiative, on September 13, 2005, Secretary Michael Leavitt, United States Department of Health and Human Services, created the American Health Information Community (AHIC). The AHIC is chartered with two primary goals:

- Recommend to the Secretary specific actions to achieve a common interoperability framework for health information technology; and
- Serve as a forum for participation for a broad range of stakeholders to provide input on achieving widespread adoption of interoperable health information technology.

The AHIC has identified four initial areas with potential for early advancement:

- Consumer Empowerment - Make available a consumer-directed and secure electronic record of health care registration information and a medication history for patients.
- Chronic Care - Allow the widespread use of secure messaging, as appropriate, as a means of communication between doctors and patients about care delivery.
- Biosurveillance - Enable the transfer of standardized and anonymized health data from the point of health care delivery to authorized public health agencies within 24 hours of its collection.
- Electronic Health Records - Create an electronic health record that includes laboratory results and interpretations, that is standardized, widely available and secure.

The federal Office of the National Coordinator for Health Information Technology (ONC) awarded multiple contracts in 2005 to entities conducting work in the field of HIT. The contracts totaled $36.1 million, which accounted for the majority of the ONC's budget. [59] Each entity was required to submit a report to the AHIC detailing the findings of their work. Project goals included: identifying interoperability standards to facilitate the exchange of patient health data, through a contract with the Healthcare Information Technology Standards Panel (HITSP); defining a certification process for health IT products, through a contract with The Certification Commission for Healthcare Information Technology (CCHIT); and designing and evaluating standards-based prototype architectures for the Nationwide Health Information Network (NHIN), through contracts awarded by the ONC. Figure 4 displays the relationship between the multiple contracts awarded by the ONC and the AHIC.[60]

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[59] The National Alliance for Health Information Technology, "Revisiting the Health IT Strategic Framework," (published April 10, 2006, visited December 13, 2007) http://www.nahit.org/cms/index.php?option=com_content&task=view&id=212&Itemid=171.

[60] Healthcare Interoperability Standards Panel, "HITSP Interoperability Specifications: Electronic Health Records Laboratory Results Reporting HITSP/IS-01, Biosurveillance HITSP/IS-02, Consumer Empowerment HITSP/IS-03, Version 1.0, Executive Overview," October 20, 2006, page 5.

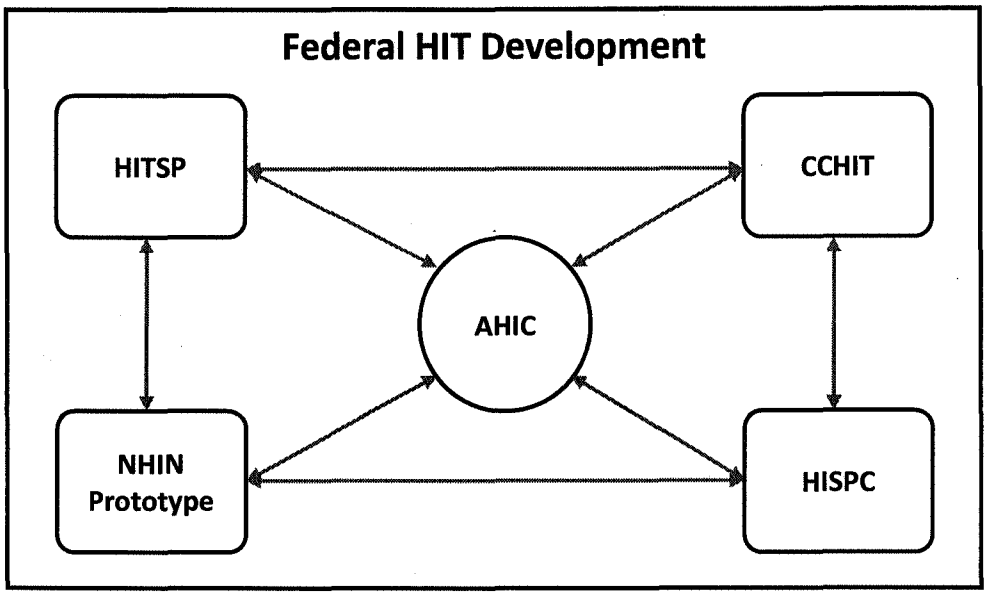

Figure 4

The AHIC charter also provides that the AHIC will develop and advance recommendations to the Secretary on a private-sector health information community initiative that will succeed the AHIC. The AHIC successor will be an independent and sustainable public-private partnership that brings together the best attributes and resources of public and private entities. This new public-private partnership will develop a unified approach to realize an effective, interoperable nationwide health information system that improves the quality, safety, and efficiency of health care in the United States. The AHIC successor will be designed, established, and ready for operation by spring 2008. The process and schedule for designing and establishing the new entity is described in the "AHIC Successor White Paper".[61]

The Healthcare Information Technology Standards Panel (HITSP)

Due to the complexity of the healthcare market and the number of stakeholders involved, many have recommended that the federal government take a leading role in harmonizing and setting standards in the field of health information technology. The ONC awarded a contract to the American National Standards Institute (ANSI) to assemble the Healthcare Information Technology Standards Panel (HITSP). The HITSP is tasked to harmonize standards across the use cases identified by the AHIC so that the vendors can build to the standards in their commercial products and so that the Certification Commission for Healthcare Information Technology (CCHIT) can certify that resulting products actually meet the standards and are interoperable.[62] HITSP's membership is comprised of health care providers, academic medical centers, medical

[61] U.S. Department of Health and Human Services, "American Health Information Community Successor, White Paper," (August 6, 2007).
[62] The MITRE Corporation, "ONC- NIH Analysis Report to the National Institutes of Health, National Center for Research Resources," March 2006, 10.

associations, vendors, and Standards Development Organizations (SDOs). As of September 26, 2007, HITSP reported 292 participants on its membership roster.[63] Under the terms of the RFP, the HITSP was required to create a minimum six year sustainable business model, which extends beyond the scope of the initial three year federal contract. The panel is more of an administrative body than a decision-making body. The consensus-driven approach is a two-edged sword--the standards may take a long time to evolve, but when they are approved, they should be acceptable to, and implementable by, major vendors in the health informatics market.[64]

The Certification Commission for Healthcare Information Technology (CCHIT)

The Certification Commission for Healthcare Information Technology (CCHIT) was formed in July 2004 by the American Health Information Management Association (AHIMA), Healthcare Information and Management Systems Society (HIMSS), and The National Alliance for Health Information Technology (Alliance). The organization is a non-profit, independent organization; the founding associations provided start-up funding and staff resources. In the field of electronic health records (EHRs)[65], there are hundreds of products on the market, but no widely accepted criteria for evaluating the product's capabilities. This is one barrier physicians often cite to EHR system adoption. CCHIT was awarded a federal contract in October 2005 to develop, create prototypes for, and evaluate the certification criteria and inspection process for EHR systems.[66] Rather than set standards, CCHIT is an independent third party that develops criteria based on commonly available standards. CCHIT relies on HITSP to harmonize those standards as part of their contract with HHS. As standards are set, CCHIT's goal is to measure and verify fulfillment of those standards by certifying the vendor's compliance. The 21 member Board of CCHIT oversees and approves the development of certification criteria as proposed by the Commission's workgroups and staff. In 2006, CCHIT released a list of EHR products certified against the 2006 Ambulatory EHR Criteria. In 2007, CCHIT updated the Ambulatory EHR Criteria and also added Inpatient EHR Criteria. The 2007 Inpatient EHR Criteria are tailored for most acute care, inpatient settings. A list of CCHIT certified EHR products can be found on CCHIT's website at www.cchit.org.

The Nationwide Health Information Network (NHIN)

A key element in the vision and plan to make health information technology interoperable is the Nationwide Health Information Network (NHIN). The ONC is advancing the NHIN as a "network of networks", built out of state and regional health

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[63] American National Standards Institute, "List of HITSP Participants," (visited December 14, 2007) http://publicaa.ansi.org/sites/apdl/Documents/Forms/AllItems.aspx (follow "Standards Activities" hyperlink; then follow "Healthcare Informatics Technology Standards Panel" hyperlink; then follow "List of HITSP orgs as of 9.26.07" hyperlink)

[64] The MITRE Corporation, "ONC- NIH Analysis Report to the National Institutes of Health, National Center for Research Resources," March 2006, 10.

[65] The Healthcare Information Management Systems Society defines *electronic health record* as, "a longitudinal electronic record of patient health information generated by one or more encounters in any care delivery setting."

[66] http://www.cchit.org/about/faq/general.asp (visited December 14, 2007).

information exchanges (HIEs)[67] and other networks so as to support the exchange of health information by connecting these networks and the systems they, in turn, connect.[68] The NHIN is not designed to be a national database filled with consumers' personal health records. Instead, the NHIN will use shared architecture (services, standards, and requirements), processes, and procedures to interconnect health information exchanges and the users they support.[69]

It is anticipated that there will be four general categories of stakeholders who will participate in the NHIN:[70]

1. Care delivery organizations that use electronic health records.
2. Consumer organizations that operate personal health records and other consumer applications.
3. Health information exchanges, which are multi-stakeholder entities that enable the movement of health-related data within state, regional, or non-jurisdictional participant groups.
4. Specialized participants, which are organizations that operate for specific purposes including, but not limited to, secondary users of data such as public health, research, and quality assessment.

There are several ways that healthcare providers and consumers will be able to access information via the NHIN. A healthcare provider may use the EHR system in their practice to access the local HIE. The local HIE will then utilize the NHIN to exchange the EHR or PHR[71] information received from the healthcare provider with specified HIEs across the nation. If the healthcare provider does not have an EHR system, the information may still be exchanged if the local HIE offers a Web portal. Similarly, a healthcare consumer may be able to access the NHIN through use of a PHR. A connection to the NHIN is made if the PHR is connected to an HIE and that HIE is connected to the NHIN.

Due to the complexity of creating the NHIN, ONC awarded four grants in November 2005 totaling $18.6 million to consortia led by Accenture, Computer Science Corporation (CSC), Northrop Grumman, and International Business Machines (IBM). The contract directed each grantee to develop a prototype architecture for the NHIN and demonstrate that architecture by interconnecting three communities that consisted of real health care organizations.

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[67] The eHealth Initiative defines *health information exchange* as, "the mobilization of healthcare information electronically across organizations within a region or community."
[68] U.S. Department of Health and Human Services, "Nationwide Health Information Network (NHIN): Background," www.hhs.gov/healthit/healthnetwork/background/ (visited December 14, 2007).
[69] "Summary of the NHIN Prototype Architecture Contracts", Engagement: 221630040 (U.S. Department of Health and Human Services, Office of the National Coordinator), May 31, 2007, 2.
[70] *Id.* at 3.
[71] The Markle Foundation defines *personal health record* as, "an Internet-based set of tools that allows people to access and coordinate their lifelong health information and make appropriate parts of it available to those who need it."

The contractors all envisioned the NHIN as compilation of multiple HIEs working in concert to create the NHIN. Each contractor identified specific functions that must be provided by the HIEs participating in the NHIN, including:[72]

- Supporting secure operation in all activities related to the NHIN.
- Protecting the confidentiality of personally identifiable health information as it is used by those who participate in the NHIN.
- Reconciling patient and provider identities without creating national indices of patients.
- Providing a local registry which may be used, when authorizations permit, to find health information about patients.
- Supporting the transfer of information from one provider or care delivery organization to another in support of collaborative care.
- Supporting secondary uses of data while protecting the identity of patients to the degree required by law and public policy.

On October 5, 2007, HHS announced the award of contracts to nine HIEs totaling $22.5 million. The purpose of the contracts is to begin trial implementations of the NHIN which will lay the groundwork for future functions and participants. The project is called the "NHIN Cooperative" and will include tests to demonstrate the exchange of private and secure health information. The contracts end in September 2008 and results will be shared through public forums and other public events. Awardees include the following organizations, representing broad-based state and regional health information exchanges:[73]

- CareSpark - Tricities region of Eastern Tennessee and Southwestern Virginia
- Delaware Health Information Network - Delaware
- Indiana University - Indianapolis metroplex
- Long Beach Network for Health - Long Beach and Los Angeles, California
- Lovelace Clinic Foundation - New Mexico
- MedVirginia - Central Virginia
- New York eHealth Collaborative - New York
- North Carolina Healthcare Information and Communications Alliance, Inc - NC
- West Virginia Health Information Network - West Virginia

<u>The Health Information Security Privacy Collaboration (HISPC)</u>

The Health Insurance Portability and Accountability Act (HIPAA) established baseline health care privacy requirements for protected health information and established security requirements for electronic protected health information.[74] However, many

[72] "Summary of the NHIN Prototype Architecture Contracts", Engagement: 221630040 (U.S. Department of Health and Human Services, Office of the National Coordinator), May 31, 2007, 5.
[73] U.S. Department of Health and Human Services, "HHS Awards Contracts for Trial Implementations of the Nationwide Health Information Network," October 5, 2007.
[74] The MITRE Corporation, "ONC- NIH Analysis Report to the National Institutes of Health, National Center for Research Resources," March 2006, 11.

states vary on their application of HIPAA -- some have not adopted policies stronger than HIPAA, while some have adopted policies that are stronger than HIPAA. The inconsistency in the way in which HIPAA is interpreted and applied and the differences between state privacy laws and HIPAA have caused great concern amongst those interested in a nationwide HIE.

RTI, Inc. (RTI), a private, nonprofit corporation, was awarded a contract from HHS in 2005 totaling $11.5 million. The purpose of the project was to asses variations in organization-level business practices, policies, and state laws that affect HIE and to identify and propose practical ways to reduce the variation to those "good" practices that will permit interoperability while preserving the necessary privacy and security requirements set by the local community.[75] RTI sub-contracted with 34 states and territories to complete the project. The state of Florida was among the sub-contract recipients.

The state teams were required to convene steering committees comprised of both public and private leaders and work groups with specific charges through which all research and recommendations would be made.

The project enabled states to engage stakeholders on a local level to identify the barriers to electronic health information exchange specific to their location. The final report issued by RTI in June of 2007, "Assessment of Variation and Analysis of Solutions", outlines issues that state project teams all identified as possibly affecting a private and secure nationwide HIE along with possible solutions to the identified challenges, both at the state and national levels.

Among the challenges identified were: differing interpretations and applications of HIPAA privacy rule requirements, misunderstandings and differing applications of the HIPAA security rule, trust in the security of health information exchange, fragmented and conflicting state laws relating to privacy and security of health information exchange, and disclosure of personal health information. Among the solutions to the challenges identified by the participating states were: creation of uniform state policy as it relates to the interpretation and application of the HIPAA rules, consolidation of state statutes related to health information exchange, creation of national standards for a master patient index or record locater to accurately match records to the appropriate patient, and education of consumers and healthcare professionals about federal and state privacy law.[76]

The Department of Veterans Affairs and the Department of Defense

The United States Department of Veterans Affairs (VA) and the United States Department of Defense (DOD) collectively reach millions of active armed forces personnel, veterans, and their families. The goal of the partnership they have formed is

[75] Dimitropoulos, Linda L., "Privacy and Security Solutions for Interoperable Health Information Exchange, Assessment of Variation and Analysis of Solutions," June 30, 2007, 2-1.
[76] *Id.* at ES-5 through ES-8.

to share electronic health data to ensure health care providers have the information they need to provide quality care to DOD/VA beneficiaries across their continuum of care.

The Veterans Health Administration's (VHA) electronic health record system, My HealtheVet (MHV), allows patients to refill prescriptions online, and provides access to health information, links to Federal and VA benefits and resources, and the patient's Personal Health Journal. The VHA continues to add capabilities to MHV to empower consumers to take a more active role in managing their health and health care.[77] In 1996, the Chief Information Office introduced the Veterans Health Information Systems and Technology Architecture (VISTA) which supports the day-to-day operations at local VA healthcare facilities.[78] VISTA incorporates all of the benefits of the Decentralized Hospital Computer Program, which was developed in the early 1980s, and serves as a new, open system, client-server based environment that takes full advantage of commercial solutions, including those provided by Internet technologies.[79]

The DOD's electronic health record system, AHLTA, is used by thousands of military medical providers and digitally captures nearly 300,000 outpatient visits every week. DoD's goal is to provide each patient with an electronic medical record that is constantly updated from the point of injury or care on the battlefield to discharge from military clinics and hospitals in the United States. These records would be completely transferable electronically to the Veterans Health Administration as part of the Joint Patient Electronic Health Record.[80]

President Bush signed the fiscal 2008 Defense Appropriations Bill in November 2007, which includes a provision requiring the VA and DOD to develop and implement a fully interoperable EHR system by September 30, 2009.[81]

In his October 24, 2007 appearance before the United States House Committee on Veterans' Affairs, Dr. Gerald M. Cross, the Principal Deputy Under Secretary of Health at the Department of Veterans Affairs, described the current data sharing relationship between the VA and the DOD:

> Today, the VA and the DOD are sharing electronic health data bidirectionally to support the care of shared patients. . . For the first time, DOD medical data captured electronically in the theater of operations are now viewable in text format to any VA provider treating these wounded warriors. We accomplished this in September of 2007 by leveraging an existing bidirectional data exchange. Subsequently, we are implementing a plan that will permit us to share unprecedented amounts of the

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[77] U.S. Department of Health and Human Services, "Health Information Technology Initiatives," http://www.hhs.gov/healthit/initiatives/ (visited December 17, 2007).
[78] U.S. Department of Veterans Affairs, "Vista Monograph Home," http://www.va.gov/vista_monograph/ (visited December 17, 2007).
[79] *Id.*
[80] U.S. Department of Health and Human Services, "Health Information Technology Initiatives", http://www.hhs.gov/healthit/initiatives/ (visited December 17, 2007).
[81] Monegain, Bernie, DoD Touts Progress on Interoperability with Veterans Affairs, Healthcare IT News, December 28, 2007, http://www.healthcareitnews.com/story.cms?id=8337 (visited January 2, 2008).

available inpatient electronic data from DOD. Currently, VA providers are able to view electronic discharge summaries, emergency department notes, and other narrative documents captured during inpatient encounters at 13 major DOD facilities that use the Essentris Clinical Information System. . . In addition to sharing available electronic documentation, DOD is sending digital radiology images and scanned inpatient paper records that do not originate in electronic format. These capabilities are in place between the key military treatment facilities that receive these patients in the continental United States, (Walter Reed, Bethesda, and Brooke Army Medical Center), and VA polytrauma centers located in Tampa, Richmond, Minneapolis, and Palo Alto. . . Today, VA continues to receive all clinically relevant data that are available in DOD's legacy system, the Composite Health Information System (CHCS), on service members separated from active military service. These data are viewable through our shared Federal Health Information Exchange repository by VA clinicians and disability claims staff using VA health and administrative information systems. To date, DOD has transferred electronic health data on over 4 million unique separated service members to VA. Of these individuals, VA has provided care or benefits to the more than 2 million veterans who have sought care or benefits from VA. The data transferred for viewing includes outpatient pharmacy data, allergy information, laboratory results, consults, admission, disposition and transfer information, medical diagnostic coding data, and military pre- and post-deployment health assessment and reassessment data on separated and demobilized National Guard and Reserve members. . . VA and DOD are leveraging our bidirectional exchanges to expand the types of data shared and to share all essential information by October 2008. By December of this year, our providers will have access to viewable encounter notes, problem lists, and procedures from DOD's modern system, AHLTA. By June 2008, we will add vital signs and by October 2008 enterprise wide capability to view scanned documents, such as paper inpatient records. . . By the fourth quarter of 2008, VA and DOD will deploy our computable laboratory capability to support automatic decision support using electronic laboratory result data transferred bidirectionally.

Medicare Electronic Health Records Demonstration Project

The federal government has created a program aimed at increasing the adoption of EHRs among physician practices. The goal of the project is to broaden the adoption and implementation of EHRs and to transform the way medicine is practiced and delivered. The program also has the potential to produce savings for the Medicare program over time due to reduced medical errors and improvement in the quality of care for consumers.

On October 30, 2007, the United States Department of Health and Human Services (HHS) directed the Centers for Medicare and Medicaid Services (CMS) to conduct a five year demonstration project that will encourage small-to-medium sized physician practices to adopt EHR. Financial incentives, in the form of bonuses, will be provided to physician groups using certified EHR systems to meet clinical quality measures. The

project is scheduled to begin in the spring of 2008 and up to 1,200 physician practices may participate.

Participating physician practices are required to put in place a Certification Commission for Healthcare Information Technology (CCHIT) certified EHR by the end of the second year. As noted previously, CCHIT is the HHS recognized certification body for EHRs and their networks.[82] As part of the demonstration, the physician practices must utilize the EHR to perform certain minimum core functions, such as clinical documentation, ordering prescriptions, ordering lab tests, and recording lab tests. These core functions have the potential to positively impact the process by which a patient is treated.

Payments made to participating practices during the first year will be based on the functions of the EHR systems that are used to manage the care of patients. Higher payments will be made to practices utilizing more sophisticated EHR functionalities. This information will be determined by a practice's score on the Office Systems Survey (OSS), which CMS will administer each year to determine the level of EHR implementation at the practice level, as well as the specific EHR functions utilized to support the delivery of care. Increased incentive payments will be made to participating practices that receive higher scores on the OSS.

The demonstration project's second year of payments will be made to physician practices using EHR systems and reporting clinical quality measures. Increased payments will be based on EHR functionalities utilized by the practice. Payments made during years three through five of the demonstration project's operation will be based on performance on the designated clinical quality measures, with an added bonus each year based on the degree to which the practice has used the EHR to change and improve the way it operates.[83]

During the five year project, it is estimated that 3.6 million consumers will be directly affected as their primary care physician adopts certified EHRs in their practices.[84] In order to increase the effectiveness of the project, CMS is encouraging private insurers to offer similar incentives to those in the current demonstration project for EHR adoption.

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[82] http://www.cchit.org/about/index.asp (visited December 31, 2007)

[83] U.S. Department of Health and Human Services, "Electronic Health Records Demonstration- Summary," www.cms.hhs.gov/DemoProjectEvalRpts/downloads/EHR_Summary.pdf.

[84] U.S. Department of Health and Human Services, "HHS Announces Project to Help 3.6 Million Consumers Reap Benefits of Electronic Health Records," October 30, 2007.

Appendix B: Efforts in Other States

An overview of HIT activity at the state level is provided below, detailing the source of authority for the activity; funding sources; and specifications of the project.[85]

Georgia Health Information Technology and Transparency (HITT) Advisory Board

Governor Sonny Perdue created the Georgia HITT Advisory Board via an Executive Order[86] on October 17, 2006 to advise the Georgia Department of Community Health (DCH) in establishing a statewide strategy for health information exchange. The Board is comprised of 12 members and 16 ad hoc experts appointed by the Commissioner of DCH. The Commissioner of the DCH awarded $853,088 in health information exchange grants to four entities in November 2007. Grants are awarded based on recommendations from the HITT Advisory Board. The awardees will match the grant funds provided. The focus of the grant awards is development of health information exchange, electronic prescribing, and/or adoption of electronic medical records across Georgia.[87] The 2006 Executive Order outlines tasks for the Board, which include:

- Provide leadership for a coordinated effort across the state to achieve health information exchange.
- Encourage the use of electronic health records that recognize interoperability standards as identified by the U.S. Department of Health and Human Services.
- Promote the security and privacy of health information.
- Conform with nationally recognized interoperability standards for exchanging health information.
- Promote marketplace transparency within the healthcare industry through the development of information to the consumer of healthcare regarding the cost and quality of healthcare.

Indiana Health Informatics Corporation (IHIC)

Authorized in 2007 by SB 551,[88] the IHIC is comprised of a seven member board and is organized as a body politic and corporate and tasked with specific activities, which include:

- Define the vision for a statewide health information exchange system.
- Prepare a plan to create a statewide health information system.
- Encourage, facilitate, and assist in the development of the statewide health information exchange system.
- Evaluate, analyze, and report on Indiana's progress toward implementing the system.

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[85] National Association of State Chief Information Officers, "Profiles of Progress II, State Health IT Initiatives," September 2007.
[86] Executive Order of Georgia Governor Sonny Perdue, October 17, 2006.
[87] Press release, Georgia Department of Community Health, "Four Georgia Health Partnerships Receive $853,088 in Grants," November 5, 2007.
[88] http://www.in.gov/apps/lsa/session/billwatch/billinfo?year=2007&session=1&request=getBill&docno=551 (visited December 31, 2007).

- Develop programs and initiatives to promote and advance the exchange of health information.

The Indiana Health Informatics Fund was created in 2007 and will contain all appropriations made by the General Assembly to the corporation and all funding received from the private sector. No appropriation has been made by the General Assembly to date.

Also in Indiana, the Indiana Health Information Exchange (IHIE) is one of the state's more successful regional health information organizations (RHIO). Created by the Regenstrief Institute and developed over the past 30 years, the IHIE utilizes a centrally managed model where patient data is replicated to a centralized database and access rights are managed by custom-developed software. IHIE offers a clinical messaging service, DOCS4DOCS®, which is a web-based service that electronically delivers test results and other clinical information. This program replaces traditional delivery methods such as courier, postal and fax. In July 2007, IHIE announced that the DOCS4DOCS® service is able to deliver clinical results directly into the EHR system of community physicians, in addition to the web-based service.

Kentucky e-Health Network (KeHN) Board and Corporation

The KeHN Board was authorized in 2005 by SB 2[89] and operates a 23 member board, including 7 core members, 8 at-large members, and 8 ex-officio members. The KeHN Board is tasked specific activities, which include:

- Review models for an electronic health network.
- Choose an electronic health network model to be implemented in Kentucky.
- Submit a description of the model chosen to the Legislative Research Commission.
- Oversee the operations and development of the KeHN.

The e-Prescribing Partnerships in Kentucky (ePPIK) Grant Program seeks to offset the costs that healthcare providers incur when purchasing health information technology necessary to implement e-prescribing. The program also encourages the formation of community partnerships amongst health care entities. In 2008, the state will provide up to $90,000 in grant funding to each entity. A total of $300,000 of the available funding comes from the Foundation for a Healthy Kentucky and the Hal Roger's Grant Program.[90]

In September 2007, the KeHN Board approved the creation of the Kentucky e-Health Corporation which operates as a non-profit corporation to implement, develop and operate a Kentucky health information network. Board members are appointed by the KeHN Board. The corporation is responsible for the implementation of the Kentucky Health Information Partnership (KHIP). KHIP is the first phase of the vision to develop a statewide e-Health Network. The project's goal is to develop a common web portal for

[89] http://www.lrc.ky.gov/record/05rs/SB2.htm (visited December 31, 2007).
[90] Kentucky e-Health Network, http://ehealth.ky.gov/initiatives/, (visited December 17, 2007).

provider-payor communications that will contain both a clinical site based on claims data and an administrative site for handling common administrative tasks electronically.[91]

Governor Fletcher has requested $5,575,000 for e-Health in FY 2009 and $11,725,000 in FY 2010. The funds will be used for operations and programs of the KeHN Board, the creation and operation of the e-health infrastructure, and e-health grant funding.

The state of Kentucky's roadmap to statewide HIE is very similar to the previously proposed Florida Health Information Network. The state approved the creation of the Kentucky e-Health Corporation which is responsible for managing the development and operations of the statewide Kentucky e-Health Network currently under development. The Kentucky state agency request to their Legislature to support HIE activities is $5.5 million in Fiscal Year 2009-2010 and $11.7 million in Fiscal Year 2010-2011.[92]

Minnesota Health Information Exchange (MHIE)

The legislature of the state of Minnesota has required all hospitals and health care providers to have an interoperable electronic health records system in place by January 1, 2015.[93] The Commissioner of Health and the e-Health Initiative Advisory Committee are tasked with creating a statewide plan to reach this goal. The Advisory Committee is comprised of 26 members who represent various public and private stakeholders.

As a result of the e-Health Initiative Advisory Committee's plan, MHIE was formed in September 2007 as a nonprofit corporation by founding partners: Allina Hospitals & Clinics, Blue Cross and Blue Shield of Minnesota, HealthPartners, Medica, and the state of Minnesota. The exchange is funded by start-up money from its founding organizations and by subscriber fees.[94] Scheduled to go live in early 2008, the MHIE will allow for a secure interchange of clinical information among provider and payor. Initial services will include: medication history, lab orders, and test results. Future services may include: radiology reports, Minnesota Department of Health disease surveillance reporting, and electronic prescriptions. Patient consent is required before access is granted to clinical information.

The Interconnected Electronic Health Record Grant Program is administered by the Minnesota Department of Health Office of Rural Health & Primary Care to support the adoption and use of electronic health records by healthcare providers in rural and medically underserved areas. Funding available for the program in 2007 was $3.5 million and $1.3 million was available in 2006.[95] Recipients are required to provide a one-to-three match of their awarded grant dollars.

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[91] Kentucky e-Health Network, http://ehealth.ky.gov/initiatives.

[92] Kentucky e-Health Network, http://ehealth.ky.gov/NR/rdonlyres/FCC7B7BF-FF78-445D-BCA6-44ED252E2985/0/BudgetRequestTalkingPointsrev1.doc (visited January 7, 2008).

[93] 62J.495, Minnesota Statutes, 2007

[94] Press release, Minnesota Office of the Governor, "Minnesota Health Information Exchange to be among largest 'e-initiatives' in the nation," September 10, 2007.

[95] Minnesota Department of Health, "Minnesota e-Health Initiative Funding Opportunities," http://www.health.state.mn.us/e-health/funding.html (visited January 5, 2008).

The Electronic Health Record System Revolving Loan Program is administered by the Minnesota Department of Health Office of Rural Health & Primary Care to assist in financing the installation or support of interoperable health record systems. The program makes six-year, no interest loans available on a first-come, first-served basis to eligible applicants, which may include community clinics, rural hospitals, physician clinics in towns with populations under 50,000, and nursing facilities. Funding available for the program in 2007 was $3.15 million.

Utah Health Information Network (UHIN)

The UHIN has been in operation since 1993 as a not-for-profit corporation and currently serves all the hospitals, ambulatory surgery centers, national laboratories, and approximately 90% of the medical providers in Utah.[96] Membership in the UHIN is comprised of approximately 17 Utah healthcare providers, insurers, and other interested parties, including state government. The UHIN operates as a consensus-based coalition. Participating healthcare providers pay an annual membership fee and payors pay a per transaction fee.[97]

The common goal of the UHIN membership is to reduce healthcare administrative costs through the use of electronic data interchange (EDI). EDI means that all the parties exchange data in a standard format using standard codes, which are adopted by the UHIN Standards Committee.[98] UHIN operates as a centralized network that does not store files. The network allows a secure delivery of healthcare data in a consistent format amongst authorized providers.

UHINet is the Internet portal used by UHIN members to send and receive HIPAA-compliant transactions. Subscribers are connected with all Utah domiciled payers as well as an additional 450 national payers through UHINet.[99] All data sent or received is encrypted.

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[96] Utah Health Information Network, "About UHIN", www.uhin.com/about/index.htm (visited December 17, 2007).
[97] Governor's Health Information Infrastructure Advisory Board, "Florida Health Information Network, Architectural Considerations for State Infrastructure," Version 6.2, April 19, 2007, 18.
[98] *Id.*
[99] National Association of State Chief Information Officers, "Profiles of Progress II, State Health IT Initiatives," September 2007, 49.

Appendix C: Florida Efforts

Florida Health Information Network (FHIN)

Specific technical functions of the proposed FHIN are described in the board's white paper and are diagramed in Figure 5.[100] In summary, the FHIN's functions include:

- Facilitate communications and data queries among RHIOs.
  - Serve as the central communication link in the state for HIE and be responsible for providing access for authorized users to clinical data stored in databases across the state.
  - Maintain an Enterprise Master Patient Index (EMPI).
  - Operate a record locator service that will use the listing of patient identifiers contained in the EMPI to query healthcare providers in each RHIO or HIN in order to collect the appropriate patient records.
- Take the lead in specifying technical standards.
  - Act as the state's lead authority in establishing and maintaining technical standards among the RHIOs and health information networks.
  - Specify standards for authenticating users to determine if they are authorized to access patient records, and to authorize RHIOs that wish to connect to the FHIN.
- Provide a portal for other databases.
  - Function as the major portal for integrating state agency healthcare datasets and make them available to authorized users.
  - Provide access to state agency datasets that are already available electronically (i.e.: The State Health Online Tracking System, SHOTS, immunization data from the Department of Health; Medicaid data from the agency; data from the federal DOD and VA).

[100] Florida Health Policy Center, "Florida's Health Information Network: What will it cost to develop?," February 2007, http://www.floridahealthpolicycenter.org/research/pdfs/FHIN%20brief.pdf (visited December 19, 2007).

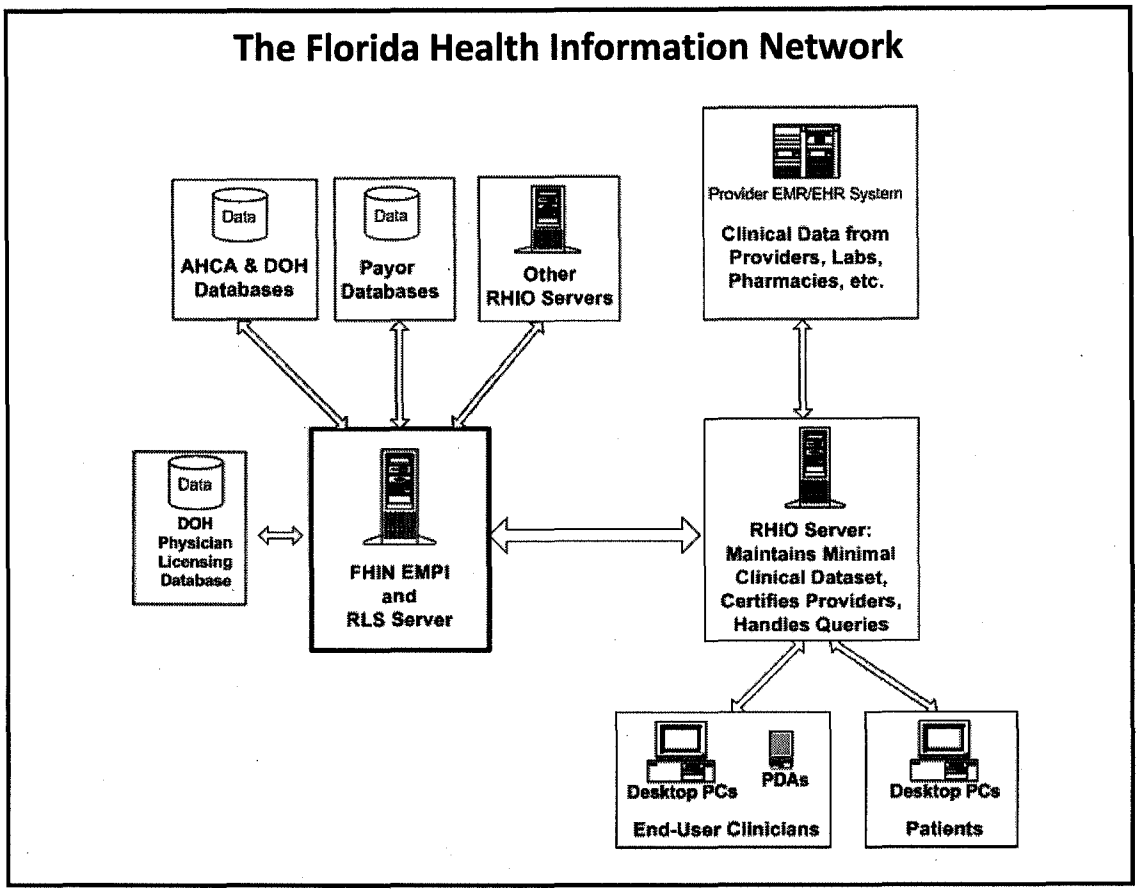

Figure 5

Legislation was filed in 2006[101] by Rep. Holly Benson and Sen. Mike Haridopolos to create the "Florida Health Information Network, Inc." as a not-for-profit corporation to develop the statewide health information network. The proposed corporation would be managed by an uncompensated board of directors. The 2006 legislation passed unanimously by the House, but died in a Senate committee. In 2007, similar legislation[102] was filed by Rep. Denise Grimsley and Sen. Jeff Atwater. Again, the legislation passed unanimously in the House, but died in a Senate committee.

FHIN Grants Program

The grants program provides support to health-related institutions and organizations that seek assistance to plan, deploy, and evaluate interoperable health information exchange projects in clinical settings.[103] Organizations eligible for funding include:

[101] CS/HB 1409, 2006, http://www.myfloridahouse.gov/Sections/Bills/billsdetail.aspx?BillId=33643&SessionId=42 (visited December 19, 2007).
[102] CS/HB 1121, 2007, http://www.myfloridahouse.gov/Sections/Bills/billsdetail.aspx?BillId=36128&SessionId=54 (visited December 19, 2007).
[103] Florida Agency for Health Care Administration, "FHIN Grants Program Requirements 2007-2008," http://ahca.myflorida.com/dhit/FHINgrantsProgram/FGPSched0708.pdf (visited December 17, 2007).

- Florida-based non-profit organizations and institutions.
- Public and private institutions such as universities, colleges, hospitals, community health centers, and laboratories.
- Units of state and local governments.
- Public health departments.
- Professional medical associations.
- Faith-based or community-based organizations.

All funding is awarded in the form of a 50/50 matching grant, which means 50% of the project must be funded by the grant recipient in the form of cash or donated materials and services with a specific cash value. From Fiscal Year 2005-2006 through Fiscal Year 2006-2007, the state's investment of $3.5 million in grant contracts was matched by $6.7 million from local investors, which is more than the required 50% match.[104] All grant applications were evaluated by the board and the board forwarded its recommendations to the Secretary of the agency. However, the board expired in July of 2007 and will no longer review FHIN grant applications. The Secretary makes the final decision regarding ranking and levels of funding for projects.

The agency received a non-recurring appropriation of $1.5 million in Fiscal Year 2005-06 to fund the program and awarded nine grants. These included five assessment and planning grants, three operations and evaluation grants and one training and technical assistance grant.[105] In Fiscal Year 2006-07, the Legislature appropriated $2 million to the agency to fund the FHIN grants program and the agency awarded six grants, all of which were operations and evaluation grants.[106] In Fiscal Year 2007-08, the Legislature appropriated $2 million to the agency to fund the FHIN grants program and the agency awarded nine grants. These included one assessment and planning grant, seven operations and evaluation grants, and one training and technical assistance grant.[107]

Florida's Regional Health Information Organizations

The agency funded nine RHIOs in Fiscal Year 2007-2008. Figure 4 depicts the location of the RHIOs that received a FHIN grant in Fiscal Year 2005-2006 through Fiscal Year 2007-2008, in addition to one independent RHIO which has not received funding. An outline of Fiscal Year 2007-2008 funded project's specifications and current activities follows.

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[104] Governor's Health Information Infrastructure Advisory Board, "Final Report of the Governor's Health Information Infrastructure Advisory Board," July 6, 2007, http://ahca.myflorida.com/dhit/Board/Brdmtg63007.pdf (visited December 19, 2007).
[105] Florida Agency for Health Care Administration, http://ahca.myflorida.com/dhit/FHINgrantsProgram/0506FHINgrantsProposals.shtml (visited December 17, 2007).
[106] Florida Agency for Health Care Administration, http://ahca.myflorida.com/dhit/FHINgrantsProgram/0607FHINgrantProposals.shtml (visited December 17, 2007).
[107] Florida Agency for Health Care Administration, http://ahca.myflorida.com/dhit/FHINgrantsProgram/0708FHINgrantProposals.shtml (visited December 17, 2007).

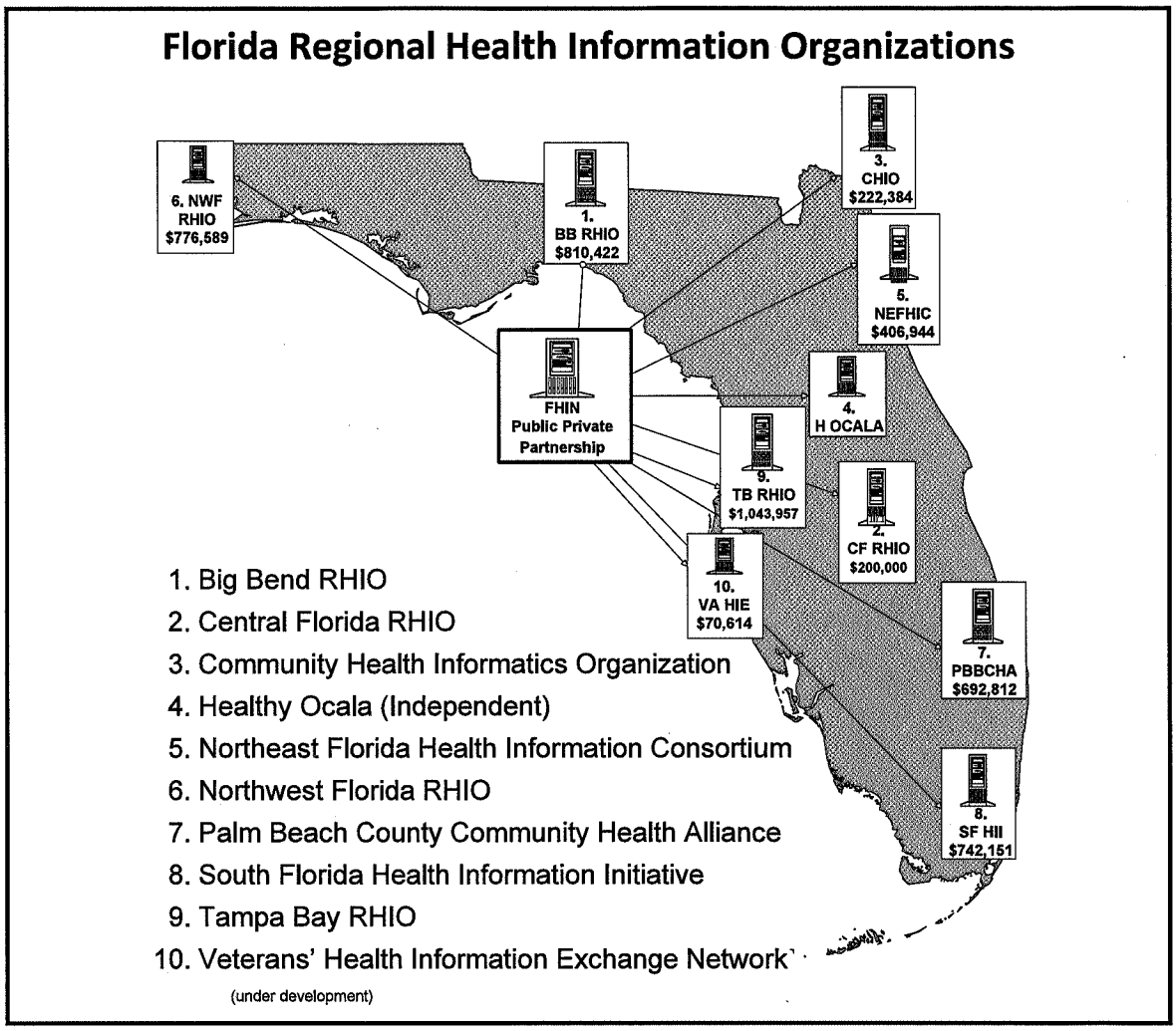

Figure 6

The Big Bend Regional Healthcare Information Organization (BBRHIO)

BBRHIO received operations grants in Fiscal Year 2005-2006 for $246,850, Fiscal Year 2006-2007 for $313,822, and Fiscal Year 2007-2008 for $249,750. Grant funding for Fiscal Year 2005-2006 through Fiscal Year 2007-2008 totals $810,422.[108]

BBRHIO utilizes a hybrid architecture[109] that supports both centralized and federated data sharing.[110] The organization developed a pilot regional health information network (RHIN) that connects test data sources from two competing healthcare providers

[108] Agency for Health Care Administration, "FHIN Grants Program Funding- FY 2005-2008".
[109] Hybrid- A hybrid model combines both federated and central repositories. Typically large hospitals would use a federated HIE model while small health care providers would tie into a central repository.
[110] Agency for Health Care Administration, "Florida Health Information Network Grants Program, Grantee Background Information," April 2007, 1.

(Tallahassee Memorial Healthcare and Capital Regional Medical Center) making the data accessible via a secure RHIN web portal.[111] BBRHIO is working to establish standardized patient intake forms that will be available via a secure browser interface for patients to pre-populate and maintain their personal information resulting in a PHR.

BBRHIO received a Rural Health Care Pilot Program grant from the Federal Communications Commission in November 2007 for a three-year $9.6 million project to construct a one gigabits per second fiber optic network that will link approximately nine rural hospitals in eight counties to the existing Florida LambdaRail backbone, and extending to community health centers and clinics through broadband wireless.[112]

Central Florida Regional Health Information Organization (CFRHIO)

CFRHIO received a planning grant in Fiscal Year 2005-2006 for $108,864 and an operations grant in Fiscal Year 2007-2008 for $200,000. Grant funding for Fiscal Year 2005-2006 through Fiscal Year 2007-2008 totals $308,864.[113]

CFRHIO plans to implement an operational health information network throughout Orange, Seminole, Osceola, Polk, Brevard, Lake and Volusia counties which will utilize a federated model for sharing of clinical information. Those accessing patient data will make use of a web browser-based software application.[114]

Phase I of the project aims to connect Orlando Regional Healthcare (7 hospitals), Florida Hospital (7 hospitals), Cognoscenti Health Institute (8 centers), Physician Associates of Florida (70 physicians/12 clinics), Orange Blossom Family Health Center, Primary Care Access Network (9 safety net clinics for the uninsured), and the University of Florida Informatics Research Laboratory.

Northeast Florida Health Information Consortium (NEFHIC)

NEFHIC received an operations grant in Fiscal Year 2007-2008 for $406,944.[115]

The NEFHIC is comprised of the Duval County Health Department (DCHD), JaxCare Inc., the Northeast Florida Regional Health Organization (NEFRHO), and the Duval County Medical Society. The DCHD will support JaxCare efforts to expand a central repository for hospital and safety net electronic health information, and NEFRO efforts

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[111] *Id.*

[112] Press release from the Federal Communications Commission, "Rural Health Care Pilot Program Applicants," November 19, 2007, http://hraunfoss.fcc.gov/edocs_public/attachmatch/DOC-278260A2.pdf (visited December 20, 2007).

[113] Agency for Health Care Administration, "FHIN Grants Program Funding- FY 2005-2008".

[114] Agency for Health Care Administration, "Florida Health Information Network Grants Program, Grantee Background Information," April 2007, 19.

[115] Agency for Health Care Administration, "FHIN Grants Program Funding- FY 2005-2008".

to provide health professionals with access to hospital and ambulatory electronic health information for the clients they serve.[116]

Jacksonville Health Information Network (JHIN), a program of JaxCare, is an existing HIE that provides authorized users with web access to health information on 98,386 patients from data provided by six competing hospitals, the University of Florida Jacksonville physicians' network, Duval County Health Department, both Federally Qualified Health Centers, and the JaxCare Health Flex plan. In Fiscal Year 2007-2008, the JHIN will add Medicaid patient records to its data repository.[117] NEFRHO plans to pilot a federated data sharing system within the community by working with JaxCare in the single sign-on opportunity for access to the JHIN Continuity of Care Records.[118]

The NEFHIC technical model integrates technologies that support two distinct groups of health care providers and their patients: (1) those who care for the Medicaid and uninsured populations; and (2) those who care for patients with commercial insurance and Medicare. JaxCare operates the JHIN for the first group through a data repository system that collects patient data from various healthcare providers, and for the latter group NEFRHO will provide authorized hospital health care practitioners with single sign-on access to EMRs maintained, in a view-only format, by hospital facilities.[119] The NEFRHO model will include accessing data from payors through a contract with Availity, a joint venture between Blue Cross Blue Shield of Florida and Humana.[120]

The Northwest Florida Regional Health Information Organization (NWFL-RHIO)

NWFL-RHIO received a planning grant in Fiscal Year 2005-2006 for $150,000 and operations grants in Fiscal Year 2006-2007 for $330,339 and Fiscal Year 2007-2008 for $296,250. Grant funding for Fiscal Year 2005-2006 through Fiscal Year 2007-2008 totals $776,589.[121]

The organization focuses on the adults who are uninsured, indigent, and not eligible for public assistance whose healthcare needs are normally met by accessing the charity care (safety net) system in Escambia County, with plans to spread into Santa Rosa County. Escambia County healthcare providers who participate in the NWFL-RHIO include: West Florida Hospital (HCA), Sacred Heart Hospital (Ascension), Baptist Hospital (Baptist Health Care), Lakeview Center (mental health), Escambia Community Clinic, Escambia Dental Cooperative, Health and Hope Clinic, St. Joseph Medical Clinic, Circle Community Clinic, and Escambia County Health Department. [122] As of

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[116] Agency for Health Care Administration, "Florida Health Information Network Grants Program, Grantee Background Information," April 2007, 22.
[117] *Id. 23.*
[118] *Id.*
[119] *Id. 24.*
[120] *Id.*
[121] Agency for Health Care Administration, "FHIN Grants Program Funding- FY 2005-2008".
[122] Northwest Florida RHIO FHIN Grant Project Presentation to AHCA and GHIIAB, "Building the EscaRosa Health Information Network," June 11, 2007, ahca.myflorida.com/dhit/FHINgrantsProgram/Presentations/NWFRHIO06112007.pdf (visited December 20, 2007).

January 2008, the following providers in Santa Rosa County are scheduled to participate in the NWFL-RHIO: Escambia Community Clinic- Santa Rosa, Santa Rosa County Health Department, Lakeview Center- Avalon, Jay Hospital, Good Samaritan Clinic, Santa Rosa Medical Center, and Gulf Breeze Hospital.[123]

Escambia County providers exchange data daily through a centralized model of HIE. Data is centralized in a repository maintained by Data Futures.[124] Integration of two ASP systems with the community messaging system enable authorized participants to view and exchange patient data.[125] NWFL-RHIO back-loads data from EHR data of participating hospital and federally qualified health centers into the current system. This process allows patient information documented before the RHIO became active to be added to the patient's EMR.[126]

NWFL-RHIO adopted an "opt-in" policy, requiring patients to sign a consent form before their data is exchanged. Without a consent form, only the physician who entered the data may view it.[127]

Palm Beach County Community Health Alliance (Alliance)

The Alliance received a planning grant in Fiscal Year 2005-2006 for $250,000 and operations grants in Fiscal Year 2006-2007 for $242,812 and Fiscal Year 2007-2008 for $200,000. Grant funding for Fiscal Year 2005-2006 through Fiscal Year 2007-2008 totals $692,812. The Alliance also received a training grant in conjunction with the Florida Association of RHIOs in Fiscal Year 2007-2008 for $44,900 to educate consumers and physicians of the potential benefits of HIE.[128]

The Alliance is a collaboration of thirty-three public and private entities working to create a more seamless system of health and mental health care for uninsured, Medicaid, and other patients among all safety net health and mental health providers in Palm Beach County.[129] The Alliance is developing a shared EHR system, called All-Care, built through electronic interfaces to existing clinical and administrative data systems. The system is scheduled to be fully operational in 2009 and will house health care data in a repository for residents of the county from all county hospitals, free clinics, health department programs, mental health centers, and other partners.[130]

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[123] *Id.*
[124] Telephone interview with Christine Isham, Project Director for NWFL-RHIO (December 20, 2007).
[125] Escambia Health Information Network, "FHIN Grantee Quarterly Progress Report, submitted to AHCA," April 10, 2007, 2.
[126] Telephone interview with Christine Isham, Project Director for NWFL-RHIO (December 20, 2007).
[127] *Id.*
[128] Agency for Health Care Administration, "FHIN Grants Program Funding- FY 2005-2008".
[129] Palm Beach County Community Health Alliance, "2007-2008 Training and Technical Assistance Project Proposal", http://ahca.myflorida.com/dhit/FHINgrantsProgram/ProposalCat3PBCCHA0708.pdf (visited December 20, 2007).
[130] Palm Beach County Community Health Alliance presentation to the Florida House of Representatives Health Quality Committee, December 11, 2007, 3.

The Alliance selected the Veterans Health Information Systems and Technology Architecture (VistA) program, a nationally implemented EMR software program developed by the federal Veteran's Administration, to provide free clinics in Palm Beach County with the ability to enter patient data into an EMR that will connect to the All-Care system.[131] The Alliance adopted an "opt-in" policy, requiring patients to sign a consent form before their data is loaded into the repository.[132]

Glades General Hospital is serving as the pilot hospital site for All-Care system testing. The Alliance has set a target of bringing Glades Hospital to live transmission of data into All-Care within the first quarter of 2008.[133]

South Florida Health Information Initiative, Inc. (SFHII)

SFHII received a planning grant in Fiscal Year 2005-2006 for $127,924 and operations grants in Fiscal Year 2006-2007 for $329,303 and Fiscal Year 2007-2008 for $284,618. Grant funding for Fiscal Year 2005-2006 through Fiscal Year 2007-2008 totals $742,151.[134]

SFHII envisions serving Broward, Miami-Dade, and Monroe counties. SFHII launched the Community Health Information Exchange (CHIE) in June 2007.[135] Initial participants in the CHIE include Mercy Hospital and Health Choice Network and its South Florida federally qualified health centers. The operational CHIE currently includes eight total data sources and 35,464 patients.[136] The medical providers associated with the two participating entities have access to the CHIE's web portal. Thirty additional providers who are representatives of the Florida Academy of Family Physicians, AvMed Health Plans, and Blue Cross Blue Shield of Florida also have access to the CHIE and provide feedback on how to incorporate the web portal into their daily work flow.[137]

As additional funding becomes available, SFHII will integrate Jackson Health System into the CHIE. Negotiations are also underway with Broward Health System to enter the CHIE.[138] SFHII hosted the "2nd Annual Health Information Exchange Summit" in November 2007, which featured speakers such as Newt Gingrich.

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[131] *Id.* at 4

[132] Palm Beach County Community Health Alliance "AllCare October/November 2007 Project Progress Report for the Agency for Health Care Administration," 2.

[133] *Id.*

[134] Agency for Health Care Administration, "FHIN Grants Program Funding- FY 2005-2008".

[135] South Florida Health Information Initiative, "FHIN Grants Program, November Monthly Report," December 3, 2007, 4.

[136] South Florida Health Information Initiative presentation to Governor's Health Information Infrastructure Advisory Board, "Community Health Information Exchange: Operationalizing the Vision," June 11, 2007.

[137] South Florida Health Information Initiative, "FHIN Grants Program, Second Quarterly Report, January 1, 2007 – March 31, 2007," 4.

[138] South Florida Health Information Initiative presentation to the Florida House of Representatives Health Quality Committee, December 11, 2007, 4.

Tampa Bay Regional Health Information Organization (TBRHIO)

TBRHIO received operations grants in Fiscal Year 2005-2006 for $467,000, Fiscal Year 2006-2007 for $330,339, and Fiscal Year 2007-2008 for $246,618. Grant funding for Fiscal Year 2005-2006 through Fiscal Year 2007-2008 totals $1,043,957.[139]

TBRHIO utilizes a centralized model. All providers send data into the RHIO depository.[140] TBRHIO serves to improve the health status of and reduce costs associated with the project's target populations of Medicaid patients diagnosed with adult diabetes, pediatric asthma, and prostate cancer.[141]

Current data exchange provides core patient discharge information from Tampa General, All Children's Hospital, and the H. Lee Moffitt Cancer Research Institute combined with information from area pharmacies. Information is displayed to the physician and patient via a website and hand-held devices.[142] All medication histories for Medicaid patients are available to authorized physicians in the Tampa Bay area through Gold Standard.[143]

TBRHIO is developing the implementation strategy to link hospital discharge summaries with EMRs of the 400+ member University of South Florida Physician's Group.[144] Three provider facilities are authorized to use the network as of April 2007. In Fiscal Year 2007-2008, the RHIO aims to double the number of authorized hospitals and/or facilities.[145]

The Florida Department of Veterans' Affairs (FDVA)

FDVA received a planning grant in Fiscal Year 2007-2008 for $70,614.

FDVA and the U.S. Department of Veterans Affairs have agreed to collaborate on the assessment and planning phase of the development and implementation of a continuity of care record (CCR) at the FDVA. Implementation of a CCR will facilitate the exchange of patient demographic and clinical data with a variety of health care providers. The FDVA plans to implement this program at the six nursing homes operated by the FDVA. Currently, their project team is in the preliminary planning stage.

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[139] Agency for Health Care Administration, "FHIN Grants Program Funding- FY 2005-2008".
[140] Agency for Health Care Administration, "Florida Health Information Network Grants Program, Grantee Background Information," April 2007, 15.
[141] Tampa Bay Partnership website, http://www.tampabay.org/subpage.asp?navid=7&id=130 (visited December 20, 2007).
[142] *Id.*
[143] Agency for Health Care Administration, "Florida Health Information Network Grants Program, Grantee Background Information," April 2007, 14.
[144] *Id.*
[145] *Id.*

Florida Medicaid EHR Pilot Program

In May 2006, the agency signed a contract with Electronic Data Systems (EDS) to develop a new Medicaid computer system and serve as the State's fiscal agent for five years beginning March 1, 2008.[146] The $308 million contract was awarded for the design, development, and implementation of an upgraded Medicaid system.[147] A portion of the contract calls for an initiative known as "Florida interChange". The initiative seeks to create an EHR for each Medicaid recipient, but will first be run as a pilot program in Leon County from November 2007 through February 2008. EDS has worked with the Big Bend RHIO to ensure compatibility with the local HIE.[148]

Medicaid patient medical information is currently collected based on the diagnostic and procedural codes entered from claims data and filed electronically with the state's Medicaid Management Information System.[149] The information in this file serves as the foundation for an EHR, which will be viewable by authorized Medicaid physicians and medical staff and may contain current health records, lab results, and x-rays.[150] The EHR will be based on medical claims data from the last six to nine months. Florida Medicaid sent letters to over 300 Medicaid providers in Leon County asking them to participate in the pilot program.[151] Those who participate will receive access to an Internet site through an assigned password. Since the system is web-based there is no need for physicians to purchase special hardware or software to participate.

EDS and Florida Medicaid will evaluate the pilot program with plans to go statewide with EHRs for all Medicaid recipients. They also plan to eventually provide access to EHRs to Medicaid patients and caregivers through a patient web-portal.[152]

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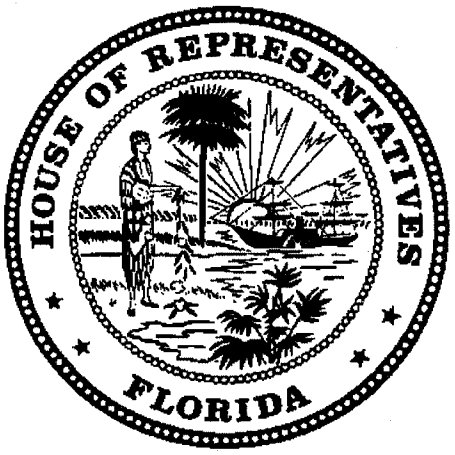
[146] Agency for Health Care Administration, Florida Medicaid Program, "Florida Medicaid Management Information System/Decision Support System Implementation," http://mymedicaid-florida.com/providerreadiness/default.aspx (visited December 19, 2007).
[147] Ferris, Nancy, "Florida Launches EHR Project for Medicaid Recipients," Government Health IT, November 26, 2007, http://www.govhealthit.com/online/news/350132-1.html (visited December 19, 2007).
[148] *Id.*
[149] Hansen, Dave, "Florida Begins Electronic Health Record Pilot Program for Medicaid Recipients," American Medical News, December 17, 2007, http://www.ama-assn.org/amednews/2007/12/17/gvsc1217.htm (visited December 19, 2007).
[150] *Id.*
[151] *Id.*
[152] *Id.*



An Evaluation of the Regulatory Scheme of Pedigree Papers

February 13, 2008

Marco Rubio
Speaker

Gayle Harrell
Chair
Health Quality Committee

I. Executive Summary

One of the most significant developments in the regulation of the wholesale distribution of prescription drugs is the pedigree paper. The pedigree paper emerged in the late 1980s as a tool to inject traceability into the marketplace to protect the integrity of the nation's prescription drug supply.

In Florida, the pedigree paper has changed substantially since it was first created in 1992, most notably in 2003 and in 2006. These changes have been enacted with little time for reflection or analysis. During the same time period, the larger body of law in which the pedigree papers law is contained, the Florida Drug and Cosmetic Act, has been revised and expanded numerous times. The result of these changes is a disorganized body of law that may hinder enforcement and compliance in reaching the ultimate goal of protecting the state's prescription drug supply.

In order to improve the organization of the Florida Drug and Cosmetic Act, the Legislature should consider significantly restructuring the act to combine relevant sections of law together that are now spread over numerous sections of law. In addition, the Legislature should consider rewriting the pedigree papers law, placing it into its own section of law in order to improve organization and clarity.

II. Pedigree Papers

A. Introduction

The prescription drug wholesale distribution market, nationwide, is generally operated by three major companies: AmerisourceBergen Corp., Cardinal Health Inc., and McKesson Corp.[1] Together, these companies hold anywhere from 90 to 95 percent of the prescription drug wholesale distribution market.[2] In addition to these "first tier" wholesale distributors, there are a number of secondary wholesale distributors who may serve a smaller or specialized market, such as distributing directly to individual physician offices.

In Florida, there are approximately 360 in-state and out-of-state prescription drug wholesale distributors (permittees).[3] The number of permittees has declined approximately 75 percent since 2003, illustrating a considerable consolidation over the past several years. This consolidation is due in part to more stringent permit application requirements enacted in 2003 by the Legislature.[4]

The pedigree paper requirement is a key tool used to regulate these prescription drug wholesale distributors. A pedigree paper is generally known as a document that

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[1] *See* http://www.marketwatch.com/news/story/growing-share-big-three-drug/story.aspx?guid=%7B9F3862C1-7E3A-4D82-94B7-A8E4AE5DAE6A%7D (last updated May 30, 2007).
[2] *Id.*
[3] *See* Department of Health, Medical Quality Assurance Annual Report: July 1, 2006 – June 30, 2007.
[4] CS/CS/SB 2312; Chapter 2003-155, L.O.F.

records the distribution of a prescription drug, from initial sale by a manufacturer, to sale by one or more wholesale distributors, to final sale to a person administering or dispensing the prescription drug. The purpose of the pedigree paper is to document prior sales in order to increase the safety of the prescription drug supply chain by preventing the introduction of counterfeited or diverted prescription drugs.

B. Federal Pedigree Papers

At the federal level, the pedigree paper must be distributed by each person engaged in the wholesale distribution of a prescription drug who is not an authorized distributor of record for the prescription drug. [5] This requirement does not preempt state regulation, but serves as a minimum requirement for wholesale distributors. The pedigree paper must identify each prior sale, purchase, or trade of the prescription drug and must be provided for each wholesale distribution, including distributions to authorized distributors of record and retail pharmacies.[6] Under the final regulations promulgated by the United States Food and Drug Administration (FDA), the pedigree paper must include the following information:

- The proprietary and established name of the drug;
- Dosage;
- Container size;
- Number of containers;
- The drug's lot or control number;
- The business name and address of all parties to each prior transaction involving the drug, starting with the manufacturer; and
- The date of each previous transaction.[7]

There are two significant exceptions to the federal pedigree paper requirement. The first, noted above, is for authorized distributors of record. The second is for "intracompany transfers", a term which is not defined in federal law.

Shortly before the December 1, 2006, effective date of the final regulations, however, the United States District Court for the Eastern District of New York issued a preliminary injunction enjoining the enforcement a portion of the final regulations.[8] This portion of the final regulations specified the information that is required to be included on the pedigree.[9] At issue is the requirement that the pedigree paper include information about the distribution of the prescription drugs all the way back to the manufacturer. An unauthorized distributor of record would not likely be able to purchase prescription drugs directly from the manufacturer; its primary source would be an ADR (see Figure 1, below). Consequently, as an ADR is exempted from

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[5] An "authorized distributor of record" or "ADR" is a wholesale distributor with whom the manufacturer has an ongoing business relationship to distribute the manufacturer's products.

[6] Pub. L. No. 102-353, §4 (1992); 21 U.S.C. §353(e) (2000) (commonly referred to as the Prescription Drug Amendments, or PDA).

[7] 21 C.F.R. §203.50(a) (2007).

[8] *RxUSA Wholesale, Inc. v. Department of Health and Human* Services, 467 F.Supp.2d 285 (E.D.N.Y. 2006).

[9] 21 C.F.R. §203.50(a) (2007).

providing a pedigree paper, and thus exempted from providing such information to the unauthorized distributor of record, the court found that the FDA regulation would "essentially wipe out all the unauthorized distributors" who would not be able to obtain such information.[10] The court also noted that the regulation "may drastically change how prescription drugs are distributed in this country and ultimately affect the cost to the consumer in terms of insurance premiums and prescription drugs."[11] The FDA has appealed the injunction to the Second Circuit Court of Appeals.

As a result of the preliminary injunction, the FDA announced that a pedigree paper must only contain the statutory minimum: the dates of all listed transactions and the names and addresses of all parties involved in those transactions.[12] In addition, the pedigree paper must contain prior transactions back to the last ADR or manufacturer.[13]

The illustration in Figure 1 is a simplified illustration of when a pedigree paper must be supplied under federal law. Notably, a large number of wholesale transactions are not subject to the PDMA pedigree paper requirement.

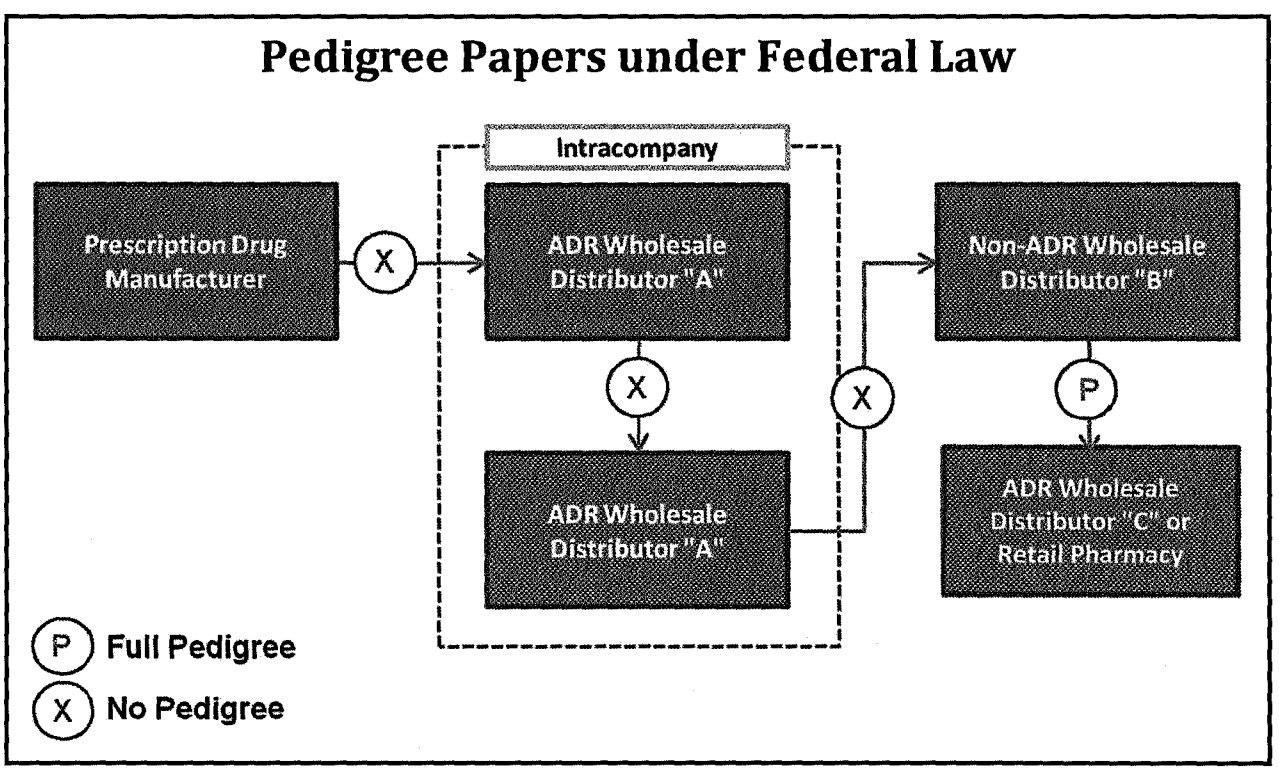

Figure 1

[10] 467 F.Supp.2d at 291.
[11] *Id.*
[12] *See* United States Food and Drug Administration, ADDENDUM to FDA's Guidance for Industry: PDMA Pedigree Requirements – Questions and Answers Related to the Preliminary Injunction ordered 12/5/06 in RXUSA Wholesalers, Inc. v. HHS (2006).
[13] *Id.*

C. Florida Pedigree Papers

In Florida, there are two forms of pedigree papers. The first form is known informally as the "direct purchase" pedigree paper because a wholesale distributor must generally purchase the prescription drug directly from the manufacturer and subsequently directly distribute (with allowance for one intracompany transfer) the prescription drug to an end user or a chain pharmacy warehouse. The second form of pedigree paper must be used for all other wholesale distributions. Figure 2 illustrates the differences between the two forms of pedigree papers.

Full Pedigree	"Direct Purchase" Pedigree
No.	Statement, under oath, that "This wholesale distributor purchased the specific unit of the prescription drug directly from the manufacturer."
Name of the prescription drug as it appears on the label.	**Same.**
Quantity, dosage form, and strength of the prescription drug.	**Same.**
Lot numbers of the prescription drug.	*Maintained by the wholesale distributor, made available to the department upon request.*
Name and address of each owner of the prescription drug and his or her signature.	Name and address of the wholesaler and the purchaser of the prescription drug.
Shipping information, including name and address of each person certifying delivery or receipt of the prescription drug.	*Maintained by the wholesale distributor, made available to the department upon request:* The point of origin of the prescription drugs, including intracompany transfers, and the date of the shipment from the manufacturer to the wholesale distributor.
Invoice number, shipping document number, or another number uniquely identifying the transaction.	*Maintained by the wholesale distributor, made available to the department upon request:* Invoice numbers from the manufacturer.
Certification that recipient wholesale distributor has authenticated pedigree papers.	**No.**
The unique serial of the specific unit of prescription drug, if the manufacturer or repackager has uniquely serialized the individual prescription drug unit.	**No.**
Name, address, telephone number and, if available, e-mail contact information of each wholesale distributor involved in the chain of the prescription drug's custody.	**No.**

Figure 2

Florida law provides several exceptions to the pedigree paper requirement, including:

- The wholesale distribution of compressed medical gas.
- The wholesale distribution of veterinary prescription drugs.
- Drop shipments of prescription drugs by prescription drug manufacturers.
- Certain distributions of prescription drugs by wholesale distributors within an affiliated group.

A "drop shipment" occurs when a wholesale distributor arranges for the direct shipment of a prescription drug from the manufacturer to an end user, such as a hospital, health care practitioner, or pharmacy. The prescription drug manufacturer provides an invoice to the wholesale distributor; the wholesale distributor, in turn, provides an invoice to the end user. At no point in the transaction does the wholesale distributor physically take possession of the prescription drug. Drop shipments are used in a number of situations, such as for prescription drugs with unusual temperature or handling requirements that are not suitable for distribution by a wholesale distributor.

Despite what may appear to be a logical construction of the pedigree paper requirement, the actual text of the statutory law is highly disorganized. For example:

- The circumstances of when a direct purchase pedigree paper may be used (as opposed to a "full" pedigree paper) are contained in the definition of "pedigree paper" in subsection (31) of section 499.003, F.S. This definition also describes the content of the pedigree papers, requires retention of related records, and provides rule authority to the Department of Health.
- The pedigree paper requirement is contained in a sub-paragraph of subsection (6) of section 499.0121, F.S.
- Exceptions to the pedigree paper requirement are contained in subsequent sub-paragraphs and paragraphs of the same section, and are not clearly labeled as exceptions.[14]

In addition, for purposes of the direct-purchase pedigree paper, the law neither defines "intracompany transfer", nor does the law clearly state the number of transfers allowed. This has lead to confusion regarding the circumstances under which the direct-purchase pedigree paper may be used by wholesale distributors.

The illustration in Figure 3 is a simplified illustration of when a pedigree paper must be supplied under Florida law. Unlike federal law and many other states, Florida law subjects a large number of wholesale transactions to the pedigree paper requirement.

[14] *See, e.g.,* s. 499.0121(6)(d)3. (exception for veterinary prescription drugs and compressed medical gasses) and s. 499.0121(6)(f) (exemption for certain wholesale distributions within an affiliated group).

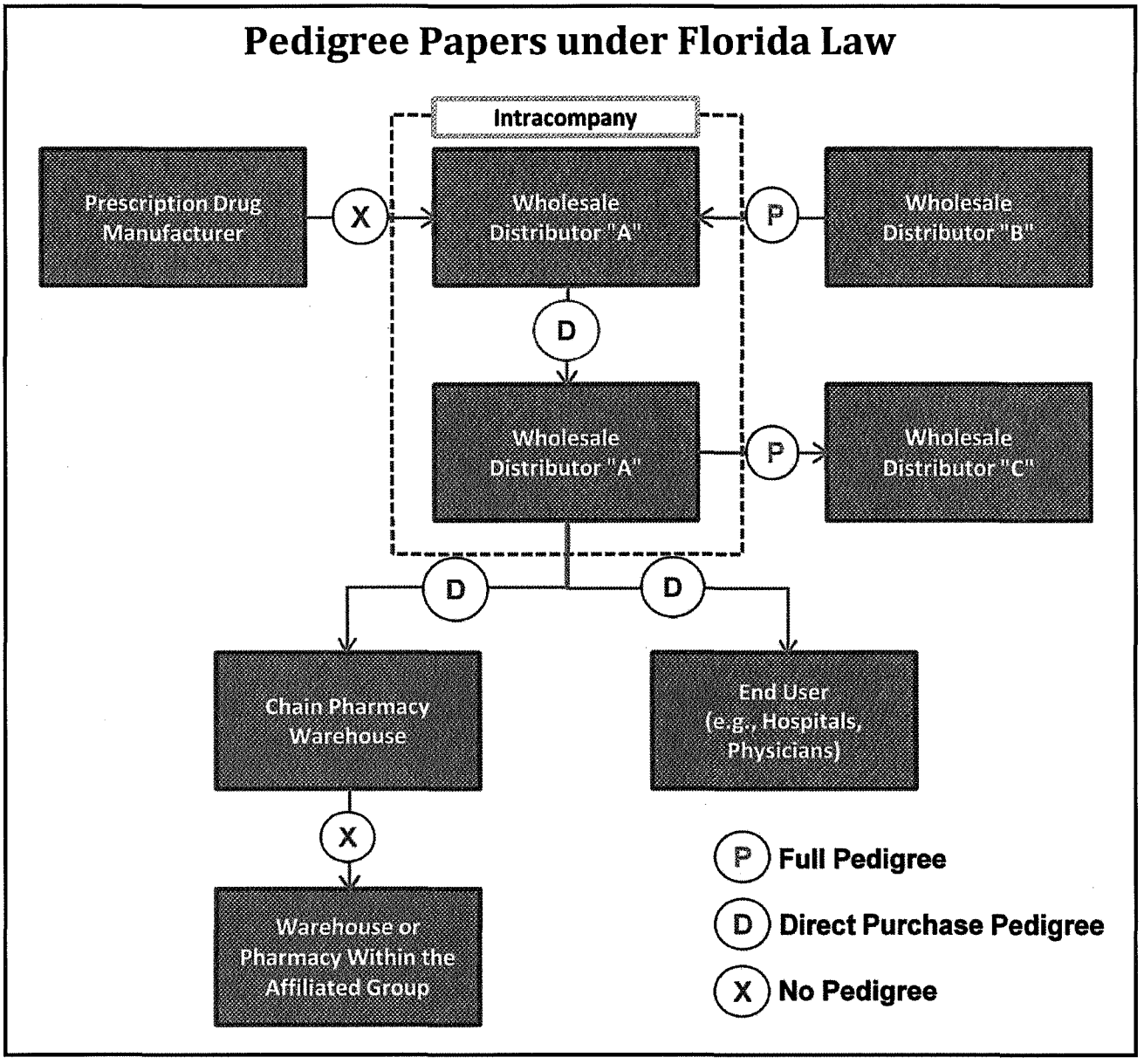

Figure 3

III. Veterinary Prescription Drug Wholesale Distributors

A number of drugs intended solely for animals are required by federal law to be prescribed by a licensed veterinarian.[15] In addition, certain drugs intended for human use are frequently prescribed for animal use, such as the antibiotic amoxicillin.

In Florida, a wholesale distributor who only distributes veterinary prescription drugs must obtain a veterinary prescription drug wholesaler permit. However, prior to 2006,

[15] 21 U.S.C. 353(f) (2005).

if a veterinary prescription drug wholesale distributor wanted to distribute human and animal prescription drugs to veterinarians, the wholesale distributor would have been required to obtain a prescription drug wholesaler permit.[16] The prescription drug wholesaler permit requires a $100,000 security bond and an extensive permit application.

In 2006, the Legislature created a new permit called a "limited prescription drug veterinary wholesaler permit."[17] The new permit authorizes the wholesaler to distribute human and animal prescription drugs to certain persons. However, the wholesaler is limited to distributing human prescription drugs worth no more than 30 percent of the wholesaler's total annual prescription drug sales.[18] Of particular note are two additional requirements:

- The wholesaler must not be permitted, licensed, or otherwise authorized in any state to wholesale human prescription drugs to any person who is authorized to sell, distribute, purchase, trade, or use these drugs on or for humans; and
- The wholesaler must maintain at all times a license or permit to engage in the wholesale distribution of prescription drugs in compliance with laws of the state in which it is a resident.

As no other state has created a permit or license similar to the limited prescription drug veterinary wholesaler permit, an out-of-state wholesaler cannot satisfy both of these requirements.

According to the Department of Health, 18 out-of-state wholesale distributors have applied for the limited prescription drug veterinary wholesaler permit. Of these applicants, none have been approved because of the inconsistency noted above.

IV. Organization of Part I of Chapter 499

Part I of chapter 499, F.S., known as the Florida Drug and Cosmetic Act (the act), generally regulates drugs, devices, and cosmetics. Its numerous provisions include:

- Criminal prohibitions against the distribution of contraband and adulterated prescription drugs.
- Regulation of the advertising and labeling of drugs, devices, and cosmetics;
- Establishment of permits for manufacturing and distributing drugs, devices, and cosmetics.
- Regulation of the wholesale distribution of prescription drugs, which includes pedigree papers.
- Regulation of the provision of drug samples.

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[16] *See* s. 499.012(g), F.S. (2005) (stating that "a veterinary prescription drug wholesaler that also distributes prescription drugs subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act which it did not manufacture must obtain a permit as a prescription drug wholesaler or out-of-state prescription drug wholesaler in lieu of the veterinary prescription drug wholesaler permit").
[17] *See* s. 499.012(h), F.S. (2007).
[18] *Id.*

- Establishment of the Cancer Drug Donation Program.
- Establishment of numerous enforcement avenues for the Department of Health, including seizure and condemnation of drugs, devices, and cosmetics.

The act has been amended numerous times over the course of the past two decades. Recent additions include the 2003 legislation that significantly strengthened the pedigree papers law and the permit application process and the 2006 legislation that created the Cancer Drug Donation Program. As a result of these numerous revisions, the act has become substantially disorganized. In particular:

- The Department of Health's enforcement authority is spread over five separate sections of law.[19]
- Criminal prohibitions are spread over five sections of law.[20]
- Permit definitions are spread over five sections of law.[21]
- Generally applicable definitions are spread over four sections of law.[22]
- The terms "legend drug", "prescription drug" and "medicinal drug" are used interchangeably to refer to prescription drugs regulated by the Federal Food, Drug, and Cosmetic Act.[23]
- The terms "wholesaler", "wholesale distributor", and "wholesale drug distributor" are used interchangeably to refer to a person who engages in the wholesale distribution of prescription drugs.[24]

The act also contains a number of incorrect cross-references, one of which, according to the Department of Health, dates back to 1995.[25]

V. Recommendations

Since the enactment of HB 371 and SB 1540 in 2006, a number of issues have been raised by stakeholders relating to the pedigree papers law and the limited prescription drug veterinary wholesaler permit, both of which are contained in the Florida Drug and Cosmetic Act (the act). Many of these issues relate to a lack of clarity and organization. The Legislature should consider undertaking a comprehensive reorganization of the act that addresses pedigree papers, the limited prescription drug veterinary wholesaler permit, and the overall structure of the act.

First, regarding the limited prescription drug veterinary wholesaler permit created by SB 1540, the inconsistency in simultaneously requiring a wholesale distributor to

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[19] Sections 499.004, 499.0053, 499.07, 499.071, and 499.081, F.S.
[20] Sections 499.0052, 499.00535, 499.00545, 499.069, and 499.0691, F.S.
[21] Sections 499.012, 499.0122, 499.013, 499.014, and 499.028, F.S.
[22] Sections 499.012, 499.0121, 499.029, and 499.0661, F.S.
[23] *See, e.g.,* s. 499.006 (using the terms "legend drug" and "prescription drug"). *See also* s. 499.003(25), F.S. (defining "legend drug", "prescription drug", and "medicinal drug" identically).
[24] *See, e.g.,* ss. 499.012(8)(b), F.S. (using the term "wholesale drug distributor") and 499.0121, F.S. (using the terms "wholesaler" and "wholesale drug distributor").
[25] *See, e.g.,* s. 499.05, F.S. (incorrectly referencing s. 499.006, instead of s. 499.066).

possess an out-of-state license to distribute prescription drugs, yet prohibiting the same wholesale distributor from being licensed to distribute human prescription drugs, should be fixed. One solution, recommended in the attached bill draft, would be to amend the law to prohibit a wholesale distributor from distributing human prescription drugs to another person who is authorized to sell, distribute, purchase, trade, or use such drugs on humans. This solution would change the focus of the prohibition from the permit to the activity—i.e., distributing human drugs for ultimate use by humans.

Second, regarding the pedigree papers law, an important first step is a rewrite that focuses on clearly delineating to whom the requirement applies, when it applies, what is required to be contained in the pedigree, and when the requirement does not apply (exceptions). The recommendation in the attached bill draft places the pedigree papers law in its own statutory section and more clearly describes the requirement and its exceptions.

Last, regarding the lack of clarity and organization that pervades most of the act, the recommendation in the attached bill draft represents a significant reorganization. Disparate sections of law are consolidated into single sections of law encompassing criminal prohibitions, enforcement authority, permit requirements, and generally applicable definitions, respectively. Terms used interchangeably, such as "legend drug", "prescription drug", and "medicinal drug", are consolidated to "prescription drug".

Appendix A: Origin of Pedigree Papers at the Federal Level

At the federal level, the pedigree paper requirement first emerged in the Prescription Drug Marketing Act of 1987[26]— commonly referred to as the PDMA. The act was signed into law on April 22, 1988 by President Reagan. Prior to the passage of the PDMA, in Congress the House of Representatives conducted numerous hearings examining the safety of the nation's prescription drug supply.[27] In particular, the House found that "the integrity of the distribution system is insufficient to prevent the introduction and eventual retail sale of substandard, ineffective or even counterfeit pharmaceuticals."[28] In addition, the House noted that "that most of the drugs that were counterfeits, stolen, expired, or obtained through fraud were handled by secondary wholesalers, who were not authorized to distribute that manufacturer's product."[29]

Congress' findings are summarized in the text of the PDMA:

> (1) American consumers cannot purchase prescription drugs with the certainty that the products are safe and effective.
> (2) The integrity of the distribution system for prescription drugs is insufficient to prevent the introduction and eventual retail sale of substandard, ineffective, or even counterfeit drugs.
> (3) The existence and operation of a wholesale submarket, commonly known as the 'diversion market', prevents effective control over or even routine knowledge of the true sources of prescription drugs in a significant number of cases.
> (4) Large amounts of drugs are being reimported to the United States as American goods returned. These imports are a health and safety risk to American consumers because they may have become subpotent or adulterated during foreign handling and shipping.
> (5) The ready market for prescription drug reimports has been the catalyst for a continuing series of frauds against American manufacturers and has provided the cover for the importation of foreign counterfeit drugs.
> (6) The existing system of providing drug samples to physicians through manufacturer's representatives has been abused for decades and has resulted in the sale to consumers of misbranded, expired, and adulterated pharmaceuticals.
> (7) The bulk resale of below wholesale priced prescription drugs by health care entities, for ultimate sale at retail, helps fuel the diversion market and is an unfair form of competition to wholesalers and retailers that must pay otherwise prevailing market prices.
> (8) The effect of these several practices and conditions is to create an unacceptable risk that counterfeit, adulterated, misbranded, subpotent, or expired drugs will be sold to American consumers.[30]

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[26] Pub. L. No. 100-293 (1988).
[27] *See* H.R. Rep. No. 100-76 (1987).
[28] *Id.* at 6.
[29] *Id.* at 17.
[30] Pub. L. No. 100-293, §2 (1988).

In his signing letter for the PDMA,[31] President Reagan noted that investigations conducted by the Department of Justice into diverted and counterfeited drugs demonstrated that "the principal factor facilitating the illegal activity that this bill is designed to combat is the almost total lack of traceability of drug products in the diversion market."[32]

Among the many provisions of the PDMA was the requirement that each person who is engaged in the wholesale distribution of prescription drugs, who is not an authorized distributor of record for such drugs, must provide to each wholesale distributor, prior to the sale of the drugs, a statement (pedigree paper) identifying each sale of the prescription drug.[33] An authorized distributor of record (ADR) is a distributor with whom the manufacturer has an ongoing business relationship.[34] Subsequent amendments to the PDMA in 1992 clarified that the pedigree paper must identify each prior sale, purchase, or trade of the prescription drug and must be provided for each wholesale distribution, including distributions to ADRs and retail pharmacies.[35] In addition, these amendments also authorized the Secretary of the United States Department of Health and Human Services to specify the format and content of the pedigree paper.[36]

In implementing the PDMA, including the pedigree paper requirement, the Federal Food and Drug Administration (FDA) published proposed regulations in March of 1994[37]; the final regulations were published on December 3, 1999.[38] Subsequent to that time, however, the FDA delayed the pedigree paper requirement over the course of 12 years, based on feedback from the industry and industry trade associations.[39] Concerns were also raised by the Small Business Administration, based on the "severe economic impact" the final regulations would have on thousands of small businesses.[40] Finally, on June 14, 2006, the FDA publicly announced that it would not delay the implementation date of the pedigree paper final regulations beyond the December 1, 2006 effective date.[41]

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[31] *Statement on Signing the Prescription Drug Marketing Act of 1987* (visited December 5, 2007) http://www.reagan.utexas.edu/archives/speeches/1988/042288g.htm.
[32] *Id.*
[33] Pub. L. No. 100-293, §6 (1988).
[34] *Id.*
[35] Pub. L. No. 102-353, §4 (1992); 21 U.S.C. §353(e) (2000) (commonly referred to as the PDA).
[36] *Id.*
[37] Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements, and Administrative Procedures, 59 Fed. Reg. 11842 (1994) (to be codified at 21 C.F.R. pts. 203 and 205).
[38] Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements, and Administrative Procedures, 64 Fed. Reg. 67720 (1999) (to be codified at 21 C.F.R. pts. 203 and 205).
[39] *See, e.g.,* Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements, and Administrative Procedures; Delay of Effective Date, 67 Fed. Reg. 6645 (2002).
[40] Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements, and Administrative Procedures; Delay of Effective Date, 66 Fed. Reg. 12850 (2001).
[41] Prescription Drug Marketing Act Pedigree Requirements; Effective Date and Compliance Policy Guide; Request for Comment, 71 Fed. Reg. 34249 (2006).

Under the final regulations, the pedigree paper must include:

- The proprietary and established name of the drug;
- Dosage;
- Container size;
- Number of containers;
- The drug's lot or control number;
- The business name and address of all parties to each prior transaction involving the drug, starting with the manufacturer; and
- The date of each previous transaction.[42]

Shortly before the December 1, 2006, effective date of the final regulations, however, the United States District Court for the Eastern District of New York issued a preliminary injunction enjoining the enforcement a portion of the final regulations.[43] This portion of the final regulations specified the information that is required to be included on the pedigree.[44] At issue is the requirement that the pedigree paper include information about the distribution of the prescription drugs all the way back to the manufacturer. As an unauthorized distributor of record would not likely be able to purchase prescription drugs directly from the manufacturer, its only source would be an ADR. Consequently, as an ADR is exempted from providing a pedigree, and thus not providing such information to the unauthorized distributor of record, the court found that the FDA regulation would "essentially wipe out all the unauthorized distributors" who would not be able to obtain such information.[45] The court also noted that the regulation "may drastically change how prescription drugs are distributed in this country and ultimately affect the cost to the consumer in terms of insurance premiums and prescription drugs."[46] The FDA has appealed the injunction to the Second Circuit Court of Appeals.

As a result of the preliminary injunction, the FDA announced that a pedigree paper must only contain the statutory minimum: the dates of all listed transactions and the names and addresses of all parties involved in those transactions.[47] In addition, the pedigree paper must contain prior transactions back to the last ADR or manufacturer.[48]

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[42] 21 C.F.R. §203.50(a) (2007).
[43] *RxUSA Wholesale, Inc. v. Department of Health and Human* Services, 467 F.Supp.2d 285 (E.D.N.Y. 2006).
[44] 21 C.F.R. §203.50(a) (2007).
[45] 467 F.Supp.2d at 291.
[46] *Id.*
[47] *See* United States Food and Drug Administration, ADDENDUM to FDA's Guidance for Industry: PDMA Pedigree Requirements – Questions and Answers Related to the Preliminary Injunction ordered 12/5/06 in RXUSA Wholesalers, Inc. v. HHS (2006).
[48] *Id.*

Appendix B: Origin of Pedigree Papers in Florida

In 1992, the Florida Legislature created a pedigree paper requirement to regulate the wholesale distribution of prescription drugs.[49] Administrative rules to implement the requirement were promulgated in 1996.[50] The rules required a non-ADR wholesale distributor engaged in the wholesale distribution of a prescription drug to provide a pedigree paper, prior to the sale of such drug, to a receiving wholesale distributor.[51] The pedigree paper was required to be a written statement identifying:

- The proprietary name or the generic name of the prescription drug;
- The name of the manufacturer or distributor reflected on the label of the product;
- Dosage form and strength;
- Container size;
- Quantity by lot number;
- The name and address of each owner of the prescription drug;
- The name and address of each location from which the prescription drug was shipped, if different from the owner's address; and
- The transaction dates.[52]

However, this requirement was apparently not strictly enforced by the Department of Health until 2001.[53] In November 2001, the Department of Health sent a letter to prescription drug wholesale distributors to clarify the pedigree paper requirements.[54] The letter noted that "the Bureau of Pharmacy Services will be looking more closely at your compliance with the pedigree paper requirements . . . We have already initiated action to revoke prescription drug wholesaler permits or impose administrative penalties in cases where pedigree papers were at issue."[55] Objections by the industry, however, forced the department to create an ad hoc committee to study the issue, which resulted in a new rule that was proposed in March of 2003.[56] The proposed rule required a person who distributes a "specified" prescription drug that it did not manufacture to provide a pedigree paper; the specified prescription drug list included 30 drugs that were frequently counterfeited or diverted.[57]

During the same time period in which the department was struggling to implement and enforce the pedigree paper requirement, Governor Jeb Bush petitioned the Florida Supreme Court to convene a statewide Grand Jury to examine the safety of prescription drugs in the state of Florida.[58] The Grand Jury issued its interim report in

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[49] CS/CS/SB 84 (1992); Chapter 92-69, L.O.F.
[50] Rule 10D-45.053, F.A.C. (1996).
[51] CS/CS SB 84 (1992); Chapter 92-69, L.O.F.
[52] *Id.*
[53] *See* First Interim Report of the Seventeenth Statewide Grand Jury, Case No. SC02-2645 (2003).
[54] *See* Sandra R. Stovall, Florida Department of Health, Letter to Regulatory Affairs (2001).
[55] First Interim Report of the Seventeenth Statewide Grand Jury, Case No. SC02-2645 (2003).
[56] 29 Fla. Admin. Weekly 992 (March 7, 2003).
[57] *Id.*
[58] Petition for Order to Impanel a Statewide Grand Jury, Case No. SC02-2645 (2002).

February, 2003.[59] The Grand Jury noted that the three largest whole distributors obtained approximately 95 percent of their stock directly from the manufacturer.[60] The remaining stock was purchased from the secondary market, where prescription drugs may move "up, down, and sideways through the distribution system[, creating] opportunities for adulterated drugs that have been diverted from other sources to enter the distribution system."[61] It is this secondary market that the Grand Jury, much like Congress, identified as the source of counterfeit or adulterated drugs. The Grand Jury noted that these drugs moved easily throughout the system because federal and state agencies failed to enforce existing law and because wholesale distributors "turn[ed] a blind eye to the corrupt practices of other wholesalers that supply them with some of their pharmaceuticals."[62]

The industry opposition to the pedigree paper at the time was that it would be "prohibitively expensive to segregate . . . stocks of drugs purchased from other wholesalers and stocks of drugs bought directly from the manufacturers."[63] The industry also objected because the pedigree paper would be passed in intracompany transfers, which are "shipments of drugs from one warehouse to another within the same company."[64] Last, the industry objected because "pedigree papers have no real value in deterring or discovering diverted or adulterated drugs . . . [and] can be easily forged."[65] In response to this last objection, the Grand Jury stated the potential for forgery is exactly the reason why the pedigree paper must be verified in order for this "tool" to work.[66]

The Grand Jury concluded that, without a pedigree paper "verified through the chain of transactions, it is impossible for consumers to know with absolute confidence that the drug that they are getting from their doctor or pharmacy has not been diverted or adulterated."[67] The report listed 40 recommendations for the Legislature, the Department of Health, the wholesale distribution industry, and the pharmaceutical manufacturers.[68] These recommendations included specifying additional information that should be reported on the pedigree paper (e.g., lot number); requiring the pedigree paper to be produced in every transaction; and requiring verification of the pedigree paper.[69]

In response to the Grand Jury report, the Florida Legislature amended the pedigree papers laws in 2003 to implement the recommendations of the Grand Jury.[70] Among

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[59] First Interim Report of the Seventeenth Statewide Grand Jury, Case No. SC02-2645 (2003).
[60] *Id.*
[61] *Id.*
[62] *Id.*
[63] *Id.*
[64] *Id.*
[65] *Id.*
[66] *Id.*
[67] *Id.*
[68] *Id.*
[69] *Id.*
[70] CS/CS/SB 2312; Chapter 2003-155, L.O.F.

other provisions, the bill mandated the provision of a pedigree paper by each person engaged in the wholesale distribution of a prescription drug, implemented over two phases.[71] In addition, more background information was required of wholesale prescription drug permittees and criminal penalties were created for, among other acts, failing to maintain or forging pedigree papers, as well as knowingly selling or purchasing contraband prescription drugs.[72]

The first phase, effective until July 1, 2006, required a wholesale distributor who distributed "specified" drugs, a list of 34 drugs that were likely to be counterfeited or diverted, to provide one of two forms of pedigree paper to a subsequent wholesale distributor, either:

- A statement that the wholesale distributor, or a member of its affiliated group, purchased the prescription drug directly from the manufacturer, or, if the wholesale distributor did not directly purchase the prescription drug,
- A statement under oath identifying:
    - Each previous sale of the specific unit of the prescription drug back to the manufacturer;
    - The lot number of the drug; and
    - The sales invoice number of each previous sale of the drug.[73]

For the wholesale distribution of all other prescription drugs:

- A wholesale distributor who was an ADR for such prescription drugs was not required to provide any documentation for a sale to a subsequent wholesale distributor. The department was required to publish, but not verify, on its website lists of ADRs provided by the manufacturers.
- A wholesale distributor who was not an ADR for such prescription drugs was required to provide a pedigree paper that contained:
    - Each previous sale of the specific unit of the prescription drug back to the last authorized distributor of record;
    - The lot number of the drug; and
    - The sales invoice number.[74]

The second phase, which would have become effective July 1, 2006, superseded the first phase and required each person, other than a manufacturer, involved in the wholesale distribution of a prescription drug to produce a more extensive pedigree paper prior to the distribution of the drug. This pedigree paper was required to be in written or electronic format and include:

- The amount, dosage form, and strength of the prescription drug;
- The lot number;
- The name and address of each owner of the drug and his or her signature;
- Its shipping information, including the name and address of each person certifying delivery or receipt of the drug; and

[71] *See* s. 499.0121(6)(d)-(f), F.S. (2003).
[72] *See* ss. 499.012 (permitting requirements) and 499.0051 (criminal violations), F.S. (2003).
[73] *See* s. 499.0121(6)(e), F.S. (2003).
[74] *See* s. 499.0121(6)(d), F.S. (2003).

- A certification that the recipient wholesaler has authenticated the pedigree paper.

In 2004, the Legislature amended the pedigree paper laws to create an exception from the pedigree paper requirement for transactions within an affiliated group.[75] Specifically, the amendment exempted a warehouse within an affiliated group from providing a "phase one" (but not "phase two") pedigree paper to its affiliated group member warehouse, provided that, if the warehouse received a prescription drug from outside its affiliated group, a pedigree paper must be obtained. The exemption expired on July 1, 2006.

In 2005, the Legislature again amended the pedigree paper laws.[76] These amendments added the following items to the "phase two" pedigree paper:

- The serial number of the individual unit of the prescription drug, if the manufacturer or repackager has uniquely serialized such unit; and
- An invoice number, a shipping document number, or another number uniquely identifying the transaction.

In addition, the amendments made permanent the affiliated group exception to the pedigree paper requirement created in 2004 and expanded the exception in two significant areas:

- Affiliated group warehouses were no longer required to provide a "phase two" pedigree paper as of July 1, 2006; and
- Affiliated group warehouses were no longer required to provide a pedigree paper (phase one or two) to a retail pharmacy.

Finally, in 2006, the Legislature further amended the pedigree paper laws.[77] The new amendments authorized a wholesale distributor to provide an alternative "pedigree paper" in a "normal distribution" or "direct purchase" transaction. In simple terms, a direct purchase transaction occurs where a wholesale distributor purchases the prescription drug directly from the manufacturer and subsequently directly distributes the prescription drug to an end user, such as a hospital, health care practitioner, or pharmacy. The amendments limited the use of the "direct purchase pedigree paper" to the following circumstances:

- The wholesale distributor must provide a sworn statement confirming that it purchased and received the specific unit of the prescription drug directly from the manufacturer;
- The prescription drug was distributed directly, or through an intracompany transfer, to an "end user"; and
- The end user was either a "chain pharmacy warehouse"[78] or a person authorized by law to purchase prescription drugs for the purpose of

[75] CS/CS/CS/CS SB 1372; Chapter 2004-387, L.O.F.
[76] CS/CS SB 874; Chapter 2005-248, L.O.F.
[77] HB 371; Chapter 2006-310.
[78] A "chain pharmacy warehouse" means a physical wholesale distribution center that exists solely to provide drugs to members of its affiliated group through intracompany transfers. These facilities are operated by companies such

administering or dispensing the drug (generally, a hospital, health care practitioner, or pharmacy).[79]

The direct purchase pedigree paper must contain:

- A statement that "This wholesale distributor purchased the specific unit of the prescription drug directly from the manufacturer";
- The manufacturers' national drug code identifier and the name and address of the wholesaler and the purchaser of the prescription drug;
- The name of the prescription drug as it appears on the label; and
- The quantity, dosage form, and strength of the prescription drug.[80]

The wholesale distributor must also maintain and make available to the department, upon request, the point of origin of the prescription drugs, including intracompany transfers; the date of the shipment from the manufacturer to the wholesale distributor; the lot numbers of such drugs; and the invoice numbers from the manufacturer.[81]

All other wholesale distributions of prescription drugs outside of this direct purchase model must be accompanied by a full pedigree paper, as required by law.[82]

In addition to the alternative form of pedigree paper, the amendments of 2006 also created an additional exception for a "drop shipment" transaction. A "drop shipment" occurs when a wholesale distributor arranges for the direct shipment of a prescription drug from the manufacturer to an end user, such as a hospital, practitioner, or pharmacy. The prescription drug manufacturer provides an invoice to the wholesale distributor; the wholesale distributor, in turn, provides an invoice to the end user. At no point in the transaction does the wholesale distributor physically take possession of the prescription drug. Drop shipments are used in a number of situations, such as for prescription drugs with unusual temperature or handling requirements that are not suitable for distribution by a wholesale distributor. Prior to the 2006 amendments, the pedigree paper requirement posed logistical difficulties in executing a drop ship agreement: the wholesale distributor was required to provide a pedigree paper prior to distributing the prescription drug and the end user was required to receive the pedigree prior to receiving the prescription drug. As the wholesale distributor does not control the timing of the shipment from the manufacturer, the end user was required to "quarantine" the prescription drug until a pedigree paper was provided by the wholesale distributor.

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as Wal-Mart, CVS, Walgreens, and Publix, who typically purchase prescription drugs through a first tier wholesale distributor.

[79] *See* s. 499.003(31)(b), F.S. (2007).

[80] *See* s. 499.003(31)(b), F.S. (2007).

[81] *Id.*

[82] *See* s. 499.003(31)(a), F.S. (2007).

The 2006 amendments exempted a drop ship transaction from the pedigree paper laws where:

- The prescription drug is shipped directly from the prescription drug manufacturer to the end user;
- The wholesale distributor does not take physical possession of the prescription drug at any point during the transaction; and
- The end user is a person authorized by law to purchase prescription drugs for the purpose of administering or dispensing the drug (generally, a hospital, health care practitioner, or pharmacy), or a member of an affiliated group, as defined in s. 499.0121(6)(h), F.S. (generally, companies such as Wal-Mart, CVS, Walgreens, and Publix).[83]

Furthermore, the wholesale distributor must provide to the end user, within 14 days of notification of shipment by the manufacturer, a sworn statement that the wholesale distributor purchased the prescription drug directly from the manufacturer and that the manufacturer shipped the prescription drug directly to the end user. The end user must obtain from the manufacturer, within 14 days of the receipt of the prescription drug, a shipping document that contains the following information:

- The name and address of the manufacturer, including the point of origin of the shipment, and the names and addresses of the wholesaler and the purchaser;
- The name of the prescription drug as it appears on the label;
- The quantity, dosage form, and strength of the prescription drug; and
- The date of the shipment from the manufacturer.[84]

Last, the wholesale distributor must maintain and make available to the department, upon request, the lot number of the prescription drug if not contained in the shipping document acquired by the end user. The failure of the wholesale distributor or the end user to acquire or provide this documentation, or forgery of the documentation, will constitute failure to acquire or provide, or forgery of, a pedigree paper—a felony violation.[85]

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[83] *See* s. 499.0121(6)(d)5., F.S. (2007).
[84] *Id.*
[85] *See* s. 499.0051, F.S. (2007).

Appendix C: Pedigree Papers in Other States

Several other states have created a pedigree paper requirement. A chart provided by the Healthcare Distribution Management Association summarizes the status of the laws of all 50 states (see Figure 4) as of October 30, 2007.

A discussion of a sample of states with a pedigree paper requirement is provided below.

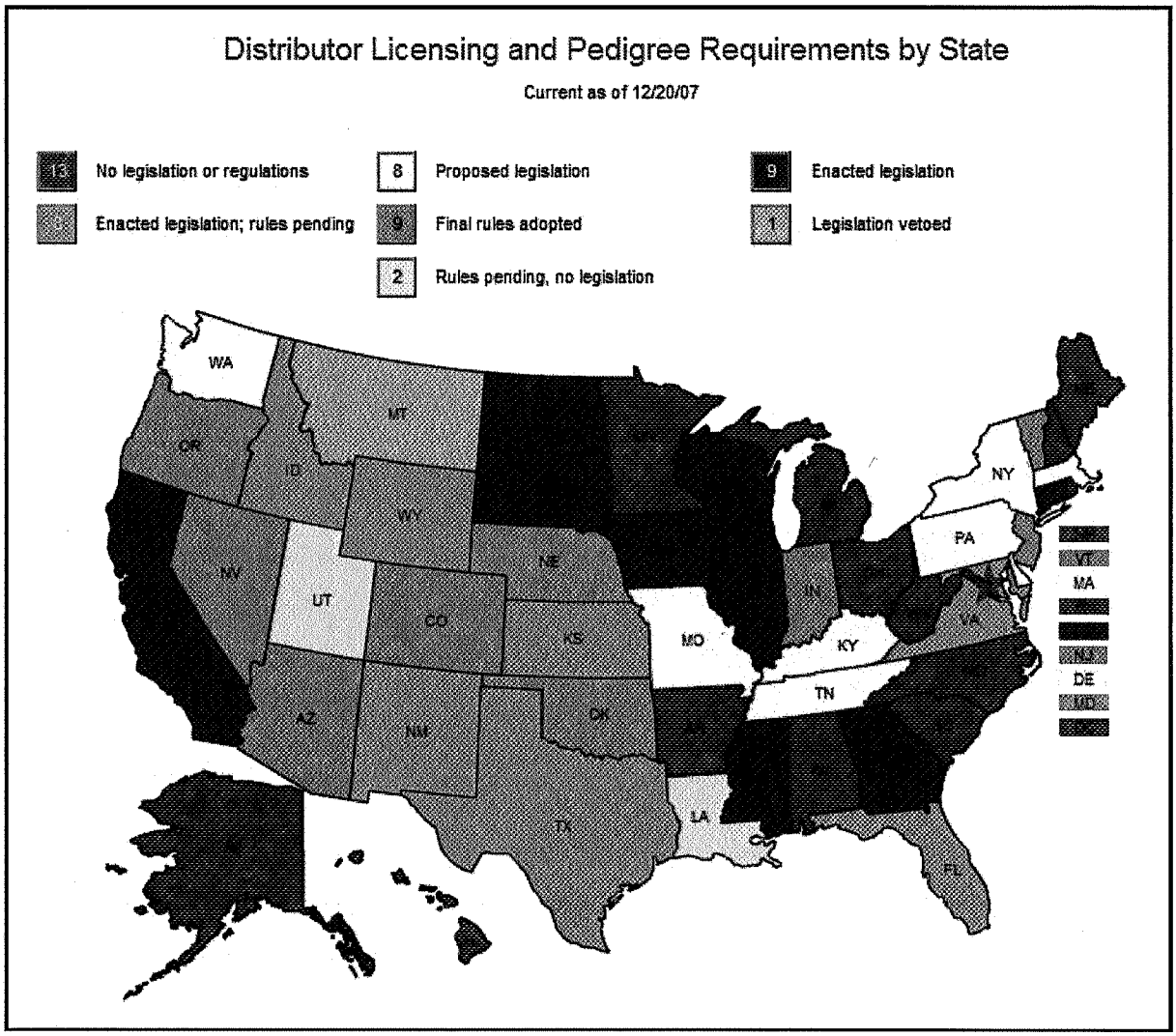

Figure 4

Arizona

In Arizona, a pedigree paper must be provided for prescription drugs that leave the "normal distribution channel."[86] The "normal distribution channel" means the chain of custody that begins with the delivery of the drug by a manufacturer to a wholesale

[86] Ariz. Rev. Stat. §32-1984 (2007).

distributor who then delivers the drug to a pharmacy or a practitioner for final receipt by a patient (end user).[87] A pedigree paper is not required, however, for intracompany transfers (between a division, subsidiary, parent or affiliated or related company under the common ownership of a person).[88]

The items that must be provided in the pedigree paper include:

- The name of the drug and the dosage form and strength;
- The size and number of containers;
- The lot number;
- The name of the manufacturer of finished dosage form;
- Name, address, and phone number of each owner of the drug;
- Name and address of each location from which the product was shipped;
- Transaction dates; and
- Certification that each recipient has authenticated the pedigree paper.[89]

California

In California, as of January 1, 2009 (unless extended by the Board to January 1, 20011) a pedigree is an electronic record of each change of ownership, from the manufacturer, to the wholesale distributor, to the final sale to a pharmacy or other person furnishing, administering, or dispensing the drug.[90] California law is significantly more stringent than any other state in that the pedigree must be originated by the manufacturer, must contain a unique identifier tracking the drug at the smallest container distributed by the manufacturer, and must be furnished for both human and animal prescription drugs. [91]

The items that must be provided in the pedigree paper include:

- The source of the dangerous drug, including the name, the federal manufacturer's registration number or a state license number and principal address of the source.
- The trade or generic name of the drug.
- The quantity of the dangerous drug and its dosage form and strength.
- The date of the transaction.
- The sales invoice number.
- The container size and number of containers.
- The expiration dates.
- The lot numbers.
- The business name, address, and the federal manufacturer's registration number or a state license number of each owner of the dangerous drug.

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[87] *Id.* at §32-1981.
[88] *Id.* at §32-1984.
[89] *Id.*
[90] Cal. Bus. & Prof. Code §4034 (2006).
[91] *Id.*

- The dangerous drug shipping information, including the name and address of each person certifying delivery or receipt of the dangerous drug.
- A certification under penalty of perjury from a responsible party of the source of the dangerous drug that the information contained in the pedigree is true and accurate.[92]

Indiana

In Indiana, a pedigree paper is a statement or record in a written or an electronic form that either:

- Records each wholesale distribution of a prescription drug from the sale by the manufacturer that leaves the normal distribution chain of custody; or
- Complies with a prescription drug pedigree law or regulation in another state or United States territory that meets the pedigree requirements under this chapter.[93]

Consequently, Indiana does not require a pedigree for distributions within the "normal distribution chain." Indiana law specifically defines which transactions are within the normal distribution chain:

- From a manufacturer to a wholesale drug distributor, to a pharmacy, and to a patient or a patient's agent;
- From a manufacturer to a wholesale drug distributor, to a chain drug warehouse, to a pharmacy affiliated with the chain drug warehouse, and to a patient or a patient's agent;
- From a manufacturer to a chain drug warehouse, to a pharmacy affiliated with the chain drug warehouse, and to a patient or a patient's agent;
- From a manufacturer to a third party logistics provider, to a wholesale drug distributor, to a pharmacy, and to a patient or a patient's agent;
- From a manufacturer to a third party logistics provider, to a wholesale drug distributor, to a chain drug warehouse, to a pharmacy affiliated with the chain drug warehouse, and to a patient or a patient's agent;
- From a manufacturer to a third party logistics provider, to a chain drug warehouse, to a pharmacy affiliated with the chain drug warehouse, and to a patient or a patient's agent; or
- As prescribed by rules adopted by the board.[94]

The items that must be provided in the pedigree paper include:

- The name of the drug and its dosage form and strength.
- The size and number of containers.
- The lot or control numbers and expiration dates.
- The name of the manufacturer of the finished drug product.

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[92] *Id.*
[93] Ind. Code §25-26-14 (2007).
[94] *Id.*

- The name, address, and telephone number of each entity involved in the chain of custody.
- The name and address of each person certifying delivery or receipt of the legend drug.
- The sales invoice number of other number unique to the shipping document;
- The dates of each transaction, including manufacturer, delivery, and receipt.
- Certification that each recipient has authenticated the pedigree paper back to the manufacturer.
- Certification from the licensed entity that the information contained on the pedigree is true.[95]

Nevada

In Nevada, a wholesale distributor who sells a prescription drug to another wholesale distributor must provide a statement of prior sales (pedigree paper) with the drug.[96] A pedigree paper is not required for the following transactions:

- Transactions between places commonly owned (100%) entities, if the common-owner is a publicly-traded corporation.[97]
- An ADR who purchased directly from the manufacturer and sells directly to an end user.[98]

The statement of prior sales is defined to mean the statement of prior sales required by the federal PDMA:

- The proprietary and established name of the drug;
- Dosage;
- The size and number of containers;
- The drug's lot or control number;
- The business name and address of all parties to each prior transaction involving the drug, starting with the manufacturer;
- The date of each previous transaction; and
- Signature of the wholesaler or his designated representative certifying the information is complete and accurate.

If the statement of prior sales indicates that more than 3 prior sales have occurred, including a sale involving an ADR, a person engaged in the wholesale distribution of prescription drugs may not sell the drug to another wholesale distributor.[99]

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[95] Ind. Admin. Code tit. 856. r.3 (2007).
[96] Nev. Admin. Code ch. 639, §603 (2007).
[97] *Id.* at §593 (2007).
[98] Nev. Rev. Stat. §639.545 (2007).
[99] *Id.* at §603 (2007).

Texas

In Texas, a pedigree paper must be provided for each prescription drug for human consumption that is not distributed through the normal distribution channel.[100] Texas law specifically defines the "normal distribution chain" as a chain of custody for a prescription drug, either directly or by drop shipment, from the manufacturer of the prescription drug, the manufacturer to the manufacturer's co-licensed product partner, the manufacturer to the manufacturer's third-party logistics provider, or the manufacturer to the manufacturer's exclusive distributor, to:

- A pharmacy to:
  - A patient; or
  - Another designated person authorized by law to dispense or administer the drug to a patient;
- An authorized distributor of record to:
  - A pharmacy to a patient; or
  - Another designated person authorized by law to dispense or administer the drug to a patient;
- An authorized distributor of record to a pharmacy warehouse to the pharmacy warehouse's intracompany pharmacy;
- A pharmacy warehouse to the pharmacy warehouse's intracompany pharmacy or another designated person authorized by law to dispense or administer the drug to a patient;
- A person authorized by law to prescribe a prescription drug that by law may be administered only under the supervision of the prescriber; or
- An authorized distributor of record to one other authorized distributor of record to a licensed practitioner for office use.[101]

The items that must be provided in the pedigree paper include:

- The name of the drug and its dosage form and strength;
- The size and number of containers;
- The lot number;
- The name of the manufacturer of the finished dosage form;
- The name, address, telephone number, and e-mail, if available, of each person who owns or possesses the drug;
- Name and address of each location from which the product shipped;
- Transaction dates; and
- Certification that each recipient of the drug has authenticated the pedigree.[102]

[100] Tex. Code §431.412 (2007).
[101] *Id.* at §431.401.
[102] *Id.* at §431.413.