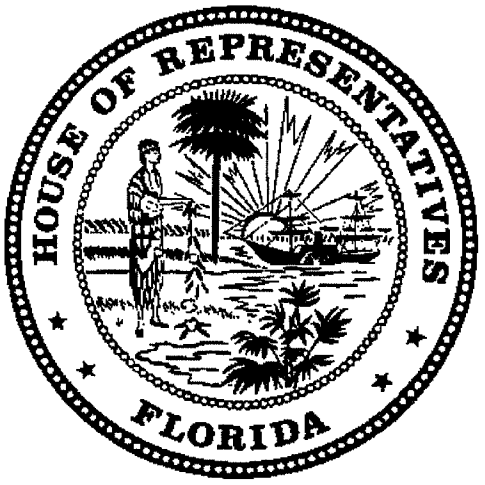

Health Care Regulation Policy Committee

Wednesday, March 25, 2009
2:30 PM – 5:00 PM
Webster Hall (212 Knott Building)

MEETING PACKET

Larry Cretul
Speaker

Jimmy Patronis
Chair

Committee Meeting Notice

HOUSE OF REPRESENTATIVES

Health Care Regulation Policy Committee

Start Date and Time: Wednesday, March 25, 2009 02:30 pm

End Date and Time: Wednesday, March 25, 2009 05:00 pm

Location: Webster Hall (212 Knott)
Duration: 2.50 hrs

Consideration of the following bill(s):

HB 33 Childhood Vaccinations by Ambler
HB 109 Clinical, Counseling, and Psychotherapy Services by Bembry
HB 285 Medicaid Low-Income Pool and Disproportionate Share Program by Patronis
HB 629 Health Care Clinics by Kreegel
HB 769 911 Emergency Dispatcher Certification by Roberson, K.
HB 873 Licensure of Health Care Providers by Williams, A.
HB 897 Controlled Substances by Llorente
HB 937 Pub. Rec./Controlled Substance Prescriptions/AHCA by Llorente
HB 1033 Emergency Cardiology Services by Renuart
HB 1097 Electronic Health Records by Grimsley
HB 1139 Nursing Licensing Fees by Roberson, Y.
HB 1343 Practice of Tattooing by Brandenburg

Presentation by SureScripts on E-Prescribing

Pursuant to Rule 7.13(a)(1) amendments from non-committee members be received by committee staff no later than Tuesday, March 24, 2009 by 6:00 pm.

NOTICE FINALIZED on 03/23/2009 16:28 by Manning.Karen

The Florida House of Representatives

Health Care Regulation Policy Committee

A G E N D A

March 25, 2009
2:30 PM - 5:00 PM
Webster Hall (212 Knott Building)

I. **Opening Remarks by Chair Patronis**

II. **Consideration of the following bill(s):**

HB 33 Childhood Vaccinations by Rep. Ambler

HB 109 Clinical, Counseling, and Psychotherapy Services by Rep. Bembry

HB 285 Medicaid Low-Income Pool and Disproportionate Share Program by Rep. Patronis

HB 629 Health Care Clinics by Rep. Kreegel

HB 769 911 Emergency Dispatcher Certification by Rep. Roberson, K.

HB 873 Licensure of Health Care Providers by Rep. Williams, A.

HB 897 Controlled Substances by Rep. Llorente

HB 937 Pub. Rec./Controlled Substance Prescriptions/AHCA by Rep. Llorente

HB 1033 Emergency Cardiology Services by Rep. Renuart

HB 1097 Electronic Health Records by Rep. Grimsley

HB 1139 Nursing Licensing Fees by Rep. Roberson, Y.

HB 1343 Practice of Tattooing by Rep. Brandenburg

III. **Presentation by SureScripts on E-Prescribing**

IV. **Closing Remarks by Chair**

V. **Adjournment**

1301 The Capitol, 402 South Monroe Street, Tallahassee, Florida 32399-1300
(850) 487-2242

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 33 Childhood Vaccinations
SPONSOR(S): Ambler
TIED BILLS: **IDEN./SIM. BILLS:** SB 308

	REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1)	Health Care Regulation Policy Committee		Akin	Calamas
2)	PreK-12 Policy Committee			
3)	Health & Family Services Policy Council			
4)	Human Services Appropriations Committee			
5)	Full Appropriations Council on General Government & Health Care			

SUMMARY ANALYSIS

House Bill 33 requires health care practitioners to disclose certain information to the parent or guardian of a minor child before administering vaccines to the minor, including:

- Vaccine ingredients and contraindications;
- Potential side effects;
- The efficacy of the vaccine;
- Risks of the disease the vaccine is designed to prevent; and
- Options for administering the vaccine, including the timing of, or combination with other vaccines

The bill prohibits administration of vaccines to minors without documentation, signed by the parent or guardian, that the information above was disclosed. The bill requires the Department of Health (DOH) to develop a standardized form to be signed by the parent or guardian and placed in the minor's medical record prior to the child attending a child care facility or a public or private school in Florida.

The bill requires health care practitioners to provide pregnant women in their 30th week of pregnancy with information on vaccinations as part of the woman's prenatal care. The bill directs DOH to create and maintain a website containing information on each childhood vaccine and the standard form for disclosure and consent required by this bill.

The bill has a significant, negative, non-recurring fiscal impact to the Department of Health, estimated at $98,135.

The bill takes effect July 1, 2009.

HOUSE PRINCIPLES

Members are encouraged to evaluate proposed legislation in light of the following guiding principles of the House of Representatives

- Balance the state budget.
- Create a legal and regulatory environment that fosters economic growth and job creation.
- Lower the tax burden on families and businesses.
- Reverse or restrain the growth of government.
- Promote public safety.
- Promote educational accountability, excellence, and choice.
- Foster respect for the family and for innocent human life.
- Protect Florida's natural beauty.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Current Situation

School-Age Vaccination Requirements

According to the Department of Health (DOH), the National Childhood Vaccine Injury Act (42 U.S.C. Section 300aa-26), requires all health care providers in the United States who administer, to any child or adult, vaccines for diphtheria, tetanus, pertussis, measles, mumps, rubella, polio, hepatitis A, hepatitis B, Haemophilus influenzae type b, trivalent influenza, pneumococcal conjugate, meningococcal, rotavirus, human papillomavirus, or varicella, shall provide a copy of the most recent and relevant edition vaccine information materials that have been produced by the Centers for Disease Control and Prevention (CDC). These vaccine information materials are entitled Vaccine Information Statements (VIS). This information is provided to parents, legal guardians or patients prior to administering any of the above-mentioned vaccines. VISs do not include detailed information regarding the vaccine ingredients as listed on the package insert or vaccine efficacy but cover the potential side effects (adverse events) of the vaccine, risks associated with the disease that the vaccination is intended to prevent, contraindications to the vaccine, and options regarding the administration of the vaccination, including the timing or combination of multiple vaccinations.[1]

Florida law requires DOH to consult with the Florida Department of Education and adopt rules governing the immunization of children against preventable communicable diseases, and requires immunizations for poliomyelitis, diphtheria, rubeola, rubella, pertussis, mumps, tetanus, and other communicable diseases as determined by those rules.[2]

DOH rules require immunizations for diphtheria, pertussis (whooping cough), tetanus, poliomyelitis, rubeola (measles), rubella, mumps, Haemophilus influenza type b, hepatitis B series, varicella (chicken pox), and certain boosters, for school entry.[3] Other childhood vaccines, although not required for school, are recommended, including: hepatitis A, meningococcal conjugate, human papillomavirus, rotavirus, pneumococcal conjucate vaccine, trivalent inactivated influenza vaccine, and live attenuated influenza

[1] Department of Health Bill Analysis, Economic Statement And Fiscal Note, House Bill 33 (2009).
[2] Fla. Stat. S. 1003.22(3)
[3] 64d-3.011, F.A.C. (2008)

vaccine.[4] Florida law requires that "the manner and frequency of administration of the immunization or testing shall conform to recognized standards of medical practice."[5]

Further, each district school board and the governing authority of each private school must establish and enforce a policy that, prior to admittance to or attendance in school, each child have a "certification of immunization for the prevention of those communicable diseases for which immunization is required by the Department of Health..."[6] These provisions together effectively require children to receive certain vaccinations, as determined by DOH, before attending school in Florida.

Florida law provides several exemptions. The school-age immunization requirements do not apply if:

- A parent objects in writing that the administration of immunizing agents conflicts with his or her religious tenets or practices;
- A physician certifies in writing that the child should be permanently exempt from the required immunization for medical reasons stated in writing, based upon valid clinical reasoning or evidence;
- A physician certifies in writing that the child has received as many immunizations as are medically indicated at the time and is in the process of completing necessary immunizations;
- DOH determines that, according to recognized standards of medical practice, the required immunization is unnecessary or hazardous; or
- An authorized school official issues a temporary exemption for up to 30 days.[7]

DOH rules establish the forms and procedures for invoking an exemption.[8]

Public Health Impact of Failure to Vaccinate or Delayed Vaccination

In highly infectious diseases, greater than 90 percent of the population needs to be vaccinated to interrupt transmission and maintain elimination of the disease in populations.[9] For example, in Switzerland, a widespread outbreak of measles occurred in 2005 despite the fact that 86 percent of the population had received one dose of the vaccine and 70 percent of the population has received two doses of the vaccine.[10]

In the United States, more than 95 percent of school-aged children have received the measles vaccine during this decade.[11] In February 2008, a measles outbreak occurred in San Diego California when an unvaccinated seven year old boy contracted the disease after traveling to Switzerland.[12] The disease spread to a documented 11 additional unvaccinated children aged 10 months to nine years, and resulted in the hospitalization of one of the 11 infected children. An additional 70 children exposed to the infection were voluntarily quarantined for 21 days after their last exposure, either because their parents declined to vaccinate them or because they were too young to be vaccinated. Of the eleven infected (unvaccinated) children, nine were old enough to be vaccinated. Eight of the nine infected children old enough to be vaccinated were unvaccinated as a result of the personal belief exemption available in California.

Because not all vaccinations are 100 percent effective in preventing a person from contracting the targeted disease, even vaccinated people are at risk when fewer than 90 percent of the population is vaccinated. In April 2006, the state of Iowa reported a large outbreak of mumps (605 reported and suspected cases) that

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[4] Centers For Disease Control, "Recommended Immunization Schedules For Persons Aged 0 Through 18 Years --- United States, 2009", Mmwr Weekly, January 2, 2009, *Available At* Http://Www.Cdc.Gov/Mmwr/Preview/Mmwrhtml/Mm5751a5.Htm?S_Cid=Mm5751a5_E (Last Viewed March 21, 2009).
[5] Fla. Stat. S. 1003.22(3)
[6] Fla. Stat. S. 1003.22(4)
[7] Fla. Stat. S. 1003.22(5)
[8] 64d-3.011, F.A.C. (2008)
[9] Centers for Disease Control, *Outbreak of Measels – San Diego California*, MMWR Weekly, February 22, 2008, *available at* http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5708a3.htm (last viewed March 24, 2009).
[10] *Id.*
[11] *Id.*
[12] Centers for Disease Control, *Outbreak of Measels – San Diego California*, MMWR Weekly, February 22, 2008, *available at* http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5708a3.htm (last viewed March 24, 2009).

began as early as December 2005.[13] The majority of cases occurred among persons aged 18-25, many of whom were vaccinated. Data from the outbreak investigations suggests that the measles, mumps, and rubella (MMR) vaccine is about 80 percent effective in preventing infection after one dose and about 90 percent effective after two doses.[14] The source of the outbreak could not be positively identified, but the mumps strain was identified as the same strain circulating in the United Kingdom (UK). An outbreak in the UK began in 2004 and involved more than 70,000 cases, occurring mostly in unvaccinated young adults.[15]

In March 2009, an outbreak of pertussis (whooping cough) occurred in Sarasota County Florida. The outbreak involved 15 cases of pertussis in a private elementary school among students, teachers, and parents.[16] On average, Sarasota County reports 6 pertussis cases *per year,* so the one-month outbreak was more than double the annual average. The cause and origin of the outbreak are presently unclear.

The public response to outbreaks typically involves identification of cases, isolation of patients and vaccination, administration of immune globulin, and voluntary quarantine of contacts who have no evidence of immunity.[17] The cost associated with control of these outbreaks can be substantial. In Iowa, the public health response to one measles case cost approximately $150,000.[18]

Express and Informed Consent

Florida law requires that "each patient be given express or informed consent before receiving treatment."[19] If the patient is a minor, express and informed consent for admission or treatment is also required from the patient's guardian. "Express and informed consent for admission or treatment of a patient under 18 years of age shall be required from the patient's guardian, unless the minor is seeking outpatient crisis intervention services."[20] Express and informed consent requires that the following information "be provided and explained in plain language to the patient...or to the patient's guardian:

- the reason for admission or treatment;
- the proposed treatment;
- the purpose of the treatment to be provided;
- *the common risks, benefits, and side effects thereof*;
- the specific dosage range for the medication, when applicable;
- *alternative treatment modalities*;
- the approximate length of care;
- *the potential effects of stopping treatment*;
- how treatment will be monitored; and
- that any consent given for treatment may be revoked orally or in writing before or during the treatment period by the patient or by a person who is legally authorized to make health care decisions on behalf of the patient."[21]

Vaccines and Autism Spectrum Disorder

Autism Spectrum Disorder (ASD)[22] is the name commonly used for pervasive developmental disorders, which include autistic disorder, Asperger's Syndrome, Rett's Syndrome[23], and childhood disintegrative

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[13] Centers for Disease Control, *Corrected: Multi State Mumps Outbreak,* April 14, 2006, *available at* http://health.state.ga.us/programs/emerprep/healthalerts/alerts/20060415.html (last viewed March 24, 2009).
[14] *Id.*
[15] *Id.*
[16] Sarasota County Government, *Local Public Health Officials Investigate Whooping Cough (Pertussis) Cases,* March 18, 2009, *available at* http://www.co.sarasota.fl.us/NewsStories/news2.asp (last viewed March 24, 2009).
[17] Centers for Disease Control, *Outbreak of Measels – San Diego California,* MMWR Weekly, February 22, 2008, *available at* http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5708a3.htm (last viewed March 24, 2009).
[18] Dayan GH, Ortega-Sanchez IR, LeBaron CW, Quinlisk MP; Iowa Measles Response Team. The cost of containing one case of measles: the economic impact on the public health infrastructure---Iowa, 2004. Pediatrics 2005;116:e1--4.
[19] Fla. Stat. S. 394.459
[20] Fla. Stat. S. 394.459
[21] Fla. Stat. S. 394.459(3)(A)(2) (Emphasis Added)

disorder.[24] A child that exhibits symptoms of Asperger's Syndrome or autistic disorder, but does not meet the criteria for either, will be diagnosed as having a pervasive developmental disorder not otherwise specified (PDD-NOS). Autism spectrum disorders are generally detected by the age of three and affect from two to six per 1,000 children. The earlier a child is diagnosed with an autism spectrum disorder, the more opportunity a child will have to learn new skills and be integrated into the community. Common characteristics shared by children with autism spectrum disorders are varying degrees of deficits in social interaction, verbal and nonverbal communication, and repetitive behaviors or interest. Many children with autism spectrum disorders have some degree of mental impairment.

Recent estimates from the Center for Disease Control and Prevention (CDC) Autism and Developmental Disabilities Monitoring network found that about one in 150 children have an ASD; this estimate is higher than estimates from the early 1990s.[25] Some believe increased exposure to preservatives in vaccines (from the addition of new vaccines recommended for children) explains the higher prevalence in recent years. Specifically, a link between the preservative mercury, contained in vaccines administered to children, and the onset of ASD has been suggested.[26] Preservatives are used in vaccines to prevent microbial growth (and infection) in the event that the vaccine is accidentally contaminated, as can occur with repeated puncture of multi-dose vials. Thimerosal, which is approximately 50 percent mercury by weight, has been one of the most widely used preservatives in vaccines since the 1930s.[27]

Several studies have been performed on the potential link between mercury and ASD, all concluding that no link exists between the thimerosal/mercury in vaccines and ASD.[28] Specifically, some have theorized that the administration of multiple vaccines containing mercury together or in a short time period, has the potential to overload the immune system of a young child, and may lead to the onset of ASD. However, evidence from several studies examining trends in vaccine use and changes in autism frequency does not support such an association.[29] Furthermore, a scientific review by the Institute of Medicine (IOM) concluded that "the evidence favors rejection of a causal relationship between thimerosal/mercury-containing vaccines and autism."[30] CDC supports the IOM conclusion.[31] In July 1999, the Public Health Service agencies, the American Academy of Pediatrics, and vaccine manufacturers agreed that thimerosal/mercury should be reduced or eliminated in vaccines as a precautionary measure. Since 2001, with the exception of some influenza (flu) vaccines, thimerosal/mercury is not used as a preservative in routinely recommended

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[22] Information For This Section Was Obtained From The National Institute Of Mental Health, "Autism Spectrum Disorders, Pervasive Developmental Disorders", U.S. Department Of Health And Human Services, With Addendum January 2007 (Citations Omitted); *Available At* : Http://Www.Nimh.Nih.Gov/Health/Publications/Autism/Nimhautismspectrum.Pdf (Last Viewed March 21, 2009).

[23] Rett Syndrome Is Linked Almost Exclusively To Females, Affecting One Out Of 10,000 To 15,000 Females. It Is Typically Diagnosed At Some Time Between A 6 And 18 Months When Autism-Like Symptoms Begin To Develop.

[24] Childhood Degenerative Disorder Is A Very Rare Autism Spectrum Disorder With A Strong Male Preponderance. Symptoms Typically Onset Between The Ages Of Three And Four Years, And May Result In The Loss Of Motor, Language And Social Skills, As Well As Bladder And Bowel Control.

[25] *Id.*

[26] A Series Of Articles In The Lancet First Posed This Theory. However, The Suggestion Of A Link Between Certain Vaccines And Autism Was Retracted By Ten Of The Thirteen Authors Of That Study In 2004. See, Wakefield Aj, Murch Sh, Anthony A, Linnell J, Casson Dm, Malik M, Berelowitz M, Dhillon Ap, Thomson Ma, Harvey P, Valentine A, Davies Se, And Walker-Smith Ja. (1998). Ileal-Lymphoid-Modular Hyperplasia, Non-Specific Colitis, And Pervasive Developmental Disorder In Children. Lancet, 351(9103), 637-641; Murch Sh, Anthony A, Cassen Dh, Et Al. (2004) Retraction Of An Interpretation. *Lancet*, 363: 750, *Available At* Http://Www.Thelancet.Com/Journals/Lancet/Article/Piis0140-6736(04)15715-2/Fulltext (Last Viewed March 21, 2009).

[27] The Information Contained In This Section Was Gathered From The United States Food And Drug Administration's Report On Thimerosal In Vaccines Found At Http://Www.Fda.Gov/Cber/Vaccine/Thimerosal.Htm And The Center For Disease Control Report *Available At* Http://Www.Cdc.Gov/Vaccinesafety/Concerns/Thimerosal.Htm.

[28] *See* Institute Of Medicine, *Immunization Safety Review: Vaccines And Autism*, Washington, Dc: National Academies Press 2004, *Available At* Http://Www.Nap.Edu/Catalog.Php?Record_Id=10997 (Last Viewed March 21, 2009), Reported In, Anne Ziegler, *Mercury In Vaccines Doesn't Hurt Kids*, January 27, 2009, *Available At* Http://Www.Fiercehealthcare.Com/Story/Study-Mercury-Vaccines-Doesnt-Hurt-Kids/2009-01-27?Utm_Medium=Rss&Utm_Source=Rss&Cmp-Id=Otc-Rss-Fh0#Comments.

[29] *See* Anne Ziegler, *Mercury In Vaccines Doesn't Hurt Kids*, January 27, 2009, *Available At* Http://Www.Fiercehealthcare.Com/Story/Study-Mercury-Vaccines-Doesnt-Hurt-Kids/2009-01-27?Utm_Medium=Rss&Utm_Source=Rss&Cmp-Id=Otc-Rss-Fh0#Comments And Institute Of Medicine, *Immunization Safety Review: Vaccines And Autism*, Washington, Dc: National Academies Press 2004.

[30] Id. At Supra, Note 16.

[31] Centers For Disease Control And Prevention, Mercury And Vaccines (Thimerosal), *Available At* Http://Www.Cdc.Gov/Vaccinesafety/Concerns/Thimerosal.Htm (Last Viewed March 21, 2009).

childhood vaccines.[32] Autism awareness groups maintain that there is a causal link between the mercury levels present in childhood vaccines and ASD.

The amount of litigation surrounding the debate over mercury in vaccines, and its alleged link to autism and other neurological defects in children has increased in recent years. Parents of autistic children across the United States have begun filing lawsuits alleging that vaccine manufacturers should have been more thorough in testing the preservative thimerosal, and should have warned parents of potential risks. In other cases, plaintiffs have alleged that the manufacturers knew of the potential harmful effects of thimerosal/mercury in vaccines and took no action to warn the public or mitigate the harm. Some courts have dismissed these claims on summary judgment in favor of the manufacturers, while other courts have allowed the claims to go forward with mixed results. [33]

Most recently, three families sought compensation from the National Vaccine Injury Compensation Program[34], alleging that vaccinations led to their children's neuro-developmental conditions. The United States Court of Federal Claims denied the claims, concluding there was no causal link between the vaccines and the injuries.[35] The Court found that "the numerous medical studies concerning these issues, performed by medical scientists worldwide, have come down strongly against the [parent's] contentions."[36] A total of 5,564 autism-related petitions have been filed with the Program since 1989; none led to compensation.[37]

In March 2008, Governor Charlie Crist created the Task Force on Autism Spectrum Disorders (Task Force).[38] The Task Force, which is administratively housed at DOH, is charged with exploring options for health coverage of autism treatments and assessing the economic impact of autism on families and the state. In addition, the 21-member Task Force is to work to coordinate and review the efforts of state agencies and organizations, encourage public-private partnerships, develop a comprehensive Florida autism website, and develop a strategy for early diagnosis and intervention. The Task Force will present a report to the Governor on March 20, 2009.

B. EFFECT OF PROPOSED CHANGES:

House Bill 33 requires health care practitioners to disclose certain information to the parent or guardian of a minor child before administering vaccines to the minor, including:

- Vaccine ingredients and contraindications
- Potential side-effects
- The efficacy of the vaccine
- Risks of the disease the vaccine is designed to prevent
- Options for administering the vaccine, including the timing of, or combination with other vaccines

The bill prohibits administration of vaccines to minors without documentation of the information disclosed above signed by the parent or guardian. The bill requires DOH to develop a standardized form to be signed by the parent or guardian and placed in the minor's medical record prior to the child attending a

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[32] *Id.* At *Supra*, Note 16.

[33] *See American Home Products Corp. V. Ferrari,* 668 S.E.2d 236 (Ga. 2008), *Aventis Pasteur, Inc. V. Skevofilax*, 914 A.2d 113 (Md. 2007), *In Re Vaccine Cases* 134 Cal. App. 4th 438, 36 Cal.Rptr.3d 80.

[34] The National Vaccine Injury Compensation Program Was Created By The National Childhood Vaccine Injury Act Of 1986 (Public Law 99-660) As A No-Fault Alternative To Traditional Tort Litigation Related To Vaccine Injuries. It Is Administered By U.S. Department Of Health And Human Services, Health Resources And Services Administration (Hrsa), And Cases Are Decided By The U.S. Court Of Federal Claims. Additional Information Is Available At The Hrsa Website: Http://Www.Hrsa.Gov/Vaccinecompensation/.

[35] *See Cedillo V. Sec'y Of U.S. Dept. Of Health And Human Svcs.*, No. 98-916v, 2009 Wl 331968 (Fed.Cl.) (Feb. 12, 2009); *Hazlehurst V. Sec'y Of U.S. Dept. Of Health And Human Svcs.*, No. 03-654v, 2009 Wl 332258 (Fed.Cl.) (Feb. 12, 2009); *Snyder V. Sec'y Of U.S. Dept. Of Health And Human Svcs.*, No. 01-162v, 2009 Wl 332044 (Fed.Cl.) (Feb. 12, 2009); Avery Johnson, *U.S. Court Rejects Vaccine Connection To Autism*, February 12, 2009, *Available At* Http://Online.Wsj.Com/Article/Sb123445313976177691.Html.

[36] *Cedillo* At 1.

[37] National Vaccine Injury Compensation Program, Statistics Report, March 6, 2009, *Available At* Http://Www.Hrsa.Gov/Vaccinecompensation/Statistics_Report.Htm (Last Viewed March 21, 2009).

[38] See Executive Order 08-36.

child care facility or a public or private school in Florida. The bill appears to apply to *all* vaccines administered to minors, not just those required for school attendance.

The bill requires health care practitioners that provide prenatal care to provide pregnant women in their 30th week of pregnancy with information on vaccinations. The bill directs DOH to create and maintain a website containing information on each childhood vaccine and the standard form for disclosure and consent required by this bill.

The effect of this bill should be increased awareness of the potential risks regarding administering vaccines to children. Health care practitioners may incur additional workloads by requiring them to provide this information regarding vaccinations to children and pregnant women under certain circumstances. According to DOH, the bill may create potential public health concerns as some parents may delay vaccinating children, which increase a child's chances of contracting a vaccine-preventable disease.

C. SECTION DIRECTORY:

Section 1: Unnumbered section of law requiring certain disclosures by health care practitioners related to vaccines and minors, creation of a standardized form, and provision of certain vaccine-related information on the DOH website.

Section 2: Providing an effective date of July 1, 2009.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   See Fiscal Comments.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None identified.

D. FISCAL COMMENTS:

The DOH immunization registry is an electronic reporting system. In order to incorporate the standardized form required in the bill into Florida's electronic immunization registry, modifications to the system will be required. The costs for accomplishing this are estimated at $98,135, which will be first year, non-recurring costs.

Estimated Expenditures		1st Year Non-recurring
Salaries		0
Other Personal Services		0
Expense	**Total Hours**	
Program Management (85/hr)	60	$5,100
Subject Matter Expert (2@ 55/hr)	100	$5,500
User Groups (average 10 resources @ 45/hr) 6 2hr meetings	120	$5,400
Project Management (85/hr)	120	$10,200
Reporting	30	
Project Documentation	30	
Comm Coord Scheduling Assessment	60	
Business Analysis (85/hr)	135	$11,475
Research	35	
Requirements Gathering	60	
Documentation/Use Case	40	
Development (130/hr)	155	$20,150
Meetings/Coordination	35	
Programming	120	
Testing (2 x 100/hr)	160	$16,000
Test Cases	80	
Test scripts	80	
Integration Test (2x100/hr)	80	$8,000
Release Packaging (130/hr)	25	$3,250
All Other Assignments /alterations/Reviews (average 100/hr)	25	$2,500
User Acceptance Testing (3x55/hr)	180	$9,900
Promotion to Production (2x55/hr)	12	$660
Total Estimated Expenditures		$98,135

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   This bill does not appear to require counties or municipalities to take an action requiring the expenditure of funds, reduce the authority that counties or municipalities have to raise revenue in the aggregate, nor reduce the percentage of state tax shared with counties or municipalities.

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

The Department of Health will be required to create a standardized form for use by practitioners to document disclosures required by the bill. The bill does not provide rulemaking authority to DOH. Sufficient rulemaking authority is found in s. 1003.22; however, the bill is not placed in any section of Florida Statutes, so that authority may not be applicable to the content of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

House Bill 33 does not amend any section of the Florida Statutes, nor does it create a new section within the Florida Statutes.

IV. AMENDMENTS/COUNCIL OR COMMITTEE SUBSTITUTE CHANGES

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. (for drafter's use only)

Bill No. **33**

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: Health Regulation Policy Committee

Representative(s) Ambler offered the following:

Amendment (with title amendment)

Remove everything after the enacting clause and insert:

Section 1. Section 1003.22, Florida Statutes, is amended to read:

1003.22 School-entry health examinations; immunization against communicable diseases; exemptions; duties of Department of Health.--

(1) Each district school board and the governing authority of each private school shall require that each child who is entitled to admittance to kindergarten, or is entitled to any other initial entrance into a public or private school in this state, present a certification of a school-entry health examination performed within 1 year prior to enrollment in school. Each district school board, and the governing authority of each private school, may establish a policy that permits a student up to 30 school days to present a certification of a school-entry health examination. A homeless child, as defined in s. 1003.01, shall be given a temporary exemption for 30 school

days. Any district school board that establishes such a policy shall include provisions in its local school health services plan to assist students in obtaining the health examinations. However, any child shall be exempt from the requirement of a health examination upon written request of the parent of the child stating objections to the examination on religious grounds.

(2) The State Board of Education, subject to the concurrence of the Department of Health, shall adopt rules to govern medical examinations and immunizations performed under this section.

(3) The Department of Health may adopt rules necessary to administer and enforce this section. The Department of Health, after consultation with the Department of Education, shall adopt rules governing the immunization of children against, the testing for, and the control of preventable communicable diseases. The rules must include procedures for exempting a child from immunization requirements. Immunizations shall be required for poliomyelitis, diphtheria, rubeola, rubella, pertussis, mumps, tetanus, and other communicable diseases as determined by rules of the Department of Health. The manner and frequency of administration of the immunization or testing shall conform to recognized standards of medical practice. The Department of Health shall supervise and secure the enforcement of the required immunization. Immunizations required by this section shall be available at no cost from the county health departments.

(4) Each district school board and the governing authority of each private school shall establish and enforce as policy that, prior to admittance to or attendance in a public or private school, grades kindergarten through 12, or any other

initial entrance into a Florida public or private school, each child present or have on file with the school a certification of immunization for the prevention of those communicable diseases for which immunization is required by the Department of Health and further shall provide for appropriate screening of its students for scoliosis at the proper age. Such certification shall be made on forms approved and provided by the Department of Health and shall become a part of each student's permanent record, to be transferred when the student transfers, is promoted, or changes schools. The transfer of such immunization certification by Florida public schools shall be accomplished using the Florida Automated System for Transferring Education Records and shall be deemed to meet the requirements of this section.

(5) The provisions of this section shall not apply if:

(a) The parent of the child objects in writing that the administration of immunizing agents conflicts with his or her religious tenets or practices;

(b) A physician licensed under the provisions of chapter 458 or chapter 459 certifies in writing, on a form approved and provided by the Department of Health, that the child should be permanently exempt from the required immunization for medical reasons stated in writing, based upon valid clinical reasoning or evidence, demonstrating the need for the permanent exemption;

(c) A physician licensed under the provisions of chapter 458, chapter 459, or chapter 460 certifies in writing, on a form approved and provided by the Department of Health, that the child has received as many immunizations as are medically indicated at the time and is in the process of completing necessary immunizations;

(d) The Department of Health determines that, according to recognized standards of medical practice, any required immunization is unnecessary or hazardous; or

(e) An authorized school official issues a temporary exemption, for a period not to exceed 30 school days, to permit a student who transfers into a new county to attend class until his or her records can be obtained. A homeless child, as defined in s. 1003.01, shall be given a temporary exemption for 30 school days. The public school health nurse or authorized private school official is responsible for followup of each such student until proper documentation or immunizations are obtained. An exemption for 30 days may be issued for a student who enters a juvenile justice program to permit the student to attend class until his or her records can be obtained or until the immunizations can be obtained. An authorized juvenile justice official is responsible for followup of each student who enters a juvenile justice program until proper documentation or immunizations are obtained.

(6) Prior to the administration of an immunization required by this section, a licensed health care provider must:

(a) Provide the child's parent, legal guardian, or other legal representative with a copy of the current vaccine information statement published about the vaccine by the Centers for Disease Control and Prevention of the United States Department of Health and Human Services;

(b) Have the child's parent, legal guardian, or other legal representative sign a statement in substantially the following form:

I have received a copy of the vaccine information statement published by the Centers for Disease Control and

Prevention. I have read or have had explained to me information about the vaccine to be administered, the benefits and risks of the vaccine, how to report an adverse reaction, the availability of the National Vaccine Injury Compensation Program, and how to get more information about childhood diseases and vaccines. I understand the benefits of the vaccine and ask that the vaccine be administered to ...(name of minor child)..., for whom I am authorized to make this request.

Signature: ...(signature)....

Name: ...(printed name of parent, legal guardian, or other legal representative)....

Date: ...(date)....

(c) Keep a copy of the parent's, legal guardian's, or legal representative's signed statement as part of the minor child's permanent medical record; and

(d) Record a notation on the statement of the batch and lot number for each vaccine administered to the child.

This section applies to each vaccine information statement published by the Centers for Disease Control and Prevention, whether or not the statement is covered by the federal National Childhood Vaccine Injury Act of 1986, 42 U.S.C. s. 300aa-26. If the Centers for Disease Control and Prevention publish a vaccine information statement that covers multiple vaccines, the health care provider may have the child's parent, legal guardian, or other legal representative sign a single statement for the vaccines covered by the vaccine information statement.

(7~~6~~)(a) No person licensed by this state as a physician or nurse shall be liable for any injury caused by his or her action or failure to act in the administration of a vaccine or other

immunizing agent pursuant to the provisions of this section if the person acts as a reasonably prudent person with similar professional training would have acted under the same or similar circumstances.

(b) No member of a district school board, or any of its employees, or member of a governing board of a private school, or any of its employees, shall be liable for any injury caused by the administration of a vaccine to any student who is required to be so immunized or for a failure to diagnose scoliosis pursuant to the provisions of this section.

(8~~7~~) The parents of any child admitted to or in attendance at a Florida public or private school, grades prekindergarten through 12, are responsible for assuring that the child is in compliance with the provisions of this section.

(9~~8~~) Each public school, including public kindergarten, and each private school, including private kindergarten, shall be required to provide to the county health department director or administrator annual reports of compliance with the provisions of this section. Reports shall be completed on forms provided by the Department of Health for each kindergarten, and other grade as specified; and the reports shall include the status of children who were admitted at the beginning of the school year. After consultation with the Department of Education, the Department of Health shall establish by administrative rule the dates for submission of these reports, the grades for which the reports shall be required, and the forms to be used.

(10~~9~~) The presence of any of the communicable diseases for which immunization is required by the Department of Health in a Florida public or private school shall permit the county health department director or administrator or the State Health Officer

to declare a communicable disease emergency. The declaration of such emergency shall mandate that all students in attendance in the school who are not in compliance with the provisions of this section be identified by the district school board or by the governing authority of the private school; and the school health and immunization records of such children shall be made available to the county health department director or administrator. Those children identified as not being immunized against the disease for which the emergency has been declared shall be temporarily excluded from school by the district school board, or the governing authority of the private school, until such time as is specified by the county health department director or administrator.

(11~~10~~) Each district school board and the governing authority of each private school shall:

(a) Refuse admittance to any child otherwise entitled to admittance to kindergarten, or any other initial entrance into a Florida public or private school, who is not in compliance with the provisions of subsection (4).

(b) Temporarily exclude from attendance any student who is not in compliance with the provisions of subsection (4).

(12~~11~~) The provisions of this section do not apply to those persons admitted to or attending adult education classes unless the adult students are under 21 years of age.

Section 2. This act shall take effect July 1, 2009.

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

Remove the entire title and insert:

Amendment No. (for drafter's use only)

An act relating to childhood vaccinations; amending s. 1003.22, F.S.; requiring health care providers to provide certain information to parents, guardians and legal representatives before administration of certain immunizations to children; requiring health care providers to obtain a signed statement from the parents, guardians and legal representatives documenting provision of the information; requiring health care providers to use a standard form for the signed statement; requiring health care providers to record the batch and lot number of each vaccine on the statement; requiring health care providers to maintain certain records; providing for a single signed statement for the administration of multiple vaccines; providing an effective date.

A bill to be entitled

An act relating to childhood vaccinations; requiring that health care providers disclose information about childhood vaccinations to a minor's parent or legal guardian before vaccinating the minor; requiring the Department of Health to develop a standardized form; prohibiting a health care provider from administering a vaccination to a minor until after the minor's parent or guardian signs the form; requiring that the parent or legal guardian sign the form within a certain time; requiring certain health care providers to provide information about childhood vaccines to patients who are pregnant; requiring the department to create and maintain a website; providing an effective date.

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

Section 1. (1) Before vaccinating a minor, a health care provider who is licensed in this state and who, as a part of his or her scope of practice, administers childhood vaccinations shall consult with and disclose to the parent or legal guardian of the minor information about any childhood vaccinations that may be administered, including, but not limited to:

(a) Information contained in the vaccine package insert that details the vaccine ingredients and contraindications.

(b) Potential side effects of the vaccine.

(c) The efficacy of the vaccine.

(d) Risks associated with the disease that the vaccination is intended to prevent.

(e) Options that are available with regard to the administration of the vaccination, including the timing or combination of multiple vaccinations.

(2) The Department of Health shall develop and provide to each health care provider who is licensed in this state and who, as a part of his or her scope of practice, administers childhood vaccinations a standardized form indicating that the health care provider has fulfilled the requirements in subsection (1). The form shall be kept with the minor's permanent medical record. The health care provider may not vaccinate a minor until after the minor's parent or legal guardian signs the standardized form. The parent or legal guardian of a minor shall sign and date the standardized form:

(a) Immediately after the consultation; or

(b) At any time after the consultation when the parent or guardian believes that he or she is adequately informed about the vaccinations, but before the child is admitted to a licensed child care facility in this state or enrolled in prekindergarten through grade 12 of a public or private school in this state.

(3) A health care provider who is licensed in this state and who, as a part of his or her scope of practice, renders prenatal care to pregnant women shall provide information about childhood vaccines to each patient who is in her 30th week of pregnancy.

(4) The Department of Health shall create and maintain a website that contains information regarding each childhood

vaccination and the standardized form described in subsection (2).

Section 2. This act shall take effect July 1, 2009.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 109 Clinical, Counseling, and Psychotherapy Services
SPONSOR(S): Bembry
TIED BILLS: None **IDEN./SIM. BILLS:** SB 498

	REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1)	Civil Justice & Courts Policy Committee	6 Y, 0 N	Bond	De La Paz
2)	Criminal & Civil Justice Policy Council	12 Y, 0 N	Bond	Havlicak
3)	Health Care Regulation Policy Committee		Ciccone JC	Calamas
4)	Health & Family Services Policy Council			
5)	Policy Council			

SUMMARY ANALYSIS

Under current law, a licensed or certified clinical social worker, marriage and family therapist, or mental health counselor may, but is not required to, disclose confidential communications with their patient or client when the patient or client has threatened physical harm against another person.

This bill provides that a licensed or certified clinical social worker, marriage and family therapist, or mental health counselor who elects to notify a potential victim or law enforcement of a threat of physical harm that has been made by a patient or client may not be sued in civil court by such patient or client for having disclosed the confidential communication wherein the threat was made.

This bill does not appear to have a fiscal impact on state or local government.

The bill provides an effective date of July 1, 2009.

HOUSE PRINCIPLES

Members are encouraged to evaluate proposed legislation in light of the following guiding principles of the House of Representatives

- Balance the state budget.
- Create a legal and regulatory environment that fosters economic growth and job creation.
- Lower the tax burden on families and businesses.
- Reverse or restrain the growth of government.
- Promote public safety.
- Promote educational accountability, excellence, and choice.
- Foster respect for the family and for innocent human life.
- Protect Florida's natural beauty.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Chapter 491, F.S., regulates the medical practices of persons who are not psychiatrists and who are providing clinical, counseling and psychotherapy services. Regulation is through the Board of Clinical Social Work, Marriage and Family Therapy, and Mental Health Counseling. The board is housed in the Department of Health. Regulated professions included clinical social work, marriage and family therapy, and mental health counseling.

Like other healthcare professions, communications between patients or clients and the practitioner are generally confidential. The legislative intent for the chapter speaks, in part, to the issue of confidentiality:

> The Legislature finds that as society becomes increasingly complex, emotional survival is equal in importance to physical survival. Therefore, in order to preserve the health, safety, and welfare of the public, the Legislature must provide privileged communication for members of the public or those acting on their behalf to encourage needed or desired counseling, clinical and psychotherapy services, or certain other services of a psychological nature to be sought out.[1]

Section 491.0147, F.S., provides that "[a]ny communication between any person licensed or certified under this chapter and her or his patient or client shall be confidential." The section then provides three exceptions: where the patient is suing the licensed person, if the patient consents to disclosure, and where there is possibility of physical harm to another. The third exception is the only one affected by this bill. A licensed person who discloses confidential communications, other than those within one of the exceptions, is subject to professional discipline.[2]

Specifically, subsection (3) of s. 491.0147, F.S., provides that communications between a patient or client and a person licensed or certified under ch. 491, F.S., may be disclosed by the licensed person to others when there is a clear and immediate probability of physical harm to the patient or client, to other individuals, or to society and the person licensed or certified under this chapter communicates the

[1] Section 491.002, F.S.

[2] Section 491.009(1)(u), F.S., provides for discipline of a licensed person for "[f]ailure of the licensee, registered intern, or certificateholder to maintain in confidence a communication made by a patient or client in the context of such services, except as provided in s. 491.0147."

information only to the potential victim, appropriate family member, or law enforcement or other appropriate authorities.

A decision to waive the confidentiality under s. 491.0147, F.S., is made by the licensed or certified person, not the patient or client. The waiver of confidentiality is permissive in nature, not mandatory. A licensed or certified person who decides not to waive the confidentiality may not be sued by an individual who is harmed when the client or patient follows through with the threat,[3] but a licensed or certified person who discloses confidential information about a client or patient without statutory authority may be sued for emotional distress.[4] The effect of these court decisions is that a licensed or certified person may avoid being sued by never disclosing threats of harm to an innocent third party, but risks suit when warning victims or notifying law enforcement of such threats.

Psychiatrists, who similarly treat persons with mental disorders and who face the same dilemma regarding when to disclose a threat of harm to the victim or law enforcement, are statutorily protected from suit when disclosing a threat to the potential victim or to law enforcement.[5]

Effect of Bill

This bill amends s. 491.0147, F.S., to provide that a licensed or certified clinical social worker, marriage and family therapist, or mental health counselor who elects to notify a potential victim or law enforcement of a threat of physical harm that has been made by a patient or client may not be sued in civil court by such patient or client for having disclosed the confidential communication wherein the threat was made.

B. SECTION DIRECTORY:

Section 1 amends s. 491.0147, F.S., regarding confidential and privileged communications.

Section 2 provides an effective date of July 1, 2009.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

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[3] *Green v. Ross*, 691 So.2d 542 (Fla. 2nd DCA 1997) (finding no duty to warn).
[4] *Gracey v. Eaker*, 837 So.2d 348 (Fla. 2002).
[5] Section 455.059, F.S., which provides in part: "No civil or criminal action shall be instituted, and there shall be no liability on account of disclosure of otherwise confidential communications by a psychiatrist in disclosing a threat pursuant to this section."

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill does not appear to require counties or municipalities to take an action requiring the expenditure of funds, reduce the authority that counties or municipalities have to raise revenue in the aggregate, nor reduce the percentage of state tax shared with counties or municipalities.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COUNCIL OR COMMITTEE SUBSTITUTE CHANGES

None.

A bill to be entitled

An act relating to clinical, counseling, and psychotherapy services; amending s. 491.0147, F.S.; providing for a waiver of confidentiality and privileged communications when, in the clinical judgment of a person licensed or certified under chapter 491, F.S., there is a clear and immediate probability of certain harm; providing immunity from liability for, and prohibiting causes of action against, such person for disclosure of otherwise confidential communications under such circumstances; providing an effective date.

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

Section 1. Subsection (3) of section 491.0147, Florida Statutes, is amended to read:

491.0147 Confidentiality and privileged communications.--Any communication between any person licensed or certified under this chapter and her or his patient or client shall be confidential. This secrecy may be waived under the following conditions:

(3) When, in the clinical judgment of the person licensed or certified under this chapter, there is a clear and immediate probability of physical harm to the patient or client, to other individuals, or to society and the person licensed or certified under this chapter communicates the information only to the potential victim, appropriate family member, or law enforcement or other appropriate authorities. There shall be no liability on

the part of, and no cause of action of any nature shall arise against, a person licensed or certified under this chapter for the disclosure of otherwise confidential communications under this subsection.

Section 2. This act shall take effect July 1, 2009.

HB 285

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 285 Medicaid Low-Income Pool and Disproportionate Share Program
SPONSOR(S): Patronis and others
TIED BILLS: **IDEN./SIM. BILLS:**

	REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1)	Health Care Regulation Policy Committee		Calamas	Calamas
2)	Health & Family Services Policy Council			
3)	Health Care Appropriations Committee			
4)	Full Appropriations Council on General Government & Health Care			
5)				

SUMMARY ANALYSIS

Section 409.911(9), F.S., establishes the Low Income Pool (LIP) Council, for the purpose of making recommendations to AHCA and the Legislature regarding the financing and distribution of LIP and disproportionate share (DSH) funds.

The bill eliminates the requirement for AHCA to establish a LIP Council, and deletes the Council's membership requirements and duties. The bill requires AHCA to make recommendations to the Legislature on the financing and distribution of the LIP and DSH funds, add provides criteria for forming those recommendations.

The bill requires AHCA to submit its recommendations to the Governor, the Speaker and the Senate President no later than February 1 of each year.

The bill has a significant negative impact on the Agency for Health Care Administration. See Fiscal Analysis.

The effective date of the bill is July 1, 2009.

HOUSE PRINCIPLES

Members are encouraged to evaluate proposed legislation in light of the following guiding principles of the House of Representatives

- Balance the state budget.
- Create a legal and regulatory environment that fosters economic growth and job creation.
- Lower the tax burden on families and businesses.
- Reverse or restrain the growth of government.
- Promote public safety.
- Promote educational accountability, excellence, and choice.
- Foster respect for the family and for innocent human life.
- Protect Florida's natural beauty.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Medicaid and Medicaid Supplemental Payments

Medicaid is a partnership of the federal and state governments established to provide coverage for health services for eligible persons. The program is administered by the Agency for Health Care Administration and financed by federal and state funds.[1] Local funds are also used as part of the state match requirement. County governments are required to pay a share of costs for nursing home services and limited inpatient care. Some counties voluntarily participate in a transfer of additional governmental funds in order to finance certain supplemental Medicaid payments. Key characteristics of Florida's Medicaid program may be summarized as follows:

- 2.3 million eligibles.
- $15.7 billion estimated spending in Fiscal Year 2008-09.
- Federal-state matching program – 55.40 percent federal share; and 44.60 percent state share.
- Florida will spend approximately $6,709 per eligible in Fiscal Year 2008-2009.
- 45 percent of all Medicaid expenditures cover:
  - Hospitals;
  - Nursing homes;
  - Intermediate Care Facilities for the Developmentally Disabled (ICF/DDs); and,
  - Low Income Pool and Disproportionate Share supplemental payments.

Supplemental Medicaid payments to providers are intended to ensure access to hospital inpatient and specialty care for Medicaid recipients and access to primary care and safety-net hospitals for the uninsured. Similar to other Medicaid expenditures, the Low Income Pool (LIP) and Disproportionate Share (DSH) programs are financed by federal and state funds. The source of the state match for LIP and DSH is primarily from voluntary contributions of counties and local taxing districts through intergovernmental transfers (IGTs), the process of transferring public funds between government entities.

The DSH payments are directed toward hospitals serving a disproportionate share of low-income individuals who either are part of the Medicaid program or are uninsured. Under federal Medicaid law,

[1] Sections 409.901(2) and (14), F.S. The Medicaid DME and medical supplies program is authorized by Title XIX of the Social Security Act and 42 C.F.R. Part 440.70. The program was implemented through ch. 409, F.S., and Chapter 59G, F.A.C.

each state receives an annual DSH allotment. Florida's federal DSH allotment for FY 2008-2009 is $188,384,000. The Florida DSH programs are codified in law in ss. 409.911 – 409.9119, F.S.

Prior to Medicaid Reform, Florida provided supplemental payments to hospitals under the federal Upper Payment Limit (UPL) regulations. These regulations place a ceiling on the maximum amount of payments that can be made to Medicaid providers. Since Florida reimbursement levels are significantly below the federally-defined maximums, the regulations allowed enhancements to the normal reimbursement programs. These enhanced payments were financed through voluntary IGTs. Recommendations for distribution of funds available under the UPL were developed by the DSH Council, the precursor to the LIP Council.

Low-Income Pool and Low-Income Pool Council

During the 2005 Legislative Session, the Legislature authorized AHCA to apply for a Medicaid reform waiver[2] contingent on the ability of the state to maintain supplemental payments to hospitals. This contingency was met by the waiver terms and conditions authorizing creation of a Low Income Pool to "provide direct payment and distributions to safety net providers in the state for the purpose of providing coverage to the uninsured".[3] This change in format for supplemental provider payments was accompanied by a significant increase in the federally-approved level of this type of supplemental spending. The federal waiver sets a capped annual allotment of $1 billion for each year of the 5-year demonstration period for the LIP.[4] The LIP program also authorized supplemental Medicaid payments to provider access systems, such as federally qualified health centers, county health departments, and hospital primary care programs, to cover the cost of providing services to Medicaid recipients, the uninsured and the underinsured.

The waiver and the LIP expire in 2011, unless renewed.

Florida law provides that distribution of the Low-Income Pool funds should:[5]

- Assure a broad and fair distribution of available funds based on the access provided by Medicaid participating hospitals, regardless of their ownership status, through their delivery of inpatient or outpatient care for Medicaid beneficiaries and uninsured and underinsured individuals;
- Assure accessible emergency inpatient and outpatient care for Medicaid beneficiaries and uninsured and underinsured individuals;
- Enhance primary, preventive, and other ambulatory care coverages for uninsured individuals;
- Promote teaching and specialty hospital programs;
- Promote the stability and viability of statutorily defined rural hospitals and hospitals that serve as sole community hospitals;
- Recognize the extent of hospital uncompensated care costs;
- Maintain and enhance essential community hospital care;
- Maintain incentives for local governmental entities to contribute to the cost of uncompensated care;
- Promote measures to avoid preventable hospitalizations;
- Account for hospital efficiency; and
- Contribute to a community's overall health system.

Section 409.911(9), F.S., required AHCA to establish a LIP Council for the purpose of providing advice and making recommendations to AHCA, for distribution of the LIP funds each year. The LIP Council reports its

[2] Implementation of the Medicaid reform waiver was authorized in HB 3-B during the 2005 B Special Legislative Session. Currently, the waiver is operational in Broward, Duval, Baker, Clay and Nassau Counties.

[3] Application for 1115 Research and Demonstration Waiver, August 30, 2005, approved by CMS as updated on October 19, 2005, at 5.

[4] Centers For Medicare & Medicaid Services Special Terms and Conditions, Section 1115 Demonstration Waiver No. 11-W-00206/4, Florida Agency for Health Care Administration, at 24.

[5] Section 409.91211(c), F.S.

findings and recommendations to the Legislature and the Governor by February 1 of each year.[6] Specifically, the LIP Council is required to:[7]

- Make recommendations on the financing of the LIP and the disproportionate share hospital program and the distribution of their funds;
- Advise AHCA on the development of the LIP plan required by the federal Centers for Medicare and Medicaid Services pursuant to the Medicaid reform waiver; and
- Advise AHCA on the distribution of hospital funds used to adjust inpatient hospital rates, rebase rates, or otherwise exempt hospitals from reimbursement limits as financed by IGTs.

LIP Council recommendations are advisory in nature, and are presented each year to the appropriations committees of the Legislature. The Legislature's decisions regarding the distribution of LIP funds as well as allocations of other resources available due to the contributed IGTs are expressed in proviso of the General Appropriations Act.

According to AHCA, the Council functions as a liaison among and between the counties and taxing districts that provide the IGTs, the entities seeking LIP funding, and the providers that receive the funding. Council members work with their counties or taxing districts to educate them on the available LIP funds and obtain a complete understanding of the funds each is willing to provide for the LIP and at what level each is willing to provide funding. Some Council members also contract with consultants to prepare LIP distribution models for review prior to making model requests from AHCA. This allows the Council members to review multiple models with different scenarios to see which model they would like the Agency to prepare for presentation at a Council meeting, which reduces AHCA's workload.[8] In preparation for developing the Council recommendations for FY2009-10, the members reviewed nearly 20 different models for how the funds might be distributed. All models are posted online. The recommended model was selected based on a voice vote of the membership.

The LIP Council consists of 17 members appointed by the AHCA secretary, as follows:[9]

- 3 representatives of statutory teaching hospitals;
- 3 representatives of public hospitals;
- 3 representatives of nonprofit hospitals;
- 3 representatives of for-profit hospitals;
- 2 representatives of rural hospitals;
- 2 representatives of units of local government which contribute funding; and
- 1 representative of family practice teaching hospitals.

As a statutory advisory body, all LIP Council meetings are subject to the open meeting and records requirements of Florida law. Public notice is provided and all meetings are held either in person or by teleconference. Proceedings of the Council are published on the AHCA website.

2008-09 Low Income Pool Funding and Expenditures

As with the former UPL Program, the LIP consists of federal Medicaid funds and state matching funds provided by local governmental entities through IGTs.[10] Twenty units of local governments contribute more than $800 million in local tax dollars to finance the state match for the Low Income Pool and Disproportionate Share Program. These funds also support the rebasing of hospital per diem rates that would otherwise be limited by statutory ceilings and the availability of general revenue. The sources of IGTs for these Medicaid expenditures are as follows:

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[6] *Id. See, e.g.*, LIP Council Recommendations to Governor and Legislature for SFY 2009-10, *available at* http://ahca.myflorida.com/medicaid/medicaid_reform/lip/lip.shtml (last viewed March 22, 2009).
[7] Section 409.911(9), F.S.
[8] Agency for Health Care Administration 2009 Bill Analysis & Economic Impact Statement, House Bill 285 (2009).
[9] Section 409.911(9), F.S.
[10] Section 409.91211(b), F.S.

Local Government or Special Taxing Authority	IGTs Contributed
Miami-Dade County	355,496,876
Broward County - North / South Broward Hospital Districts	237,599,004
Palm Beach County - Health Care District of Palm Beach County	38,408,380
Volusia County - Halifax Hospital Medical Ctr. Taxing District	33,889,161
Hillsborough County	33,659,294
Pinellas County	24,165,594
Duval County	23,079,734
Sarasota County Public Hospital Board	20,856,614
Lake County - North / South Lake Hospital Taxing District	16,400,949
Orange County	14,588,316
Lee County - Lee Memorial Health System	10,427,172
Indian River Taxing District	9,667,910
Citrus County Hospital Board	7,526,160
Bay County	5,800,000
Marion County	3,803,219
Collier County	2,789,131
Columbia County Lake Shore Hospital Authority	2,789,131
Brevard County - North Brevard Hospital District	1,145,074
Gulf County	1,000,000
St. Johns County	356,563
TOTAL	**$843,448,282**

As a result of these contributions, the state is able to finance nearly $2 billion in expenditures including $1 billion in LIP payments to hospitals and other providers; $663 million in rebased hospital per diem rates for 61 hospitals; $251 million for DSH payments to 65 hospitals; and $64 million in buy back rate reductions to provider service networks, children's hospitals and rural hospitals.

Effect of Proposed Changes

The bill eliminates the statutory requirement for AHCA to establish a LIP Council, and deletes the Council's membership requirements and duties. The bill requires AHCA take up the LIP Council's duty to make recommendations to the Legislature on the financing and distribution of the low-income pool and disproportionate share funds.

The bill requires AHCA to make those recommendations "on the basis of objective and equitable criteria", and to consider the amounts of Medicaid, charity and uncompensated care provided by hospitals in making the recommendations.

The bill requires AHCA to submit its recommendations to the Governor, the Speaker and the Senate President no later than February 1 of each year.

The effective date of the bill is July 1, 2009.

B. SECTION DIRECTORY:

Section 1: Amends s. 409.911, relating to the disproportionate share program, deleting requirement that AHCA establish a LIP Council, requiring AHCA to make recommendations on the financing and distribution of LIP and disproportionate share funds.

Section 2: Providing an effective date of July 1, 2009.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

   See Fiscal Comments.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

According to AHCA, the Agency will need additional staff to prepare the recommendations. Three full time positions are needed: one Senior Data Base Analyst (pay grade 25) to pull data and calculate and assist with the development of models, one full time analyst position (pay grade 24) in order to prepare the recommendations and work with the counties and taxing districts, and one support staff position (pay grade 12) for a total cost of $188,575 (including $94,287 in General Revenue).

The bill does not authorize additional FTE for AHCA.

FISCAL IMPACT ON AHCA/FUNDS:						
					Amount Year 1 FY 09-10	**Amount Year 2 FY 10-11**
1. Non-Recurring Impact:						
Revenues:						
Licenses					$0	$0
Fees					$0	$0
Transfers In / Another Agency					$0	$0
Total Non-Recurring Revenues					$0	$0
Expenditures:						
Salaries					**$0**	**$0**
OPS						
Other Personal Services		1.00	@	$0	$0	$0
		0.00	@	$0	$0	$0
Total Non-Recurring OPS					$0	$0
Expense (Agency Standard Expense & Operating Capital Outlay Package)						

Professional Staff		2.00	@	$3,000	$6,000	$0
Support Staff		1.00	@	$2,400	$2,400	$0
		0.00	@	$0	$0	$0
Additional Travel Expense		0.00	@	$0	$0	$0
		0.00			$0	$0
Total Non-Recurring Expense					$8,400	**$0**
Operating Capital Outlay (Agency Standard Expense & Operating Capital Outlay Package)						
Laptop Computers		0.00	@	$1,400	$0	$0
		0.00	@	$0	$0	$0
Total Operating Capital Outlay					$0	**$0**
Special Categories						
					$0	$0
					$0	$0
					$0	$0
					$0	$0
					$0	$0
					$0	$0
					$0	$0
					$0	$0
					$0	$0
					$0	$0
					$0	$0
					$0	$0
					$0	$0
					$0	$0
					$0	$0
Total Non-Recurring Special Categories					$0	$0
Total Non-Recurring Expenditures					$8,400	$0
2. Recurring Impact:						
	Class Code	**FTEs**	**Pay Grade**	**Rate**		
Revenues:						
Licenses					$0	$0
Fees					$0	$0
Grants					$0	$0
					$0	$0

Transfers In/Another Agency					$0	$0
Total Recurring Revenues					**$0**	**$0**
Expenditures:						
Salaries						
Senior Data Base Analyst	2122	1.00	**25**	47,858	$61,187	$61,187
Medical/Health Care Program Analyst	5875	1.00	**24**	45,216	$57,809	$57,809
Administrative Secretary	0108	1.00	**12**	22,540	$28,817	$28,817
		0.00	**0**	0	$0	$0
		0.00	**0**	0	$0	$0
		0.00	**0**	0	$0	$0
		0.00	**0**	0	$0	$0
		0.00	**0**	0	$0	$0
		0.00	**0**	0	$0	$0
		0.00	**0**	0	$0	$0
		0.00	**0**	0	$0	$0
		0.00	**0**	0	$0	$0
		0.00	**0**	0	$0	$0
		0.00	**0**	0	$0	$0
		0.00	**0**	**0**	**$0**	**$0**
		0.00	**0**	0	$0	$0
		0.00	**0**	0	$0	$0
		0.00	**0**	0	$0	$0
Total Salary and Benefits		3.00	**FTEs**	115,614	$147,813	$147,813
OPS						
Other Personal Services		0.00	@	$0	$0	$0
		0.00	@	$0	$0	$0
Total OPS					**$0**	**$0**
Expenses						
Professional Staff		2.00	@	$11,320	$22,400	$22,400
Support Staff		1.00	@	$5,620	$5,500	$5,500
	$0	$0	$0			
Additional Travel Expenses		2.00	@	$1,634	$3,268	$3,268
					$0	$0
Total Expenses					$31,168	$31,168
Contracted Services		**4.00**		$0	**$0**	**$0**
Human Resources Services						
FTE Positions		3.00	@	$398	$1,194	$1,194

OPS Positions		0.00	@	$132	$0	$0
Total Human Resources Services					$1,194	$1,194
Special Categories						
					$0	$0
					$0	$0
					$0	$0
					$0	$0
					$0	$0
					$0	$0
					$0	$0
					$0	$0
					$0	$0
					$0	$0
					$0	$0
					$0	$0
					$0	$0
					$0	$0
					$0	$0
					$0	$0
Total Special Categories					$0	$0
Total Recurring Expenditures		**3.00**	**FTEs**	**115,614**	**$180,175**	**$180,175**
3. Long Run Effects Other Than Normal Growth:						
4. Total Revenues and Expenditures:						
Sub-Total Non-Recurring Revenues					$0	$0
Sub-Total Recurring Revenues					$0	$0
Total Revenues					**$0**	**$0**
Sub-Total Non-Recurring Expenditures					$8,400	$0
Sub-Total Recurring Expenditures					$180,175	$180,175
Total Expenditures		**3.00**	**FTEs**		**$188,575**	**$180,175**
Difference (Total						

Revenues minus Total Expenditures)						
					($188,575)	**($180,175)**
5. Funding of Expenditures:						
General Revenue Fund (1000)		50%			$94,287	$90,087
Medical Care Trust Fund (2474)		50%			$94,288	$90,088
		0%			$0	$0
		0%			$0	$0
Total		**100%**			**$188,575**	**$180,175**

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

AHCA has sufficient rulemaking authority pursuant to s. 409.919, F.S.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COUNCIL OR COMMITTEE SUBSTITUTE CHANGES

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. (for drafter's use only)

Bill No. **285**

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: Health Regulation Policy Committee

Representative(s) Patronis offered the following:

Amendment (with title amendment)

Remove everything after the enacting clause and insert:

Section 1. Subsection (9) of section 409.911, Florida Statutes, is amended to read:

409.911 Disproportionate share program.--Subject to specific allocations established within the General Appropriations Act and any limitations established pursuant to chapter 216, the agency shall distribute, pursuant to this section, moneys to hospitals providing a disproportionate share of Medicaid or charity care services by making quarterly Medicaid payments as required. Notwithstanding the provisions of s. 409.915, counties are exempt from contributing toward the cost of this special reimbursement for hospitals serving a disproportionate share of low-income patients.

(9) The Agency for Health Care Administration shall create a Medicaid Low-Income Pool Council by July 1, 2006. The Low-Income Pool Council shall consist of 24 ~~17~~ members, including 2 members appointed by the President of the Senate, 2 members appointed by the Speaker of the House of Representatives, 3

representatives of statutory teaching hospitals, 3 representatives of public hospitals, 3 representatives of nonprofit hospitals, 3 representatives of for-profit hospitals, 2 representatives of rural hospitals, 2 representatives of units of local government which contribute funding, ~~and~~ 1 representative of family practice teaching hospitals, 1 representative of federally qualified health centers, 1 representative from the Department of Health, and 1 nonvoting representative of the Agency for Health Care Administration, who shall serve as chair of the council. Except for fulltime employees of a public entity, individuals who qualify as lobbyists under s. 11.045 or s. 112.3215 may not serve as members of the council. Of the members appointed by the Senate President, one and only one shall be a physician. Of the members appointed by the Speaker of the House of Representatives, one and only one shall be a physician. Physicians appointed by the Senate President and the Speaker of the House of Representatives must be physicians who routinely take call in a trauma center, as defined in s. 395.4001, or a hospital emergency department. The council shall:

(a) Make recommendations on the financing of the low-income pool and the disproportionate share hospital program and the distribution of their funds.

(b) Advise the Agency for Health Care Administration on the development of the low-income pool plan required by the federal Centers for Medicare and Medicaid Services pursuant to the Medicaid reform waiver.

(c) Advise the Agency for Health Care Administration on the distribution of hospital funds used to adjust inpatient hospital rates, rebase rates, or otherwise exempt hospitals from reimbursement limits as financed by intergovernmental transfers.

(d) Submit its findings and recommendations to the Governor and the Legislature no later than February 1 of each

year.

Section 2. This act shall take effect July 1, 2009.

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

Remove the entire title and insert:

An act relating to the Medicaid low-income pool and disproportionate share program; amending s. 409.911, F.S.; repealing the Low-Income Pool Council; requiring that the Agency for Health Care Administration make recommendations 5 to the Legislature regarding the financing and distribution of low-income pool and disproportionate share funds; requiring the agency to submit recommendations to the Governor and the Legislature annually; providing an effective date.

A bill to be entitled

An act relating to the Medicaid low-income pool and disproportionate share program; amending s. 409.911, F.S.; repealing the Low-Income Pool Council; requiring that the Agency for Health Care Administration make recommendations to the Legislature regarding the financing and distribution of low-income pool and disproportionate share funds; requiring the agency to submit recommendations to the Governor and the Legislature annually; providing an effective date.

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

Section 1. Subsection (9) of section 409.911, Florida Statutes, is amended to read:

409.911 Disproportionate share program.--Subject to specific allocations established within the General Appropriations Act and any limitations established pursuant to chapter 216, the agency shall distribute, pursuant to this section, moneys to hospitals providing a disproportionate share of Medicaid or charity care services by making quarterly Medicaid payments as required. Notwithstanding the provisions of s. 409.915, counties are exempt from contributing toward the cost of this special reimbursement for hospitals serving a disproportionate share of low-income patients.

(9) The Agency for Health Care Administration shall ~~create a Medicaid Low-Income Pool Council by July 1, 2006. The Low-Income Pool Council shall consist of 17 members, including 3~~

~~representatives of statutory teaching hospitals, 3 representatives of public hospitals, 3 representatives of nonprofit hospitals, 3 representatives of for-profit hospitals, 2 representatives of rural hospitals, 2 representatives of units of local government which contribute funding, and 1 representative of family practice teaching hospitals. The council shall:~~

~~(a)~~ make recommendations to the Legislature on the financing of the low-income pool and the disproportionate share ~~hospital~~ program and the distribution of their funds to hospitals on the basis of objective and equitable criteria that include consideration of the amount of Medicaid, charity, and uncompensated care provided by hospitals. The agency shall submit its recommendations to the Governor, the President of the Senate, and the Speaker of the House of Representatives no later than February 1 of each year.

~~(b) Advise the Agency for Health Care Administration on the development of the low-income pool plan required by the federal Centers for Medicare and Medicaid Services pursuant to the Medicaid reform waiver.~~

~~(c) Advise the Agency for Health Care Administration on the distribution of hospital funds used to adjust inpatient hospital rates, rebase rates, or otherwise exempt hospitals from reimbursement limits as financed by intergovernmental transfers.~~

~~(d) Submit its findings and recommendations to the Governor and the Legislature no later than February 1 of each year.~~

Section 2. This act shall take effect July 1, 2009.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 629 Health Care Clinics
SPONSOR(S): Kreegel
TIED BILLS: **IDEN./SIM. BILLS:**

	REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1)	Insurance, Business & Financial Affairs Policy Committee	20 Y, 0 N	Reilly	Cooper
2)	Health Care Regulation Policy Committee		Ciccone JC	Calamas CC
3)	General Government Policy Council			
4)				
5)				

SUMMARY ANALYSIS

In 2003, the Florida Legislature enacted the "Health Care Clinic Act" to curtail fraud and abuse in the personal injury protection (PIP) insurance system. Under Florida's Motor Vehicle No-Fault Law, motor vehicle owners are required to maintain $10,000 of PIP coverage, which is available for certain express damages sustained in a motor vehicle accident, regardless of fault.

Under the Health Care Clinic Act, entities that provide health care services to individuals and which tender charges for reimbursement for such services are defined as "clinics" and must obtain a license to operate from the Agency for Health Care Administration. In addition to providing for the licensure of clinics, the act also sets forth a listing of entities that are exempted from the definition of clinic. Exempt entities are not subject to licensure and regulation under the act.

House Bill 629 exempts from the definition of clinics under the Health Care Clinic Act entities that do not seek reimbursement from insurance companies for medical services paid pursuant to PIP coverage.

The bill provides an effective date of July 1, 2009.

HOUSE PRINCIPLES

Members are encouraged to evaluate proposed legislation in light of the following guiding principles of the House of Representatives

- Balance the state budget.
- Create a legal and regulatory environment that fosters economic growth and job creation.
- Lower the tax burden on families and businesses.
- Reverse or restrain the growth of government.
- Promote public safety.
- Promote educational accountability, excellence, and choice.
- Foster respect for the family and for innocent human life.
- Protect Florida's natural beauty.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

State Health Care Clinics

a. Licensure

Part X of ch. 400, F.S., contains the Health Care Clinic Act (the act) (ss. 400.990-400.995, F.S.). The act was passed in 2003 to reduce fraud and abuse in the personal injury protection (PIP) insurance system. Florida's Motor Vehicle No-Fault Law[1] requires motor vehicle owners to maintain $10,000 of personal injury protection (PIP) insurance. PIP benefits are available for certain express damages sustained in a motor vehicle accident, regardless of fault.

Pursuant to the act, the Agency for Health Care Administration (AHCA) licenses health care clinics, ensures that such clinics meet basic standards, and provides administrative oversight. Any entity that meets the definition of a "clinic" ("an entity at which health care services are provided to individuals and which tenders charges for reimbursement for such services...") must be licensed as a clinic.[2] A clinic license lasts for a 2-year period, and each clinic location must be licensed separately.

Section 400.991, F.S., provides licensure requirements to ensure that clinics meet certain standards, and provide administrative oversight. According to AHCA, there are an estimated 2,200 licensed health care clinics in Florida.[3] The fees payable by each clinic to AHCA for licensure cannot exceed $2,000, adjusted for changes in the Consumer Price Index for the previous 12 months. Each clinic must file in its application for licensure information regarding the identity of the owners, medical providers employed, the medical director, and proof that the clinic is in compliance with applicable rules. The clinic must also present proof of financial ability to operate a clinic.

A level 2 background screening pursuant to ch. 435, F.S., is required of each applicant for clinic licensure. Pursuant to section 409.991(5), F.S., a license may not be granted to a clinic if the applicant has been found guilty of, regardless of adjudication, or has entered a plea of nolo

[1] Sections 627.730-627.7405, F.S., the Florida Motor Vehicle No-Fault Law, were repealed on October 1, 2007 pursuant to s. 19, ch. 2003-411 L.O.F. The No-Fault Law was revived and reenacted effective January 1, 2008 pursuant to ch. 2007-324 L.O.F.
[2] S. 400.9905(4), F.S.
[3] AHCA presently regulates approximately 2,200 health care clinics throughout Florida. Correspondence from AHCA on file with the Insurance, Business & Financial Affairs Policy Committee.

contendere or guilty to any offense prohibited under the level 2 standards for screening or a violation of insurance fraud under s. 817.234, F.S., within the past 5 years.

Each clinic must have a medical director or clinic director who agrees in writing to accept legal responsibility pursuant to s. 400.9935, F.S., for the following activities on behalf of the clinic:

- Ensuring that all practitioners providing health care services or supplies to patients maintain a current, active, and unencumbered Florida license;
- Reviewing patient referral contracts or agreements made by the clinic;
- Ensuring that all health care practitioners at the clinic have active appropriate certification or licensure for the level of care being provided;
- Serving as the clinic records owner;
- Ensuring compliance with the recordkeeping, office surgery, and adverse incident reporting requirements of ch. 456, F.S., the respective practice acts, and rules adopted under the Health Care Clinic Act; and
- Conducting systematic reviews of clinic billings to ensure billings are not fraudulent or unlawful. If an unlawful charge is discovered, immediate corrective action must be taken.

Licensed clinics are subject to unannounced inspections by Division of Insurance Fraud personnel and must allow full and complete access to the premises and to billing records. AHCA may deny, revoke, or suspend a health care clinic license and impose administrative fines of up to $5,000 per violation pursuant to s. 400.995, F.S.

b. Exemptions from Licensure[4]

Although all clinics must be licensed by AHCA, s. 400.9905(4), F.S., contains a listing of entities that are not considered a "clinic" for purposes of licensure,[5] including:

- Entities licensed or registered by the state under one or more of the specified practice acts and that only provide services within the scope of their license;
- Entities that own, directly or indirectly, an entity licensed or registered by the state under one or more of the specified practice acts and that only provide services within the scope of their license;
- Entities under common ownership directly or indirectly, with an entity licensed or registered by the state under one or more of the specified practice acts and only provide services within the scope of their license;
- Entities exempted from federal taxation under 26 U.S.C. sec. 501(c)(3) or sec. 501(c)(4);
- A community college or university clinic;
- Entities owned or operated by the federal or state government, including agencies, subdivisions and municipalities;
- Clinical facilities affiliated with an accredited medical school at which training is provided for medical students, residents, or fellows;
- Entities that provide only oncology or radiation therapy services by physicians licensed under chs. 458 or 459, F.S.; and
- Clinical facilities affiliated with a college of chiropractic accredited by the Council on Chiropractic Education at which training is provided for chiropractic students.

Florida Motor Vehicle No-Fault Law

In Florida, motorists are required to maintain personal injury protection (PIP) coverage and property damage liability coverage.[6] PIP provides $10,000 of coverage for the following: payment of 80 percent of reasonable medical expenses, 60 percent of loss of income, and a death benefit of $5,000 or the

[4] AHCA issues approximately 600 exemptions per year. However, such exemptions are on the "honor system" and clinics must voluntarily obtain a certificate of exemption from health care clinic licensure. Correspondence from AHCA on file with the Insurance, Business & Financial Affairs Policy Committee.

[5] Section 400.9905(4)(a-l), F.S.

[6] Section 627.7275, F.S.

D. FISCAL COMMENTS:

See comments in the section entitled "Fiscal Impact on State Government: Revenues."

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

The bill will exempt from regulatory oversight by the Agency for Health Care Administration (AHCA) an unknown number of entities that will not be considered "clinics" under the Health Care Clinic Act.

IV. AMENDMENTS/COUNCIL OR COMMITTEE SUBSTITUTE CHANGES

remainder of the unused PIP benefits, whichever is less, for bodily injury sustained in a motor vehicle accident, without regard to fault. PIP covers the named insured, relatives residing in the same household, persons operating the insured motor vehicle, passengers in the insured motor vehicle, and persons struck by the motor vehicle. This coverage also provides the policyholder with immunity from liability for economic damages (medical expenses) up to the $10,000 policy limits and for non-economic damages (pain and suffering) for most injuries.

The most common types of PIP fraud are health care clinic fraud and staged accidents.[7] In fiscal year, 2007/2008, nearly half of the Division of Insurance Fraud's convictions involved fraudulent claims for PIP benefits and there were 1,176 complaints of fraudulent activity committed by health care providers.[8]

Effect of the Bill

House Bill 629 exempts from the definition of clinics under the Health Care Clinic Act entities that do not seek reimbursement from insurance companies for medical services paid pursuant to PIP coverage. Thus, such entities are not subject to licensure and regulation under the act.

B. SECTION DIRECTORY:

Section 1. Excludes additional entities from the regulatory requirements of the Health Care Clinic Act (ss. 400.990-400.995, F.S).

Section 2. Provides an effective date of July 1, 2009.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   Indeterminant. The Agency for Health Care Administration (AHCA) has stated that the number of clinics that accept personal injury protection payments cannot be determined.[9]

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

To the extent that additional entities are exempted from licensing and registration requirements under the Health Care Clinic Act, such entities will not be required to pay a licensing fee every two years.

[7] See Report Number 2006-102, "Florida's Motor Vehicle No-Fault Law," by staff of the Florida Senate Banking and Insurance Committee. Available at: http://www.flsenate.gov (last accessed March 13, 2009).
[8] Correspondence from the Department of Financial Services on file with the Insurance, Business & Financial Affairs Policy Committee.
[9] Correspondence from AHCA on file with the Insurance, Business & Financial Affairs Policy Committee.

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. (for drafter's use only)

Bill No. **629**

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: Health Regulation Policy Committee

Representative(s) Kreegel offered the following:

Amendment (with title amendment)

Remove everything after the enacting clause and insert:

Section 1. Paragraph (m) is added to subsection (4) of section 400.9905, Florida Statutes, to read:

400.9905 Definitions.--

(4) "Clinic" means an entity at which health care services are provided to individuals and which tenders charges for reimbursement for such services, including a mobile clinic and a portable equipment provider. For purposes of this part, the term does not include and the licensure requirements of this part do not apply to:

(m) Entities that do not seek reimbursement from insurance companies for medical services paid pursuant to personal injury protection coverage required by s. 627.736.

Section 2. Subsection (10) is added to section 400.9935, Florida Statutes, to read:

400.9935 Clinic responsibilities.--

(10) Any clinic holding an active license and any entity holding a current certificate of exemption may request a unique identification number from the Office of Insurance Regulation for the purposes of submitting claims to personal injury protection insurance carriers for services or treatment pursuant to part XI of chapter 627. Upon request, the Office of Insurance Regulation shall assign a unique identification number to clinics holding a active licenses and entities holding current certificates of exemption. The Office of Insurance Regulation shall publish on its internet website the identification number of each clinic and entity in a format conducive to searches by personal injury protection insurance carriers for the purposes of s. 627.736(5)(b)1.g.

Section 3. Paragraph (b) of subsection (5) of section 627.736, Florida Statutes, is amended to read:

627.736 Required personal injury protection benefits; exclusions; priority; claims.--

(5) CHARGES FOR TREATMENT OF INJURED PERSONS.--

(b)1. An insurer or insured is not required to pay a claim or charges:

e. For any treatment or service that is upcoded, or that is unbundled when such treatment or services should be bundled, in accordance with paragraph (d). To facilitate prompt payment of lawful services, an insurer may change codes that it determines to have been improperly or incorrectly upcoded or unbundled, and may make payment based on the changed codes, without affecting the right of the provider to dispute the change by the insurer, provided that before doing so, the insurer must contact the health care provider and discuss the reasons for the insurer's change and the health care provider's

reason for the coding, or make a reasonable good faith effort to do so, as documented in the insurer's file; ~~and~~

f. For medical services or treatment billed by a physician and not provided in a hospital unless such services are rendered by the physician or are incident to his or her professional services and are included on the physician's bill, including documentation verifying that the physician is responsible for the medical services that were rendered and billed; and~~.~~

g. For any service or treatment billed by a provider not holding an identification number issued by the Office of Insurance Regulation pursuant to s. 400.9935(10).

Section 4. This act shall take effect July 1, 2009.

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

Remove the entire title and insert:

amending s. 400.9905, F.S.; revising the definition of the term "clinic" to provide that pt. X of ch. 400, F.S., the Health Care Clinic Act, does not apply to entities that do not seek reimbursement from insurance companies for medical services paid pursuant to personal injury protection coverage; amending s. 400.9905, F.S.; providing for a unique identifier for licensed clinics and entities holding certificates of exemption; requiring the Office of Insurance Regulation to issue unique identification numbers an publish the numbers on its internet website in a certain format; amending s. 627.736, F.S.; providing the personal injury protection insurance carriers are not required to pay claims from certain entities; providing an effective date.

A bill to be entitled

An act relating to health care clinics; amending s. 400.9905, F.S.; revising the definition of the term "clinic" to provide that pt. X of ch. 400, F.S., the Health Care Clinic Act, does not apply to entities that do not seek reimbursement from insurance companies for medical services paid pursuant to personal injury protection coverage; providing an effective date.

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

Section 1. Paragraph (m) is added to subsection (4) of section 400.9905, Florida Statutes, to read:

400.9905 Definitions.--

(4) "Clinic" means an entity at which health care services are provided to individuals and which tenders charges for reimbursement for such services, including a mobile clinic and a portable equipment provider. For purposes of this part, the term does not include and the licensure requirements of this part do not apply to:

(m) Entities that do not seek reimbursement from insurance companies for medical services paid pursuant to personal injury protection coverage required by s. 627.736.

Section 2. This act shall take effect July 1, 2009.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 769 911 Emergency Dispatcher Certification
SPONSOR(S): Roberson
TIED BILLS: **IDEN./SIM. BILLS:** SB 2040

	REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1)	Health Care Regulation Policy Committee		Holt	Calamas
2)	Military & Local Affairs Policy Committee			
3)	Health & Family Services Policy Council			
4)	Full Appropriations Council on General Government & Health Care			
5)				

SUMMARY ANALYSIS

In 2008, the Legislature established a voluntary certification program for 911 emergency dispatchers. The bill makes the 911 emergency dispatcher certification program mandatory.

Effective October 1, 2012, any person serving as a 911 emergency dispatcher must be certified; unless they are a trainee for a period not to exceed 6 months and the trainee must be under the direct supervision of a certified dispatcher who has at least 2 years experience. Prior to October 1, 2012, individuals may still seek certification on a voluntary basis. The bill deletes the requirement that at least two years of supervised full-time employment as a 911 emergency dispatcher since January 1, 2002 are necessary for certification. The bill permits that a person may attend a more stringent training program, thus not limiting a person to a program that is equivalent to the most recently approved emergency dispatcher course. However, the bill does not define or provide parameters for what is considered a more stringent program.

The bill will have a significant positive fiscal impact from the establishment of certification leisure and biannual renewal fees to be deposited to the Emergency Medical Services Trust Fund within the Department of Health. There would also be an increase in expenditures based of the increase workload but it would not exceed the revenues (see fiscal analysis).

The bill takes effect October 1, 2009.

HOUSE PRINCIPLES

Members are encouraged to evaluate proposed legislation in light of the following guiding principles of the House of Representatives

- Balance the state budget.
- Create a legal and regulatory environment that fosters economic growth and job creation.
- Lower the tax burden on families and businesses.
- Reverse or restrain the growth of government.
- Promote public safety.
- Promote educational accountability, excellence, and choice.
- Foster respect for the family and for innocent human life.
- Protect Florida's natural beauty.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background:

Florida's Public Policy on 911 Services

Section 365.171, F.S., sets forth the provisions which govern Florida's public policy on the emergency telephone number "911." The provision specifies that it is the intent of the Legislature to:

"establish and implement a cohesive statewide emergency telephone number "911" plan which will provide citizens with rapid direct access to public safety agencies by dialing the telephone number '911' with the objective of reducing response time to situations requiring law enforcement, fire, medical, rescue, and other emergency services."

911 Emergency Dispatchers

According to the United States Department of Labor, emergency dispatchers monitor the location of emergency services personnel from one or all of the jurisdiction's emergency services departments. These workers dispatch the appropriate type and number of units in response to calls for assistance. Dispatchers are often the first point of contact for the public when emergency assistance is required. If trained for emergency medical services, the dispatcher may provide medical instruction to those on the scene of the emergency until the medical staff arrives.[1]

When handling calls, dispatchers question each caller carefully to determine the type, seriousness, and location of the emergency. The information obtained is generally posted electronically by computer. The dispatcher then quickly decides the priority of the incident, the kind and number of units needed, and the location of the closest and most suitable units available. When appropriate, dispatchers stay in close contact with other service providers. In a medical emergency, dispatchers keep in close touch not only with the dispatched units, but also with the caller. They may give extensive first-aid instructions before the emergency personnel arrive. Dispatchers continuously give updates on the patient's condition to the ambulance personnel and often serve as a link between the medical staff in a hospital and the emergency medical technicians in the ambulance.[2]

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[1] United States Department of Labor, Bureau of Labor Statistics, "Occupational Outlook Handbook- Dispatchers," http://www.bls.gov/oco/ocos138.htm (last visited March 22, 2009).

[2] *Ibid.*

Department of Education Curriculum Framework and Standards

The Division of Workforce Education at the Department of Education (DOE) publishes curriculum frameworks and standards aligned to the sixteen Career Clusters delineated by the United States Department of Education. Each program's course standards are composed of two parts: a curriculum framework and the student performance standards. The curriculum framework includes four major sections: major concepts/content, laboratory activities, special notes, and intended outcomes. Student performance standards are listed for each intended outcome.[3]

The Public Safety Telecommunication program is designed to prepare students for employment as a police, fire, ambulance, or emergency medical dispatcher. The program is divided into two levels. The first level, "Occupational Completion Point A", is a 208 hour curriculum designed for police, fire, and ambulance dispatchers. The second level, "Occupational Completion Point B", is to be completed after the first level through an additional 24 hour curriculum designed for emergency medical dispatchers.[4]

Voluntary 911 Emergency Dispatcher Certification Program

In 2008, the Legislature established a voluntary certification program for 911 emergency dispatchers that is regulated by the Department of Health ("department").[5] Current law states that a "911 emergency dispatcher" is a person who is employed by a state agency or local government as a public safety dispatcher or 911 operator whose duties and responsibilities include: [6]

- Answering 911 calls;
- Dispatching law enforcement officers, fire rescue services, emergency medical services, and other public safety services to the scene of an emergency;
- Providing real-time information from federal, state, and local crime databases; or
- Supervising or serving as the command officer to a person or persons having such duties and responsibilities.

However, the term does not include administrative support personnel, including, but not limited to, those whose primary duties and responsibilities are in accounting, purchasing, legal, and personnel.

Applicants for certification must submit specified forms, pay a certification fee[7], and meet the educational and training requirements for certification and recertification as a 911 emergency dispatcher.[8]

The department determines whether the applicant meets the requirements for certification and issues a certificate to any person who meets the requirements. The requirements are:[9]

- Completion of an appropriate 911 emergency dispatcher training program that is equivalent to the most recently approved emergency dispatcher course of the Department of Education and consists of not less than 208 hours;
- Completion and documentation of at least 2 years of supervised full-time employment as a 911 emergency dispatcher since January 1, 2002;
- Certification under oath that the applicant is not addicted to alcohol or any controlled substance;
- Certification under oath that the applicant is free from any physical or mental defect or disease that might impair the applicant's ability to perform his or her duties;
- Submission of the application fee prescribed in subsection (3); and
- Submission of a completed application to the department indicates compliance with the requirements for certification.[10]

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[3] Florida Department of Education, "Curriculum Framework, Public Safety Telecommunication," July 2008, http://www.fldoe.org/workforce/dwdframe/ps_cluster_frame08.asp (last visited March 13, 2008).
[4] Ibid.
[5] Chapter 2008-51, L.O.F.
[6] Section 401.465(1), F.S.
[7] The fee for initial certification is $75 and biannual renewal is $100.
[8] Section 401.465(2)(a), F.S.
[9] Section 401.465(2)(b), F.S.
[10] Application is done through DH Form 5066. (64J-3.001, F.A.C.)

Each 911 emergency dispatcher certificate expires automatically if not renewed at the end of the 2-year period. A certificate that is not renewed at the end of the 2-year period automatically reverts to an inactive status for a period that may not exceed 180 days and may be reactivated and renewed within the 180-day period if the certificateholder meets the qualifications for renewal and pays a $50 late fee.[11] The department may suspend or revoke a certificate at any time if it determines that the certificateholder does not meet the applicable qualifications.[12]

Section 401.411, F.S., provides for the disciplinary action, such that the department may deny, suspend, or revoke a license, certificate, or permit or may reprimand or fine a 911 emergency dispatcher certificateholder on any of the following grounds:

- Addiction to alcohol or any controlled substance;
- Engaging in or attempting to engage in the possession, except in legitimate duties under the supervision of a licensed physician, or the sale or distribution of any controlled substance as set forth in chapter 893;
- A conviction in any court in any state or in any federal court of a felony, unless the person's civil rights have been restored;
- Knowingly making false or fraudulent claims; procuring, attempting to procure, or renewing a certificate, license, or permit by fakery, fraudulent action, or misrepresentation;
- Unprofessional conduct, including, but not limited to, any departure from or failure to conform to the minimal prevailing standards of acceptable practice as an emergency medical technician or paramedic, including undertaking activities that the emergency medical technician or paramedic is not qualified by training or experience to perform;
- Sexual misconduct with a patient, including inducing or attempting to induce the patient to engage, or engaging or attempting to engage the patient, in sexual activity;
- Failure to give to the department true information upon request regarding an alleged or confirmed violation;
- Fraudulent or misleading advertising or advertising in an unauthorized category;
- Practicing as an emergency medical technician, paramedic, or other health care professional operating under this part without reasonable skill and safety to patients by reason of illness, drunkenness, or the use of drugs, narcotics, or chemicals or any other substance or as a result of any mental or physical condition; and
- The failure to report to the department any person known to be in violation of s. 401.411, F.S.

The Effects of the Bill

The bill makes the voluntary 911 emergency dispatcher certification program mandatory. Effective October 1, 2012, any person serving as a 911 emergency dispatcher must be certified; unless they are a trainee for a period not to exceed 6 months and the trainee must be under the direct supervision of a certified dispatcher who has at least 2 years experience. Until to October 1, 2012, individuals may still seek certification on a voluntary basis. The bill deletes the requirement that at least two years of supervised full-time employment as a 911 emergency dispatcher after to January 1, 2002 is necessary for certification. The bill permits that a person may attend a more stringent training program, thus not limiting a person to a program that is equivalent to most recently approved emergency dispatcher course. However, the bill does not define or provide parameters for what is considered a more stringent program.

B. SECTION DIRECTORY:

Section 1. Amends 401.465, F.S., relating to 911 emergency dispatcher certification.
Section 2. Provides an effective date of October 1, 2009.

[11] Section 401.465(2)(d), F.S.
[12] Section 401.465(2)(e), F.S.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

The fee for initial certification is $75 and renewal certification is $100. The department projects 6,171 individuals will seek dispatcher certification in the first year and approximately 142, 145, and 149 individuals will seek certification respectively each year. The license is renewed on a biannual basis.

Estimated Revenue	1st Year (2010)	2nd Year (2011)	3rd Year (2012)	4th Year (2011)
Initial Registration Fee @ $75	$ 462,825	$ 10,650	$ 10,875	$ 11,175
Registration Renewal Fee @ $100	$ -	$ -	$ 617,100	$ 14,100
Total Estimated Revenues	$ 462,825	$ 10,650	$ 627,975	$ 25,275

2. Expenditures:

For the purposes of this analysis, the Department of Health estimates that there are 6,033 dispatchers in the state based on information gathered from each county's State of Florida Emergency Telephone Number 911 Plan from the Department of Management Services and the Florida Highway Patrol. Based on several years of U.S. Census data, the state's population has grown about 2.3%. In addition if there's currently 1 emergency dispatcher per 3,229 Florida residents. Thus, there will be approximately 6,171 emergency dispatchers by 2010 with a projected increase of emergency dispatchers of 142 in 2011, 145 in 2012, and 149 in 2013.

Currently, the department has an outside vendor who processes initial and renewal applications and related fees. The contract is based on a $7.95 per application rate. However, the contract will most likely increase with the additional number of applications processed under the contract.

The department has projected that the increase in workload to issue and process certification applications and provide regulatory functions for 911 dispatchers requires a 1.0 full-time equivalent position.

Estimated Expenditures	1st Year (2010)	2nd Year (2011)	3rd Year (2012)	4th Year (2013)
Salaries				
1.0 - Reg Spec II, PG 17	$ 27,926	$ 27,926	$27,926	$27,926
Fringe Benefits @29%	$ 8,099	$ 8,099	$ 8,099	$ 8,099
Expense				
Standard package allowed	$ 10,112	$ 6,700	$ 6,700	$ 6,700
Operating Capital Outlay				
Standard package allowed	$ 1,000			
Contracted Services				
Initial & Renewal processing @ $7.95 per application	$ 45,060	$ 1,129	$50,212	$ 2,314
Total Estimated Expenditures	$ 92,197	$ 43,854	$92,937	$45,039

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   Not applicable.

2. Expenditures:

   Not applicable.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

This bill would establish an initial and renewal licensure fee to individuals requesting in the amount of $75 and $100 respectfully. There would also be an impact to private sector EMS providers for the cost of the 911 dispatcher training. There may be an increase in enrollment at facilities such as community colleges that offer the 911 emergency dispatcher training program.

D. FISCAL COMMENTS:

The bill requires the assessed fees to be deposited into the Emergency Medical Services Trust Fund. However, the regulatory duties of processing, monitoring, and enforcement are handled by the Division of Medical Quality Assurance (MQA). In order for MQA to be reimbursed for the expenses associated with these regulatory duties an interagency agreement and non-operating transfer of monies is required.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

The department has sufficient rule-making authority to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

The bill does not define or provide parameters for what is considered a more stringent certification program.

IV. AMENDMENTS/COUNCIL OR COMMITTEE SUBSTITUTE CHANGES

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

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

Bill No. **HB 769**

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: Health Care Regulation Policy Committee

Representative(s) K. Roberson offered the following:

Amendment (with title amendment)

Remove everything after the enacting clause and insert:

Section 1. Paragraphs (c) and (d) are added to subsection (1) of section 401.465, Florida Statutes, and subsection (2) of that section is amended, to read:

401.465 911 emergency dispatcher certification.--

(1) DEFINITIONS.--As used in this section, the term:

(c) "Certified dispatch training center" means any public safety agency as defined in s.365.171(3)(d)employing 911 emergency dispatchers whose training program is equivalent to the most recently approved emergency dispatch course in public safety telecommunications of the Department of Education and consists of not less than 208 hours.

(d) "Certified dispatch training program" means a 911 emergency dispatch training program that is equivalent to the most recently approved emergency dispatch course in public safety telecommunications of the Department of Education and consists of not less than 208 hours, that is offered by an

educational institution approved by the Department of Education to offer such program.

(2) PERSONNEL; STANDARDS AND CERTIFICATION.--

(a) Effective October 1, 2012, any person serving as a 911 emergency dispatcher must be certified by the department. Notwithstanding this requirement, a public safety agency as defined s. 365.171(3)(d) may employ a 911 emergency dispatcher trainee for a period not to exceed 6 months, provided that the trainee is under the direct supervision, as determined by rule of the department, of a certified 911 emergency dispatcher with a minimum of 2 years' experience.

(b) ~~(a)~~ An applicant ~~Any person who desires~~ to be certified or recertified as a 911 emergency dispatcher must ~~may~~ apply to the department under oath on forms provided by the department. The department shall establish by rule educational and training criteria for the certification and recertification of 911 emergency dispatchers.

(c) ~~(b)~~ The department shall determine whether the applicant meets the requirements specified in this section and in rules of the department and shall issue a certificate to any person who meets such requirements. Such requirements must include, but need not be limited to, the following:

1. Completion of an appropriate 911 emergency dispatcher training program that is equivalent to the most recently approved emergency dispatcher course of the Department of Education and consists of not less than 208 hours; Certified Dispatch Training Centers and Certified Dispatch Training Programs must apply to the department on forms provided by the department, to receive approval prior to being used in satisfaction of this requirement.

~~2. Completion and documentation of at least 2 years of supervised full-time employment as a 911 emergency dispatcher since January 1, 2002;~~

2.~~3.~~ Certification under oath that the applicant is not addicted to alcohol or any controlled substance;

3.~~4.~~ Certification under oath that the applicant is free from any physical or mental defect or disease that might impair the applicant's ability to perform his or her duties;

4.~~5.~~ Submission of the application fee prescribed in subsection (3); and

5.~~6.~~ Submission of a completed application to the department which indicates compliance with subparagraphs 1., 2., 3., and 4.

(d)~~(c)~~ The department shall establish by rule a procedure for the quadrennial ~~biennial~~ renewal certification of 911 emergency dispatchers.

(e)~~(d)~~ Each 911 emergency dispatcher certificate expires automatically if not renewed at the end of the 4-year ~~2-year~~ period and may be renewed if the holder meets the qualifications for renewal as established by the department. A certificate that is not renewed at the end of the 4-year ~~2-year~~ period automatically reverts to an inactive status for a period that may not exceed 180 days. Such certificate may be reactivated and renewed within the 180-day period if the certificateholder meets all other qualifications for renewal and pays a $50 late fee. Reactivation shall be in a manner and on forms prescribed by department rule.

(f)~~(e)~~ The department may suspend or revoke a certificate at any time if it determines that the certificateholder does not meet the applicable qualifications.

(g) ~~(f)~~ A certificateholder may request that his or her 911 emergency dispatcher certificate be placed on inactive status by applying to the department before his or her current certification expires and paying a fee set by the department which may not exceed $100.

1. A certificateholder whose certificate has been on inactive status for 1 year or less may renew his or her certificate pursuant to the rules adopted by the department and upon payment of a renewal fee set by the department which may not exceed $100.

2. A certificateholder whose certificate has been on inactive status for more than 1 year may renew his or her certificate pursuant to rules adopted by the department.

3. A certificate that has been inactive for more than 6 years automatically expires and may not be renewed.

(h) ~~(g)~~ The department shall establish by rule a procedure for the initial certification of 911 emergency dispatchers as defined in this section who have documentation of at least 5 years of supervised full-time employment as a 911 emergency dispatcher since January 1, 2002. This provision for initial certification of 911 emergency dispatchers shall sunset on October 1, 2012.

(3) CERTIFIED DISPATCH TRAINING CENTER; STANDARDS AND CERTIFICATION.--

(a) Certified dispatch training centers shall report all individuals that have successfully completed a 911 emergency dispatch course in public safety telecommunication to the department within two (2) weeks of completion date and shall certify to the department compliance for certification as described in this section.

(b) The department shall establish by rule a procedure for the quadrennial review and approval of certified dispatch training centers to verify compliance with training standards required by this section.

(4) CERTIFIED DISPATCH TRAINING PROGRAM; STANDARDS AND CERTIFICATION.--

(a) Certified dispatch training programs shall report all individuals that have successfully completed a 911 emergency dispatch course in public safety telecommunication to the department within two (2) weeks of completion date and shall certify to the department compliance for certification as described in this section.

(b) The department shall establish by rule a procedure for the quadrennial review and approval of the certified dispatch training programs to verify compliance with training standards required by this section.

(5)~~(3)~~ FEES.--

(a) The fee for application for the 911 emergency dispatcher original certificate is $75.

(b) The application fee for the 911 emergency dispatcher biennial renewal certificate is $100.

(c) Fees collected under this section shall be deposited into the Emergency Medical Services Trust Fund and used solely for salaries and expenses of the department incurred in administering this section.

(d) If a certificate issued under this section is lost or destroyed, the person to whom the certificate was issued may, upon payment of a fee set by the department which may not exceed $25, obtain a duplicate or substitute certificate.

(e) Upon surrender of the original 911 emergency dispatcher certificate and receipt of a replacement fee set by

the department which may not exceed $25, the department shall issue a replacement certificate to make a change in name.

(f) The department shall charge a fee not to exceed $100 for the initial review and approval of 911 emergency dispatch training programs offered by certified dispatch training centers and certified dispatch training programs to determine compliance with s. 401.465(2)(c)1. A fee not to exceed $75.00 shall be charged for quadrennial review and approval of training programs authorized by this section.

(g) Employees of certified dispatch training centers are exempt from all fees.

(6) GENERAL APPLICATION PROCEDURES.--

(a) The department may by rule require any category of application or certification to be applied for or renewed online using an online application. In the case of online renewal, the department shall provide a fail-safe manner in which the applicant may print a receipt for the properly prepared application. Alternatively, when online application or renewal system is in operation, the licensing authority may require payment of an additional fee, not exceeding $25.00, to be paid by applicants who elect to use paper applications or renewal forms in lieu of the online system.

(b) Certified dispatch training centers may electronically certify to the department employees who have completed training in compliance with this section.

Section 2. Paragraphs (g) and (k) of subsection (1) of section 401.411, Florida Statutes, are amended to read:

401.411 Disciplinary action; penalties.--

(1) The department may deny, suspend, or revoke a license, certificate, or permit or may reprimand or fine any licensee,

certificateholder, or other person operating under this part for any of the following grounds:

(g) Unprofessional conduct, including, but not limited to, any departure from or failure to conform to the minimal prevailing standards of acceptable practice under this part ~~as an emergency medical technician or paramedic~~, including undertaking activities when ~~that the emergency medical technician or paramedic is~~ not qualified by training or experience to perform.

(k) Practicing as an emergency medical technician, paramedic, ~~or other~~ health care professional, or other professional operating under this part without reasonable skill and safety to the public ~~patients~~ by reason of illness, drunkenness, or the use of drugs, narcotics, or chemicals or any other substance or as a result of any mental or physical condition.

Section 2. This act shall take effect October 1, 2009.

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

Remove the entire title and insert:

An act relating to 911 emergency dispatcher certification; amending s. 401.465, F.S.; creating definitions for certified dispatch training center and certified dispatch training program; providing conditions under which a public safety agency may employ a 911 emergency dispatcher trainee for a limited period; requiring any person serving as a 911 emergency dispatcher to be certified by the Department of Health on or after a specified date; providing that applicants must apply on a specified form; deleting supervisory requirements to meet certification; providing for quadrennial renewal; providing sunset provision for initial certification; providing certification standards for certified dispatch training center

and certified dispatch training program; providing the department rule making authority; providing a fee for quadrennial review and approval of training programs; providing general application procedures for licensure applications; providing conforming changes to apply disciplinary actions to a individual certified 911 emergency dispatcher; providing an effective date.

A bill to be entitled

An act relating to 911 emergency dispatcher certification; amending s. 401.465, F.S.; requiring any person serving as a 911 emergency dispatcher to be certified by the Department of Health on or after a specified date; providing conditions under which a public safety agency may employ a 911 emergency dispatcher trainee for a limited period; providing clarifying language with respect to certification or recertification as a 911 emergency dispatcher; revising requirements for certification as a 911 emergency dispatcher; providing an effective date.

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

Section 1. Subsection (2) of section 401.465, Florida Statutes, is amended to read:

401.465 911 emergency dispatcher certification.--

(2) PERSONNEL; STANDARDS AND CERTIFICATION.--

(a) Effective October 1, 2012, any person serving as a 911 emergency dispatcher must be certified by the department. Notwithstanding this requirement, a public safety agency as defined s. 365.171(3)(d) may employ a 911 emergency dispatcher trainee for a period not to exceed 6 months, provided that the trainee is under the direct supervision, as determined by rule of the department, of a certified 911 emergency dispatcher with a minimum of 2 years' experience.

(b) ~~(a)~~ An applicant ~~Any person who desires~~ to be certified or recertified as a 911 emergency dispatcher must ~~may~~ apply to

the department under oath on forms provided by the department. The department shall establish by rule educational and training criteria for the certification and recertification of 911 emergency dispatchers. Prior to October 1, 2012, any person who desires to be certified or recertified as a 911 emergency dispatcher may apply to the department as described in this section.

(c) ~~(b)~~ The department shall determine whether the applicant meets the requirements specified in this section and in rules of the department and shall issue a certificate to any person who meets such requirements. Such requirements must include, but need not be limited to, the following:

1. Completion of an appropriate 911 emergency dispatcher training program that is equivalent to or more stringent than the most recently approved emergency dispatcher course of the Department of Education and consists of not less than 208 hours;

~~2. Completion and documentation of at least 2 years of supervised full-time employment as a 911 emergency dispatcher since January 1, 2002;~~

2. ~~3.~~ Certification under oath that the applicant is not addicted to alcohol or any controlled substance;

3. ~~4.~~ Certification under oath that the applicant is free from any physical or mental defect or disease that might impair the applicant's ability to perform his or her duties;

4. ~~5.~~ Submission of the application fee prescribed in subsection (3); and

5.~~6.~~ Submission of a completed application to the department which indicates compliance with subparagraphs 1., 2., 3., and 4.

(d)~~(c)~~ The department shall establish by rule a procedure for the biennial renewal certification of 911 emergency dispatchers.

(e)~~(d)~~ Each 911 emergency dispatcher certificate expires automatically if not renewed at the end of the 2-year period and may be renewed if the holder meets the qualifications for renewal as established by the department. A certificate that is not renewed at the end of the 2-year period automatically reverts to an inactive status for a period that may not exceed 180 days. Such certificate may be reactivated and renewed within the 180-day period if the certificateholder meets all other qualifications for renewal and pays a $50 late fee. Reactivation shall be in a manner and on forms prescribed by department rule.

(f)~~(e)~~ The department may suspend or revoke a certificate at any time if it determines that the certificateholder does not meet the applicable qualifications.

(g)~~(f)~~ A certificateholder may request that his or her 911 emergency dispatcher certificate be placed on inactive status by applying to the department before his or her current certification expires and paying a fee set by the department which may not exceed $100.

1. A certificateholder whose certificate has been on inactive status for 1 year or less may renew his or her certificate pursuant to the rules adopted by the department and

upon payment of a renewal fee set by the department which may not exceed $100.

2. A certificateholder whose certificate has been on inactive status for more than 1 year may renew his or her certificate pursuant to rules adopted by the department.

3. A certificate that has been inactive for more than 6 years automatically expires and may not be renewed.

(h) ~~(g)~~ The department shall establish by rule a procedure for the initial certification of 911 emergency dispatchers as defined in this section who have documentation of at least 5 years of supervised full-time employment as a 911 emergency dispatcher since January 1, 2002.

Section 2. This act shall take effect October 1, 2009.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 873 Licensure of Health Care Providers
SPONSOR(S): Williams
TIED BILLS: **IDEN./SIM. BILLS:** SB 1926

	REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1)	Health Care Regulation Policy Committee		Holt	Calamas
2)	Health & Family Services Policy Council			
3)	Health Care Appropriations Committee			
4)	Full Appropriations Council on General Government & Health Care			
5)				

SUMMARY ANALYSIS

The bill allows a rural hospital that has held an inactive license for at least 20 months to have its license renewed again for an additional 12 months. This would allow a rural hospital with an inactive license to maintain inactive licensure status for up to 36 months if it meets the eligibility requirements.

To be eligible for the additional renewal a rural hospital must meet the statutory rural hospital criteria specified in s.395.602(2), F.S., and demonstrate progress towards reopening, but not be able to reopen, prior to the inactive license expiration date.

The bill has no fiscal impact to state or local governments.

The bill takes effect upon becoming a law.

HOUSE PRINCIPLES

Members are encouraged to evaluate proposed legislation in light of the following guiding principles of the House of Representatives

- Balance the state budget.
- Create a legal and regulatory environment that fosters economic growth and job creation.
- Lower the tax burden on families and businesses.
- Reverse or restrain the growth of government.
- Promote public safety.
- Promote educational accountability, excellence, and choice.
- Foster respect for the family and for innocent human life.
- Protect Florida's natural beauty.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation:

The Agency for Health Care Administration ("agency") license and regulates hospitals pursuant to part I of chapter 395, F.S. In addition to the specific licensure requirements of that part, hospitals are subject to the Health Care Licensing Procedures Act in part II of chapter 408, F.S.[1] The Act was created to address unnecessary duplication and variation in the requirements for licensure by the agency.[2] The Act was intended to streamline and create a consistent set of basic licensing requirements for all providers in order to minimize confusion, standardize terminology, and include issues that are otherwise not adequately addressed in the Florida Statutes pertaining to specific providers.[3] The Act applies to hospitals.[4]

Licensure Process

Section 408.806, F.S., provides the application process for licensure of hospitals. An applicant for licensure must submit an application to the agency under oath and an associated fee in order for an application to be accepted and considered timely.

To renew a license an applicant must submit an application and associated fee at least 60 days *prior* to the expiration of the current license. If the renewal application and fee are received by *prior* to the license expiration date, the license does not expire even if the license expiration date occurs during the agency's review of the renewal application.[5] If the application for initial licensure is due to a change of ownership then the application must be received by the agency at least 60 days prior to the date of change of ownership.

The agency is required to notify the licensee by mail or electronically at least 90 days prior to the expiration of a license that a renewal license is necessary to continue operation. The agency will assess a late fee of $50 per day to a licensee for failure to timely submit a renewal application agency, but the total amount of the late fee may not exceed 50 percent of the licensure fee or $500, whichever

[1] Chapter 2006-192, L.O.F.
[2] Section 408.801(2), F.S.
[3] *Ibid.*
[4] Section 408.802, F.S.
[5] Section 408.806(2), F.S.

is less.[6] If an application is received after the required filing date and exhibits a hand-canceled postmark obtained from a United States post office dated on or before the required filing date, no fine will be levied.[7] Within 30 days of receipt of an application for a license, the agency is required to notify the applicant in writing of any apparent errors or omissions and request any additional information. Any information that is omitted from an application for licensure, license renewal, or change of ownership, other than an inspection, must be provided to the agency within 21 days after the agency's request or the application will be deemed incomplete and will be withdrawn from further consideration and the submitted fees are forfeited. The agency is required to approve or deny an application within 60 days following the receipt of a complete application. Licenses are generally issued biennially, unless a spefic license category specifies a shorter period.[8]

There are three primary licensure categories:[9]

- **Standard License**—a standard license may be issued to an applicant at the time of initial licensure, license renewal, or change of ownership. A standard license is issued when the applicant is in compliance with state law and administrative rules. Unless revoked, a standard license expires two years after the date of issue.[10]

- **Provisional License**—a provisional license is issued to an applicant who has under gone a background screening but not received the results from the Florida Department of Law Enforcement.[11] In addition an applicant with a pending license but a determination of whether to denying or revoking a license may be issued a provisional license effective until a final action is determined.[12]

- **Inactive License**—an inactive license may be issued to a health care provider, subject to the certificate-of-need provisions in part I of chapter 408, F.S., if the provider is currently licensed[13] and temporarily unable to provide services but reasonably expected to resume services within 12 months. Such designation may be made for a period not to exceed 12 months but may be renewed by the agency for up to 12 additional months if the licensee demonstrates progress towards reopening. A request by a licensee for an inactive license or an extension must be submitted to the agency and include:[14]
    - A written justification for the inactive license with the beginning and ending dates of inactivity specified;
    - A plan for the transfer of any clients to other providers; and
    - Appropriate licensure fees.

  The agency may not accept a request that is:
    - Submitted after initiating closure;
    - After any suspension of service; or
    - After notifying clients of closure or suspension of service, unless the action is a result of a disaster[15] at the licensed premises.

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[6] Section 408.806(2)(d), F.S.
[7] *Ibid.*
[8] Section 408.806(3), F.S.
[9] Section 408.808, F.S.
[10] Section 408.808(1), F.S.
[11] Section 408.809(3), F.S.
[12] Section 408.808(2), F.S.
[13] The license may not be a provisional license.
[14] Section 408.808(3), F.S.
[15] A "disaster" is considered a sudden emergency occurrence beyond the control of the licensee, whether natural, technological, or manmade, which renders the provider inoperable at the premises.

Upon agency approval, the provider must notify clients of any necessary discharge or transfer that may be required by law. The beginning of the inactive license period is the date the provider ceases operations. The end of the inactive license period shall become the licenses' expiration date. All licensure fees must be current, paid in full, and may be prorated. Reactivation of an inactive license requires the approval of a renewal application, associated licensure fees and necessary inspections indicating compliance with all required licensure provisions.

Statutory Designated Rural Hospitals

Part III of chapter 395, F.S., provides for rural hospitals. A "rural hospital" is an acute care hospital that has 100 or fewer licensed beds, an emergency room and is:[16]

- The sole provider within a county with a population density of no greater than 100 persons per square mile;
- An acute care hospital, in a county with a population density of no greater than 100 persons per square mile, which is at least 30 minutes of travel time, on normally traveled roads under normal traffic conditions, from any other acute care hospital within the same county;
- A hospital supported by a tax district or sub-district whose boundaries encompass a population of 100 persons or fewer per square mile;
- A hospital in a constitutional charter county with a population of over 1 million persons that has imposed a local option health service tax pursuant to law and in an area that was directly impacted by a catastrophic event on August 24, 1992, for which the Governor of Florida declared a state of emergency and has 120 beds or less that serves an agricultural community with an emergency room utilization of no less than 20,000 visits and a Medicaid inpatient utilization rate greater than 15 percent; or
- A hospital with a service area[17] that has a population of 100 persons or fewer per square mile.

Population densities must be determined based upon the most recently completed United States census. An acute care hospital that has not previously been designated as a rural hospital and that meets the criteria will be granted such designation upon application, including submission of supporting documentation to the agency.

The Effects of the Bill

The bill allows a rural hospital that has held an inactive license for at least 20 months to have its license renewed again for an additional 12 months. This would allow a rural hospital with an inactive license to maintain inactive license status for up to 36 months if it meets the eligibility requirements.

To be eligible a rural hospital must meet the statutory rural hospital criteria specified in s.395.602(2), F.S., and must demonstrate progress towards reopening, but not be able to reopen prior to the inactive license expiration date. The bill does not define what constitutes "demonstrated progress".

B. SECTION DIRECTORY:

Section 1. Amends 408.808, F.S. relating to licensure categories.
Section 2. Provides that the bill takes effect upon becoming a law.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

[16] Section 395.602(2), F.S.

[17] A "service area" has the fewest number of zip codes accounting for 75 percent of the hospital's discharges for the most recent 5-year period (based on information available from the hospital inpatient discharge database in the Florida Center for Health Information and Policy Analysis at the Agency for Health Care Administration) or a hospital designated as a critical access hospital, as defined in s. 408.07(15), F.S.

1. Revenues:

   None.

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

No additional rule-making authority is necessary to implement the provision in the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

To be eligible for the additional inactive licensure renewal, a rural hospital must demonstrate progress towards reopening. The bill does not define what constitutes "demonstrated progress", and so may not give sufficient guidance to the agency in determining whether to issue a renewal. This may implicate Art. II S. 3 of the Florida Constitution.

IV. AMENDMENTS/COUNCIL OR COMMITTEE SUBSTITUTE CHANGES

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

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

Bill No. **873**

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: Health Regulation Policy Committee

Representative(s) Williams, A. offered the following:

Amendment (with title amendment)

Remove line(s) 26 and insert:

to 12 additional months. The licensee, if construction or renovation is required, must have had plans approved by the agency and must have commenced construction pursuant to 408.032(4). Where construction or renovation are not required, the licensee must provide proof of having made an enforceable capital expenditure of greater than 25 percent of the total costs associated with the purchase of equipment, hiring of staff and purchasing of supplies needed to operate the facility upon opening. A request by a licensee for an inactive

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

Remove line(s) 5 and insert:

under certain circumstances; requiring plan approval and commencement of construction under certain circumstances;

requiring certain proof of enforceable capital expenditures under certain circumstances; providing an effective date.

A bill to be entitled

An act relating to licensure of health care providers; amending s. 408.808, F.S.; providing for renewal of inactive license status for statutory rural hospitals under certain circumstances; providing an effective date.

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

Section 1. Subsection (3) of section 408.808, Florida Statutes, is amended to read:

408.808 License categories.--

(3) INACTIVE LICENSE.--An inactive license may be issued to a health care provider subject to the certificate-of-need provisions in part I of this chapter when the provider is currently licensed, does not have a provisional license, and will be temporarily unable to provide services but is reasonably expected to resume services within 12 months. Such designation may be made for a period not to exceed 12 months but may be renewed by the agency for up to 12 additional months upon demonstration by the licensee of the provider's progress toward reopening. However, if after 20 months in an inactive license status, a statutory rural hospital, as defined in s. 395.602, has demonstrated progress toward reopening, but may not be able to reopen prior to the inactive license expiration date, the inactive designation may be renewed again by the agency for up to 12 additional months. A request by a licensee for an inactive license or to extend the previously approved inactive period must be submitted to the agency and must include a written

justification for the inactive license with the beginning and ending dates of inactivity specified, a plan for the transfer of any clients to other providers, and the appropriate licensure fees. The agency may not accept a request that is submitted after initiating closure, after any suspension of service, or after notifying clients of closure or suspension of service, unless the action is a result of a disaster at the licensed premises. For the purposes of this section, the term "disaster" means a sudden emergency occurrence beyond the control of the licensee, whether natural, technological, or manmade, which renders the provider inoperable at the premises. Upon agency approval, the provider shall notify clients of any necessary discharge or transfer as required by authorizing statutes or applicable rules. The beginning of the inactive license period is the date the provider ceases operations. The end of the inactive license period shall become the license expiration date. All licensure fees must be current, must be paid in full, and may be prorated. Reactivation of an inactive license requires the approval of a renewal application, including payment of licensure fees and agency inspections indicating compliance with all requirements of this part, authorizing statutes, and applicable rules.

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

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 897 Controlled Substances
SPONSOR(S): Llorente
TIED BILLS: HB 937 **IDEN./SIM. BILLS:**

	REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1)	Health Care Regulation Policy Committee		Calamas	Calamas CEC
2)	Public Safety & Domestic Security Policy Committee			
3)	Health & Family Services Policy Council			
4)	Full Appropriations Council on General Government & Health Care			
5)				

SUMMARY ANALYSIS

The bill requires the Agency for Health Care Administration (AHCA) to design and implement a prescription drug monitoring database to monitor dispensing of Schedule II, III and IV controlled substances.

The bill requires pharmacies and dispensing practitioners to report certain information about the dispensing of those substances within 15 days of dispensing in a manner consistent with state and federal privacy and security laws. The bill requires the Department of Health and regulatory boards to promulgate rules defining what information must be reported, and requires AHCA to promulgate rules defining the manner of reporting. The bill provides several exemptions from the reporting requirements for controlled substances:

- Administered by a health care practitioner directly to a patient
- Dispensed by a health care practitioner and limited to a 72-hour supply
- Dispensed by a health care practitioner or a pharmacist to an inpatient of a facility with an institutional pharmacy
- Ordered from an institutional pharmacy
- Used for patients receiving care from a hospital, nursing home, assisted living facility, home health agency, hospice, or intermediate care facility for the developmentally disabled

The bill makes it a first degree misdemeanor for any person to knowingly fail to make a report required by the bill.

The bill provides that all "costs incurred by the agency" in implementing the bill "shall be through federal, private, or grant funding applied for by the state".

The bill creates a significant negative impact to the Grants and Donations Trust Fund within AHCA. The impact is estimated to be $4,036,348 in the first year and a recurring impact of $2,930,348 for the implementation of the controlled substance data system. (See Fiscal Analysis.)

The effective date of the bill is July 1, 2009.

HOUSE PRINCIPLES

Members are encouraged to evaluate proposed legislation in light of the following guiding principles of the House of Representatives

- Balance the state budget.
- Create a legal and regulatory environment that fosters economic growth and job creation.
- Lower the tax burden on families and businesses.
- Reverse or restrain the growth of government.
- Promote public safety.
- Promote educational accountability, excellence, and choice.
- Foster respect for the family and for innocent human life.
- Protect Florida's natural beauty.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Current Situation

Controlled Substances Dispensing

Chapter 893, F.S., sets forth the Florida Comprehensive Drug Abuse Prevention and Control Act. Controlled substances are classified into five schedules in order to regulate the manufacture, distribution, preparation, and dispensing of the substances. Substances in Schedule I have a high potential for abuse and have no currently accepted medical use in the United States. Schedule II drugs have a high potential for abuse and a severely restricted medical use. Cocaine and morphine are examples of Schedule II drugs. Schedule III controlled substances have less potential for abuse than Schedule I or Schedule II substances and have some accepted medical use. Substances listed in Schedule III include anabolic steroids, codeine, and derivatives of barbituric acid. Schedule IV and Schedule V substances have a low potential for abuse, compared to substances in Schedules I, II, and III, and currently have accepted medical use. Substances in Schedule IV include phenobarbital, librium, and valium. Substances in Schedule V include certain stimulants and narcotic compounds.

Section 893.05, F.S., allows a practitioner, in good faith and in the course of his or her professional practice only, to prescribe, administer, dispense, mix, or otherwise prepare a controlled substance. Section 893.02, F.S., defines practitioner to mean a licensed medical physician, a licensed dentist, a licensed veterinarian, a licensed osteopathic physician, a licensed naturopathic physician, or a licensed podiatrist, if such practitioner holds a valid federal controlled substance registry number.

Section 893.04, F.S., authorizes a pharmacist, in good faith and in the course of professional practice to dispense controlled substances upon a written or oral prescription under specified conditions:

- An oral prescription must be promptly reduced to writing by the pharmacist;
- The written prescription must be dated and signed by the prescribing practitioner on the date issued; and
- The face of the prescription or written record for the controlled substance must include:
  - The full name and address of the person for whom, or the owner of the animal for which, the controlled substance is dispensed;
  - The full name and address of the prescribing practitioner and the prescriber's federal controlled substance registry number;

- If the prescription is for an animal, the species of animal for which the controlled substance is prescribed;
- The name of the controlled substance prescribed and the strength, quantity, and directions for the use thereof;
- The number of the prescription, as recorded in the prescription files of the pharmacy in which it is filed; and
- The initials of the pharmacist filling the prescription and the date filled.

Section 893.04(1)(d), F.S., requires the proprietor of the pharmacy in which a prescription for controlled substances is filled to retain the prescription on file for a period of 2 years. The original container in which a controlled substance is dispensed must bear a label with the following information:

- The name and address of the pharmacy from which the controlled substance was dispensed;
- The date on which the prescription for the controlled substance was filled;
- The number of the prescription, as recorded in the prescription files of the pharmacy in which it is filled;
- The name of the prescribing practitioner;
- The name of the patient for whom, or of the owner and species of the animal for which, the controlled substance is prescribed;
- The directions for the use of the controlled substance prescribed in the prescription; and
- A clear, concise warning that it is a crime to transfer the controlled substance to any person other than the patient for whom prescribed.

Chapter 893, F.S., imposes other limitations on controlled substance prescriptions. A prescription for a Schedule II controlled substance may be dispensed only upon a written prescription of a practitioner, except in an emergency situation, as defined by rule of the department, when such controlled substance may be dispensed upon oral prescription. No prescription for a Schedule II controlled substance may be refilled.[1] No prescription for a controlled substance listed in Schedules III, IV, or V may be filled or refilled more than five times within a period of 6 months after the date on which the prescription was written unless the prescription is renewed by a practitioner.[2] A pharmacist may dispense a one-time emergency refill of up to a 72-hour supply of the prescribed medication for any medicinal drug other than a medicinal drug listed in Schedule II.[3]

Prescription Drug Diversion and Abuse

According to the Substance Abuse and Mental Health Services Administration, more than 6.3 million Americans reported using prescription drugs for nonmedical reasons in 2003.[4] The National Institute on Drug Abuse seeks to reverse this trend by increasing awareness and promoting additional research on the topic. Most people who take prescription medications take them responsibly; however, the nonmedical use or abuse of prescription drugs remains a serious public health concern in the United States. Certain prescription drugs – opioid substances, central nervous system depressants, and stimulants – when abused can alter the brain's activity and lead to dependence and possible addiction.

Prescription drug abuse also occurs when a person illegally obtains a legal prescription drug for nonmedical use. People obtain these drugs in a variety of ways, including "doctor shopping," in which the person continually switches physicians so that they can obtain enough of the drug to feed their addiction. By frequently switching physicians, the doctors are unaware that the patient has already been prescribed the same drug and may be abusing it. A study in Australia indicated that most doctor shoppers switch only sporadically. However, the top 25 percent shop very actively, travel widely, and see many different

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[1] s. 893.04(1)(f), F.S.
[2] s. 893.04(1)(g), F.S.
[3] *See* 21 C.F.R. 1306.11(d)(1), which provides that in an emergency situation, a pharmacist may dispense a Schedule II controlled substance upon receiving oral authorization of a prescribing practitioner if the quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period.
[4] Overview of Findings from the 2003 National Survey on Drug Use and Health, *see* http://oas.samhsa.gov/nhsda/2k3nsduh/2k3Overview.htm (last viewed March 16, 2007).

practitioners, often on the same day. Doctor shoppers generally take the medicine themselves. Compared to the number of doctors consulted, in a recent survey most doctor shoppers have their prescriptions dispensed at few pharmacies.[5]

Use of prescription pain relievers without a doctor's prescription or only for the experience or feeling they caused ("nonmedical" use) is, after marijuana use, the second most common form of illicit drug use in the United States.[6] According to the Drug Abuse Warning Network (DAWN), approximately 324,000 emergency department visits in 2006 involved the nonmedical use of pain relievers (including both prescription and over-the-counter pain medications).[7]

The Substance Abuse and Mental Health Services Administration (SAMHSA) sponsors an annual national survey on drug use and health. The most recent survey[8] indicates there are 7.0 million (2.8 percent) persons aged 12 or older who used prescription-type psychotherapeutic drugs nonmedically in the past month. Of these, 5.2 million used pain relievers, an increase from 4.7 million in 2005.

Of those 7 million people who used pain relievers nonmedically in the past 12 months, 55.7 percent reported they received the drug from a friend or relative for free. Another 9.3 percent bought the drugs from a friend or family member. Another 19.1 percent reported they obtained the drug through just one doctor. Only 3.9 percent got the pain relievers from a drug dealer or other stranger, and only 0.1 percent reported buying the drug on the Internet. Among those who reported getting the pain reliever from a friend or relative for free, 80.7 percent reported in a follow-up question that the friend or relative had obtained the drugs from just one doctor, while only 1.6 percent reported that the friend or relative had bought the drug from a drug dealer or other stranger.[9]

According to recent U.S. DEA statistics, the top 25 pain management clinics for dispensing of time release opiods and other pain relievers are all located in Florida.[10]

National data indicate that the percent of the population using prescription pain relievers for nonmedical purposes in the past year ranged from a low of 2.48 percent in area of the District of Columbia to a high of 7.92 percent in northwest Florida. In Florida, for example: Palm Beach County measured 4.53 percent; Broward County measured 3.82 percent; Miami-Dade and Monroe Counties measured 3.59 percent; and Escambia, Okaloosa, Santa Rosa and Walton Counties combined measured 7.92 percent.[11]

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[5] *See*, www.hic.gov.au (last viewed March 24, 2009).

[6] Substance Abuse and Mental Health Services Administration, Office of Applied Studies, Results from the 2007 National Survey on Drug Use and Health: National findings (DHHS Publication No. SMA 08-4343, NSDUH Series H-34) (2008), *see* http://oas.samhsa.gov/p0000016.htm (last viewed March 21, 2009); *cited in*, The NSDUH Report, Trends in Nonmedical Use of Prescription Pain Relievers: 2002 to 2007, Feb. 5, 2009, *see* http://www.oas.samhsa.gov/2k9/painRelievers/nonmedicalTrends.cfm (last viewed March 21, 2009).

[7] Substance Abuse and Mental Health Services Administration, Office of Applied Studies, Drug Abuse Warning Network, 2006: National Estimates of Drug-Related Emergency Department Visits, (August 2008), *see* http://dawninfo.samhsa.gov/files/ED2006/DAWN2K6ED.pdf (last viewed March 24, 2009), *cited in*, The NSDUH Report, Trends in Nonmedical Use of Prescription Pain Relievers: 2002 to 2007, Feb. 5, 2009, *see* http://www.oas.samhsa.gov/2k9/painRelievers/nonmedicalTrends.cfm (last viewed March 21, 2009).

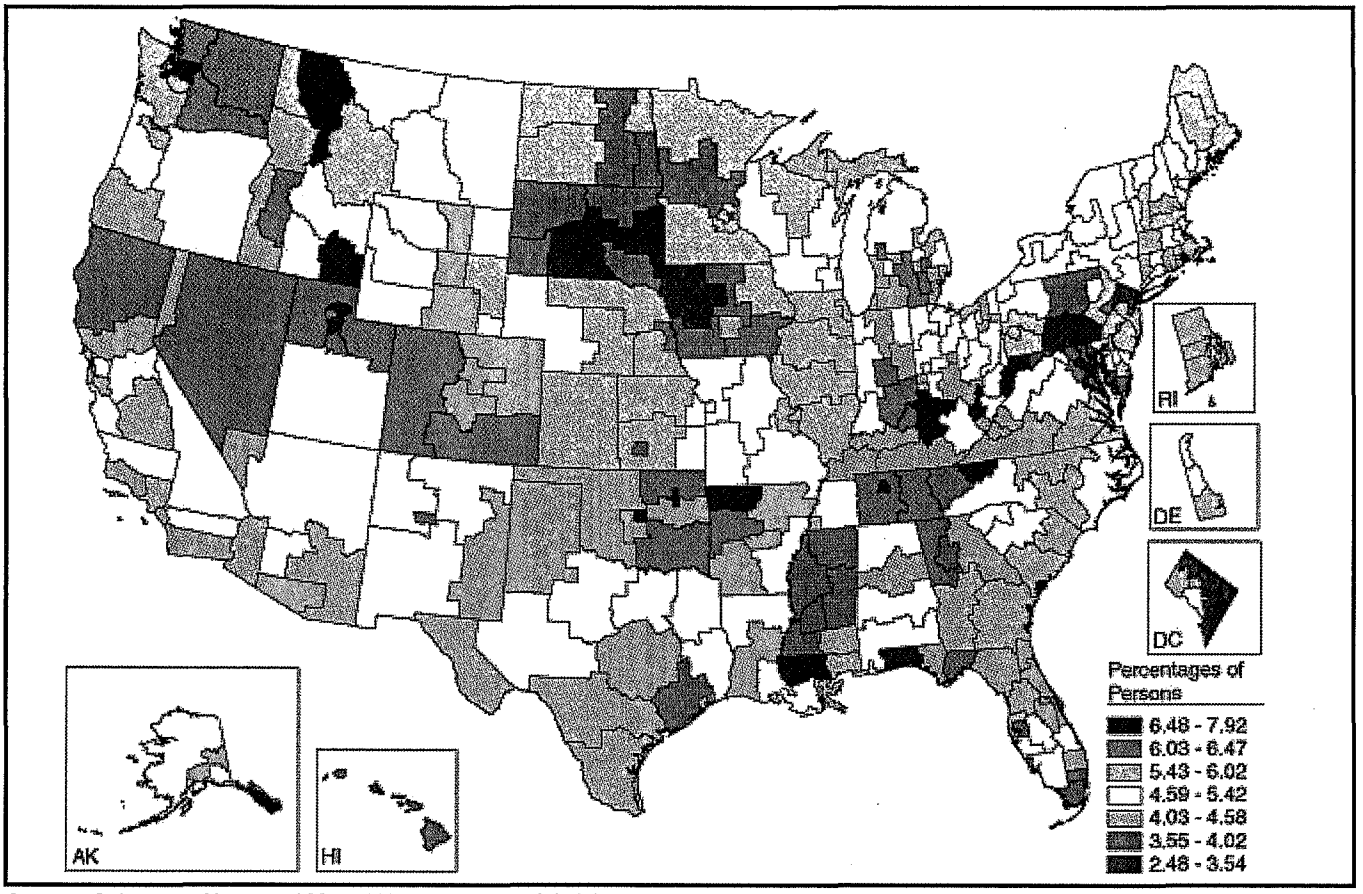
[8] 2006 National Survey on Drug Use and Health, U.S. Substance Abuse and Mental Health Services Administration, *see* http://www.oas.samhsa.gov/nsduh/2k6nsduh/2k6Results.cfm#High (last viewed March 21, 2009).

[9] *Id.*

[10] Data drawn from the Automation of Reports and Consolidated Orders System, U.S. Department of Justice Drug Enforcement Administration, provided by the Florida Office of Drug Control via email March 22, 2009, on file with the Health Regulation Policy Committee, *see* http://www.deadiversion.usdoj.gov/arcos/index.html (last viewed March 24, 2009).

[11] Substance Abuse and Mental Health Services Administration, Office of Applied Studies, The NSDUH Report: Nonmedical Use of Pain Relievers in Substate Regions: 2004 to 2006, June 19, 2008, *see* http://www.oas.samhsa.gov/2k8/pain/substate.cfm (last viewed March 21, 2009).

Figure 1. Nonmedical Use of Pain Relievers in the Past Year among Persons Aged 12 or Older, by Substate Region*: Percentages, Annual Averages Based on 2004, 2005, and 2006 NSDUHs



Source: Substance Abuse and Mental Health Services Administration, Office of Applied Studies. (June 19, 2008). The NSDUH Report: Nonmedical Use of Pain Relievers in Substate Regions: 2004 to 2006.

The Florida Medical Examiners Commission reports on drug-related deaths in Florida, and specifically tracks deaths caused by abuse of prescriptions drugs[12]. According to the Commission, prescription drugs are found in deceased persons in lethal amounts more often than illicit drugs.[13] According to the Commission's data, 1581 deaths in Florida from January 2008 through June 2008 were caused by prescription drugs.[14] That averages to 8.6 deaths per day.

Prescription Drug Monitoring Programs

Currenty, 38 states have enacted legislation establishing prescription-drug-monitoring programs, and 32 states have operational programs.[15] Prescription-drug-monitoring programs collect prescription data from pharmacies in either paper or electronic format. The data may be reviewed and analyzed for educational, public health, and investigational purposes. The goals of prescription monitoring systems are dependent on the mission of the state agency that operates the program or uses the data. Each state that has implemented a prescription-drug-monitoring program has its own set of goals for its program. Prescription monitoring systems may cover a specified number of controlled substances. Several states

[12] Florida Department of Law Enforcement, Medical Examiners Commission, Drugs Identified in Deceased Persons Interim Report, November 2008, *see* http://www.fdle.state.fl.us/content/getdoc/036671bc-4148-4749-a891-7e3932e0a483/Publications.aspx (last viewed March 21, 2009). The prescription drugs tracked by the Commission are prescription benzodiazepines, Barisoprodol/Meprobamate, and all opioids, excluding heroin.
[13] *Id.*
[14] Florida Department of Law Enforcement, *supra* note 11 at Table 1, Summary of Drug-Related Deaths January – June 2008.
[15] National Alliance for Model State Drug Laws, Status of State Prescription Drug Monitoring Programs, *see* http://www.namsdl.org/presdrug.htm (last viewed March 21, 2009).

cover only controlled substances listed in Schedule II; while others cover a range of controlled substances listed in Schedules II through V.[16]

Prescription-drug-monitoring programs may cover a specified number of controlled substances. Several states cover only controlled substances listed in Schedule II, while others cover a range of controlled substances listed in Schedules II through V. Prescription-drug-monitoring programs may also combine the use of serialized prescription forms by prescribing practitioners that are tracked by state officials and an electronic data system that tracks the prescriptions.

Advocates claim the potential advantages of an electronic prescription data collection system include the following:

- Identifies "doctor shoppers" by tracking all their prescribing physicians and purchases from pharmacies. Doctor shopping is when a person continually switches physicians so that they can obtain enough of a drug to feed their addiction;
- Provides complete and reliable information on prescribing and dispensing activities so that investigators can identify, rank, and set priorities for cases;
- Maximizes investigators' effectiveness by providing prescription data in a convenient, comprehensive, and timely method;
- Reduces intrusion into professional practices because investigators no longer need to make office visits to gather information on practitioner prescribing patterns; and
- Reduces the need for investigators to make pharmacy visits in order to gather data on pharmacy or pharmacists' dispensing patterns.

Privacy and Security

The 1996 Health Insurance Portability and Accountability Act (HIPAA) required the federal government to issue regulations protecting the privacy of health information. The U.S. Department of Health and Human Services (HHS) issued Standards for Privacy of Individually Identifiable Health Information on December 28, 2000, which took effect on April 14, 2003. The regulations establish a set of national standards for the protection of health information, and apply to health plans, health care clearinghouses and certain health care providers. The regulations permit states to afford greater privacy protections to health information. Exceptions for state law are provided for public health and state regulatory reporting.[17]

Some opponents of prescription monitoring systems dislike the concept of mandatory disclosure of protected health information and point to federal and state privacy laws as barriers to these monitoring systems. There is a possibility that the tracking system could violate the Florida Constitution's Right to Privacy. In 1980, the citizens of Florida approved an amendment to Florida's Constitution, which grants Florida citizens an explicit right of privacy. Contained in Article I, Section 23, the Constitution provides:

> Right of privacy--Every natural person has the right to be let alone and free from governmental intrusion into the person's private life except as otherwise provided herein. This section shall not be construed to limit the public's right of access to public records and meetings as provided by law.

This right to privacy protects Florida's citizens from the government's uninvited observation of or interference in those areas that fall within the range of the zone of privacy afforded under this provision.

Unlike the implicit privacy right of the Federal Constitution, Florida's express privacy provision is of itself a fundamental right that, once implicated, demands evaluation under a compelling state interest standard. The federal right of privacy is more limited than the state provision, and extends only to such fundamental interests as marriage, procreation, contraception, family relationships, and the rearing and education of children. Since the people of this state have exercised their prerogative and enacted an amendment to the Florida Constitution that expressly and succinctly provides for a strong right of privacy not found in the

[16] Some states, like Ohio, include non-controlled pain medications with high risk of abuse.
[17] U.S. Department of Health & Human Services, Health Information Privacy, *see* http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/index.html (last viewed March 21, 2009).

United States Constitution, it is much broader in scope than that of the Federal Constitution. Subsequently, the court has consistently held that Article I, section 23 was adopted in an effort to grant Floridians greater privacy protection than that available under the Federal Constitution.[18]

Funding

Beginning in 2002, Congress appropriated funding to the U.S. Department of Justice to support a Prescription Drug Monitoring Program.[19] The Program awards funds in the form of Harold Rogers grants to state regulatory and law enforcement agencies for the purposes of:

- Building a data collection and analysis system at the state level.
- Enhancing existing programs' ability to analyze and use collected data.
- Facilitating the exchange of collected prescription data among states.
- Assessing the efficiency and effectiveness of the programs funded by the grant program.[20]

In 2008, 17 grant awards were made to various state agencies and an educational institution, between $50,000 and $670,000, including an award to the Florida Department of Children and Family Services of $50,000.[21] Grants were awarded for planning, implementation and enhancement of prescription drug monitoring programs, and for training and technical assistance. Funding for Fiscal Year 2009 has not yet been determined.

American Society for Automation in Pharmacy

The American Society for Automation in Pharmacy (ASAP) is an organization whose mission is to "assist its member in advancing the application of computer technology in the pharmacist's role as caregiver and in the efficient operation and management of a pharmacy."[22] Its members include independent pharmacies and hospital pharmacies as well as individuals from colleges of pharmacy, state boards of pharmacy, state and national associations, and government agencies. The ASAP publishes standards for the implementation of prescribed drug monitoring programs.[23]

Electronic Prescribing

Electronic prescribing is the electronic generation and transmission of a patient's prescription by a health care practitioner at the point of care. Electronic prescribing involves a secure, electronic connection between the physician and the pharmacy. In addition, electronic prescribing software generally allows a healthcare practitioner to not only securely access the patient's health plan formulary, but also the patient's medication history, all at the point of care. Medication history is generally available in an 11 to 24 month rolling window, and it generally includes both written and electronically transmitted prescriptions. Numerous software companies offer stand-alone electronic prescribing products. While the cost of the product varies, some products are available at no cost to the healthcare practitioner.[24]

In 2007, the Legislature passed and the Governor signed into law SB 1155. That bill required AHCA to work with private-sector initiatives and relevant stakeholders to create a "clearinghouse" of information on electronic prescribing for healthcare practitioners, facilities, and pharmacies. As required by the bill, AHCA developed a website that provides information on the process and advantages of electronic prescribing, the availability of electronic prescribing software, including no-cost and low-cost software, and state and

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[18] In re T.W., 551 So.2d 1186 (Fla. 1989).
[19] U.S. Department of Justice Appropriations Act (Public Law 107-77).
[20] U.S. Department of Justice, Bureau of Justice Assistance, Harold Rogers Prescription Drug Monitoring Program, *see* http://www.ojp.usdoj.gov/BJA/grant/prescripdrugs.html (last viewed March 21, 2009).
[21] U.S. Department of Justice, Bureau of Justice Assistance, Harold Rogers Prescription Drug Monitoring Program FY 2008 Grantees, *see* http://www.ojp.usdoj.gov/BJA/grant/prescripdrugs.html (last viewed March 21, 2009).
[22] *See* http://www.asapnet.org/index.html.
[23] The Standards are available for purchase at http://www.asapnet.org/bookstore.html (last viewed March 24, 2009).
[24] *See e.g.,* http://www.nationalerx.com/ and http://www.iscribe.com/ (offering free web-based electronic prescribing software) (last viewed March 21, 2009); Florida ePrescribe Clearinghouse, Products and Services, *see* http://www.fhin.net/eprescribe/Technology/products.shtml (last viewed March 21, 2009).

federal electronic prescribing incentive programs.[25] AHCA also reports annually to the Governor and Legislature on the implementation of electronic prescribing by health care practitioners, facilities and pharmacies.

According to AHCA and the Institute of Medicine, electronic prescribing offers numerous benefits, including:[26]

- Reduced health care and legal costs by preventing medication prescription errors caused by events such as illegible hand writing, look-alike or sound-alike drugs, drug-to-drug interactions, incorrect dosing, drug allergy reactions, duplication of drugs, etc.;
- Real-time communications between doctors, pharmacies and patients;
- Provision of drug pricing, payer coverage and preferred drug information;
- Improved clinical outcomes by creating complete patient medication history and providing critical drug alerts and patient specific information at the health care professionals' fingertips; and
- Reduction of fraud and crime by increasing the security of prescriptions.

According to AHCA's most recent report, E-prescribing improved prescription security by providing a complete audit trail of each transaction, from the prescribing physician's office to the dispensing pharmacy, to the patient picking up the prescription. E-prescribing requires a secure log-in process for prescribing practitioners and pharmacies, which must be credentialed and approved before they can participate.[27,28] E-prescribing provides an additional back-up for prescription records, which makes it useful in situations of natural disaster when paper records may be destroyed.[29]

According to AHCA, eliminating paper and handwritten prescriptions can reduce fraud and abuse related to alterations of the paper prescription. For example, this paper prescription for head lice written to a Medicaid recipient was altered to include 190 tablets of Vicodin, a controlled substance. According to AHCA, this alteration was discovered when the pharmacist returned the prescription to the prescribing doctor with a note about his illegible handwriting.[30]

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[25] Florida E-Prescribe Clearinghouse, *see* http://www.fhin.net/eprescribe/Index.shtml (last viewed March 24, 2009); Agency for Health Care Administration, *see* http://ahca.myflorida.com/dhit/ElectronicPrescribing/ePrescribeIndex.shtml (last viewed March 24, 2009).

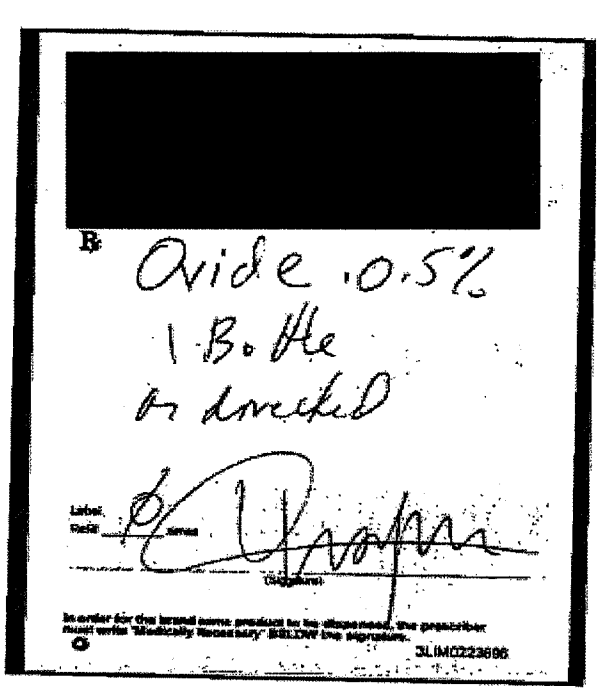
[26] Agency for Health Care Administration, Advantages of ePrescribing, *see* http://www.fhin.net/eprescribe/Benefits/Benefits.shtml (last viewed March 24, 2009), *citing* Institute of Medicine, Committee on Identifying and Preventing Medication Errors, "Preventing Medication Errors: Quality Chasm Series" (2006).

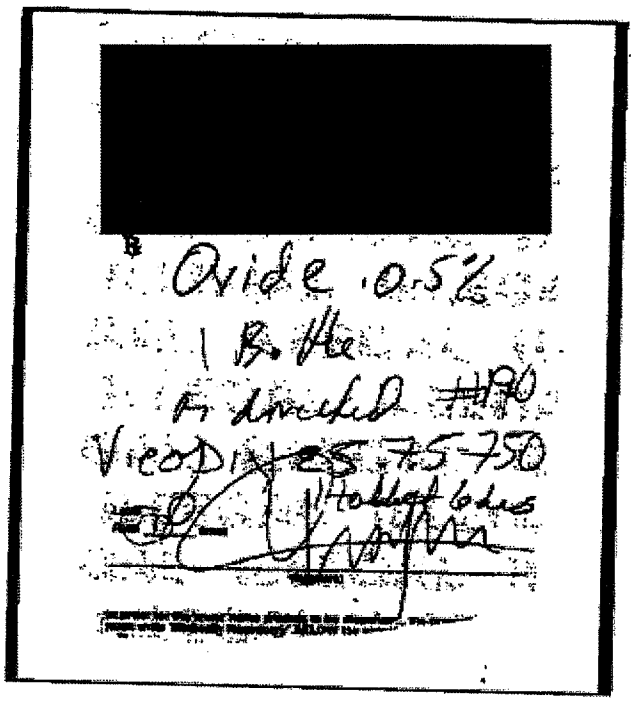
[27] Agency for Health Care Administration, Florida Center for Health Information and Policy Analysis, Second Annual Florida Electronic Prescribing Report, January 2009, *see* http://www.fhin.net/eprescribe/Index.shtml (last viewed March 21, 2009). "Secure access is possible using a virtual private network (VPN) connection over the Internet, which creates a protected electronic channel for the safe transmission of encrypted medication information. Infrastructure technology partners, vendors and others are bound through strong contracts to ensure the authentication of users, the integrity of prescriptions, and the privacy and security of personal health information that passes through the secure networks. Unwarranted prescription activity can be identified much more readily in the electronic system through the use of embedded auditing features."

[28] *Id.* at 7.

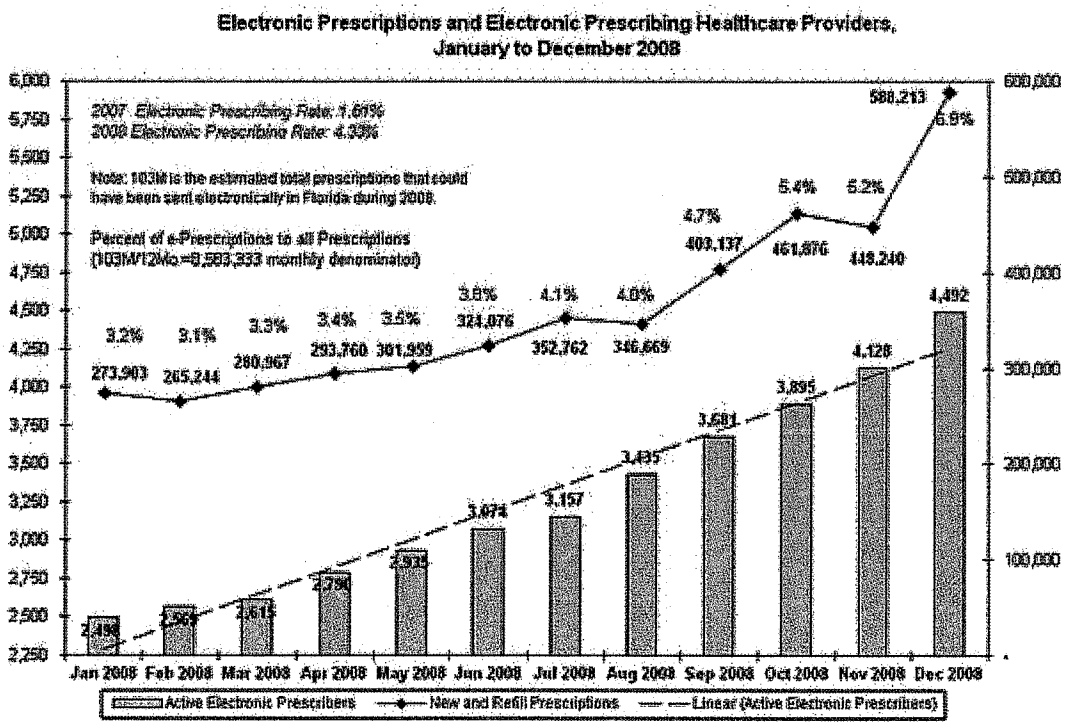
[29] *Id.*

[30] *Id.* at 6.





The use of e-prescribing is rising. Of the 6,157 licensed pharmacies in Florida, 71.33 percent were activated to receive electronic prescriptions in 2008, an increase from 63 percent in 2007.[31] Similarly, in 2007 the highest monthly total of e-prescribing healthcare professionals was 2,331. The highest monthly total of e-prescribing physicians in 2008 was 4,492, an increase of 92.75 percent.[32] Among e-prescribers, the number of e-prescriptions issued per month rose 72 percent between 2007 and 2008.[33]



Source: SureScripts-RxHub, *cited in*, Agency for Health Care Administration, ePrescribing Clearinghouse, ePrescribing Dashboard 2008 Metrics.

[31] Agency for Health Care Administration, ePrescribing Clearinghouse, ePrescribing Dashboard 2008 Metrics, *see* http://www.fhin.net/eprescribe/Dashboard/FLmetrics.shtml (last viewed March 21, 2009).
[32] *Id.*
[33] *Id.*

Some opponents of e-prescribing believe it imposes a significant financial burden on prescribing practitioners, and is a precursor to interoperable electronic medical records, the value of which is currently debated by medical community.[34]

Funding

Medicare has a new program to encourage physicians to adopt e-prescribing systems.[35] Beginning in 2009, and during the next four years, Medicare will provide incentive payments to eligible health care practitioners who use electronic prescribing. Practitioners will receive a 2 percent incentive payment in 2009 and 2010; a 1 percent incentive payment in 2011 and 2012; and a one half percent incentive payment in 2013. Beginning in 2012, Medicare health care practitioners not using electronic prescribing will receive reduced payments for Medicare-covered services.[36] Exemptions may be awarded on a case-by-case basis if it is determined that compliance would result in significant hardship for the practitioner.[37]

The recently enacted American Recovery and Investment Act (ARRA)[38] authorized approximately $19 billion for Medicare and Medicaid incentives to assist providers in adopting health information technology as well as state loan programs. The incentives will be available for five years, starting in 2011.

Effect of Proposed Changes

The bill requires AHCA to design and implement a prescription drug monitoring database to monitor dispensing of Schedule II, III and IV controlled substances, consistent with the standards of the American Society for Automation in Pharmacy.

The bill requires pharmacies and dispensing practitioners to report certain information about the dispensing of those substances within 15 days of dispensing in a manner consistent with state and federal privacy and security laws. The bill requires the Department of Health and regulatory boards to promulgate rules defining what information must be reported, which may include, but is not limited to, any data required under s. 893.04, F.S., and requires AHCA to promulgate rules defining the manner of reporting. The bill provides that the costs of such reporting may not be "material or extraordinary", and provides guidance for interpreting that term. The bill makes it a first degree misdemeanor for any person to knowingly fail to make a report required by the bill, punishable as provided in s. 775.082 F. S. or S. 775.083 F. S.[39]

The bill provides several exemptions from the reporting requirements for controlled substances:

- Administered by a health care practitioner directly to a patient
- Dispensed by a health care practitioner and limited to a 72-hour supply
- Dispensed by a health care practitioner or a pharmacist to an inpatient of a facility with an institutional pharmacy
- Ordered from an institutional pharmacy
- Used for patients receiving care from a hospital, nursing home, assisted living facility, home health agency, hospice, or intermediate care facility for the developmentally disabled

The bill allows information in the database to be "transmitted" by "any person or agency authorized to receive it pursuant to chapter 119".[40] Recipients of such information must purge the information from their records after 24 months, unless the information relates to an ongoing investigation or prosection.

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[34] *See, e.g.,* Stephen R. West, "Congress Shouldn't Practice Medicine", *Tallahassee Democrat*, February 8, 2009, available at http://tallahassee.com/article/20090208/OPINION05/902080311/1006/opinion (last viewed March 21, 2009); "Obama's $80 Billion Exaggeration", *Wall Street Journal*, *see* http://online.wsj.com/article/SB123681586452302125.html (last viewed March 21, 2009).
[35] Pursuant to the Medicare Improvements for Patients and Providers Act of 2008.
[36] *Id.* Reimbursement will be reduced by 1 percent in 2012, 1.5 percent in 2013 and 2 percent in 2014.
[37] Agency for Health Care Administration, ePrescribing Clearinghouse, ePrescribing Initiatives and Incentive Programs, *see* http://www.fhin.net/eprescribe/ePrescribingInitiatives/NationalIncentivePrograms.shtml (last viewed March 21, 2009).
[38] Public Law 111-05 (2009).
[39] These sections provide for a sentence of up to one year of imprisonment and up to $1,000 in fines.
[40] Chapter 119, F.S., governs public records.

The bill provides that all "costs incurred by the agency" in implementing the bill "shall be through federal, private, or grant funding applied for by the state".

The effective date of the bill is July 1, 2009.

B. SECTION DIRECTORY:

Section 1: Creates section 893.055, F.S., relating to an electronic monitory system for prescription of certain controlled substances.

Section 2: Provides an effective date of July 1, 2009.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   Uncertain. The bill provides that all "costs incurred by the agency" in implementing the bill "shall be through federal, private, or grant funding applied for by the state". If AHCA successfully obtains federal, private or grant funding, those funds would be revenue increases.

2. Expenditures:

   AHCA estimates a significant fiscal impact, including two FTEs and contracted services. In the first year, AHCA estimates a cost of $4,036,348 for the contract to design and maintain the system. AHCA's estimated recurring impact is $2,930,348 for the implementation of the controlled substance data system.

   See Fiscal Comments.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The bill requires dispensing practitioners and pharmacists to report certain information within 15 days of dispensing certain controlled substances. The bill requires AHCA to develop rules as to how the reporting shall be accomplished, but provides that costs to the private sector "may not be material or extraordinary", and includes examples of charges that meet that requirement. The costs associated with reporting will vary according to the technological and personnel capabilities of each pharmacy and dispensing practitioner.

Prevention and prosecution of prescription drug abuse, and greater awareness by practitioners of patient doctor shopping, may lead to lower health care costs overall.

D. FISCAL COMMENTS:

The bill requires AHCA to design and establish a prescription drug monitoring system. Estimates for such systems vary.

Department of Health Fiscal Estimates

Department of Health estimates for in-house design and implementation of such a system are significant:[41]

	1st Year (09-10)	2nd Year (10-11) (Annualized /Recurr.)	3rd Year (11-12) (Annualized/ Recurr.)
Salary			
1 Operations & Management Consultant II (OMC II), PG 423	$54,858	$54,858	$54,858
3 Regulatory Specialist II (RS II), PG017	$118,881	$118,881	$118,881
1 Government Analyst II (GA II), PG 026	$51,748	$51,748	$51,748
1 Operations & Management Consultant Manager (OMC Mgr), PG425	$61,737	$61,737	$61,737
Expense			
Non-Recurring Expense Package (OMC II), limited travel	$3,412		
Non-Recurring Expense Package (3-RSII), no travel	$10,236		
Non-Recurring Expense Package (GA I), limited travel	$3,412		
Non-Recurring Expense Package (OMC Mgr), maximum travel	$3,412		
Non-Recurring Expense Package (11 Contracted positions)	$37,532		
Recurring Expense Package (OMC II), limited travel	$12,268	$12,268	$12,268
Recurring Expense Package (3-RSII), no travel	$20,100	$20,100	$20,100
Recurring Expense Package (GA I), limited travel	$12,268	$12,268	$12,268
Recurring Expense Package (OMC Mgr), maximum travel	$20,212	$20,212	$20,212
Non-Recurring Expense Package (Contracted positions), no travel	$73,700	$20,100	$6,700
Promotion (printing & postage)	$10,000	$10,000	$10,000
Rulemaking Conference Room Rentals	$10,000		
Rulemaking Travel	$16,800		
System Development (non-recurring)			
Windows Standard Server 2003	$3,248		
RDBMS	$0		
Dynamic PDF Generator	$1,497		
Dynamic PDF Merger	$799		
Fax Software	$250		
Backup Software License	$8,000		
System Administration (recurring)			
RDBMS Maintenance	$70,393	$70,393	$80,952
Software Maintenance and Defect Remediation	$0	$437,008	$480,709
Indirect Operating Expenses	$1,500	$1,500	$1,500
Computer Hardware	$1,000	$1,500	$1,500
Network Equipment	$25,000	$25,000	$25,000
Hardware Maintenance	$0	$0	$0

[41] Department of Health Bill Analysis, Economic Statement and Fiscal Note, House Bill 1015 (2009).

Backup Tapes		$60,000	$66,000
Private secure data circuit		$60,000	$60,000
Contracted Services			
Promotion (mail processing)	$1,500	$1,500	$1,500
FAW Publications	$500		
System Development (non-recurring)			
Project Managers - 2 @ 2080 hrs	$447,200		
.Net Developers - 4 @ 2080 hrs	$748,800		
Business Analyst - 1 @ 2080 hrs	$187,200		
Testing Expert - 2 @ 2080 hrs	$374,400		
Database Administrator (DBA) - 1 @ 2080 hrs	$208,000		
Data-Integration consultant - .5 @ 1040 hrs	$104,000		
Infrastructure Support consultant - .5 @ 1040 hrs	$104,000		
System Administration (recurring)			
Data Contractor	$325,000	$505,000	$510,250
Database Administrator (DBA) - 1 @ 2080 hrs	$0	$137,500	$151,250
Project Manager - 2 @ 2080 hrs	$0	$447,200	
System/Network Administrator	$100,000	$110,000	$121,000
Operating Capital Outlay			
OCO standard package (6 FTE)	$6,000		
OCO standard package (11 Contracted positions)	$11,000		
System Development (non-recurring)			
RDBMS Enterprise License	$319,968		
Windows Enterprise Server 2003	$4,521		
Crystal Enterprise (per proc)	$30,000		
DF IntelliServer	$300,000		
Initial Tape sets for backup services	$60,000		
Web Server	$15,178		
App Server	$42,640		
DB server	$85,280		
Staging Server	$21,320		
Crystal Server	$42,640		
DF IntelliServer	$21,320		
Security Server	$63,960		
Fax Desktop with card	$1,009		
Human Resources			
HR standard package (6 FTE)	$2,406	$2,406	$2,406
TOTAL ESTIMATED EXPENSES	**$4,260,105**	**$2,241,179**	**$1,870,839**

Office of Drug Control Fiscal Estimates

The Office of Drug Control notes that costs may range between $100,000 and $4,000,000, and provided estimates based on two models:[42]

1. Tasks partially retained by the state with use of FTE and non-FTE (i.e. contracted) personnel and contracted goods and services:
    - First year: $1,222,500
    - Second year: $1,865,000
    - Follow-on years: $1,850,000

2. Most of the tasks contracted with no FTE:
    - First year: $550,000
    - Second year: $695,000
    - Follow-on years: $680,000

Specifically:

Program Management and IT staff costs:
Project manager, administrative assistant, systems analyst, programmer, database administrator and epidemiologist. Cost is estimated to be $470,000

Implementation: The Operating requirements previously discussed in option one, servers, server operating software, licenses, the development, printing and mailing of notification of the implementation date, limited training classes (formal and informal) and training manual, requisite installation for travel: $320,000.

Annual Operation: The operating costs and the administrative, data collection and IT staff functions already discussed including clinical and technical support personnel, communications, requests by patient for prescription history review, supplies, and travel: $550,000.

DOH Rule Development: Travel costs for two meetings of ten members for Rule Development: $30,000. There would be no or limited costs for those within the Tallahassee area or those within day time travel distance.

DOH Rule workshop statewide: Costs for seven workshops for two people and materials: $25,000.

The Office of Drug Control also suggests that training be provided (although this is not currently required by the bill):

- An orientation course during the implementation phase of the prescription drug validation program.
- A course for persons who are authorized to access the prescription drug validation program information, but who did not participate in the orientation course.
- A DOH educational program to inform the public about the prescription drug validation program.

The Office estimates the cost of training (including a training consultant, travel and material/website development) is: First year: $55,000, second year: $55,000 and then thereafter for the follow-on years: $40,000.

Agency for Health Care Administration Fiscal Estimates

The Agency for Health Care Administration also finds a significant fiscal impact, including two FTEs and contracted services.

Summary:

[42] EOG / Office of Drug Control 2009 Bill Analysis & Economic Impact Statement for House Bill 897 (2009).

The first year, the fiscal impact is expected to be $4,036,348 for the contract to design and maintain the system. The estimated recurring impact is $2,930,348 for the implementation of the controlled substance data system.

The FTEs would be responsible for contract management, database maintenance as well as responding to requests from patients, providers, pharmacies and law enforcement agencies. Pharmacies will incur the cost of reporting all prescribed controlled substances to the Agency every 15 days.

Detail:
The first year impact would be $4,036,348 and the estimated recurring impact is $2,930,348 for the implementation of the controlled substance data system. The State of Tennessee has a program similar to the controlled substance prescription monitoring program in the bill. Tennessee has approximately 1,300 reporting pharmacies. Tennessee's estimated start up costs to contract for the development of their PMP database was $750,000 and $200,000 annually to maintain. Florida has approximately 4,500 pharmacies, so the estimated start up costs to contract for the development of a PMP database is $1,100,000 and approximately $400,000 annually to maintain. The bill allows providers and pharmacists to make submissions to the Agency in written or any electronic or magnetic format, including, but not limited to, electronic submission via the Internet or magnetic disc or tape, each controlled substance listed in Schedule II, Schedule III, or Schedule IV which it dispenses. It is estimated that 20%, or about 1,000 reporting providers and/or pharmacies will use a nonstandard form of reporting which will need to be put into a format that the controlled substance PMP database can read. Each provider and/or pharmacy is required to submit reports every 15 days, or twice a month. The Agency will contract with a vendor to format the nonstandard submissions for $2,400,000 annually based on an estimated average $100 per report which may vary, depending on whether the information is submitted on paper, tape, or disc.

In the first year, one FTE government analyst II (10% above minimum) would be required, spending approximately 75% of work time developing the request for proposals, contract development and contract monitoring and 25% of work time on other activities including notifying to providers and pharmacies of the new reporting requirement and directing the administrative assistant who would be primarily responsible for handling requests for public access or answering routine questions from pharmacies and physicians related to the program.

It is estimated that the number of requests for access to records from patients would be 2,000 based on the number of requests from patients received by Florida Medicaid for access to records increased by a factor of ten. It is estimated that the average time to process requests is 1.00 hours. This time includes review of the written request and search for the patient's records that would be provided under contract. The work hours required to process requests each year would be 2000 work hours (2,000 applications x 1 hour).

In the first year, one FTE administrative assistant II (10% above minimum) would be required, spending 50% of work time assisting with and documenting the request for proposal, contract development and contract monitoring process and 50% assisting with requests from physicians, pharmacists, law enforcement agencies and the general public. In the second year, 80% of time would be spent on processing requests for access from law enforcement and the general public, and answering routine questions from physicians and pharmacists.

FISCAL IMPACT ON AHCA/F	**Amount Year 1 FY 09-10**	**Amount Year 2 FY 10-11**
1. Non-Recurring Impact:		
Revenues:		
Licenses	$0	$0
Fees	$0	$0
Grants	$0	$0

				$0	$0
Transfers In / Another Agen				$0	$0
Total Non-Recurring Revenu				**$0**	**$0**
Expenditures:					
Salaries				$0	$0
OPS					
Other Personal Services	1.00	@	$0	$0	$0
	0.00	@	$0	$0	$0
Total Non-Recurring OPS				$0	$0
Expense (Agency Standard Expense & Operating Capital Outlay Package)					
Professional Staff	2.00	@	$3,000	$6,000	$0
Support Staff	0.00	@	$2,400	$0	$0
Additional Travel Expense	0.00	@	$0	$0	$0
	0.00			$0	$0
Total Non-Recurring Expe				**$6,000**	**$0**
Operating Capital Outlay (Agency Standard Expense & Operating Capital Outlay Package)					
Laptop Computers	0.00	@	$0	$0	$0
Total Operating Capital Ou				**$0**	**$0**
Special Categories					
Contracted Services				$1,100,000	$0
				$0	$0
Total Non-Recurring Specia Categories				$1,100,000	$0
Total Non-Recurring Expenc				**$1,106,000**	**$0**

2. Recurring Impact:

	Class Code	FTEs	Pay Grade	Rate		
Revenues:						
Licenses					$0	$0
Fees					$0	$0
Grants					$0	$0
Transfers In/Another Agenc					$0	$0
Total Recurring Revenues					**$0**	**$0**
Expenditures:						
Salaries						
Government Analyst II	2225	1.00	**26**	51,215	$65,479	$65,479
Administrative Assistant II	0712	1.00	**18**	32,403	$41,427	$41,427
		0.00	**0**	0	$0	$0
		0.00	**0**	0	$0	$0
		0.00	**0**	0	$0	$0
Total Salary and Benefits		2.00	**FTEs**	83,618	$106,906	$106,906
OPS						
Other Personal Services		0.00	@	$0	$0	$0
		0.00	@	$0	$0	$0

Total OPS				$0	$0
Expenses					
Professional Staff	2.00	@	$11,320	$22,640	$22,640
Support Staff	0.00	@	$5,620	$0	$0
Additional Travel Expenses	0.00	@	$0	$0	$0
				$0	$0
Total Expenses				$22,640	$22,640
Contracted Services	2.00		$0	$0	$0
Human Resources Service					
FTE Positions	2.00	@	$401	$802	$802
OPS Positions	0.00	@	$132	$0	$0
Total Human Resources Se				$802	$802
Special Categories					
Contracted Services				$2,800,000	$2,800,000
				$0	$0
				$0	$0
Total Special Categories				$2,800,000	$2,800,000
Total Recurring Expenditure	**2.00**	**FTEs**	**83,618**	**$2,930,102**	**$2,930,102**

3. Long Run Effects Other Than Normal Growth:

4. Total Revenues and Expenditures:

Sub-Total Non-Recurring Rev				$0	$0
Sub-Total Recurring Revenue				$0	$0
Total Revenues				**$0**	**$0**
Sub-Total Non-Recurring Expenditures				$1,106,000	$0
Sub-Total Recurring Expendit				$2,930,348	$2,930,348
Total Expenditures	**2.00**	**FTEs**		**$4,036,348**	**$2,930,348**

Difference (Total Revenues minus Total Expenditures) **($4,036,348)** **($2,930,348)**

5. Funding of Expenditures:

	$0	$0
Total	**$0**	**$0**

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

State collection of patient-specific information on the use of controlled substances by law-abiding individuals may implicate the express right of privacy contained in Article I, Section 23, of the Florida Constitution.

B. RULE-MAKING AUTHORITY:

The bill requires the Department of Health and regulatory boards to promulgate rules defining what information must be reported, which may include, but is not limited to, any data required under s. 893.04, F.S., and requires AHCA to promulgate rules defining the manner of reporting. The bill appears to provide sufficient rulemaking authority for these functions. However, the bill does not provide AHCA rulemaking authority to design and implement the prescription drug database. It is unclear whether rules are necessary to comply with that directive.

C. DRAFTING ISSUES OR OTHER COMMENTS:

The bill requires the Department of Health and regulatory boards to promulgate rules defining what information must be reported, which may include, but is not limited to, any data required under s. 893.04, F.S., and requires AHCA to promulgate rules defining the manner of reporting. This bifurcation of rulemaking duties may create inefficiencies. In addition, it is unclear whether the rules promulgated by the Department of Health and its regulatory boards are intended to create obligations on practitioners enforceable by Department of Health through disciplinary action upon a license.

The bill allows for access to the prescription drug monitoring database by "any person or agency authorized to receive it pursuant to chapter 119". Chapter 119 does not provide specific authorization to access the prescription drug monitoring database; rather, it presumptively allows public access to the database. House Bill 937 creates an express public records exemption for the prescription drug monitoring database, but does not place that exemption in chapter 119. This provision appears to conflict with the public records exemption in House Bill 937.

The bill provides that all "costs incurred by the agency" in implementing the bill "shall be through federal, private, or grant funding applied for by the state". The bill may not provide sufficient authority for AHCA to receive private donations to implement the prescription drug monitoring database.

There is no provision in this bill to require the Agency for Health Care Administration to notify persons if there is an accidental or deliberate data breach, which is necessary to protect the public and persons prescribed controlled substances.

IV. AMENDMENTS/COUNCIL OR COMMITTEE SUBSTITUTE CHANGES

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. (for drafter's use only)

Bill No. **HB 897**

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: Health Care Regulation Policy Committee

Representative Porth offered the following:

Amendment (with title amendment)

Between lines 113 and 114, insert:

Section 2. Subsection (4) is added to section 458.309, Florida Statutes, to read:

458.309 Rulemaking authority.--

(4)(a) Each physician who practices in a privately owned pain-management facility and who primarily engages in the treatment of pain by prescribing narcotic or controlled substance medications shall register the facility with the department unless it is licensed as a facility under chapter 395. The department shall inspect the facility annually to ensure that it complies with rules adopted by the board pursuant to paragraph (b) unless the facility is accredited by a nationally recognized accrediting agency approved by the board. The actual costs for registration and inspection or accreditation shall be paid by the physician seeking to register the facility. For the purposes of this subsection, a physician

is primarily engaged in the treatment of pain by prescribing narcotic or controlled substance medications when the majority of the patients are seen on any day when the facility is open and are issued narcotic or controlled substance prescriptions for the treatment of nonmalignant pain.

(b) The board shall adopt rules setting forth standards of practice for physicians who practice in privately owned pain-management facilities and who primarily engage in the treatment of pain by prescribing narcotic or controlled substance medications. These rules shall address, but need not be limited to, the following subjects:

1. Facility operations.

2. Physical operations.

3. Infection control requirements.

4. Health and safety requirements.

5. Quality assurance requirements.

6. Patient records.

7. Training requirements for all facility health care practitioners.

8. Inspections.

Section 3. Subsection (3) is added to section 459.005, Florida Statutes, to read:

459.005 Rulemaking authority.--

(3)(a) Each physician who practices in a privately owned pain-management facility and who primarily engages in the treatment of pain by prescribing narcotic or controlled substance medications shall register the facility with the department unless it is licensed as a facility under chapter 395. The department shall inspect the facility annually to ensure that it complies with rules adopted by the board pursuant

to paragraph (b) unless the facility is accredited by a nationally recognized accrediting agency approved by the board. The actual costs for registration and inspection or accreditation shall be paid by the physician seeking to register the facility. For the purposes of this subsection, a physician is primarily engaged in the treatment of pain by prescribing narcotic or controlled substance medications when the majority of the patients are seen on any day when the facility is open and are issued narcotic or controlled substance prescriptions for the treatment of nonmalignant pain.

(b) The board shall adopt rules setting forth standards of practice for physicians who practice in privately owned pain-management facilities and who primarily engage in the treatment of pain by prescribing narcotic or controlled substance medications. These rules shall address, but need not be limited to, the following subjects:

1. Facility operations.

2. Physical operations.

3. Infection control requirements.

4. Health and safety requirements.

5. Quality assurance requirements.

6. Patient records.

7. Training requirements for all facility health care practitioners.

8. Inspections.

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

Remove line 18 and insert:

funding sources; amending ss. 458.309 and 459.005, F.S.; requiring certain physicians who engage in pain management to register their facilities with the department; requiring the department to inspect each facility; requiring the Board of Medicine to adopt rules setting forth standards of practice for certain physicians who engage in pain management; providing criteria for the rules; providing an effective date.

A bill to be entitled

An act relating to controlled substances; creating s. 893.055, F.S.; providing definitions; requiring the Agency for Health Care Administration to establish a statewide, comprehensive electronic system to monitor the prescribing and dispensing of controlled substances listed in Schedule II, Schedule III, or Schedule IV; providing reporting requirements; requiring the agency to notify certain dispensers and prescribers of the implementation date for the reporting of controlled substances; specifying circumstances under which a pharmacy or practitioner is exempt from participating in the system; requiring prescribing or dispensing pharmacists and practitioners to submit information in a certain format; providing a penalty; requiring that the department and regulatory boards adopt rules; requiring that all costs incurred by the agency be paid through federal, private, or grant funding sources; providing an effective date.

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

Section 1. Section 893.055, Florida Statutes, is created to read:

893.055 Electronic-monitoring system for prescription of controlled substances listed in Schedule II, Schedule III, or Schedule IV.--

(1) As used in this section, the term:

(a) "Agency" means the Agency for Health Care

Administration.

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

(c) "Pharmacy" means any pharmacy that is subject to licensure or regulation by the department pursuant to chapter 465 and that dispenses or delivers a controlled substance included in Schedule II, Schedule III, or Schedule IV in s. 893.03 to a patient in this state.

(2) By June 30, 2010, the agency shall design and establish an electronic system consistent with standards of the American Society for Automation in Pharmacy to monitor the prescribing of controlled substances listed in Schedule II, Schedule III, or Schedule IV in s. 893.03 by health care practitioners and the dispensing of such controlled substances to an individual by a dispensing practitioner pursuant to chapter 465 or a pharmacy permitted or registered by the Board of Pharmacy pursuant to chapter 465.

(3) Each time a controlled substance listed in Schedule II, Schedule III, or Schedule IV is dispensed to an individual, the controlled substance must be reported to the agency through the system as soon thereafter as possible, but not more than 15 days after the date the controlled substance is dispensed. A pharmacy or dispensing practitioner may meet the reporting requirements of this section by providing to the agency in written or any electronic or magnetic format, including, but not limited to, electronic submission via the Internet or magnetic disc or tape, each controlled substance listed in Schedule II, Schedule III, or Schedule IV which it dispenses.

(4) The agency shall notify each dispenser and prescriber

subject to the reporting requirements in this section of the implementation date for the reporting requirements as set forth in the rules of the agency.

(5) This section does not apply to controlled substances:

(a) Administered by a health care practitioner directly to a patient.

(b) Dispensed by a health care practitioner authorized to prescribe controlled substances directly to a patient and limited to an amount adequate to treat the patient for a period of not more than 72 hours.

(c) Dispensed by a health care practitioner or a pharmacist to an inpatient of a facility that holds an institutional pharmacy permit.

(d) Ordered from an institutional pharmacy permitted under s. 465.019 in accordance with the institutional policy for such controlled substances or drugs.

(e) Dispensed by a pharmacist or administered by a health care practitioner to a patient or resident receiving care from a hospital, nursing home, assisted living facility, home health agency, hospice, or intermediate care facility for the developmentally disabled which is licensed in this state.

(6) The data required to be reported under this section shall be determined by the department by rule and may include, but is not limited to, any data required under s. 893.04.

(7) A practitioner or pharmacist who dispenses a controlled substance listed in Schedule II, Schedule III, or Schedule IV in s. 893.03 must submit the information required by this section in an electronic or other format approved by rule

of the agency. The cost to the dispenser in submitting the information required by this section may not be material or extraordinary. Costs not considered to be material or extraordinary include, but are not limited to, regular postage, compact discs, zip-drive storage, regular electronic mail, magnetic tapes, diskettes, and facsimile charges. The information submitted to the agency under this section may be transmitted to any person or agency authorized to receive it pursuant to chapter 119, and that person or agency may maintain the information received for up to 24 months before purging the information from its records. All transmissions required by this subsection must comply with relevant privacy and security laws of the state and federal government. However, any authorized agency receiving such information may maintain it for longer than 24 months if the information is pertinent to an ongoing investigation or prosecution.

(8) Any person who knowingly fails to report the dispensing of a controlled substance listed in Schedule II, Schedule III, or Schedule IV as required by this section commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

(9) The department and the regulatory boards for the health care practitioners subject to this section shall adopt rules to administer this section.

(10) All costs incurred by the agency in administering the prescription-monitoring system shall be through federal, private, or grant funding applied for by the state. The agency and state government shall cooperate in seeking grant funds at

no cost to the agency.

Section 2. This act shall take effect July 1, 2009.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 937 Pub. Rec./Controlled Substance Prescriptions/AHCA
SPONSOR(S): Llorente
TIED BILLS: HB 897 **IDEN./SIM. BILLS:**

	REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1)	Health Care Regulation Policy Committee		Calamas	Calamas
2)	Governmental Affairs Policy Committee			
3)	Health & Family Services Policy Council			
4)	Full Appropriations Council on General Government & Health Care			
5)				

SUMMARY ANALYSIS

The bill creates section 893.056, F.S., and establishes a public records exemption for certain information contained in the prescription drug monitoring database required by House Bill 897. The exemption provides that personal identifying information concerning a patient, a practitioner, a pharmacist or a pharmacy contained in records held by any agency having access to or operating the database is confidential and exempt from disclosure. The bill provides a specific statement of public necessity for the public records exemptions.

The bill requires the Agency for Health Care Administration (AHCA) to make certain disclosures of the confidential and exempt records to health care practitioners, patients and law enforcement and judicial entities, for certain purposes. The bill requires AHCA to screen and respond to requests for data.

The bill imposes criminal penalties. The bill makes willful and knowing improper disclosures of database information a third degree felony, punishable as provided in ss. 775.082, 775.083, or 775.084, F.S.

The bill creates a significant negative impact to the Grants and Donations Trust Fund within AHCA to implement the provisions of this bill and HB 897. (See Fiscal Analysis.)

The bill provides for an effective date of July 1, 2009.

HOUSE PRINCIPLES

Members are encouraged to evaluate proposed legislation in light of the following guiding principles of the House of Representatives

- Balance the state budget.
- Create a legal and regulatory environment that fosters economic growth and job creation.
- Lower the tax burden on families and businesses.
- Reverse or restrain the growth of government.
- Promote public safety.
- Promote educational accountability, excellence, and choice.
- Foster respect for the family and for innocent human life.
- Protect Florida's natural beauty.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Current Situation

Public Records Law

Article I, section 24(a) of the Florida Constitution sets forth the state's public policy regarding access to government records. The section guarantees every person a right to inspect or copy any public record of the legislative, executive, and judicial branches of government. The Legislature, however, may provide by general law for the exemption of records from the requirements of Article I, s. 24(a), Florida Constitution. The general law must state with specificity the public necessity justifying the exemption (public necessity statement) and must be no broader than necessary to accomplish its purpose.

Public policy regarding access to government records is further addressed in the Florida Statutes. Section 119.07(1), F.S., also guarantees every person a right to inspect and copy any state, county, or municipal record. Furthermore, the Open Government Sunset Review Act1 provides that a public records or public meetings exemption may be created or maintained only if it serves an identifiable public purpose, and may be no broader than is necessary to meet one of the following public purposes:

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

Article I, section 24(c) of the Florida Constitution provides that bills containing public records exemptions include a specific statement of public necessity. Such a bill must contain only the public records exemption, and requires a two-thirds vote of the members present and voting for passage.

Prescription Drug Monitoring Database

House Bill 897 (2009) requires the Agency for Health Care Administration to design and implement at prescription drug monitoring system to track the dispensing of Schedule II, III and IV controlled substances in Florida. Under the bill's directives, dispensing health care practitioners would be

required to report certain information to the state drug database within 15 days of dispensing those controlled substances. The bill requires the Department of Health to promulgate rules governing what information must be provided, which may include but is not limited to:

- The full name and address of the person for whom the controlled substance is dispensed;
- The full name and address of the prescribing practitioner and the prescriber's federal controlled substance registry number;
- The name of the controlled substance prescribed and the strength, quantity, and directions for the use thereof;
- The number of the prescription, as recorded in the prescription files of the pharmacy in which it is filed; and
- The initials of the pharmacist filling the prescription and the date filled;
- The name and address of the pharmacy from which the controlled substance was dispensed;
- The date on which the prescription for the controlled substance was filled;
- The name of the prescribing practitioner.

The bill would require state collection of personally identifiable information on Floridians receiving prescribed controlled substances.

HIPAA

The 1996 Health Insurance Portability and Accountability Act (HIPAA) required the federal government to issue regulations protecting the privacy of health information. The U.S. Department of Health and Human Services (HHS) issued Standards for Privacy of Individually Identifiable Health Information on December 28, 2000, which took effect on April 14, 2003. The regulations establish a set of national standards for the protection of health information, and apply to health plans, health care clearinghouses and certain health care providers. The regulations permit states to afford greater privacy protections to health information. Exceptions for state law are provided for public health and state regulatory reporting.[1]

Effect of Proposed Changes

The bill creates section 893.056, F.S., which establishes a public records exemption for certain information contained in the prescription drug monitoring database required by House Bill 897. The bill provides that personal identifying information concerning a patient, a practitioner, a pharmacist or a pharmacy contained in records held by any agency having access to or operating the database is confidential and exempt from disclosure.

In addition to creating the public records exemption and confidentiality status, the bill requires AHCA to make certain disclosures of the confidential and exempt records to certain entities for certain purposes, as follows:

- The Department of Health or the relevant health regulatory board responsible for the licensure, regulation, or discipline of practitioners, pharmacists, or other persons who are authorized to prescribe, administer, or dispense controlled substances and who are involved in a specific investigation involving a designated person;

- A criminal justice agency, as defined in s. 119.011, F.S., which enforces the laws of this state or the United States relating to controlled substances and which has initiated an active investigation involving a specific violation of law;

- A practitioner as defined in s. 893.02, F.S., or an employee of the practitioner who is acting on behalf of and at the direction of the practitioner, who requests such information and certifies that

[1] U.S. Department of Health & Human Services, Health Information Privacy, *available at* http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/index.html (last viewed March 21, 2009).

the information is necessary to provide medical treatment to a current patient in accordance with 893.05, F. S.;

- A pharmacist as defined in s. 465.003, F.S., or a pharmacy intern or pharmacy technician who is acting on behalf of and at the direction of the pharmacist, who requests such information and certifies that the requested information will be used to dispense controlled substances to a current patient in accordance with s. 893.04, F.S.;

- A patient who is identified in the record upon a written request for the purpose of verifying that information;

- A judge or a probation or parole officer administering a drug or the probation program of a criminal defendant arising out of a violation of chapter 893 or of a criminal defendant who is documented by the court as a substance abuser and who is eligible to participate in a court-ordered drug diversion treatment, or probation program; and

- A duly appointed medical examiner, or an investigator of the medical examiner who is acting on behalf of or at the direction of the medical examiner, who requests such information and certifies that the information is necessary in an active death investigation as provided in s. 406.11, F.S., which involves a suspected drug-related death.

The bill requires AHCA to screen and respond to requests for data, to properly identify individuals and records, and to ascertain authorization in the case of minors or other patients under guardianship. The bill appears to allow release of de-identified or aggregated data. The bill does not provide authority to disclose or use the data for purposes of research or public health.

In addition to the public records exemption and the authority for certain disclosures, the bill imposes criminal penalties. The bill makes willful and knowing improper disclosures of database information a third degree felony, punishable as provided in ss. 775.082, 775.083, or 775.084, F.S.[2]

Finally, the bill provides a specific statement of public necessity for the public records exemptions.

B. SECTION DIRECTORY:

Section 1: Creates s. 893.056, F.S., providing for public records exemptions, providing for disclosures, providing criminal penalties.

Section 2: Provides a statement of public necessity pursuant to Article I, s. 24(c) of the Florida Constitution.

Section 3: Provides an effective date of July 1, 2009, contingent upon the enactment of House Bill 897 or similar legislation.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

[2] These sections provide for a sentence of up to five years of imprisonment (or, for habitual offenders, up to 10 years) and up to $5,000 in fines,.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

FISCAL IMPACT ON AHCA/FUNDS:					**Amount Year 1 FY 09-10**	**Amount Year 2 FY 10-11**
Expenditures:						
Salaries						
Administrative Assistant II	0712	1.00	**18**	32,403	$41,427	$41,427
		0.00	**0**	0	$0	$0
		0.00	**0**	0	$0	$0
		0.00	**0**	0	$0	$0
Total Salary and Benefits		1.00	**26**	51,215	$65,479	$65,479

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

House Bill 897, to which this bill is tied, provides that all "costs incurred by the agency" in implementing the bill "shall be through federal, private, or grant funding applied for by the state".

The bill requires AHCA to screen and respond to requests for data, to properly identify individuals and records, and to ascertain authorization in the case of minors or other patients under guardianship. The costs to the Agency to provide patients information about their records in the controlled substance database may increase over time if requests from the general public increase to ensure that a patient's records are properly released to the requesting person, correctly identified as the patient, or authorized representative of a patient.

According to AHCA, the directives of HB 897 will require two FTEs at AHCA. Part of one FTE's work will be dedicated to complying with the directives of HB 937, in Year Two of the database implementation, as follows: In the first year, one FTE administrative assistant II (10% above minimum) would spend 50 percent of work time assisting with requests from physicians, pharmacists, law enforcement agencies and the general public. In the second year, 80 percent of work time would be spent on processing requests for access from law enforcement and the general public, and answering routine questions from physicians and pharmacists.

AHCA estimates that the number of requests for access to records from patients would be 2,000 based on the number of requests from patients received by Florida Medicaid for access to records increased by a factor of ten. It is estimated that the average time to process requests is 1.00 hours. This time includes review of the written request and search for the patient's records that would be provided under contract. The work hours required to process requests each year would be 2000 work hours (2,000 applications x 1 hour).

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

   Vote Requirement
   Article I, s. 24(c) of the Florida Constitution, requires a two-thirds vote of the members present and voting for passage of a newly created public records or public meetings exemption. The bill creates a public records exemption. Thus, it requires a two-thirds vote for passage.

   Public Necessity Statement
   Article I, s. 24(c) of the Florida Constitution, requires a statement of public necessity (public necessity statement) for a newly created public records or public meetings exemption. The public necessity statement is contained in Section 2 of the bill.

B. RULE-MAKING AUTHORITY:

   None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

   None.

IV. AMENDMENTS/COUNCIL OR COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to public records; creating s. 893.056, F.S.; exempting from public records requirements information and records reported to the Agency for Health Care Administration under the electronic-monitoring system for the tracking of prescriptions of controlled substances listed in Schedules II-IV; authorizing certain persons and entities access to patient-identifying information; providing guidelines for the use of such information and penalties for violations; providing for future legislative review and repeal of the exemption under the Open Government Sunset Review Act; providing a finding of public necessity; providing a contingent effective date.

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

Section 1. Section 893.056, Florida Statutes, is created to read:

893.056 Public records exemption for the electronic-monitoring system for the tracking of prescriptions of controlled substances listed in Schedule II, Schedule III, or Schedule IV in s. 893.03.--

(1) Identifying information, including, but not limited to, the name, address, telephone number, insurance plan number, social security number or government-issued identification number, provider number, Drug Enforcement Administration number, or any other unique identifying number of a patient, patient's agent, health care practitioner, pharmacist, pharmacist's agent,

or pharmacy which is contained in records held by the Agency for Health Care Administration or any other agency as defined in s. 119.011(2) under s. 893.055, the electronic-monitoring system for the tracking of prescriptions of controlled substances, is confidential and exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution.

(2) The Agency for Health Care Administration shall disclose such confidential and exempt information to:

(a) The Department of Health or the relevant health regulatory board responsible for the licensure, regulation, or discipline of practitioners, pharmacists, or other persons who are authorized to prescribe, administer, or dispense controlled substances and who are involved in a specific investigation involving a designated person.

(b) A criminal justice agency, as defined in s. 119.011, which enforces the laws of this state or the United States relating to controlled substances and which has initiated an active investigation involving a specific violation of law.

(c) A practitioner as defined in s. 893.02, or an employee of the practitioner who is acting on behalf of and at the direction of the practitioner, who requests such information and certifies that the information is necessary to provide medical treatment to a current patient in accordance with s. 893.05.

(d) A pharmacist as defined in s. 465.003, or a pharmacy intern or pharmacy technician who is acting on behalf of and at the direction of the pharmacist, who requests such information and certifies that the requested information will be used to

dispense controlled substances to a current patient in accordance with s. 893.04.

(e) A patient who is identified in the record upon a written request for the purpose of verifying that information.

(f) A judge or a probation or parole officer administering a drug or the probation program of a criminal defendant arising out of a violation of chapter 893 or of a criminal defendant who is documented by the court as a substance abuser and who is eligible to participate in a court-ordered drug diversion, treatment, or probation program.

(g) A duly appointed medical examiner, or an investigator of the medical examiner who is acting on behalf of or at the direction of the medical examiner, who requests such information and certifies that the information is necessary in an active death investigation as provided in s. 406.11 which involves a suspected drug-related death.

(3) Any agency that obtains such confidential and exempt information pursuant to this section must maintain the confidential and exempt status of that information; however, the Agency for Health Care Administration or a criminal justice agency that has lawful access to such information may disclose confidential and exempt information received from the Agency for Health Care Administration to a criminal justice agency as part of an active investigation of a specific violation of law.

(4) Any person who willfully and knowingly violates this section commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(5) This section is subject to the Open Government Sunset Review Act in accordance with s. 119.15 and shall stand repealed on October 2, 2014, unless reviewed and saved from repeal through reenactment by the Legislature.

Section 2. The Legislature finds that it is a public necessity that personal identifying information of a patient, a practitioner as defined in s. 893.02, Florida Statutes, or a pharmacist as defined in s. 465.003, Florida Statutes, contained in records that are reported to the Agency for Health Care Administration under s. 893.055, Florida Statutes, the electronic-monitoring system for the tracking of prescriptions of controlled substances, be made confidential and exempt from disclosure. Information concerning the prescriptions that a patient has been prescribed is a private, personal matter between the patient, the practitioner, and the pharmacist. Nevertheless, reporting of prescriptions on a timely and accurate basis by practitioners and pharmacists will ensure the ability of the state to review and provide oversight of prescribing and dispensing practices. Further, the reporting of this information will facilitate investigations and prosecutions of violations of state drug laws by patients, practitioners, or pharmacists, thereby increasing compliance with those laws. However, if in the process the information that would identify a patient is not made confidential and exempt from disclosure, any person could inspect and copy the record and be aware of the patient's prescriptions. The availability of such information to the public would result in the invasion of the patient's privacy. If the identity of the patient could be correlated with

his or her prescriptions, it would be possible for the public to become aware of the diseases or other medical concerns for which a patient is being treated by his or her physician. This knowledge could be used to embarrass or to humiliate a patient or to discriminate against him or her. Requiring the reporting of prescribing information, while protecting a patient's personal identifying information, will facilitate efforts to maintain compliance with the state's drug laws and will facilitate the sharing of information between health care practitioners and pharmacists, while maintaining and ensuring patient privacy. Additionally, exempting from disclosure the personal identifying information of practitioners will ensure that an individual will not be able to identify which practitioners prescribe the highest amount of a particular type of drug and to seek those practitioners out in order to increase the likelihood of obtaining a particular prescribed substance. Further, protecting personal identifying information of pharmacists ensures that an individual will not be able to identify which pharmacists or pharmacies dispense the largest amount of a particular substance and identify that pharmacy for robbery or burglary. Thus, the Legislature finds that the personal identifying information of a patient, a practitioner as defined in s. 893.02, Florida Statutes, or a pharmacist as defined in s. 465.003, Florida Statutes, contained in records reported under s. 893.055, Florida Statutes, must be confidential and exempt from disclosure.

Section 3. This act shall take effect July 1, 2009, if House Bill 897, or similar legislation establishing an

electronic system to monitor the prescribing of controlled substances, is adopted in the same legislative session or an extension thereof and becomes law.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1033 Emergency Cardiology Services
SPONSOR(S): Renuart and others
TIED BILLS: **IDEN./SIM. BILLS:** SB 1938

	REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1)	Health Care Regulation Policy Committee		Holt	Calamas
2)	Health & Family Services Policy Council			
3)	Health Care Appropriations Committee			
4)	Full Appropriations Council on General Government & Health Care			
5)				

SUMMARY ANALYSIS

The bill requires the establishment of a specific system of care, to be identified as a "STEMI system of care". STEMI is identified in the bill as "an ST elevated myocardial infarction", an emergency cardiac condition commonly referred to as a heart attack. This bill establishes a system of care requiring emergency medical service providers to deliver individuals experiencing cardiac emergencies to appropriate medical facilities that are certified by the Agency for Health Care Administration as a percutaneous coronary intervention center ("PCI center"). The proposed statutory placement of these provisions is in Part I, Chapter 395, Florida Statutes (F.S.), the part that governs hospital licensure.

The bill will have a significant negative fiscal impact on the Emergency Medical Services Trust Fund within the Department of Health of approximately of $119,000 to $198,000 and a potential insignificant fiscal impact to local governments for the purchase of STEMI equipment (see fiscal impact).

The bill takes effect July 1, 2009.

HOUSE PRINCIPLES

Members are encouraged to evaluate proposed legislation in light of the following guiding principles of the House of Representatives

- Balance the state budget.
- Create a legal and regulatory environment that fosters economic growth and job creation.
- Lower the tax burden on families and businesses.
- Reverse or restrain the growth of government.
- Promote public safety.
- Promote educational accountability, excellence, and choice.
- Foster respect for the family and for innocent human life.
- Protect Florida's natural beauty.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background:

Society of Chest Pain Centers

The Society of Chest Pain Centers (SCPC) is a non-profit international society dedicated to the belief that heart disease can be eliminated as the number one cause of death worldwide.[1] Currently, there are 40 licensed hospitals in Florida that are accredited by the Society of Chest Pain Centers.[2] The accreditation process helps the facility define and actualize its strengths, identify and improve weaknesses, and recognize opportunities to enhance processes. The review process provides a road map to indentify gaps, sets standards, and starts the journey to improve cardiac patient care.[3]

The accreditation process considers eight elements or areas that a facility must demonstrate expertise include:

1. Emergency Department Integration with the Emergency Medical System
2. Emergency Assessment of Patients with Symptoms of Possible Asymptomatic Carotid Stenosis (ACS)[4] - Timely Diagnosis and Treatment of ACS
3. Assessment of Patients with Low Risk for ACS and No Assignable Cause for their Symptoms
4. Process Improvement
5. Personnel, Competencies, and Training
6. Organizational Structure and Commitment
7. Functional Facility Design
8. Community Outreach

Facilities that meet or exceed these criteria are assigned one of three possible designations:

- **Accredited Chest Pain Center** is the designation earned by a healthcare facility, having met the standards for accreditation.

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[1] Society of Chest Pain Centers. Available online at: http://www.scpcp.org/dnn/ (last viewed March 22, 2009).
[2] Society of Chest Pain Centers, List of CPC Accredited Facilities. (2009) Available online at: http://www.scpcp.org/dnn/Accreditation/ChestPainCenter/ListofCPCAccreditedFacilities/tabid/210/Default.aspx (last viewed March 22, 2009).
[3] *Ibid.*
[4] ACS is a condition in which the main vessels supplying blood to the brain are narrowed but the patient has no stroke symptoms.

- **Accredited Chest Pain Center with Percutaneous Coronary Intervention (PCI)**[5] is the designation earned by a healthcare facility that meets the standards accreditation and uses primary PCI as the facility's reperfusion[6] strategy of first choice for STEMI.

- **Provisionally Accredited Chest Pain Center** is the designation given to a healthcare facility that has met the majority of standards, but some items remain incomplete and has completed a site visit. A provisionally accredited facility may not call itself an "Accredited Chest Pain Center" or use the seal of accreditation. A provisionally accredited facility may call itself only a "Provisionally Accredited Chest Pain Center".[7]

Cardiovascular Services

Section 408.0361, F.S., provides that each provider of diagnostic cardiac catheterization services shall comply with rules adopted by the Agency for Health Care Administration ("agency") to establish licensure standards governing the operation of adult inpatient diagnostic cardiac catheterization programs. The rules ensure that the programs:

- Comply with the most recent guidelines of the American College of Cardiology and American Heart Association Guidelines for Cardiac Catheterization and Cardiac Catheterization Laboratories.
- Perform only adult inpatient diagnostic cardiac catheterization services and will not provide therapeutic cardiac catheterization or any other cardiology services.
- Maintain sufficient appropriate equipment and health care personnel to ensure quality and safety.
- Maintain appropriate times of operation and protocols to ensure availability and appropriate referrals in the event of emergencies.
- Demonstrate a plan to provide services to Medicaid and charity care patients.

The agency created licensure standards establishing two hospital cardiac program licensure levels:

- **Level I** program authorizes the performance of adult percutaneous cardiac intervention *without* onsite cardiac surgery; a hospital must demonstrate it has provide a minimum of 300 adult inpatient and outpatient diagnostic cardiac catheterizations or treated patients with a diagnosis of ischemic heart disease in the past 12-months.
- **Level II** program authorizes the performance of percutaneous cardiac intervention *with* onsite cardiac surgery; a hospital must demonstrate it has provide a minimum of 1,100 adult inpatient and outpatient cardiac catheterizations, of which at least 400 must be therapeutic catheterizations, or discharged at least 800 patients with the principal diagnosis of ischemic heart disease within the past 12-months.

All hospitals licensed for Level I or Level II adult cardiovascular services must participate in clinical outcome reporting systems operated by the American College of Cardiology and the Society for Thoracic Surgeons.[8]

In addition, the agency created a technical advisory panel that developed recommendations that the agency used to develop and adopt rules for cardiology services and the licensure of Level I and II cardiac programs.[9] Members of the panel[10] included representatives from:[11]

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[5] Commonly known as coronary angioplasty or simply angioplasty, PCI is used to open blocked blood vessels that cause heart attacks.
[6] The restoration of blood flow to an organ, after it was cut off.
[7] Society of Chest Pain Centers, What is Chest Pain Center Accreditation? (2009) Available online at: http://www.scpcp.org/dnn/Accreditation/ChestPainCenter/WhatisChestPainCenterAccreditation/tabid/61/Default.aspx (last viewed March 22, 2009).
[8] Section 408.0361(5)(b), F.S.
[9] 59A-3.2085, F.A.C.
[10] The panel was disbanded in December 2008 following the conclusion of the rule promulgation process.

- Florida Hospital Association,
- Florida Society of Thoracic and Cardiovascular Surgeons,
- Florida Chapter of the American College of Cardiology,
- Florida Chapter of the American Heart Association; and
- Any other entities with experience in statistics and outcome measurement.

The agency adopted rules dealing with the following for adult cardiovascular services:[12]

- A risk adjustment procedure that accounts for the variations in severity and case mix found in hospitals in this state;
- Outcome standards specifying expected levels of performance in Level I and Level II adult cardiovascular services. Such standards may include, but shall not be limited to, in-hospital mortality, infection rates, nonfatal myocardial infarctions, length of stay, postoperative bleeds, and returns to surgery; and
- Specific steps to be taken by the agency and licensed hospitals that do not meet the outcome standards within specified time periods, including time periods for detailed case reviews and development and implementation of corrective action plans.

According to the agency, a rule was enacted to deal with adult cardiovascular services after four years of painstaking and often contentious effort, culminating in a protracted proposed rule challenge.[13]

ST-Elevation Myocardial Infarction (STEMI)

A STEMI is commonly referred to as a heart attack. According to the American Heart Association, every year, almost 400,000 people experience a STEMI, the deadliest type of heart attack.[14]

According to a article in Circulation, there are several barriers that limit the rapid transport of patients with STEMI to the most appropriate facility: a minority (10%) of EMS systems have 12-lead ECG capabilities, which is needed to recognize a STEMI event; a minority (4% to 5%) of EMS patients with chest pain have STEMI; a mandate exists to deliver the patient to the nearest facility even when fibrinolysis[15] may be contraindicated and the facility does not provide PCI; and transport times may be long in rural areas.[16] If a patient is brought to a non–PCI-capable facility and primary PCI is necessary, it is not unusual for the patient to wait for the next available ambulance to gain access to PCI. Furthermore, critically ill patients often require stabilization before transport, which could hamper the response and treatment timeline.[17]

In 1999, the American College of Cardiology and the American Heart Association adopted joint guidelines on the management of patients with STEMI.[18] The purpose of the guidelines was to focus on the numerous advances in the diagnosis and management of patients with STEMI. The guidelines specifically discuss pre-hospital issues with emergency medical services systems to ensure that patients receive quick, appropriate care in route to a hospital. If the hospital is not a PCI capable facility then the patient is usually transferred via inter-hospital transfer to a PCI capable facility. Below is a diagram of a recommended Emergency Medical Services (EMS) provider transport and care process.

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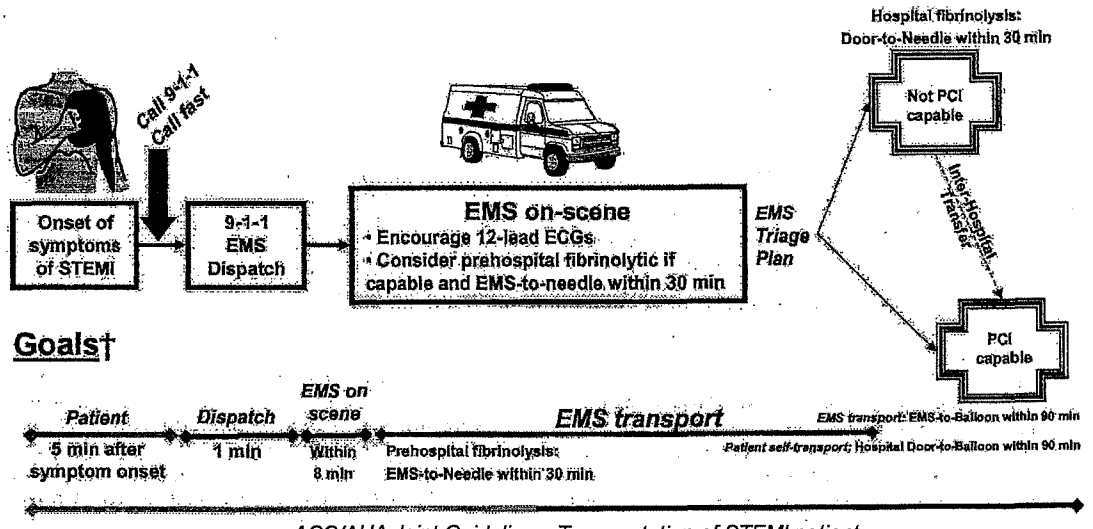
[11] Section 408.0361(5)(a), F.S.
[12] *Ibid.*
[13] Agency for Health Care Administration Bill Analysis and Economic Impact Statement for HB 1033 (2009) and 59A-3.2085, F.A.C
[14] American Heart Association, Mission: Lifeline. Available online at: http://www.americanheart.org/presenter.jhtml?identifier=3050213 (last viewed March 22, 2009).
[15] Drugs used to dissolve blood clots.
[16] Circulation. *Recommendation to Develop Strategies to Increase the Number of ST-Segment–Elevation Myocardial Infarction Patients With Timely Access to Primary Percutaneous Coronary Intervention.* (2006) Available online at: http://circ.ahajournals.org/cgi/content/full/113/17/2152 (last viewed March 22, 2009).
[17] *Ibid.*
[18] Circulation. *A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Revise the 1999 Guidelines for the Management of Patients with Acute Myocardial Infarction).* (2004;110).



ACC/AHA Joint Guidelines: Transportation of STEMI patient

Recently, a study was released in the Annuals of Emergency Medicine that looked at the practice of bypassing the nearest community hospital for STEMI patients in favor of a more distant specialty center able that is a PCI capable facility.[19] The study tried to determine whether EMS transport of out-of-hospital STEMI patients directly to more distant specialty percutaneous coronary intervention centers will alter 30-day survival compared with transport to the nearest community hospital fibrinolytic therapy. The findings in the study determined that in select out-of-hospital STEMI care scenarios, EMS transport of acute STEMI patients directly to percutaneous coronary intervention centers may offer small but uncertain survival benefits over nearest community hospital fibrinolytic therapy.[20]

The Effects of the Bill

The bill creates a new section of law that provides cardiac assessment criteria and treatment protocols for emergency medical services providers in the state. The bill requires the agency to certify percutaneous coronary intervention centers ("PCI center"). According to the bill, a PCI center is a licensed provider of adult interventional cardiology services as provided in s. 408.0361, F.S. Currently, the agency licenses PCI centers as either a Level I or Level II adult cardiovascular service provider. Since, the agency already licenses hospitals according to the level of PCI services they may provide (Level I or Level I facilities), it is unclear what additional certification of "PCI centers" would add to the current regulatory scheme.

The bill requires the agency to direct all licensed hospitals under chapter 395, F.S., to participate in the coordination of local STEMI systems of care. However, the bill does not provide any enforcement authority to the agency. According to the bill, entities in the STEMI systems of care, include but are not limited to: hospitals with or without open-heart surgery programs on site; stand-alone PCI centers; and hospitals that are not equipped with PCI centers. The bill mentions "stand-alone PCI centers" but this facility may conflict with the definition of a licensed level I or Level II adult cardiovascular services program in part because the facility may not be located in a hospital. According to the bill, each hospital that is part of the STEMI system of care is required to provide detailed documentation of the patient care process, to include, the length of time each step of the patient care process. Additionally, the bill requires the hospital to provide the documentation to the emergency medical services (EMS) director for the purpose of quality improvement.

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[19] Annuals of Emergency Medicine. *Direct paramedic transport of acute myocardial patients to percutaneous coronary intervention centers: a decision analysis.* (Feb 2009). Available online at: http://www.ncbi.nlm.nih.gov/pubmed/18801596 (last viewed March 22, 2009).

[20] *Ibid.*

The bill states that by June 1, 2010, or 6 months after the agency adopts a rule governing the certification of PCI centers, whichever is later, the Department of Health ("department") is required to send a list of each PCI center and its address to each licensed emergency medical services provider[21] and director in the state. However, the bill also requires the agency to post a list of the licensed PCI centers on its internet website by December 1, 2009. It is unclear why both the agency and the department need to provide lists and the timelines appear to conflict. Both the agency and the department are required to either post or send the lists by June 1 annually thereafter.

The bill requires the department to develop sample cardiac triage assessment criteria. The criteria must be posted on the departments' internet website and a copy of the criteria must be provided to each licensed EMS provider and EMS director no later than July 10, 2010. The bill requires every EMS provider licensed under chapter 401, F.S., to comply with the provisions of the bill by July 1, 2010 or 6 months after it receives the list of certified PCI centers, whichever is later. Depending upon when the list of certified PCI centers is posted, there may be a problem with the time period between the creation of the criteria and implementation. If the criteria is posted on the departments' internet website on July 10 , 2010, then EMS providers may not have sufficient time to implement the protocol. Moreover, the bill encourages each licensed EMS provider to use the cardiac triage assessment criteria provided by the department or one that is substantially similar.

The bill requires each medical director of a licensed EMS provider to develop and implement assessment, treatment, and transportation protocols for cardiac patients. The protocols must be employed to assess, treat, and transport STEMI patients to the most appropriate hospital. In addition the protocols must include the use of a community plan to address transport of cardiac patients to an appropriate facility in a manner that addresses community-specific resources and needs. The bill does not reference the use of the American College of Cardiology and the American Heart Association adopted joint guidelines as a basis for the development or implementation of protocols for cardiac patients.

The bill requires the department to develop and provide technical support, equipment recommendations, and necessary training for the effective identification of acute STEMI for each licensed EMS provider and emergency medical services director. The department is required to use the American Heart Association's advanced cardiac life support chest pain algorithm, a substantially similar program, or a program with evidence-based guidelines as a model. Furthermore, the bill requires the department to conduct a biannual survey to develop an equipment inventory, equipment standards, training requirements, and performance standards in applying the protocols for all licensed EMS providers in the state. A report of the survey findings must be provided to all EMS providers, EMS directors, the Emergency Medical Services Advisory Council, and other stakeholders. It is unclear how the information collected in the survey will be used by the department or stakeholders and many years the survey should be conducted.

The bill encourages the department to help identify and provide opportunities, partnerships, and resources for licensed EMS providers to secure appropriate STEMI equipment. Furthermore, the bill provides that the department may annually convene stakeholders to facilitate the sharing of experiences and best practices following the implementation of the assessment criteria. The bill requires the department to post best practices on their website.

B. SECTION DIRECTORY:

Section 1. Creates s. 395.1042, F.S., relating to emergency medical services providers and cardiac assessment criteria and protocols.

Section 2. Provides an effective date of July 1, 2009.

[21] Emergency medical services providers are regulated under part III of chapter 401, F.S.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   The fiscal impact to the department:

   Training & Technical Support
   According to the department, the technical support and training that must be provided to the 266 licensed EMS provider agencies and directors is projected to cost $70,000. The extent of the technical support is difficult to quantify at this time. However, the cost of training can be estimated from previous training efforts provided by DOH. A course for Ambulance Strike Team training cost approximately $10,000 per course with an unlimited number of participants. The training was provided in a train-the-trainer format, which the department has deemed the most efficient use of funds. There is an undetermined turnover rate among licensed EMS providers, therefore, it is anticipated that this training would need to be completed on a biennial basis.

   Program Evaluation
   According to the department, staff time will be required to determine what programs were substantially similar to the chest pain algorithm for pre-hospital assessment, triage, and treatment of patients with suspected STEMI.

   Inventory of Equipment
   Staff time will also be required to administer a biennial survey of the 266 licensed EMS provider agencies to develop an inventory of their equipment, identify their equipment needs, training requirements, and performance regarding the practical application of protocols and the identification of acute STEMI in the field.

   Annual Meeting
   A recent cost analysis of other annual meeting revealed an average cost of $21,274 per meeting. The cost includes meeting space rental at a central location and travel reimbursement for approximately 25 stakeholders and DOH staff. Using this rationale, the department could incur an annual cost of $21,273.23 per year to convene a stakeholder meeting. This estimate does not include staff preparation time for the stakeholder meetings.

   Website
   The department, Bureau of EMS, currently has a Emergency Medical Services for Children program. The duties of this program are to improve statewide communication and education by regularly updating a website, strengthening partnerships with other state agencies, conducting surveys, and managing stakeholders, organizations and consumer groups regarding children affected by emergencies. The program has 1 FTE-Community/Social Services Specialist. Using this rationale, the addition of 1 FTE is provided. The Community Planner for Children Program often finds it necessary to use administrative support staff from other sections to meet deadlines, process surveys, and collaborate with stakeholders. An Administrative Assistant 1 is provided to increased workload that is required.

Estimated Expenditures	1st Year	2nd Year (Annualized/Recurr.)
Salaries		
1.0 FTE – Community Planner, Pay Grade 22 (Annual salary $36, 468 w/ 29% fringe)	$47,044	$47,044
1.0 FTE – Administrative Assistant I, Pay Grade 15 (Annual salary $25,479 w/ 29% fringe)	$32,868	$32,868
Other Personal Services		
Biennial Training Cost	$70,000	
Expense		
Stakeholder meeting cost	$21,273	$21,273
Standard Expense Package with Limited Travel – 1.0 FTE	$15,680	$12,268
Standard Expense Package - 1.0 FTE	$8,397	$5,426
Operating Capital Outlay		
2.0 FTE Operating Capital Outlay *(OCO) Package*	$2,000	
Human Resources	*$801*	*$801*
Total Estimated Expenditures to the Emergency Medical Services Trust Fund:	$198,063	$119,680

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   Local governments may have to support the purchase of a 12-lead EKG machine for each ambulance.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The provisions in the bill would in effect require all EMS providers to have a 12-lead EKG/ECG machine aboard all ambulances or emergency response vehicles. A 12-lead EKG is suppose to be the best instrument to use in the detection of a STEMI event. Not all ambulances currently utilize a 12-lead EKG. A broadband all-digital system such as the LIFEPAK 12 defibrillator or monitor enables paramedics to transmit 12-lead ECGs in the field to a secure web-based system. The system relays the information securely via the Internet to hospital care teams and catheterization labs, or directly to a

cardiologist's handheld device.[22] The LIFEPAK 12 defibrillator/monitor series from Medtronic Physio-Co can range from $7,500 to $13,495.[23]

D. FISCAL COMMENTS:

The agency currently provides a list of PCI centers to emergency medical providers and currently posted on the Agency website. According to the agency, EMS providers currently use the information on the website in developing their protocols for determining appropriate medical facilities. The fiscal impact to the agency would be insignificant since most of the activity required in the bill is already taking place under existing regulatory requirements.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable. This bill does not appear to: require the counties or cities to spend funds or take an 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:

The bill provides sufficient rule making authority to the agency to adopt rules for governing the certification of PCI centers. The department has sufficient rule making authority in s. 401.35, F.S.

C. DRAFTING ISSUES OR OTHER COMMENTS:

There are emergency service providers that only provide inter-facility transfers and do not perform emergency services. It may be advantageous to provide an exemption for providers that do not perform emergency services.

The bill does not include a sanction for hospitals that do not participate in the coordination of local STEMI systems of care. The bill identifies the participants in a STEMI system to include hospitals with PCI centers, hospitals without PCI centers and "stand-alone PCI centers". The term "stand-alone PCI centers" is not identified elsewhere in the bill, and would not meet the definition of a PCI center if not a hospital with a licensed Level I or Level II adult cardiovascular services program.
The bill requires all licensed EMS providers to have a 12-lead EKG or STEMI equipment aboard all ambulances or emergency response vehicles. Current law[24], requires that each licensed hospital with an emergency department have a two-way radio that is capable interfacing with designated municipal aid channels and communicating with all ground basic life support service vehicles, advanced life support service vehicles, and rotorcraft air ambulances that operate within the hospitals service area under state permit. It is not clear how a web-based system would transmit the EKG in transport to the hospitals and it is not known whether most EMS providers have a cell phone or computer with blue tooth technology available, especially in the rural areas of the state.

IV. AMENDMENTS/COUNCIL OR COMMITTEE SUBSTITUTE CHANGES

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[22] Pre-hospital 12-Lead ECGs Help Reduce EMS-to-Balloon Times. Available online at: www.monoc.org/admin/docs/news/general/Physio-Control%20STEMI%20Case%20Study% *(last viewed March 21, 2009).*
[23] Dixie Medical Equipment, Lifepak 12 Biphasic defibrillator/monitor. Available online at: http://www.dixiemed.com/proddetail.php?prod=LP123BiPA&_s_ref=G56mfU0dS&kw="lifepak%2012"&creative=2989213848&gclid=CKejy-WauZkCFRBhnAodf2Bv_g (last viewed March 22, 2009).
[24] Section 395.1031, F.S.

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

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

Bill No. **1033**

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: Health Care Regulation Policy Committee

Representative(s) Renuart offered the following:

Amendment (with title amendment)

Remove everything after the enacting clause and insert:

Section 1. Emergency medical services providers; triage and transportation of victims of an acute ST-elevation myocardial infarction to the most appropriate medical facility with a specific preference to medical facilities with a percutaneous coronary intervention center; definitions.--

(1)(a) The Legislature finds that rapid identification and treatment of serious heart attacks, known as ST-elevation myocardial infarction or STEMI, can significantly improve outcomes by reducing death and disability by rapidly restoring blood flow to the heart in accordance with the latest evidence-based standards.

(b) The Legislature further finds that a strong emergency system to support survival from life-threatening heart attacks is needed in this state in order to treat victims in a timely manner and to improve outcomes and the overall care of heart

attack victims.

(c) Therefore, the Legislature directs all local emergency medical providers and hospitals to establish a STEMI system of care to help improve outcomes for individuals suffering from a life-threatening heart attack.

(2) As used in this section, the term:

(a) "Agency" means the Agency for Health Care Administration.

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

(c) "STEMI system of care" means a local agreement between emergency medical service providers and local hospitals to deliver patients identified as having an ST-elevation myocardial infarction to appropriate medical facilities.

(d) "Percutaneous coronary intervention center" means a provider of adult interventional cardiology services licensed by the agency under s. 408.0361, Florida Statutes.

(3) The department shall develop sample assessment criteria relating to cardiac triage. The department must post this sample assessment criteria on its website and provide a copy of the assessment criteria to each licensed emergency medical services provider and medical director of emergency medical services by July 1, 2010. Each licensed provider of emergency medical services licensed under chapter 401 is required to submit existing cardiac triage protocols or to develop assessment criteria relating to cardiac triage which specifically addresses transportation and treatment plans for acute STEMI patients.

(4) The medical director of each licensed emergency medical services provider shall submit and implement existing protocols or develop and implement protocols for the assessment, treatment, and transportation of cardiac patients and employ those protocols to assess, treat, and transport patients having

a STEMI to the most appropriate hospital. These protocols must include use of a community plan to address the transport of cardiac patients to appropriate facilities in a manner that addresses community specific resources and needs. The plan must also address a data-sharing agreement between hospitals and EMS.

(5) The department shall develop and provide to each licensed emergency medical services provider and medical director of emergency medical services technical support, equipment recommendations, and necessary training recommendations for the effective identification of patients who are having an acute STEMI. The department shall base the sample assessment criteria relating to cardiac triage on the most recent version an advanced cardiovascular life support chest pain algorithm for pre-hospital assessment, triage, and treatment of patients suspected of having a STEMI that uses evidence-based guidelines such as those developed by the American Heart Association or a substantially similar program. The department shall conduct a biennial survey of all applicable licensed emergency medical services providers to develop an inventory of their equipment and identify their equipment needs, training requirements, and performance regarding the practical application of protocols and the identification of an acute STEMI in the field. The department shall report its survey findings and provide a copy of the survey to emergency medical services providers, directors of emergency medical services, the Emergency Medical Services Advisory Council and other stakeholders.

(6) The department shall assist in identifying and providing all licensed emergency medical services providers with opportunities, partnerships, and resources for securing appropriate equipment for identifying STEMI in the field. These sources may include the Emergency Medical Services Grant Fund

pursuant to sections 401.101-401.121.

(7) After implementation of the assessment criteria, local STEMI systems are encouraged to meet semi-annually to assess quality improvement measures.

(8) After implementation of the assessment criteria, the department shall convene stakeholders at least once a year, if necessary, to facilitate the sharing of experiences and best practices. The best practices shall be made available on the department's website. These meetings may take place at one of the annual EMS meetings, via teleconference, web conference or other methods appropriate to distribute and share information.

(9) Each emergency medical services provider licensed under chapter 401, must comply with this section by July 1, 2010.

(10) Medical directors of emergency medical shall determine the most appropriate transport destinations for suspected STEMI patients.

(11) The department shall adopt rules necessary to administer this section.

Section 2. (1) Any hospital licensed under chapter 395, must participate in coordinating a local STEMI system of care.

(2) Participants should include, but need not be limited to, hospitals, primary percutaneous coronary intervention centers with and without open-heart centers onsite, those facilities designated as chest pain centers and those hospitals not equipped to provide services related to percutaneous coronary intervention.

(3) The hospital portion of a STEMI system of care shall submit detailed, timed documentation of each step in the patient-care process to the American College of Cardiology-National Cardiovascular Data Registry in accordance with the timetables and procedures established by the registry for 100

percent of all STEMI patients. All data shall be reported using the specific data elements, definitions and transmission format as set forth by the American College of Cardiology-National Cardiovascular Data Registry. Hospital reports shall include but not be limited to: door to reperfusion time, door to cardiac catheterization laboratory time, emergency department arrival time, and emergency department exit time. Medical directors shall have access to the American College of Cardiology-National Cardiovascular Data Registry to access data on the treatment of their patients for the exclusive use of quality improvement of the entire STEMI system, within 30 days of patient discharge.

(4) Hospitals shall provide a copy of the reporting data to the emergency medical services director for each suspected STEMI patient treated by their respective EMS team.

Section 3. The department of Health and the Agency for Health Care Administration are authorized to create rules to implement the data sharing of this act.

Section 4. This act shall take effect July 1, 2009.

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

Remove the entire title and insert:

An act relating to cardiology services; providing legislative findings; providing definitions; requiring the department to develop sample assessment criteria relating to cardiac triage with public access on its website; encourages providers of medical services to use the sample assessment criteria relating cardiac triage; requiring each medical director of an emergency medical services provider to develop and implement certain protocols for cardiac patients; providing requirements for the protocols; requiring the department to develop and provide

technical support, equipment recommendations, and training for indentification of patients having acutre ST-elevation myocardial infarction; requiring the department to base the sample assessment criteria relating to cardiac triage on specified programs; requiring the department to conduct a survey of licensed emergency medical services providers and report its findings to certain stakeholders; requires the department to identify and provide to emergency medical services providers opportunities and resources to secure appropriate equipment for the identification of ST-elevation myocardial infarction; requiring the department to meet with stakeholders; providing a timeframe for emergency medical services providers to comply with the act; authorizing medical directors to determine appropriate transport locations for patients; requiring the department to adopt rules; requiring all hospitals licensed in Florida to participate in the coordination of a local STEMI system of care; proving requirements for documentation of time for the process of patient care for the hospital portion of the STEMI system of care, including sharing with EMS; provides for rulemaking; providing an effective date.

WHEREAS, every year, approximately 24,000 people in this state suffer a life-threatening heart attack known as a STEMI, one-third of whom die within 24 hours after the attack, and

WHEREAS, fewer than 20 percent of heart attack victims receive emergency reperfusion to open blocked arteries, and

WHEREAS, studies have shown that individuals suffering a life-threatening heart attack have better outcomes if they receive emergency reperfusion, and

WHEREAS, studies have shown that percutaneous coronary intervention or PCI is the optimum treatment for a patient

suffering from an ST-elevated myocardial infarction or STEMI heart attack, and

WHEREAS, studies have shown that opening a blocked coronary artery using emergency PCI within recommended timeframes can effectively prevent or significantly minimize permanent damage caused by a heart attack to the heart, and

WHEREAS, even fewer patients receive the procedure within the timeframe recommended by the American Heart Association, and

WHEREAS, damage to the heart muscle can result in death, congestive heart failure, atrial fibrillation, and other chronic diseases of the heart, and

WHEREAS, organizations such as the American Heart Association, the American College of Cardiology, and the Florida College of Emergency Physicians recommend deploying protocols and systems to help ensure that people suffering from a life threatening heart attack receive the latest evidence-based care, such as timely reperfusion and emergency PCI, within recommended timeframes, and

WHEREAS, Florida's system of trauma services and system of emergency stroke treatment have dramatically improved the care provided for individuals suffering from a traumatic injury or a stroke, and

WHEREAS, a localized emergency cardiac system can help ensure that people suffering from a life-threatening heart attack will receive the latest evidence-based care within recommended timeframes, NOW, THEREFORE,

A bill to be entitled

An act relating to emergency cardiology services; creating s. 395.1042, F.S.; providing definitions; requiring the Agency for Health Care Administration to post and update a list of percutaneous coronary intervention centers on its Internet website; requiring the Department of Health to send a list of such centers to emergency medical services providers and emergency medical services directors in the state; directing the department to develop and distribute sample cardiac triage assessment criteria and post it on its Internet website; providing for licensed emergency medical services providers to use similar assessment criteria; requiring the director of each emergency medical services provider to develop and use certain specified protocols; providing additional duties of the department relating to support, training, and equipment; requiring the department to conduct a biennial survey; requiring a report; providing for stakeholder meetings; requiring the agency to direct certain hospitals to participate in local ST elevated myocardial infarction (STEMI) systems of care; requiring documentation of the patient care process to be submitted to the medical director; requiring compliance by a certain date; providing an effective date.

WHEREAS, every year, approximately 24,000 people in this state suffer a life-threatening heart attack, one-third of whom die within 24 hours after the attack, and

WHEREAS, fewer than 20 percent of heart attack victims

receive emergency angioplasty to open blocked arteries, and

WHEREAS, studies have shown that individuals suffering a life-threatening heart attack have better outcomes if they receive emergency reperfusion, and

WHEREAS, studies have shown that percutaneous coronary intervention (PCI) is the optimum treatment for a patient suffering from an ST elevated myocardial infarction (STEMI) heart attack, and

WHEREAS, studies have shown that opening a blocked coronary artery with emergency PCI within recommended timeframes can effectively prevent or significantly minimize permanent damage to the heart, and

WHEREAS, even fewer patients receive the procedure within the timeframe recommended by the American Heart Association, and

WHEREAS, damage to the heart muscle can result in death, congestive heart failure, atrial fibrillation, and other chronic diseases of the heart, and

WHEREAS, organizations such as the American Heart Association, the American College of Cardiology, and the Florida College of Emergency Physicians recommend deploying protocols and systems to help ensure that people suffering from a life-threatening heart attack receive the latest evidence-based care, such as timely reperfusion or emergency PCI, within recommended timeframes, and

WHEREAS, Florida's trauma services system and emergency stroke treatment system have dramatically improved the care provided for individuals suffering from a traumatic injury or a stroke, and

WHEREAS, a localized emergency cardiac system can help people suffering from a life-threatening heart attack receive the latest evidence-based care within recommended timeframes, and

WHEREAS, rapid identification and treatment of a STEMI heart attack can significantly improve outcomes by reducing death and disability by rapidly restoring blood flow to the heart, and

WHEREAS, a strong emergency response system is needed in communities throughout our state in order to treat heart attack victims in a timely manner and to improve the overall care of those victims, and

WHEREAS, the Legislature strongly encourages local emergency medical service providers to establish a STEMI system of care to help improve outcomes for individuals who have survived a life-threatening heart attack, NOW, THEREFORE,

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

Section 1. Section 395.1042, Florida Statutes, is created to read:

395.1042 Emergency medical services providers; cardiac assessment criteria and protocols.--

(1) As used in this section, the term:

(a) "Percutaneous coronary intervention center" or "PCI center" means a provider of adult interventional cardiology services licensed by the agency under s. 408.0361.

(b) "STEMI" means an ST elevation myocardial infarction.

(c) "STEMI system of care" means a local agreement between emergency medical service providers and local hospitals to deliver identified STEMI patients to appropriate medical facilities.

(2) By December 1, 2009, and by June 1 of each year thereafter, the agency shall post on its Internet website a list of PCI centers licensed by the agency.

(3) By June 1, 2010, or 6 months after the agency adopts a rule governing certification of PCI centers under s. 408.036(3)(o), whichever is later, and by June 1 of each year thereafter, the department shall send a list of the names and addresses of each PCI center licensed by the agency to each licensed emergency medical services provider and emergency medical services director in the state.

(4) The department shall develop sample cardiac triage assessment criteria, post the criteria on its Internet website, and provide a copy of the criteria to each licensed emergency medical services provider and emergency medical services director no later than July 1, 2010. Each licensed medical services provider is encouraged to use cardiac triage assessment criteria that are substantially similar to the sample cardiac triage assessment criteria provided by the department under this subsection.

(5) The medical director of each licensed emergency medical services provider shall develop and implement assessment, treatment, and transportation protocols for cardiac patients and employ those protocols to assess, treat, and transport STEMI patients to the most appropriate hospital. Such

protocols shall include use of a community plan to address transport of cardiac patients to appropriate facilities in a manner that addresses community-specific resources and needs.

(6) The department shall develop and provide technical support, equipment recommendations, and necessary training for effective identification of acute STEMI patients to each licensed emergency medical services provider and emergency medical services director. The department shall use the American Heart Association's advanced cardiovascular life support chest pain algorithm for prehospital assessment, triage, and treatment of patients with suspected STEMI, a substantially similar program, or a program with evidence-based guidelines as a model for its sample cardiac triage assessment criteria. The department shall conduct a biennial survey of all applicable licensed emergency medical services providers to develop an inventory of their equipment and identify their equipment needs, training requirements, and performance regarding the practical application of protocols and the identification of acute STEMI in the field. The department shall report its survey findings and provide a copy of the survey to emergency medical services providers, emergency medical services directors, the Emergency Medical Services Advisory Council, and other stakeholders.

(7) The department is encouraged to identify and provide opportunities, partnerships, and resources to secure appropriate equipment for identification of STEMI in the field to all licensed emergency medical service providers.

(8) After implementation of the assessment criteria, the department shall convene stakeholders at least once a year, if

necessary, to facilitate the sharing of experiences and best practices. The best practices shall be made available on the department's Internet website.

(9) The agency shall direct all hospitals licensed under this chapter to participate in the coordination of local STEMI systems of care.

(a) Participants in a STEMI system of care shall include, but not be limited to, hospitals with primary PCI centers, with or without open-heart surgery programs on site, stand-alone PCI centers, and hospitals that are not equipped with PCI centers.

(b) The hospital portion of the STEMI system of care shall include detailed documentation of the time at which each step of the patient care process occurred. This information shall be submitted to the medical director of emergency medical services for the purpose of quality improvement.

(10) Each emergency medical services provider licensed under chapter 401 shall comply with this section by July 1, 2010, or 6 months after the date it receives the list of PCI centers sent pursuant to subsection (4), whichever is later.

Section 2. This act shall take effect July 1, 2009.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1097 Electronic Health Records
SPONSOR(S): Grimsley
TIED BILLS: **IDEN./SIM. BILLS:**

	REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1)	Health Care Regulation Policy Committee		Lowell	Calamas
2)	Civil Justice & Courts Policy Committee			
3)	Health & Family Services Policy Council			
4)	Health Care Appropriations Committee			
5)				

SUMMARY ANALYSIS

The bill clarifies that a patient's records held by a hospital may be disclosed without the consent of the patient, or his or her legal representative, to health care practitioners and providers currently involved in the care or treatment of the patient. The bill clarifies that lab results may be provided by a clinical laboratory to other health care practitioners and providers involved in the care or treatment of the patient for use in connection with the treatment of the patient.

The bill also creates the Florida Electronic Health Records Exchange Act and defines several common health information technology terms such as electronic health records system, health information exchange, and health record. The bill provides civil immunity for a health care provider who, in good faith, releases or accesses a patient's health record without the patient's consent for the treatment of an emergency medical condition when the provider is unable to obtain the patient's consent due to the patient's condition. In addition, the bill requires AHCA to create a universal patient authorization form that may be used by a health care provider for the release of health records. The bill states that anyone who forges a signature on such form or obtains the form or health record of another person under false pretenses may be liable for compensatory damages plus attorney's fees and costs. The bill also provides civil immunity for a health care provider who releases a health record in reliance on information provided to the provider on a properly-completed form.

Finally, the bill creates the Electronic Medical Records System Adoption Loan Program, subject to a specific appropriation. The agency is required to provide one-time, no-interest loans to physicians or business entities whose shareholders are physicians for the initial costs of implementing an electronic medical records system.

The agency is authorized to distribute the loan in a lump-sum amount, and the loan proceeds may be used to purchase hardware and software, as well as subscription services, professional consultations, and staff training. The agency is required to provide loan recipients a list of electronic medical record systems recognized or certified by national standards-setting entities. The agency is further required to distribute a minimum of 25 percent of loan funds to physicians or business entities operating within a rural county. The loan must be repaid within 6 years and payments must commence within 3 months of the funding of the loan.

The loan program established by the bill is subject to a specific appropriation. Absent this specific appropriation, the bill would have minimal fiscal impact on the agency. If specific appropriation is provided for the loan program, the bill has an indeterminate fiscal impact on the agency.

The bill takes effect upon becoming a law.

HOUSE PRINCIPLES

Members are encouraged to evaluate proposed legislation in light of the following guiding principles of the House of Representatives

- Balance the state budget.
- Create a legal and regulatory environment that fosters economic growth and job creation.
- Lower the tax burden on families and businesses.
- Reverse or restrain the growth of government.
- Promote public safety.
- Promote educational accountability, excellence, and choice.
- Foster respect for the family and for innocent human life.
- Protect Florida's natural beauty.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Terminology

Discussions of health information technology often contain numerous technical terms that are difficult to understand for those who are not familiar with such usage. In addition, there is very little agreement amongst organizations in the health information technology community regarding the definitions of these terms. However, for the purposes of this analysis, the following terms are used:

- Electronic Health Record (EHR). Also known as an electronic medical record, an electronic health record is a computer-based record of one or more clinical encounters between a healthcare provider and a specific patient. An EHR may include a number of data items, from patient demographics to diagnostic images.

- Electronic Health Records System (EHR system). An electronic health record system is a software program that allows computer-based management of clinical information documenting the delivery of health care to multiple patients. An EHR system may include multiple functionalities, such as management of procedure results and electronic entry of clinical and prescription data.

- Electronic Prescribing System (E-Prescribing System). An electronic prescribing system is a software program for electronically creating and transmitting a prescription to a participating pharmacy. An e-prescribing system maintains a record of a patient's prescriptions and notifies a health care practitioner of conflicting medications. EHR systems generally include e-prescribing functionality; however, an e-prescribing system may also be purchased and operated independently.

- Health Information Exchange (HIE). A health information exchange is an electronic system used to acquire, process, and transmit electronic health records, which can be shared in real-time among authorized health care providers, health care facilities, health insurers, and other recipients to facilitate provision of health care services.

- The Health Insurance Portability and Accountability Act (HIPAA). The federal Health Insurance Portability and Accountability Act of 1996 established baseline health care privacy requirements

for protected health information and established security requirements for electronic protected health information.

- Regional Health Information Organization (RHIO). A regional health information organization is 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.

Rate of Adoption of Health Information Technology

Widespread adoption of EHR and e-prescribing systems holds the promise of improving patient safety and reducing the cost of health care by preventing unnecessary procedures. However, in a 2005 report, the National Center for Health Statistics (NCHS) within the United States Centers for Disease Control and Prevention noted that adoption of information technology within the health care sector is trailing behind other sectors in the economy of the United States.[1] The adoption of EHRs by hospitals and physicians has been particularly slow. As part of its annual National Health Care Survey, NCHS found that, from 2001 through 2003:

- The most frequent IT application used in physician offices was an electronic billing system. Nearly three-fourths (73 percent) of physicians submitted claims electronically. Electronic submission of claims was more likely among physicians in the Midwest and South, in nonmetropolitan areas, among physicians under 50 years of age, and for physicians with 10 or more managed care contracts. Physicians in medical specialties such as psychiatry, dermatology, or sports medicine (among others) were least likely to submit claims electronically.

- EHRs were used more frequently in hospital settings (31 percent in emergency departments) than in physician offices (17 percent). Among physician office practices, there were no statistically significant differences in EMR use by region, metropolitan status, specialty, physician age, type of practice, or number of managed care contracts.

A more recent 2007 NCHS report indicates that physician office use of EHR systems continues to grow; roughly 29 percent use full or partial (i.e., part paper) EHR systems, a 22 percent increase since 2005, and a 60 percent increase since 2001.[2] The report also noted that EHR system use was higher in health maintenance organizations than among private practice physicians.[3]

Federal Health Information Technology Efforts

The federal government has embarked upon three recent initiatives to incentivize the adoption of health information technology. The first initiative is an incentive payment program for the adoption of an EHR system and reporting and performance on 26 quality measures.[4] The program began in 2008 and will operate over a five-year period in two phases in 12 locations. The first phase will begin on June 1, 2009.[5] The second phase includes six counties in the Jacksonville area, namely Baker, Clay, Duval, Nassau, Putnam and St. Johns counties.[6]

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[1] C.W. Burt and E. Hing, *Use of Computerized Clinical Support Systems in Medical Settings: United States, 2001–03*, Advance Data from Vital and Health Statistics no. 353, March 15, 2005.
[2] E. Hing, C.W. Burt, and D. Woodwell, *Electronic Medical Record Use by Office-Based Physicians and Their Practices: United States, 2006*, Advance Data from Vital and Health Statistics no. 393, October 26, 2007.
[3] *Id.*
[4] Centers for Medicare and Medicaid Services, "ELECTRONIC HEALTH RECORDS (EHR) DEMONSTRATION," http://www.cms.hhs.gov/DemoProjectsEvalRpts/downloads/EHR_DemoSummary.pdf (visited March 20, 2009).
[5] *Id.*
[6] *Id.*

The second initiative is the E-Prescribing Incentive Program, which, beginning January 1, 2009, provides incentive payments to health care practitioners for e-prescribing.[7] A "successful" e-prescriber under the program will gain an incentive payment of 2 percent in calendar years 2009 and 2010; 1 percent in calendar years 2011 and 2012; and .5 percent in calendar year 2013.[8] Health care practitioners who do not qualify as successful e-prescribers will be penalized beginning in 2012; the penalty is 1 percent in 2012; 1.5 percent in 2013; and 2 percent in 2014.[9]

The third initiative is part of the "American Recovery and Reinvestment Act of 2009," (ARRA) which was signed into law by President Barack Obama on February 17, 2009. Included in the ARRA is the "Health Information Technology for Economic and Clinical Health Act."[10] Approximately $19 billion is appropriated to incentivize the adoption of EHR systems, including:

- State planning and implementation grants to promote health information technology. Grants require state match beginning in fiscal year 2011.[11]
- Competitive state grants to establish loan programs to facilitate the adoption and improvement of EHR systems by health care providers, as well as training personnel and improving the secure exchange of health information. Loans must be paid back within 10 years and the interest rate may not exceed the market rate. Each state must provide $1 of non-federal funds as match for each $5 of federal funds received. Each state is allowed to use 4 percent of the grant funds to pay the reasonable costs of administering the loan program.[12]
- Medicare incentive payments over a five-year period to healthcare professionals for "meaningful" use[13] of EHR systems, beginning in 2011 and ending in 2016. Incentives range from a maximum of $48,400 for those who adopt in 2011 to no payment for those adopting EHR systems after 2015. Health care professionals who do not adopt meaningful use of an EHR system by 2015 will be penalized according to the following schedule—1 percent in 2016; 2 percent in 2017; and 3 percent in 2018 and thereafter.[14]

State Health Information Technology Efforts

Florida Health Information Network Grants Program

In 2006, the Legislature authorized the Agency for Healthcare Administration (AHCA) to administer a grants program to advance the development of a health information network.[15] According to the agency, grants are currently awarded to regional health information organizations (RHIOs) in three categories:[16]

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

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[7] Centers for Medicare and Medicaid Services, "E-Prescribing Incentive Program Overview," http://www.cms.hhs.gov/ERXincentive/ (visited March 20, 2009).
[8] Centers for Medicare and Medicaid Services, "Medicare's Practical Guide to the E-Prescribing Incentive Program," http://www.cms.hhs.gov/ERxIncentive/Downloads/erx_incentive_program_simple_factsheet.pdf (visited March 20, 2009) (In order to be a "successful" e-prescriber, a health care practitioner must "report the e-prescribing quality measure through [his or her] Medicare Part B claims on at least 50% of applicable cases during the reporting year").
[9] *Id.*
[10] H.R. 1, 111th Congress, §13001 (2009).
[11] *Id.* at §13301.
[12] *Id.*
[13] *Id* at §4101 ("Meaningful" use of an EHR system means (a) using EHR technology in a meaningful manner, such as e-prescribing; (b) the EHR technology is connected in a manner that provides for the electronic exchange of health information to improve the quality of health care, such as promoting care coordination; and (c) reporting clinical quality measures).
[14] *Id.*
[15] Section 408.05(4)(b), F.S.
[16] Agency for Health Care Administration, "FY 2007-2008 Grants Program Requirements," http://ahca.myflorida.com/dhit/FHINgrantsProgram/FGPSched0708.pdf (visited March 21, 2009).

- Training and technical assistance grants, which 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. No funding was appropriated in Fiscal Year 2008-2009.

Approximately 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 health information exchange. The RHIOs and their aggregate funding levels include:

- Big Bend RHIO – $810,422
- Central Florida RHIO – $200,000
- Community Health Informatics Organization – $222,384
- Healthy Ocala – no funding sought
- Northeast Florida Health Information Consortium – $406,944
- Northwest Florida RHIO – $776,589
- Palm Beach County Community Health Alliance – $692,812
- South Florida Health Information Initiative – $742,151
- Tampa Bay RHIO – $1,043,957
- Veterans' Health Information Exchange Network – $70,614

Electronic Prescribing Clearinghouse

In 2007, the Legislature created the Electronic Prescribing Clearinghouse within AHCA.[17] The stated intent of the clearinghouse is to "promote the implementation of electronic prescribing by health care practitioners, health care facilities, and pharmacies in order to prevent prescription drug abuse, improve patient safety, and reduce unnecessary prescriptions."[18] AHCA is required to annually publish a report by January 31 regarding the progress of implementing electronic prescribing.

The latest report, published in January 2009, provided several findings, including:

- The annual e-prescribing rate for all prescriptions that could have been e-prescribed grew from 1.6 percent in 2007 to 4.3 percent in 2008.
- The monthly e-prescribing rate was 6.9 percent in December 2008, compared to the national rate of approximately 7 percent.[19]

Privacy and Security of Health Records

Health Insurance Portability and Accountability Act

The Health Insurance Portability and Accountability Act of 1996 (HIPAA), among other requirements, required the Secretary of the United States Department of Health and Human Services (HHS) to issue privacy regulations governing individually identifiable health information, if Congress did not enact privacy legislation within three years of the passage of HIPAA. Congress did not enact privacy legislation and thus, HHS drafted a rule ("the Privacy Rule") that became final on December 28, 2000.[20] According to HHS, the primary purpose of the Privacy Rule is to "assure that individuals' health

[17] Chapter 2007-156, L.O.F.
[18] *Id.*
[19] Agency for Health Care Administration, "Second Annual Florida 2008 Electronic Prescribing Report," http://www.fhin.net/eprescribe/ePandHIEinFL/Florida2008ePrescribeRptv5.3finalCorr030209.pdf (visited March 20, 2009).
[20] Summary of the HIPAA Privacy Rule, Office for Civil Rights, United States Department of Health and Human Services http://www.hhs.gov/ocr/privacysummary.pdf (last updated May 2003).

information is properly protected while allowing the flow of health information needed to provide and promote high quality health care and to protect the public's health and well being. The Rule strikes a balance that permits important uses of information, while protecting the privacy of people who seek care and healing."[21]

Generally, the Privacy Rule set forth the circumstances under which a "covered entity"[22] (and its business associates) may use and disclose "protected health information."[23] A covered entity may disclose protected health information, without a patient's authorization, for the following purposes:

- Treatment, Payment, and Health Care Operations.
- Opportunity to Agree or Object.
- Incident to an otherwise permitted use and disclosure.
- Public Interest and Benefit Activities.
- Limited Dataset for the purposes of research, public health or health care operations.

HIPAA generally preempts state privacy laws, unless they provide a stronger level of protection. This may include prescription drug monitoring programs, to the extent that they require covered entities to provide protected health information to the state database. However, the Secretary of HHS may determine that the law is not preempted if he or she determines that "the state law has as its principal purpose the regulation of the manufacture, registration, distribution, dispensing, or other control of any controlled substances."[24]

Health Information and Security Privacy Collaboration Project

Many 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 the United States Department of Health and Human Services 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.[25] 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 an HIE 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

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[21] *Id.*

[22] Generally, health plans, health care providers, and health care clearinghouses.

[23] Protected health information includes information relating to (a) the individual's past, present or future physical or mental health or condition, (b) the provision of health care to the individual, or (c) the past, present, or future payment for the provision of health care to the individual,

[24] 45 C.F.R. §160.203(a)(2) (2007).

[25] Dimitropoulos, Linda L., "Privacy and Security Solutions for Interoperable Health Information Exchange, Assessment of Variation and Analysis of Solutions," June 30, 2007, 2-1.

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.[26]

With regard to Florida law, the agency's Privacy and Security Project Legal Work Group identified several barriers to health information exchange in statutory law, including:

- Inconsistent language regarding the disclosure of patient records without consent in the hospital and physician patient records sections.[27]
- Lack of authority for treating physicians to access lab results directly from the clinical lab under chapter 483, F.S.[28]

Effect of Proposed Changes

The bill clarifies that a patient's records held by a hospital may be disclosed without the consent of the patient, or his or her legal representative, to health care practitioners and providers currently involved in the care or treatment of the patient. The bill clarifies that lab results may be provided by a clinical laboratory to other health care practitioners and providers involved in the care or treatment of the patient for use in connection with the treatment of the patient.

The bill also creates the Florida Electronic Health Records Exchange Act and defines several common health information technology terms such as electronic health records system, health information exchange, and health record. The bill provides civil immunity for a health care provider who, in good faith, releases or accesses a patient's health record without the patient's consent for the treatment of an emergency medical condition when the provider is unable to obtain the patient's consent due to the patient's condition. In addition, the bill requires AHCA to create a universal patient authorization form that may be used by a health care provider for the release of health records. The bill states that anyone who forges a signature on such form or obtains the form or health record of another person under false pretenses may be liable for compensatory damages plus attorney's fees and costs. The bill also provides civil immunity for a health care provider who releases a health record in reliance on information provided to the provider on a properly-completed form.

Finally, the bill creates an Electronic Medical Records System Adoption Loan Program, subject to a specific appropriation. The agency is required to provide one-time, no-interest loans to physicians or business entities whose shareholders are physicians for the initial costs of implementing an electronic medical records system. The agency is prohibited from providing a loan to an applicant who has:

- Been found guilty of violating s. 456.072(1) or been disciplined under the applicable licensing chapter in the previous 5 years.
- Been found guilty of or entered a plea of guilty or nolo contendere to a violation of ss. 409.920 or 409.9201, F.S. (Medicaid fraud).
- Been sanctioned pursuant to s. 409.913 for fraud or abuse (Medicaid fraud).

The agency is authorized to distribute the loan in a lump-sum amount, and the loan proceeds may be used to purchase hardware and software, as well as subscription services, professional consultations, and staff training. The agency is required to provide loan recipients a list of electronic medical record systems recognized or certified by national standards-setting entities. The agency is further required to distribute a minimum of 25 percent of loan funds to physicians or business entities operating within a

[26] *Id.* at ES-5 through ES-8.
[27] Sections 395.3025 and 456.057, F.S., respectively.
[28] Section 483.181, F.S.

rural county. The loan must be repaid within 6 years and payments must commence within 3 months of the funding of the loan.

The physician or business entity must further provide the following security for the loan:

- An irrevocable letter of credit in an amount equal to the amount of the loan;
- An escrow account in an amount equal to the amount of the loan; or
- A pledge of the accounts receivable of the physician or business entity.

If a physician or business entity defaults, and the default continues for 30 days, the entire balance of the loan becomes due and payable, subject to an interest rate of 18 percent annually.

B. SECTION DIRECTORY:

Section 1. Amends s. 395.3025, F.S., relating to patient and personnel records; copies; examination.

Section 2. Creates s. 408.051, F.S., relating to the Florida Electronic Health Records Exchange Act.

Section 3. Creates s. 408.0512, F.S., relating to the electronic medical records system adoption loan program.

Section 4. Amends s. 483.181, F.S., relating to acceptance, collection, identification, and examination of specimens.

Section 5. Provides an effective date of upon becoming a law.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   AHCA has requested three positions to review and process loan applications, monitor loan repayments, and conduct outreach activities. This request is based on an estimated 300 loan applications, which represents approximately 1 percent of licensed physicians. AHCA has estimated a $252,222 fiscal impact in Fiscal Year 2009-10 and $160,102 fiscal impact in Fiscal Year 2010-11, exclusive of loan funding.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The bill will authorize AHCA to provide one-time, no-interest loans to physicians or business entities whose shareholders are physicians for the initial costs of implementing an electronic medical records system.

D. FISCAL COMMENTS:

The fiscal impact estimated by AHCA is based on implementing the loan program created in the bill. Since the loan program is subject to a specific appropriation, the fiscal impact appears to be indeterminate. In addition, if AHCA were to seek a federal grant under the ARRA to establish an EHR loan program, AHCA would be authorized to use up to 4 percent of the grant funds to pay the reasonable costs of administering the program. These administrative funds may ameliorate AHCA's estimated fiscal impact.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable. 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:

The agency is provided sufficient rulemaking authority to implement the provisions of this bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COUNCIL OR COMMITTEE SUBSTITUTE CHANGES

None.

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

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

Bill No. **1097**

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: Health Care Regulation Policy Committee

Representative(s) Grimsley offered the following:

Amendment (with title amendment)

Remove everything after the enacting clause and insert:

Section 1. Subsection (4) of section 395.3025, Florida Statutes, is amended to read:

395.3025 Patient and personnel records; copies; examination.--

(4) Patient records are confidential and must not be disclosed without the consent of the patient or his or her legal representative ~~person to whom they pertain~~, but appropriate disclosure may be made without such consent to:

(a) Licensed facility personnel, ~~and~~ attending physicians, or other health care practitioners and providers currently involved in the care or treatment of the patient for use only in connection with the treatment of the patient.

(b) Licensed facility personnel only for administrative purposes or risk management and quality assurance functions.

(c) The agency, for purposes of health care cost containment.

(d) In any civil or criminal action, unless otherwise prohibited by law, upon the issuance of a subpoena from a court of competent jurisdiction and proper notice by the party seeking such records to the patient or his or her legal representative.

(e) The agency upon subpoena issued pursuant to s. 456.071, but the records obtained thereby must be used solely for the purpose of the agency and the appropriate professional board in its investigation, prosecution, and appeal of disciplinary proceedings. If the agency requests copies of the records, the facility shall charge no more than its actual copying costs, including reasonable staff time. The records must be sealed and must not be available to the public pursuant to s. 119.07(1) or any other statute providing access to records, nor may they be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the agency or the appropriate regulatory board. However, the agency must make available, upon written request by a practitioner against whom probable cause has been found, any such records that form the basis of the determination of probable cause.

(f) The Department of Health or its agent, for the purpose of establishing and maintaining a trauma registry and for the purpose of ensuring that hospitals and trauma centers are in compliance with the standards and rules established under ss. 395.401, 395.4015, 395.4025, 395.404, 395.4045, and 395.405, and for the purpose of monitoring

patient outcome at hospitals and trauma centers that provide trauma care services.

(g) The Department of Children and Family Services or its agent, for the purpose of investigations of cases of abuse, neglect, or exploitation of children or vulnerable adults.

~~(h) The State Long-Term Care Ombudsman Council and the local long-term care ombudsman councils, with respect to the records of a patient who has been admitted from a nursing home or long-term care facility, when the councils are conducting an investigation involving the patient as authorized under part II of chapter 400, upon presentation of identification as a council member by the person making the request. Disclosure under this paragraph shall only be made after a competent patient or the patient's representative has been advised that disclosure may be made and the patient has not objected.~~

(h) ~~(i)~~ A local trauma agency or a regional trauma agency that performs quality assurance activities, or a panel or committee assembled to assist a local trauma agency or a regional trauma agency in performing quality assurance activities. Patient records obtained under this paragraph are confidential and exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution.

(i) ~~(j)~~ Organ procurement organizations, tissue banks, and eye banks required to conduct death records reviews pursuant to s. 395.2050.

(j) ~~(k)~~ The Medicaid Fraud Control Unit in the Department of Legal Affairs pursuant to s. 409.920.

(k) ~~(l)~~ The Department of Financial Services, or an agent, employee, or independent contractor of the

department who is auditing for unclaimed property pursuant to chapter 717.

(l) ~~(m)~~ A regional poison control center for purposes of treating a poison episode under evaluation, case management of poison cases, or compliance with data collection and reporting requirements of s. 395.1027 and the professional organization that certifies poison control centers in accordance with federal law.

Section 2. Section 408.051, Florida Statutes, is created to read:

408.051 Florida Electronic Health Records Exchange Act.--

(1) SHORT TITLE.--This section may be cited as the "Florida Electronic Health Records Exchange Act."

(2) DEFINITIONS.--As used in this section, the term:

(a) "Electronic health record" means a record of a person's medical treatment that is created by a licensed health care provider and stored in an interoperable and accessible digital format.

(b) "Qualified electronic health record" means an electronic record of health related information on an individual that includes patient demographic and clinical health information such as medical history and problem lists, and has the capacity to provide clinical decision support, support physician order entry, capture and query information relevant to health care quality, and exchange electronic health information with, and integrate such information from other sources.

(c) "Certified electronic health record technology" means a qualified electronic health record that is certified pursuant to section 3001(c)(5) of the Public

Health Service Act as meeting standards adopted under section 3004 of such Act that are applicable to the type of record involved such as an ambulatory electronic health record for office-based physicians or an inpatient hospital electronic health record for hospitals.

(d) "Health record" means any information, recorded in any form or medium, which relates to the past, present, or future health of an individual for the primary purpose of providing health care and health-related services.

(e) "Identifiable health record" means any health record that identifies the patient or with respect to which there is a reasonable basis to believe the information can be used to identify the patient.

(f) "Patient" means an individual who has sought, is seeking, is undergoing, or has undergone care or treatment in a health care facility or by a health care provider.

(g) "Patient representative" means a parent of a minor patient, a court-appointed guardian for the patient, a health care surrogate, or a person holding a power of attorney or notarized consent appropriately executed by the patient granting permission to a health care facility or health care provider to disclose the patient's health care information to that person. In the case of a deceased patient, the term also means the personal representative of the estate of the deceased patient; the deceased patient's surviving spouse, surviving parent, or minor child of the deceased patient; or the attorney for the patient's surviving spouse, parent or adult child; or the attorney for the parent or guardian of a surviving minor child.

(3) EMERGENCY RELEASE OF IDENTIFIABLE HEALTH RECORD.--

A health care provider may release or access an identifiable health record of a patient without the patient's consent for use in the treatment of the patient for an emergency medical condition, as defined in s. 395.002(8), when the health care provider is unable to obtain the patient's consent or the consent of the patient representative due to the patient's condition or the nature of the situation requiring immediate medical attention. A health care provider who in good faith releases or accesses an identifiable health record of a patient in any form or medium under this section is immune from civil liability for accessing or releasing an identifiable health record.

(4) UNIVERSAL PATIENT AUTHORIZATION FORM.--

(a) By July 1, 2010, the agency shall develop forms in both paper and electronic formats which may be used by a health care provider to document patient authorization for the use or release, in any form or medium, of an identifiable health record.

(b) The agency shall adopt by rule the authorization form and accompanying instructions and make the authorization form available on the agency's website, pursuant to s. 408.05.

(c) A health care provider receiving an authorization form containing a request for the release of an identifiable health record shall accept the form as a valid authorization to release an identifiable health record. A health care provider may elect to accept the authorization form in either electronic or paper format or both. The individual or entity that submits the authorization form containing a request for the release of an identifiable

health record shall determine which format is accepted by the health care provider prior to submitting the form.

(d) An individual or entity that submits a request for an identifiable health record is not required under this section to use the authorization form adopted and distributed by the agency.

(e) The exchange by a health care provider of an identifiable health record upon receipt of an authorization form completed and submitted in accordance with agency instructions creates a rebuttable presumption that the release of the identifiable health record was appropriate. A health care provider that releases an identifiable health record in reliance on the information provided to the health care provider on a properly completed authorization form does not violate any right of confidentiality and is immune from liability under this section.

(f) A health care provider that exchanges an identifiable health record upon receipt of an authorization form shall not be deemed to have violated or waived any privilege protected under the statutory or common law of this state.

(5) PENALTIES.--A person who does any of the following may be liable to the patient or a health care provider that has released an identifiable health record in reliance on an authorization form presented to the health care provider by the person for compensatory damages caused by an unauthorized release, plus reasonable attorney's fees and costs:

(a) Forges a signature on an authorization form or materially alters the authorization form of another person without the person's authorization; or

(b) Obtains an authorization form or an identifiable health record of another person under false pretenses.

Section 3. Section 408.0512, Florida Statutes, is created to read:

408.0512 Electronic health records system adoption loan program.--

(1) Subject to the availability of eligible donations from public or private entities and funding made available through Section 3014 of the Public Health Services Act, the agency may operate a certified electronic health records technology loan fund subject to a specific appropriation as authorized by the General Appropriations Act or as provided through the provisions of s. 216.181(11)(a) and (b).

(2) The agency shall adopt rules related to standard terms and conditions for use in the loan program.

Section 4. Subsection (1) of section 409.916, Florida Statutes, is amended to read:

409.916 Grants and Donations Trust Fund.--

(1) The agency shall deposit any funds received from pharmaceutical manufacturers and all other funds received by the agency from any other person as the result of a Medicaid cost containment strategy, in the nature of a rebate, grant, or other similar mechanism into the Grants and Donations Trust Fund. The agency shall deposit any funds received from private donations for the purpose of funding a certified electronic health records technology loan fund into the Grants and Donations Trust Fund.

Section 5. Section 456.0393, Florida Statutes, is created to read:

456.0393 Electronic Prescribing; information required for licensure renewal.--

(1) As used in this section, the term:

(a) "Electronic prescribing" has the same meaning as provided in s. 408.0611.

(b) "Meaningful use" means electronically prescribing at least 50 percent of prescriptions written by the physician.

(2) Effective January 1, 2012, each physician who applies for license renewal under chapters 458 or 459, except a person registered pursuant to ss. 458.345 and 459.021, must, in conjunction with the renewal of such license, submit confirmation, on a form approved by the board, of the meaningful use of electronic prescribing software during the current licensure cycle.

(3) Failure to comply with the requirements of this section shall constitute grounds for disciplinary action under each respective practice act and under s. 456.072(1)(k).

(4) Each board may adopt rules to carry out the provisions of this section.

Section 6. Subsection (2) of section 483.181, Florida Statutes, is amended to read:

483.181 Acceptance, collection, identification, and examination of specimens.--

(2) The results of a test must be reported directly to the licensed practitioner or other authorized person who requested it, and appropriate disclosure may be made by the clinical laboratory without a patient's consent to other health care practitioners and providers involved in the care or treatment of the patient as specified in s. 456.057(7)(a). The report must include the name and address of the clinical laboratory in which the test was actually

performed, unless the test was performed in a hospital laboratory and the report becomes an integral part of the hospital record.

Section 7. This act shall take effect upon becoming a law.

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

Remove the entire title and insert:

An act relating to electronic health records; amending s. 395.3025, F.S.; expanding access to a patient's health records in order to facilitate the exchange of data between certain health care facility personnel, practitioners, and providers and attending physicians; repealing access to a patient's health records by the State Long-Term Care Ombudsman Council and the local long-term care ombudsman councils; creating s. 408.051, F.S.; creating the "Florida Electronic Health Records Exchange Act"; providing definitions; authorizing the release of certain health records under emergency medical conditions without the consent of the patient or the patient representative; providing for immunity from civil liability; providing duties of the Agency for Health Care Administration with regard to the availability of specified information on the agency's Internet website; requiring the agency to develop and implement a universal patient authorization form in paper and electronic formats for the release of certain health records; providing procedures for use of the form; providing penalties; providing for certain compensation and attorney's fees and costs; creating s. 408.0512, F.S.; authorizing the Agency for Health Care Administration to operate an electronic health records system adoption loan

program, subject to specific appropriation; requiring the agency to adopt rules related to standard terms and conditions for the loan program; amending s. 409.916, F.S.; requiring the agency to deposit into the Grants and Donations Trust Fund private donations provided for the purpose of funding a certified electronic health records technology loan fund; creating s. 456.0393, F.S.; requiring physicians to provide confirmation of the meaningful use of electronic prescribing software in conjunction with licensure renewal; amending s. 483.181, F.S.; expanding access to laboratory reports in order to facilitate the exchange of data between certain health care practitioners and providers; providing an effective date.

A bill to be entitled

An act relating to electronic health records; amending s. 395.3025, F.S.; expanding access to a patient's health records to facilitate the electronic exchange of data between certain health care facility personnel, practitioners, and providers and attending physicians; creating s. 408.051, F.S.; creating the "Florida Electronic Health Records Exchange Act"; providing definitions; authorizing the release of certain health records under emergency medical conditions without patient consent; providing for immunity from civil liability; providing duties of the agency with regard to the availability of specified information on the agency's Internet website; requiring the agency to develop and implement a universal patient authorization form in paper and electronic formats for the release of certain health records; providing procedures for usé of the form; providing penalties; providing for certain compensation and attorney's fees and costs; creating s. 408.0512, F.S.; requiring the Agency for Health Care Administration to operate an electronic medical records system adoption loan program, subject to specific appropriation; providing eligibility criteria; prohibiting the agency from providing loans to physicians or businesses that have violated certain provisions of law; providing for uses of the loan; providing guidelines for distribution of funds by the agency; requiring the agency to develop terms and conditions for the loan program; requiring physicians and

businesses to provide additional security agreements under certain circumstances; providing for payments to be deposited in the agency's Administrative Trust Fund; establishing procedures for managing cases of default; amending s. 483.181, F.S.; expanding access to laboratory reports to facilitate the exchange of data between certain health care practitioners and providers; providing an effective date.

WHEREAS, the use of electronic health information technology has been proven to benefit consumers by increasing the quality and efficiency of health care delivery throughout the state, and

WHEREAS, clear and concise standards for sharing privacy-protected medical information among authorized health care providers will enable providers to have cost-effective access to the medical information needed to make sound decisions about health care, and

WHEREAS, maintaining the privacy and security of identifiable health records is essential to the adoption of procedures for sharing of electronic health records among health care providers involved in the treatment of patients, NOW, THEREFORE,

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

Section 1. Subsection (4) of section 395.3025, Florida Statutes, is amended to read:

395.3025 Patient and personnel records; copies; examination.--

(4) Patient records are confidential and must not be disclosed without the consent of the patient or his or her legal representative ~~person to whom they pertain~~, but appropriate disclosure may be made without such consent to:

(a) Licensed facility personnel, ~~and~~ attending physicians, or other health care practitioners and providers currently involved in the care or treatment of the patient for use only in connection with the treatment of the patient.

(b) Licensed facility personnel only for administrative purposes or risk management and quality assurance functions.

(c) The agency, for purposes of health care cost containment.

(d) In any civil or criminal action, unless otherwise prohibited by law, upon the issuance of a subpoena from a court of competent jurisdiction and proper notice by the party seeking such records to the patient or his or her legal representative.

(e) The agency upon subpoena issued pursuant to s. 456.071, but the records obtained thereby must be used solely for the purpose of the agency and the appropriate professional board in its investigation, prosecution, and appeal of disciplinary proceedings. If the agency requests copies of the records, the facility shall charge no more than its actual copying costs, including reasonable staff time. The records must be sealed and must not be available to the public pursuant to s. 119.07(1) or any other statute providing access to records, nor may they be available to the public as part of the record of

investigation for and prosecution in disciplinary proceedings made available to the public by the agency or the appropriate regulatory board. However, the agency must make available, upon written request by a practitioner against whom probable cause has been found, any such records that form the basis of the determination of probable cause.

(f) The Department of Health or its agent, for the purpose of establishing and maintaining a trauma registry and for the purpose of ensuring that hospitals and trauma centers are in compliance with the standards and rules established under ss. 395.401, 395.4015, 395.4025, 395.404, 395.4045, and 395.405, and for the purpose of monitoring patient outcome at hospitals and trauma centers that provide trauma care services.

(g) The Department of Children and Family Services or its agent, for the purpose of investigations of cases of abuse, neglect, or exploitation of children or vulnerable adults.

(h) The State Long-Term Care Ombudsman Council and the local long-term care ombudsman councils, with respect to the records of a patient who has been admitted from a nursing home or long-term care facility, when the councils are conducting an investigation involving the patient as authorized under part II of chapter 400, upon presentation of identification as a council member by the person making the request. Disclosure under this paragraph shall only be made after a competent patient or the patient's representative has been advised that disclosure may be made and the patient has not objected.

(i) A local trauma agency or a regional trauma agency that performs quality assurance activities, or a panel or committee

assembled to assist a local trauma agency or a regional trauma agency in performing quality assurance activities. Patient records obtained under this paragraph are confidential and exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution.

(j) Organ procurement organizations, tissue banks, and eye banks required to conduct death records reviews pursuant to s. 395.2050.

(k) The Medicaid Fraud Control Unit in the Department of Legal Affairs pursuant to s. 409.920.

(l) The Department of Financial Services, or an agent, employee, or independent contractor of the department who is auditing for unclaimed property pursuant to chapter 717.

(m) A regional poison control center for purposes of treating a poison episode under evaluation, case management of poison cases, or compliance with data collection and reporting requirements of s. 395.1027 and the professional organization that certifies poison control centers in accordance with federal law.

Section 2. Section 408.051, Florida Statutes, is created to read:

408.051 Florida Electronic Health Records Exchange Act.--

(1) SHORT TITLE.--This section may be cited as the "Florida Electronic Health Records Exchange Act."

(2) DEFINITIONS.--As used in this section, the term:

(a) "Electronic health record" means a record of a person's medical treatment that is created by a licensed health care provider and stored in an interoperable and accessible

digital format.

(b) "Electronic health records system" means an application environment consisting of at least two of the following components: a clinical data repository, clinical decision support, a controlled medical vocabulary, a computerized provider order entry, a pharmacy, or clinical documentation. The application must be used by health care practitioners to document, monitor, and manage health care delivery within a health care delivery system and must be capable of interoperability within a health information exchange.

(c) "Health information exchange" means an electronic health records system used to acquire, process, and transmit electronic health records that 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 the provision of health care services.

(d) "Health record" means any information, recorded in any form or medium, that relates to the past, present, or future health of an individual for the primary purpose of providing health care and health-related services.

(e) "Identifiable health record" means any health record that identifies the patient or with respect to which there is a reasonable basis to believe the information can be used to identify the patient.

(f) "Patient" means an individual who has sought, is seeking, is undergoing, or has undergone care or treatment in a health care facility or by a health care provider.

(g) "Patient representative" means a parent of a minor patient, a court-appointed guardian for the patient, a health care surrogate, or a person holding a power of attorney or notarized consent appropriately executed by the patient granting permission to a health care facility or health care provider to disclose the patient's health care information to that person. In the case of a deceased patient, the term also means the personal representative of the estate of the deceased patient; the deceased patient's surviving spouse, surviving parent, or surviving adult child; the parent or guardian of a surviving minor child of the deceased patient; or the attorney for any such person.

(3) EMERGENCY RELEASE OF IDENTIFIABLE HEALTH RECORD.--A health care provider may release or access an identifiable health record of a patient without the patient's consent for use in the treatment of the patient for an emergency medical condition, as defined in s. 395.002(8), when the health care provider is unable to obtain the patient's consent due to the patient's condition or the nature of the situation requiring immediate medical attention. A health care provider who in good faith releases or accesses an identifiable health record of a patient in any form or medium under this section shall be immune from civil liability for accessing or releasing an identifiable health record.

(4) UNIVERSAL PATIENT AUTHORIZATION FORM.--

(a) By July 1, 2010, the agency shall develop forms in both paper and electronic formats that may be used by a health care provider to document patient authorization for the use or

release, in any form or medium, of an identifiable health record.

(b) The agency shall adopt by rule the authorization form and accompanying instructions and make the authorization form available on the agency's website, pursuant to s. 408.05.

(c) A health care provider receiving an authorization form containing a request for the release of an identifiable health record shall accept the form as a valid authorization to release an identifiable health record. A health care provider may elect to accept the authorization form in either electronic or paper format or both. The individual or entity that submits the authorization form containing a request for the release of an identifiable health record shall determine which format is accepted by the health care provider prior to submitting the form.

(d) An individual or entity that submits a request for an identifiable health record is not required under this section to use the authorization form adopted and distributed by the agency.

(e) The exchange by a health care provider of an identifiable health record upon receipt of an authorization form completed and submitted in accordance with agency instructions creates a rebuttable presumption that the release of the identifiable health record was appropriate. A health care provider that releases an identifiable health record in reliance on the information provided to the health care provider on a properly completed authorization form does not violate any right of confidentiality and is immune from liability under this

section.

(f) A health care provider that exchanges an identifiable health record upon receipt of an authorization form shall not be deemed to have violated or waived any privilege protected under the statutory or common law of this state.

(5) PENALTIES.--A person who does any of the following may be liable to the patient or a health care provider that has released an identifiable health record in reliance on an authorization form presented to the health care provider by the person for compensatory damages caused by an unauthorized release, plus reasonable attorney's fees and costs:

(a) Forges a signature on an authorization form or materially alters the authorization form of another person without the person's authorization; or

(b) Obtains an authorization form or an identifiable health record of another person under false pretenses.

Section 3. Section 408.0512, Florida Statutes, is created to read:

408.0512 Electronic medical records system adoption loan program.--

(1) Subject to a specific appropriation, the agency shall operate an electronic medical records system adoption loan program for the purpose of providing a one-time, no-interest loan to eligible physicians licensed under chapter 458 or chapter 459 or to an eligible business entity whose shareholders are licensed under chapter 458 or chapter 459 for the initial costs of implementing an electronic medical records system.

(2) In order to be eligible for a loan under this section, each physician must demonstrate that he or she has practiced continuously within the state for the previous 3 years.

(3) The agency may not provide a loan to a physician who has or a business entity whose physician has:

(a) Been found guilty of a violation of s. 456.072(1) or been disciplined under the applicable licensing chapter in the previous 5 years.

(b) Been found guilty of or entered a plea of guilty or nolo contendere to a violation of s. 409.920 or s. 409.9201.

(c) Been sanctioned pursuant to s. 409.913 for fraud or abuse.

(4) A loan may be provided to an eligible physician or business entity in a lump-sum amount to pay for the costs of purchasing hardware and software, subscription services, professional consultation, and staff training. The agency shall provide guidance to loan recipients by providing, at a minimum, a list of electronic medical records systems recognized or certified by national standards-setting entities as capable of being used to communicate with a health information exchange.

(5) The agency shall distribute a minimum of 25 percent of funds appropriated to this program to physicians or business entities operating within a rural county as defined in s. 288.106(1)(r).

(6) The agency shall, by rule, develop standard terms and conditions for use in the loan program. At a minimum, these terms and conditions shall require:

(a) Loan repayment by the physician or business entity

within a reasonable period of time, which may not be longer than 72 months after the funding of the loan.

(b) Equal periodic payments that commence within 3 months after the funding of the loan.

(c) The eligible physician or business entity to execute a promissory note and a security agreement in favor of the state. The security agreement shall be a purchase-money security interest pledging as collateral for the loan the specific hardware and software purchased with the loan proceeds. The agency shall prepare and record a financing statement under chapter 679. The physician or business entity shall be responsible for paying the cost of recording the financing statement. The security agreement shall further require that the physician or business entity pay all collection costs, including attorney's fees.

(7) The agency shall further require the physician or business entity to provide additional security under one of the following paragraphs:

(a) An irrevocable letter of credit, as defined in chapter 675, in an amount equal to the amount of the loan.

(b) An escrow account consisting of cash or assets eligible for deposit in accordance with s. 625.52 in an amount equal to the amount of the loan. If the escrow agent is responsible for making the periodic payments on the loan, the required escrow balance may be diminished as payments are made.

(c) A pledge of the accounts receivable of the physician or business entity. This pledge shall be reflected on the financing statement.

(8) All payments received from or on behalf of a physician or business entity under this program shall be deposited into the agency's Administrative Trust Fund to be used to fund new loans.

(9) If a physician or business entity that has received a loan under this section ceases to provide care or services to patients, or if the physician or business entity defaults in any payment and the default continues for 30 days, the entire loan balance shall be immediately due and payable and shall bear interest from that point forward at the rate of 18 percent annually. Upon default, the agency may offset any moneys owed to the physician or business entity from the state and apply the offset against the outstanding balance.

(10) If a physician defaults in any payment and if the default continues for 30 days, the default shall constitute grounds for disciplinary action under chapter 458 or chapter 459 and under s. 456.072(1)(k).

Section 4. Subsection (2) of section 483.181, Florida Statutes, is amended to read:

483.181 Acceptance, collection, identification, and examination of specimens.--

(2) The results of a test must be reported directly to the licensed practitioner or other authorized person who requested it, and appropriate disclosure may be made by the clinical laboratory without a patient's consent to other health care practitioners and providers involved in the care or treatment of the patient as specified in s. 456.057(7)(a). The report must include the name and address of the clinical laboratory in which

the test was actually performed, unless the test was performed in a hospital laboratory and the report becomes an integral part of the hospital record.

Section 5. This act shall take effect upon becoming a law.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1139 Nursing Licensing Fees
SPONSOR(S): Roberson and others
TIED BILLS: **IDEN./SIM. BILLS:** SB 2030

	REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1)	Health Care Regulation Policy Committee		Holt	Calamas
2)	Health & Family Services Policy Council			
3)	Human Services Appropriations Committee			
4)	Full Appropriations Council on General Government & Health Care			
5)				

SUMMARY ANALYSIS

The bill requires the Department of Health to establish a mandatory special fee of $3.50 per licensee to fund the continuing operation of the Florida Center for Nursing (FCN). The FCN was established to address issues of supply and demand for nursing, including issues of recruitment, retention, and utilization of nurse workforce resources. The special fee will be assessed upon initial licensure and renewal of each of each nursing license. As of June 2009, there were 314,564 licensed nurses (14,211 ARNPs, 229,658 RNs and 70,695 LPNs).

The bill has a potential increase in state revenues of $997,864 to $1,100,974. These revenues would be transferred to the Grants and Donations Trust Fund within the department to support the FCN (see fiscal comments).

The bill takes effect July 1, 2009.

HOUSE PRINCIPLES

Members are encouraged to evaluate proposed legislation in light of the following guiding principles of the House of Representatives

- Balance the state budget.
- Create a legal and regulatory environment that fosters economic growth and job creation.
- Lower the tax burden on families and businesses.
- Reverse or restrain the growth of government.
- Promote public safety.
- Promote educational accountability, excellence, and choice.
- Foster respect for the family and for innocent human life.
- Protect Florida's natural beauty.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background:

The Board of Nursing and Licensure

As of June 2009, there were 314,564 licensed nurses (14,211 ARNPs, 229,658 RNs and 70,695 LPNs).[1] Of the total 314, 564 licenses about 29,460 are in inactive or delinquent status and 39,855 are out-of-state, active military or retired licenses.[2] Therefore are 245,249 active in-state licensed nurses.[3] Licensure renewals are broken into 4 groups; two groups renew each year, one in February-April and the other during May-July. Licensure renewal is currently conducted online and by paper.

The Florida Center for Nursing

In March 2001, the Florida Nurses Association convened a legislative summit of nursing leaders in Tallahassee. Participants represented nurse executives, nurse educators, and nurse advocates from across the state all of whom were members of one or more of the following groups:

- Florida Nurses Association;
- Florida Hospital Association;
- Florida Organization of Nurse Executives;
- Deans and Directors of Nursing Education Programs; and
- Florida Board of Nursing

At the summit, the concept of a Florida FCN for Nursing (FCN), based on North Carolina's Center for Nursing, was proposed and received unanimous support. In 2001, the Legislature established the Florida Center for Nursing ("FCN").[4] The FCN was created to address issues of supply and demand for nursing, including issues of recruitment, retention, and utilization of nurse workforce resources.[5] The Legislature specified that the FCN will repay the state's investment by providing an ongoing strategy for the allocation of the state's resources directed towards nursing.[6]

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[1] Department of Health, Division of Medical Quality Assurance, Annual Report: July 1, 2008-June 30, 2008.
[2] *Ibid.*
[3] *Ibid.*
[4] Chapter 2001-277, F.S.
[5] Section 464.0195(1), F.S.
[6] *Ibid.*

The FCN is governed by a policy-setting board of directors. The board consists of 16 members, with a simple majority of the board being nurses who represent various practice areas. Other members include representatives of other health care professions, business and industry, health care providers, and consumers. Currently, the board members must meet the following criteria:[7]

- Four members are *recommended* by the President of the Senate, at least one must be a registered nurse recommended by the Florida Organization of Nurse Executives and at least one must represent the hospital industry and is recommended by the Florida Hospital Association;
- Four members *recommended* by the Speaker of the House of Representatives, at least one must be a registered nurse recommended by the Florida Nurses Association and one must represent the long-term care industry;
- Four members *recommended* by the Governor, two must be registered nurses;
- One nurse educator recommended by the Board of Governors who is a dean of a College of Nursing at a state university;
- Three nurse educators *recommended* by the State Board of Education, one of whom must be a director of a nursing program at a state community college

The member appoints are staggered and last for 3 years, and no member may serve more than two consecutive terms.

The primary goals of the FCN are to: [8]

- Develop a strategic statewide plan for nursing manpower in this state by establishing and maintaining a database on nursing supply and demand in the state, to include, current supply and demand, and future projections; and selecting from the plan priorities to be addressed.

- Convene various groups representative of nurses, other health care providers, business and industry, consumers, legislators, and educators; Review and comment on data analysis prepared for the center; recommend systemic changes, including strategies for implementation of recommended changes; and evaluate and report the results of these efforts to the Legislature and others.

- Enhance and promote recognition, reward, and renewal activities for nurses in the state by promoting nursing excellence programs such as magnet recognition by the American Nurses Credentialing Center; proposing and creating additional reward, recognition, and renewal activities for nurses; and promoting media and positive image-building efforts for nursing.

In addition, the Florida Board of Nursing is required to include on its initial and renewal application forms a question asking the nurse to voluntarily contribute to funding the Florida Center for Nursing in addition to paying the fees imposed at the time of licensure and licensure renewal. Any revenues collected from nurses over and above the required fees are transferred from the Medical Quality Assurance Trust Fund to the Grants and Donations Trust Fund within the Department of Health to solely to support and maintain the goals and functions of the center.[9]

Funding

The FCN has been funded through a contract with the Department of Health. The funds come from annual appropriations as well as voluntary contributions. The FCN has received the following funds:

Fiscal Year	Voluntary Contributions	Legislative Appropriation
2008-2009	$2,542*	450,000 GR
2007-2008	9,970	480,000 GR
2006-2007	13,589	500,000 GR

[7] Section 464.0196, F.S.
[8] Section 464.0195(2), F.S.
[9] Section 464.0195(3), F.S.

2005-2006	9,198	250,000 GR
2004-2005	12,278	250,000 Tobacco
2003-2004	40,307	250,000 Tobacco
2002-2003	35,326	

**The balance as of February 28, 2009.*

According to the FCN they have also obtained some external funding. In December 2007, the FCN received $75,000 from Blue Cross / Blue Shield of Florida, Inc. to create small grant to establish the FCN's Retention & Recruitment Funded Project Initiative. In November 2008 the FCN joined the AARP/FCN to Champion Nursing in America to collaborate on a grant assessing the current nurse workforce data capacity in 30 states and development of minimum nurse supply, demand, and education datasets. The grant award was $85,000. In addition the FCN has submitted a grant application for a grant offered by the Blue Foundation for a Healthy Florida, Inc. The grant award is for $280,897 and the date of the award is from September 2009 to August 2011. The goal of the project is to maximize the use of simulation technology in the preparation of new and continuing education of current RNs in Florida to address our nursing shortage by increasing the nurse supply through increased production and retention.[10]

Effects of the Bill

The bill requires the Department of Health to establish a mandatory special fee of $3.50 per licensee to fund the continuing operation of the FCN. The fee is assessed upon initial licensure and renewal of each of each nursing license. Therefore, the collection of the special fee and the voluntary contributions will be collected to support the goals and functions of the FCN.

B. SECTION DIRECTORY:

Section 1. Amends s. 464.0195, F.S., relating to the goals of Florida FCN for Nursing.
Section 2. Provides that the bill takes effect July 1, 2009.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   Currently, there are 314,564 licensed nurses, however; approximately 30,000 licenses are delinquent or inactive. Assessing a $3.50 special fee would collect approximately $997,864 to $1,100,974.

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

All nurses will see an increase of $3.50 in the initial and renewal fee for licensure.

[10] Email dated March 19, 2009 from the Executive Director of the Florida Center for Nursing on file with the Health Care Regulation Policy Committee staff.

D. FISCAL COMMENTS:

Under the provisions of the bill, the special fee will be assess on all nurses irrespective if they are in-state, out-of-state, active duty military, or in retired status.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COUNCIL OR COMMITTEE SUBSTITUTE CHANGES

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

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

Bill No. **HB 1139**

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: Health Care Regulation Policy Committee

Representative(s) Roberson, Y. offered the following:

Amendment (with title amendment)

Remove everything after the enacting clause and insert:

Section 1. Subsection (3) of section 464.0195, Florida Statutes, is amended to read:

464.0195 Florida Center for Nursing; goals.--

(3) The Board of Nursing shall include on its initial and renewal application forms a question asking each ~~the~~ nurse to voluntarily contribute to funding the Florida Center for Nursing in addition to paying the fees imposed at the time of licensure and licensure renewal. Revenues collected from nurses over and above the required fees shall be transferred from the Medical Quality Assurance Trust Fund to the Grants and Donations Trust Fund within the Department of Health and shall be used solely to support and maintain the goals and functions of the center. At the time of renewal, but prior to the opportunity to donate, the Board of Nursing shall provide nurses a summary of the work of the Florida Center for Nursing, the link to the Florida Center

for Nursing website, and the following statement: "The Florida Center for Nursing's operating revenue comes in part from your donations. In order for the Florida Center for Nursing to continue its work on behalf of nurses, please donate."

Section 2. This act shall take effect July 1, 2009.

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

Remove the entire title and insert:

A bill entitled An relating to nursing licensing fees; amending s. 464.0195, F.S.; requiring the Department of Health to provide at the time of renewal a paragraph summarizing the work of the Florida Center for Nursing, a website link, and a statement; providing an effective date.

A bill to be entitled

An act relating to nursing licensing fees; amending s. 464.0195, F.S.; requiring the Department of Health to establish a special fee to be used for the Florida Center for Nursing; requiring the special fee to be collected at the issuance and renewal of the nursing licenses for registered nurses, licensed practical nurses, clinical nurse specialists, and advanced registered nurse practitioners; providing for transfer of the fees from the Medical Quality Assurance Trust Fund to the department's Grants and Donations Trust Fund; providing for use of the fees; providing an effective date.

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

Section 1. Subsection (3) of section 464.0195, Florida Statutes, is amended to read:

464.0195 Florida Center for Nursing; goals.--

(3) The department shall establish a special fee of $3.50 per licensee to fund the continuing operation of the Florida Center for Nursing. The special fee shall be assessed upon the initial licensure and renewal of each license under this part. The Board of Nursing shall include on its initial and renewal application forms a question asking each ~~the~~ nurse to voluntarily contribute to funding the Florida Center for Nursing in addition to paying the fees imposed at the time of licensure and licensure renewal. Revenues collected from the special fee and the voluntary contributions from nurses over and above the

required fees shall be transferred from the Medical Quality Assurance Trust Fund to the Grants and Donations Trust Fund within the Department of Health and shall be used solely to support and maintain the goals and functions of the center.

Section 2. This act shall take effect July 1, 2009.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1343 Practice of Tattooing
SPONSOR(S): Brandenburg
TIED BILLS: **IDEN./SIM. BILLS:** SB 1130

	REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1)	Health Care Regulation Policy Committee		Ciccone	Calamas
2)	Health & Family Services Policy Council			
3)	Human Services Appropriations Committee			
4)	Full Appropriations Council on General Government & Health Care			
5)				

SUMMARY ANALYSIS

House Bill 1343 creates several new sections of law and establishes the "Tattoo Practice and Tattoo Establishment Act."

The bill directs the Department of Health ("DOH" or "the department") to establish in consultation with the professional tattooing industry, requirements for licensure and registration of tattooists and tattoo establishments in Florida. The bill provides specific licensure criteria for a tattooist and registration criteria for an intern, an apprentice, or a guest tattooist.

The bill authorizes the department to inspect tattoo studios for compliance with certain sanitation standards and provides penalties for violations, including license revocation, suspension, and monetary fine and probation, reprimand, or renewal denial of licensure or registration.

The bill creates several new third degree felonies relating to specific acts of non compliance, and provides that a person who fails to maintain certain records commits a second degree misdemeanor. The bill authorizes the courts to initiate penalties in addition to any other punishment established in the proposal.

The bill authorizes the department to adopt rules to implement the act, and collect fees to administer the program.

The bill appears to have no direct fiscal impact on state funds. The cost of the program is off-set by the generated revenues of the program.

The bill provides an effective date of July 1, 2009.

HOUSE PRINCIPLES

Members are encouraged to evaluate proposed legislation in light of the following guiding principles of the House of Representatives

- Balance the state budget.
- Create a legal and regulatory environment that fosters economic growth and job creation.
- Lower the tax burden on families and businesses.
- Reverse or restrain the growth of government.
- Promote public safety.
- Promote educational accountability, excellence, and choice.
- Foster respect for the family and for innocent human life.
- Protect Florida's natural beauty.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Current Situation

Florida:

Current state law addresses the subject of human tattooing in three primary areas: who may perform tattooing, restrictions with regard to minors, and penalties due to non-compliance. Specifically, s. 877.04, F.S., provides that it is unlawful for any person to tattoo the body of any human being, except if the tattoo is performed by:

- A person licensed to practice medicine under ch. 458 and ch. 459, F.S.;[1]
- A person licensed to practice dentistry under ch. 466, F.S.;[2] or,
- A person under his or her general supervision as defined by the Board of Medicine.

Any person who tattoos or applies permanent make-up must either be licenses as, or work under the "general supervision" as defined in ch. 64B8-2.002, Florida Administrative Code of a medical Doctor, a Doctor of Osteopathy, a Doctor of Dental Surgery, or a doctor of Medical Dentistry. Additionally, it is unlawful for the body of a minor to be tattooed without the written notarized consent of the parent or legal guardian. Any person who violates this section is guilty of a misdemeanor of the second degree and punishable under s. 775.082 and s. 775.083, F.S.

Oversight of Tattoo Studios

Section 381.0098(1), F.S., establishes legislative intent relating to protecting the public's health and provides safety standards for the packaging, transport, storage, treatment and disposal of biomedical waste. Biomedical waste is defined as any solid or liquid waste which may present a threat of infection to humans, including waste products that include discarded disposable sharps,[3] human blood, blood products and body fluids..."[4] A biomedical waste generator is defined as "...a facility, or person that produces or generates biomedical waste...."[5] The statute directs the Department of Health and the

[1] Chapters 459 and 459, F.S., provide for licensure of medical doctors and osteopathic doctors, respectively.
[2] Chapter 466, F.S, provides for licensure of dentists.
[3] Section 381.0098(2)(d), F.S., defines "sharps" as those biomedical wastes which as a result of their physical characteristics are capable of puncturing, lacerating, or otherwise breaking the skin when handled.
[4] Section 381.0098(2)(a), F.S.
[5] Section 381.0098(2)(b), F.S.

Department of Environmental Protection to develop an interagency agreement to ensure maximum efficiency in coordinating, administering, and regulating biomedical waste. The DOH has no authority to issue a license to a tattooist or a tattoo studio. However, the department does have authority to issue a biomedical waste-generator permit to a tattooist or a tattoo studio.

In accordance with Ch.64E-16.011, Florida Administrative Code, the department prescribes minimum sanitary practices relating to the management of biomedical waste and the regulation of biomedical waste generators. In accordance with ch. 64E-16.011(1), Florida Administrative Code, tattoo studios are considered biomedical waste generators and as such are required to obtain an annual permit from the department. These studios are inspected by department personnel at least once a year and re-inspections may be conducted when a facility is found to be in non-compliance with sanitation practices. Current law does not provide authorization for the department to inspect these establishments relating to other sanitation aspects of tattoo studios, or the licensure or registration of tattoo artists.

As a result of the department's oversight of tattoo studios as biomedical waste generators, it is estimated that there are approximately 800 permanent make-up and tattoo establishments in Florida. While the department believes that the majority of tattooists and tattoo studios function well in terms of protecting the public, procedures vary from studio to studio and there is no central location of records or core training curricula for the industry or the individual.[6] The American Tattooing Institute offers an on-line or mail order certification course that includes studies in skin anatomy and physiology, blood borne pathogens, OSHA standards, food and drug administration information, and body art specialist's code of ethics training.[7] At least one tattoo studio in Florida provides on-site training.[8]

National:

At least 38 states have implemented laws regarding tattooing and body piercing. Twenty-eight states have laws that prohibit both body piercing and tattooing on minors without parental permission.[9] Parental permission requirements vary among states ranging from signed notarized documentation[10] to explicit in-person consent of the child's parent or guardian.[11] The majority of states laws establish financial penalties, incarceration time, or both for violators.

The U.S. Food and Drug Administration (USFDA) and the Department of Health and Human Services, Centers for Disease Control and Prevention's (CDC) literature speak to a variety of potential risks in acquiring a tattoo on the body. Such risks include:

- Infection – Dirty needles can pass infections, such as hepatitis and HIV.
- Allergies – Allergies to different ink pigments can cause problems.
- Scarring – Unwanted scar tissue may form on an initial or removed tattoo.
- MRI complications – Though rare, swelling or burning in the tattoo area when having a magnetic resonance image can occur.

The USFDA has not approved any tattoo pigments for injection into the skin. This applies to all tattoo pigments, including those used for ultraviolet (UV) and glow-in-the dark tattoos. Many pigments used in tattoo inks are industrial-grade colors suitable for printers' ink or automobile paint. In addition, the use of henna in temporary tattoos has also not been approved by the USFDA. [12]

The CDC establishes that a risk of HIV transmission exists if instruments contaminated with blood are either not sterilized or disinfected or are used inappropriately between clients. The CDC recommends that single-use instruments intended to penetrate the skin be used once, then disposed of. In addition, reusable instruments or devices that penetrate the skin or contact a client's blood should be thorough

[6] Department of Children and Family Services Staff Analysis, March 2009, on file with the Committee.
[7] http://www.tatsmart.com, last researched March 21, 2009
[8] http://www.addicted2tattoos.com/tattootraining, last researched March 24, 2009
[9] http://www.ncsl.org/programs/health, National Conference of State Legislatures, last viewed March 21, 2009.
[10] California penal code s.652
[11] Montana Code Annotated s. 45-5-623
[12] http://www.fda.gov/consumerupdate, last viewed March 21, 2009

cleaned and sterilized between clients. The CDC stresses that tattooists should be educated regarding HIV transmission and take precautions to prevent this transmission in their setting.[13]

Effect of the Bill

House Bill 1343 creates several new sections of law as Part XVII of ch. 468, F.S., and establishes the "Tattoo Practice and Tattoo Establishment Act." The bill expands the licensing authority of the department by including tattooists and tattoo studios in the current listing of professions and facilities licensed or otherwise inspected by the department.

The effect of this bill would be to allow the department to conduct full inspections of tattoo studios, and to monitor these studios to ensure that sanitation standards are maintained at a level protective of the public's health. The bill would require a new uniform level of education and training by tattooists, and would require that tattoo studios conduct business in a uniformly clean and sanitary environment. The bill may change the way some studios operate by specifically regulating certain studio infrastructure such as: the surface area of floors, tables and chairs to ensure sanitization; utility and bathroom facility functioning and availability; trash containment and disposal of materials, including dyes and inks used on a customer, etc. The bill adds an additional level of protection especially for minors seeking tattoos, by authorizing the department to inspect tattoo studios and their business records.

The bill establishes new licensing and registration fees and in so doing provides a revenue source that is intended to administer the program. The department would be required to develop rules to implement the program.

The penalty section of the bill (newly created s. 468.861, F.S.) establishes several new third degree felonies relating to the following acts:

- Owning, operating, or soliciting business as a tattoo studio in the state without first procuring a license, unless specifically exempted;
- Obtaining or attempting to obtain a license to operate a tattoo studio by means of fraud, misrepresentation, or concealment;
- Tattooing a minor;
- Practicing tattooing upon an impaired customer or a customer who has exuding sores, weeping dermatitis, or a contagious disease, exuding the common cold; or
- Practicing tattooing when the tattooist has exuding sores, weeping dermatitis, or a contagious disease, exuding the common cold.

The bill provides second degree misdemeanor penalties for failure to maintain required records, or who knowingly makes false entries in such records. In addition to other punishments provided in the proposal, the court may suspend or revoke the license or registration of any licensee who is found guilty of any violation in the proposal.

The bill provides an effective date of July 1, 2009.

B. SECTION DIRECTORY:

Section 1. Creates Part XVII of ch. 468, F.S., consisting of sections 468.85, 468.852-859, 468.61 and 468.861, F.S., relating to establishing the "Tattoo Practice and Tattoo Establishment Act;" provides definitions; licensure requirements; exemptions; prohibited acts; licensure qualifications; licensure renewal; practice requirements for tattooists; requirements for tattoo establishments; fees; disposition of fees; department rulemaking authority; intern and apprentice tattooist program criteria; and penalties.

Section 2. Provides an effective date of July 1, 2009.

[13] http://www.cdc.gov/hiv, last viewed March 21, 2009

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

	1st Year	2nd Year
800 tattoo establishments @ $150	$120,000	$120,000
Average 2 licensed or registered tattooists 1,600 @ $50	$ 80,000	$ 80,000
25 apprentice or guest tattooists @ $25	$ 625	$ 625
Total Estimated Revenue	**$200,625**	**$200,625**

2. Expenditures:

	1st Year	2nd Year (Annualized/Recurr.)
Salaries Inspections of 800 establishments for 1 ESII (10% over base + travel) @ 2 hr/inspection and travel @ $24/hr	$ 38,400	$ 38,400
Reinspection of 20% of 800 establishments For 1 ESII @ 2 hr/inspection and travel @ $24/hr 15% 2nd year	$ 7,680	$ 6,528
Complaint Investigation of 15% of 800 Establishments @ 1.5 hr/inspection + travel 15% 2nd year	$ 3,137	$ 2,667
Support staff at CHD processing 3200 applications, Issuing 3200 licenses, and registrations hrs @ 11.31/hr for 1600 hours	$ 18,096	$ 18,096
Training developed provided by 1 Env. Man and 1 EES III to CHD inspectors at 10 sites, 4 hrs/site + 40 hrs development = 80 hrs @ 47.47/hr 5 sites 2nd year	$ 3,797	$ 1,898
Training Travel 4250 airfare + $1200 lodging + $740 meals + $800 per diem x 2 + $400 car rental	$ 6,380	$ 3,190
Rule Promulgation:		
1 Env. Admin. @27.26/hr x 90 hrs	$ 2,453	
1 Env. Man @ 24.27/hr x 45 hrs	$ 1,092	
1 ES III @ 23.20/hr x 30 hrs	$ 696	
1 Support @ 11.31/hr x 20	$ 226	
FAW Notices	$ 1,000	
Total Estimated Expenditures	**$ 82,957**	**$ 70,779**

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Currently, individual tattooists do not pay a license fee. The bill requires each tattoo establishmnent to pay an annual fee not to exceed $500. Each licensed tattooist or registered intern tattooist will be required to pay an annual license fee not to exceed $250. Each apprentice tattooist or guest tattooist is required to pay an annual registration fee not to exceed $150. Apprentice tattooist or license reactivation fees are not addressed.

It is possible that newly licensed tattooists or tattoo studios will experience an increase in business through the reduction of unlicensed tattooists.

D. FISCAL COMMENTS:

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

The bill does not appear to require counties or municipalities to spend funds or take any action requiring the expenditure of funds; reduce the authority that municipalities or counties have to raise revenue in the aggregate; or reduce the percentage of a state tax shared with counties or municipalities.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The bill provides rule making authority for the department.

C. DRAFTING ISSUES OR OTHER COMMENTS:

IV. AMENDMENTS/COUNCIL OR COMMITTEE SUBSTITUTE CHANGES

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. (for drafter's use only)

Bill No. **1343**

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: Health Regulation Policy Committee

Representative(s) Brandenburg offered the following:

Amendment (with title amendment)

Remove everything after the enacting clause and insert:

Section 1. Section 877.04, Florida Statutes, is amended to read:

877.04 Tattooing prohibited; penalty.--

(1) It is unlawful for any person to tattoo the body of any human being; except that tattooing may be performed by a person licensed to practice medicine or dentistry under chapters 458 and 459 or chapter 466, or by a person under his or her general supervision as defined by the Board of Medicine.

(2) Any person who violates the provisions of this section shall be guilty of a felony of the third degree~~misdemeanor of the second degree~~, punishable as provided in s. 775.082 or s. 775.083.

(3) No body of a minor shall be tattooed without the written notarized consent of the parent or legal guardian.

Section 2. This act shall take effect July 1, 2009.

Amendment No. (for drafter's use only)

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

Remove the entire title and insert:

amending s. 877.04, F.S.; raising the criminal penalty for human tattooing by unauthorized persons and for tattooing a minor without written notarized consent of parent or legal guardian; providing an effective date.

A bill to be entitled

An act relating to the practice of tattooing; creating part XVII of ch. 468, F.S., the Tattoo Practice and Tattoo Establishment Act; providing definitions; prohibiting the practice of tattooing unless a person is licensed or registered by the Department of Health; requiring the licensure of a tattoo establishment; requiring that the department establish requirements for licensure and registration; exempting physicians licensed under ch. 458 or ch. 459, F.S., from regulation under the act; prohibiting a tattooist from tattooing under certain circumstances; specifying requirements for licensure and license renewal; providing requirements for registration as an intern tattooist or apprentice tattooist; providing requirements for licensure for a tattoo establishment; requiring a tattooist to complete a course in continuing education; prohibiting the transfer of a license or registration; providing practice requirements for tattooists, intern tattooists, and apprentice tattooists; providing requirements for a tattooist who operates a tattoo establishment; specifying fees for initial licensure and registration and annual renewal thereof; specifying acts that constitute grounds under which the department may take disciplinary action; providing for disciplinary proceedings and fines; authorizing the department to adopt rules to administer the act; providing requirements for persons applying for registration as an intern tattooist or apprentice tattooist; providing

penalties for certain violations involving the practice of tattooing; authorizing the department or the state attorney to enjoin a continuing violation of the act; providing an effective date.

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

Section 1. Part XVII of chapter 468, Florida Statutes, consisting of sections 468.85, 468.851, 468.852, 468.853, 468.854, 468.855, 468.856, 468.857, 468.858, 468.859, 468.86, and 468.861, is created to read:

468.85 Short title.--This part may be cited as the "Tattoo Practice and Tattoo Establishment Act."

468.851 Definitions.--As used in this part, the term:

(1) "Active license or registration" means a current license or registration issued by the department which is not suspended or revoked.

(2) "Apprentice tattooist" means a person registered with the department to learn tattooing under the direct supervision of a licensed tattooist.

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

(4) "Direct supervision" means supervision by a licensed tattooist who is physically on the premises of the tattoo establishment.

(5) "Guest tattooist" means a person who has a professional background in tattooing in another state, who is registered with the department to learn tattooing under the direct supervision of a licensed tattooist, and whose

registration expires after 45 days and may not be renewed for 6 months.

(6) "Inservice hours" means the number of hours that an autoclave is in operation.

(7) "Intern tattooist" means a person who has a professional background in tattooing in another state and who is registered with the department to learn tattooing under the direct supervision of a licensed tattooist.

(8) "Tattoo" means a mark or design made on or under the skin by a process of piercing and engraving a pigment, dye, or ink in the skin.

(9) "Tattoo establishment" means any permanent location, place, area, structure, or business used for the practice of tattooing or for instruction on tattooing.

(10) "Tattooist" means a person licensed under this part to practice tattooing or provide instruction on tattooing.

468.852 License required.--

(1)(a) A person may not practice tattooing in this state unless the person is licensed as a tattooist or is registered as an intern tattooist, an apprentice tattooist, or a guest tattooist under this part.

(b) A business may not be identified as a tattoo establishment unless the establishment is licensed in accordance with this part.

(2) The department shall establish requirements for licensure and registration, in consultation with the professional tattooing industry in this state, and shall develop forms by which to verify an applicant's training and employment

prior to licensure or registration.

468.853 Exemption.--This part does not apply to a physician licensed under chapter 458 or to an osteopathic physician licensed under chapter 459 when the physician is practicing his or her profession.

468.854 Prohibited acts.--A person may not:

(1) Operate a tattoo establishment or practice tattooing unless the person holds an active license or registration and practices in accordance with this part.

(2) Practice tattooing on a minor.

(3) Practice tattooing upon an impaired customer or a customer who has exuding sores, weeping dermatitis, or a contagious disease, excluding the common cold.

(4) Practice tattooing when the tattooist has exuding sores, weeping dermatitis, or a contagious disease, excluding the common cold.

468.855 Qualifications for licensure; license renewal.--

(1) Any person who desires to be licensed as a tattooist or registered as an intern tattooist, guest tattooist, or apprentice tattooist must apply to the department for a license or registration.

(2) An applicant for licensure as a tattooist must meet the following requirements:

(a) Successfully pass the licensure examination for tattooing from the department.

(b) Submit a completed application to the department and pay the application fee.

(c) Submit proof of completion of an education course on

blood-borne pathogens and communicable diseases.

(d)1. For licensure on or before December 31, 2009, submit written recommendations for licensure from five professional tattooists who are practicing in this state, demonstrate 5 years of previous practice of professional tattooing, and provide proof of status as a professional tattooist by:

a. Submitting an occupational license as a tattooist from any municipality or county;

b. Providing proof of employment in or ownership of property that has an occupational license for the purpose of tattooing; or

c. Submitting copies of prior federal income tax filings as a professional tattooist.

2. For licensure after December 31, 2009, submit written recommendations for licensure from five tattooists who have been licensed for at least 3 years and have supervised an intern tattooist or apprentice tattooist for a minimum of 1 year.

(3) An applicant for registration as an intern tattooist must submit to the department:

(a) A completed application and the application fee.

(b) Proof of direct supervision by a licensed tattooist.

(4) An applicant for registration as an apprentice tattooist must submit to the department:

(a) A completed application and the application fee.

(b) Proof of direct supervision by a licensed tattooist.

(5) An applicant may obtain licensure of a tattoo establishment if the applicant submits a completed application and application fee to the department and the department

verifies that:

(a) The establishment, furnishings, and equipment are clean and in good repair.

(b) The floors, tables, and chairs in the tattoo station and sterilization area are constructed of smooth surfaces that can be sanitized.

(c) Running water is installed in the establishment in compliance with local ordinances.

(d) There is a functioning toilet that is easily accessible to customers.

(e) There is at least one sink for hand washing which is easily accessible to the tattooist and equipped with running water, antibacterial soap, and single-use disposable towels.

(f) There are a sufficient number of trash containers that are easily accessible to the tattooist for the disposal of towels or other absorbent material, and for the disposal of dyes, inks, or pigments previously used on a customer.

(g) The establishment is in compliance with the local building, occupational, zoning, and health codes.

(h) All water-carried sewage is disposed of by a public sewage system or a sewage system that is constructed and operating in conformance with local ordinances.

(i) There is a functioning autoclave on the premises of the establishment for sterilizing tattoo-related equipment.

(6) The applicant for licensure or registration must provide proof to the department of meeting the requirements for licensure or registration.

(7) The department shall renew a license or registration

according to rules adopted by the department. A tattooist must complete a course of continuing education on blood-borne pathogens and communicable diseases, as prescribed by the department.

(8) A license or registration issued by the department under this part is not transferable.

468.856 Practice requirements for tattooists; requirements for tattoo establishments.--

(1) A licensed tattooist must:

(a) Provide direct supervision to an intern tattooist who is registered with the department as being under the supervision of the licensed tattooist.

(b) Provide direct supervision to an apprentice tattooist who is registered with the department as being under the supervision of the licensed tattooist.

(c) Display a current license in a manner that is easily visible to the public.

(d) Practice tattooing only in a licensed tattoo establishment that complies with the requirements of this part.

(e) Before applying a tattoo, provide the customer with information on procedures for follow-up care after receiving the tattoo and obtain written acknowledgement from the customer of receipt of such information.

(f) Ensure that each person applying a tattoo under the supervision of the licensed tattooist washes his or her hands before and after each application.

(g) Maintain sanitary conditions at all times in the tattoo establishment, as defined by department rule.

(h) Use sterilized needles and tubes that have been sterilized in an autoclave before use on a customer for at least:

1. Twenty minutes at 15 pounds of pressure per square inch at a temperature of 240° Fahrenheit or 116° Celsius; or

2. Fifteen minutes at 20 pounds of pressure per square inch at a temperature of 250° Fahrenheit or 121° Celsius.

(i) At least once every 90 days or 40 inservice hours, whichever comes first, verify that the autoclave is properly sterilizing needles and tubes by use of the KILIT Ampule Sterilization Test or its equivalent. A tattooist must maintain an autoclave log for each use and list the amount of equipment placed in the autoclave, the time the equipment is placed into and removed from the autoclave, the temperature of the autoclave, the pressure used by the autoclave, the final results, and the signature of his or her name or initials when removing the equipment from the autoclave. A tattooist must also maintain records of autoclave verification for at least 3 years, and the records are subject to inspection by the department.

(j) Use only single-use towels or other absorbent material for drying, cleaning, disinfecting, scrubbing, or bandaging the skin of the tattooist or the customer. The towel or material must be immediately disposed of after use.

(k) Use only single-use containers for dyes, inks, or pigments. The containers of dyes, inks, or pigments must be disposed of immediately after use.

(l) Use single-use razors and dispose of each razor immediately after use, or use a shaver that is disinfected after

each use.

(m) Comply with all state and local health codes and ordinances.

(n) Report to the department any person or establishment in violation of this part.

(o) Store all stencils, needles, and tubes when not in use in clean, closed cabinets or containers.

(2) An intern tattooist must:

(a) Practice tattooing only under the direct supervision of a licensed tattooist.

(b) Display a current registration in a manner that is easily visible to the public.

(c) Identify himself or herself as an intern tattooist in oral or written communication to the public which is intended to promote the intern's practice or recognition as a tattooist.

(d) Comply with the requirements for practice as a licensed tattooist enumerated in paragraphs (1)(d)-(o).

(3) An apprentice tattooist must:

(a) Practice tattooing only under the direct supervision of a licensed tattooist.

(b) Display a current registration in a manner that is easily visible to the public.

(c) Comply with the requirements for practice as a licensed tattooist enumerated in paragraphs (1)(d)-(o).

(4) A tattooist who operates a tattoo establishment must:

(a) Comply with the requirements for licensure enumerated in s. 468.855.

(b) Display a current license for the establishment in a

manner that is easily visible to the public.

(c) Display a copy of procedures for follow-up care after receiving a tattoo and provide a copy to all customers.

(d) Ensure that each tattooist who operates in the tattoo establishment meets all applicable requirements of this part.

(e) Maintain for at least 3 years copies of autoclave sterilization tests. Copies of the tests from the previous year must be maintained on the premises of the tattoo establishment.

(f) Allow periodic inspection and enforcement by authorized agents of the department.

(g) Report to the department any person or tattoo establishment in violation of this part.

(5) Any person who is licensed or registered under this part must notify the department within 14 days following any change in the name or address of the licensee or registrant.

486.857 Fees; disposition.--The department shall establish by rule fees for initial licensure or registration, annual renewal fees, and reactivation fees for an inactive license or registration in accordance with ss. 456.004 and 456.025. A license or registration that is not timely renewed becomes inactive.

(1) The annual fee for a tattoo establishment license may not exceed $500.

(2) The annual fee for licensure as a tattooist may not exceed $250.

(3) The annual fee for registration as an intern tattooist may not exceed $250.

(4) The annual fee for registration as an apprentice

tattooist may not exceed $150.

(5) The fee for registration as a guest tattooist may not exceed $150 per registration.

468.858 Disciplinary grounds.--

(1) In addition to the grounds set forth in s. 456.072, the following acts constitute grounds for which the department may take disciplinary action against a person licensed or registered under this part:

(a) Violating a state or local health code or ordinance.

(b) Making a false, deceptive, or misleading advertisement or deceptively failing to identify oneself as an intern, apprentice, or guest tattooist.

(c) Providing false information on an application for licensure or registration or on an autoclave test.

(d) Violating any applicable provision of this part, a rule adopted under this part, a lawful order of the department, or any applicable provision of chapter 456 or rule adopted under chapter 456.

(e) Having a comparable license, registration, or certification revoked, suspended, or otherwise acted against by the licensing authority of another state, territory, or country.

(f) Being found guilty of or pleading nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to the practice of tattooing or operating a tattoo establishment.

(g) Committing fraud, deceit, negligence, or misconduct in practicing tattooing or operating a tattoo establishment.

(h) Aiding, assisting, procuring, or advising any

unlicensed person in the practice of tattooing or the operation of a tattoo establishment.

(2) The department may revoke, suspend, fine, place on probation with conditions, reprimand, or deny subsequent renewal of licensure or registration to any licensee or registrant who violates subsection (1).

(3) Disciplinary proceedings shall be conducted as provided in chapters 120 and 456.

(4) The maximum fine per violation is $1,500, and the department shall adopt by rule procedures for taking disciplinary action against a licensee or registrant.

468.859 Rulemaking.--The department shall adopt rules to administer this part.

468.86 Intern and apprentice tattooist programs.--

(1)(a) Any person applying for registration as an intern tattooist must apply on forms supplied by the department. The applicant must provide to the department:

1. A written agreement from the supervising tattooist that the applicant will serve the internship under the direct supervision of the supervising tattooist.

2. Proof of practice in a licensed tattoo establishment.

3. Proof of compliance with the conditions of registration for an intern tattooist, set forth in s. 468.855.

4. Proof of successful completion of a course of study on first aid and blood-borne pathogens and communicable diseases.

(b) An applicant for registration as an intern tattooist must provide any material requested by the department to verify compliance with the intern program.

(2)(a) Any person applying for registration as an apprentice tattooist must apply on forms supplied by the department. The applicant must provide to the department:

1. A written agreement from the supervising tattooist that the applicant will serve the apprenticeship under the direct supervision of the supervising tattooist.

2. Proof of practice in a licensed tattoo establishment.

3. Proof of compliance with the conditions of registration for an apprentice tattooist, set forth in s. 468.855.

4. Proof of successful completion of a course of study on first aid and blood-borne pathogens and communicable diseases.

(b) An applicant for registration as an apprentice tattooist must provide any material requested by the department to verify compliance with the apprenticeship program.

(c) An apprentice tattooist must use the words "apprentice tattooist" in any advertisement or written document relating to the practice of tattooing by the apprentice tattooist.

468.861 Penalties.--

(1) Each of the following acts constitutes a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084:

(a) Owning, operating, or soliciting business as a tattoo establishment in this state without first procuring a license from the department, unless specifically exempted by this part.

(b) Obtaining or attempting to obtain a license to operate a tattoo establishment by means of fraud, misrepresentation, or concealment.

(c) Tattooing a minor.

(d) Practicing tattooing upon an impaired customer or a customer who has exuding sores, weeping dermatitis, or a contagious disease, excluding the common cold.

(e) Practicing tattooing when the tattooist has exuding sores, weeping dermatitis, or a contagious disease, excluding the common cold.

(2) A person who fails to maintain the records required by this part or who knowingly makes false entries in such records commits a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083.

(3) In addition to any other punishment provided for in this section, the court may suspend or revoke the license or registration of any licensee or registrant who is found guilty of any violation of subsection (1) or subsection (2).

(4) If the department or any state attorney has probable cause to believe that an establishment or person has violated subsection (1), the department or state attorney may bring an action to enjoin the establishment or person from engaging in or continuing such violation or doing any act in furtherance thereof, and the court may provide any other relief it finds appropriate.

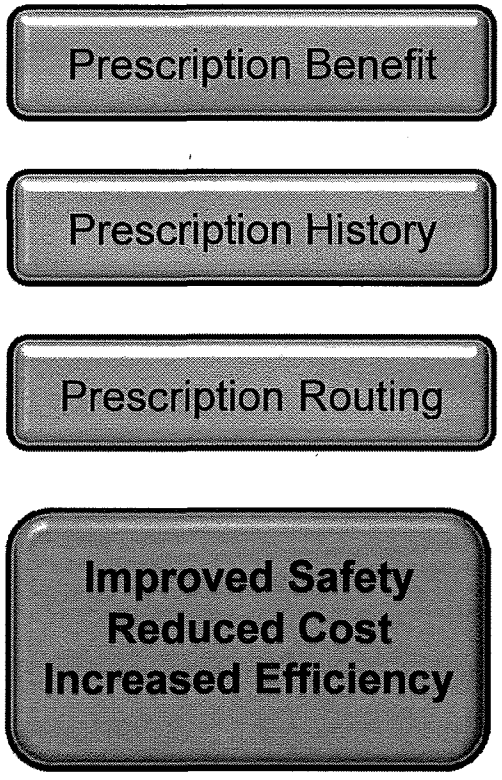
Section 2. This act shall take effect July 1, 2009.

Presentation by SureScripts on E-Prescribing

The E-Prescribing Advantage

Tom Groom
SVP, Business Development

Definition of E-Prescribing



E-Prescribing provides authorized prescribers with secure access to real-time prescription benefits and prescription history to make informed prescribing decisions that are clinically appropriate and economical for the patient.

E-Prescribing also enables the routing of electronic prescriptions from the prescriber's office to the patient's choice of pharmacy and allows prescription renewal requests to be electronically routed from a pharmacist to the prescriber's office for approval.

Surescripts Overview

- Surescripts is the result of a 2008 merger between the country's two leading health information networks: RxHub and SureScripts.
- Surescripts gives healthcare providers:
  - Secure, electronic access to prescription information that can save their patients' lives,
  - Improve efficiency and reduce the cost of healthcare for all.
- Available during emergencies or routine care, the Surescripts network is used every day by thousands of physicians, physician assistants, nurse practitioners and other prescribers across all 50 states.
- The Surescripts network connects these prescribers to all of the nation's major chain pharmacies, the nation's leading payers and independent pharmacies nationwide.

Founders:

CVS CAREMARK, EXPRESS SCRIPTS®, medco®, NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES, NCPA NATIONAL COMMUNITY PHARMACISTS ASSOCIATION

E-Prescribing: How it works

E-Prescribing Improves Patient Safety, Reduces Costs & Promotes Workflow Efficiency

Payer

Provides:
- ❑ Prescription Benefit
- ❑ Prescription History

Physician

Reviews:
- ❑ Patient information
- ❑ Prescription Benefit
- ❑ Prescription History

Generates:
- ❑ NewRx
- ❑ RxRenewal Response

Pharmacist

Provides:
- ❑ Prescription History
- ❑ RxRenewal Requests

Processes:
- ❑ NewRx
- ❑ RxRenewal Responses

Benefits for Payers:
Improves quality of care
Drives down healthcare costs
Saves beneficiaries money
Reduces medication errors

Benefits for Physicians:
Confirms prescription benefits
Enables prescription history review
Eliminates poor handwriting errors
Reduces pharmacy callbacks

Benefits for Pharmacists:
Provides "clean" prescriptions
Reduces time on faxes and calls
Allows more patient consulting time
Improves patient convenience

Surescripts Services

- **Prescription Benefit:** Access to more than **220M** member records uniquely identified using demographic elements. Information includes patient pharmacy eligibility, benefit and coverage, and formulary at the point of care. Patient eligibility is also available to pharmacists at the point of dispensing.

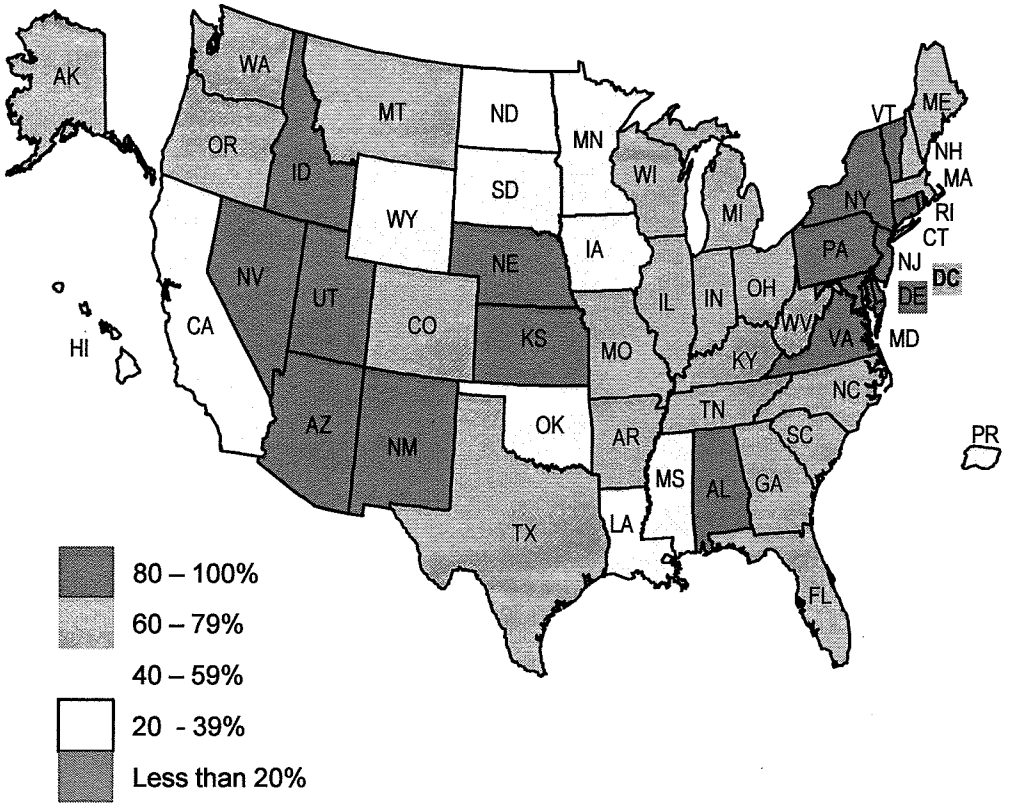
- **Prescription History:** Drug history for all patient coverages and includes original prescription and refills. Data can indicate:
  - ☑ **Patient compliance with prescribed regimens**
  - ☑ **Therapeutic interventions**
  - ☑ **Drug-drug and drug-allergy interactions**
  - ☑ **Adverse drug reactions**
  - ☑ **Duplicate therapy**

  Information is available for outpatient, inpatient and emergency departments.

- **Prescription Routing:** Electronic delivery of prescriptions between prescribers and pharmacies and refill requests between pharmacists and prescribers.

Payer Member Records – March 2009

220M Member Records Accessible through Surescripts



- Authorized access provided to 27 data sources* (payer system platforms)
- 49 states have patient accessibility of 50% or greater (includes D.C. and Puerto Rico)
- Average multiple coverage rate is 15% nationwide**
- Accessible patient age stratification:
  - <18 yrs: 21%
  - 18 - 64 yrs: 60%
  - 65 + yrs: 19%

**Includes lives accessible in production, does not include lives under contract*

***Based on eligibility requests received by SureScripts-RxHub in 2008*

Prescription Benefit

Provides electronic delivery of patient prescription benefit information from payers to prescribers in the ambulatory care setting.

Patient Eligibility Data

- Name, Address, Date of Birth, Gender
- Cardholder, Group, Health Plan, PBM
- Retail/Mail Benefit Status,

Patient Formulary Data

- Formulary Status, Medication Alternatives
- Drug Coverage, Co-pay

Prescription History

Provides electronic delivery of patient prescription history from payers and pharmacies to prescribers.

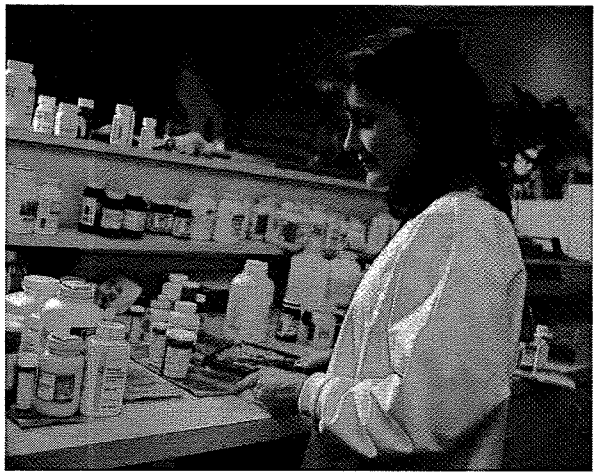
Prescription History Data

- Date Range of History
- Drug Name (Brand/Generic)
- Oldest Fill Date, Most Recent Fill Date
- Number of Fills, Days Supply, Quantity Dispensed
- Pharmacies/Prescribers

Prescription Routing

Provides the exchange of electronic prescriptions between prescribers and pharmacists

- Physician and pharmacy distribution lists
- New prescription routing to retail and mail order pharmacies
- Prescription Renewal/Refill routing from pharmacy to physician
- Prescription Change request
- Prescription Fill Status from pharmacy to physician (future)



Medication History for Hospitals

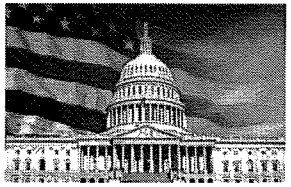
- Provides clinicians convenient access to up-to-date medication history for patients they are treating in an inpatient setting
  - Person search
  - Dispensed claims medication history
  - Delivered to the acute care setting via strategic distribution partners (DrFirst, Emerging Health, GE Healthcare, Healthcare Systems, InterMedHx, Regenstrief, Siemens, others…)
  - HL7 Interface
    - ADT
    - RDS
    - ORU

Value Drivers: Disaster Relief

- In response to the lessons learned in the aftermath of Hurricane Katrina, a collaborative of public and private organizations launched ICERx.org (In Case of Emergency Prescription Database).
- This online resource allows authorized physicians and pharmacists to get evacuees' medication records, regardless of whether they are moved to new locations in-state or out of state
- Prescription history information is pooled from a variety of sources, including Surescripts, payers and state Medicaid programs.
- This information allows health care professionals to safely renew prescriptions for evacuees and help coordinate care, while avoiding harmful prescription errors and potential drug interactions.
- For more information, visit www.icerx.org.

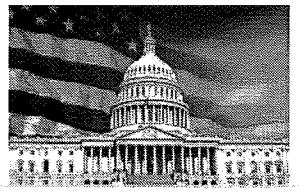
Industry Standards Leadership

Accredited Standards Committee (ASC X12)
American Health Information Community (AHIC)
Certification Commission for Healthcare Information Technology (CCHIT)
Electronic Healthcare Network Accreditation Commission (EHNAC)
Health Information Technology Standards Panel (HITSP)
Health Level 7 (HL7)
National Drug Council for Prescription Drug Program (NCPDP)
Workgroup for Electronic Data Interchange (WEDI)
Surescripts Workgroups



Political and Regulatory Landscape: MIPPA

- E-Prescribing incentives created under MIPPA --the Medicare Improvements for Patients and Providers Act of 2008
- Creates Medicare bonus payments for physicians who adopt e-prescribing by 2012, then penalizes those who don't
  - Offers a 2% incentive payment to eligible physicians for two years beginning in 2009, drops the bonus to 1% in 2011 and 2012 and to 0.5% in 2013; then decrease Medicare reimbursements for non-adopters by 1% in 2012, 1.5% in 2013 and 2% in 2014 and later.
  - Beginning on 1/1/09, MIPPA incentive payments will be based on the proportion of self-reported ambulatory patient visits
    - That used specified e-prescribing quality measures in at least 50% of the applicable cases during the year.
    - That used a "qualified" system
  - Complete details are on the CMS website at www.cms.hhs.gov/pqri



Political and Regulatory Landscape: Stimulus Legislation

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- The **American Recovery and Reinvestment Act** has major health-related provisions, which account for $150B
- Provides $17B to promote adoption of certified EHRs by hospitals and physicians with penalties for late or non-adoption
  - Incentives through Medicare
    - Hospitals get $2,000,000 *plus discharge bonuses (total payout could be $10 million +)*
    - Physicians can earn between $44,000 over five years if they are utilizing a certified EHR in 2011 ($15,000, then $12,000, $8,000, $4,000 and $2,000)
  - Incentives through Medicaid
    - Payments for 85% of EHR purchase for qualifying physicians, who must meet qualifying volume and practice site criteria
    - Payments are $25,000 in year 1, $10,000 in year 2, and up to 5% for no more than 5 years, with maximum of $63,750
- Provides additional multi-billion-dollar funding (mostly through grants) for states and federally qualified health centers to build HIT infrastructure and adopt technology. Details TBD.

Surescripts Participants – March 2009

Payers
Aetna
Argus
BCBS Alabama
CatalystRx
CVS|Caremark
RxAmerica
Excellus
Express Scripts
HealthTrans
InformedRx
Laker Software
Navitus
McKesson/Relay Health
Medco Health Solutions
MedImpact
MedMetrics Health Partner
PharmaStar
Pharmacy Data Management, Inc.
Prescription Solutions
Prime Therapeutics:
BCBS Illinois
BCBS Florida
BCBS Texas
BCBS Oklahoma
BCBS New Mexico
BCBS Kansas
BCBS Nebraska
RESTAT
SXC
Independent Health
MC-21
Presbyterian Health
US Scripts
Walgreens Health Initiatives
WellPoint

Medicaid (Fee For Service)
ACS
New Mexico
EDS, an HP Company
Arkansas
Delaware
Connecticut
MediCAL
First Health Services Corporation
New Hampshire
Michigan
Nevada
South Carolina
MedMetrics

Connectivity Partners
Laker SW
Health Vision
SXC

Hospital Distributors
DB Motion
DrFirst
Emerging Health
GE Healthcare
Healthcare Systems
HealthVision
Integrated Informatics
InterMedHx
Regenstrief Institute
Siemens Healthcare
Standard Register

Emergency Preparedness
Laker SW
ePAP
ICERx.org

Retail Pharmacy Networks
ACME
Albertsons
Aurora
CVS Caremark
Duane Reade
eRx Network
FredMeyer
Fred's
Fry's
Giant
Giant Eagle
Good Neighbor
Hannaford
Happy Harry's
Harris Teeter
HyVee
Kerr Drug
Kmart
Longs Drugs
MediCap
Medicine Shoppe
Meijer
Osco
Pathmark
QFC
Ralphs
Rite Aide
RNA
Safeway
Sam's Club
SavMor
Savon
ShopRite
Smith's
Stop&Shop
Sweetbay
SXC RxExpress
Target
Times
Ukrop's
Walgreens
Wal-Mart
Winn Dixie

...and thousands of Independent Pharmacies

Mail Pharmacy Networks
CVS Caremark
Express Scripts
Medco Health Services
Prescription Solutions
Prime Therapeutics
Walgreens
WellPoint, NextGen

BOLD - Participant in production
ITALICS - Participant in certification
NORMAL - Participant contracted

Surescripts Participants – March 2009

Standalone Electronic Prescribing Systems

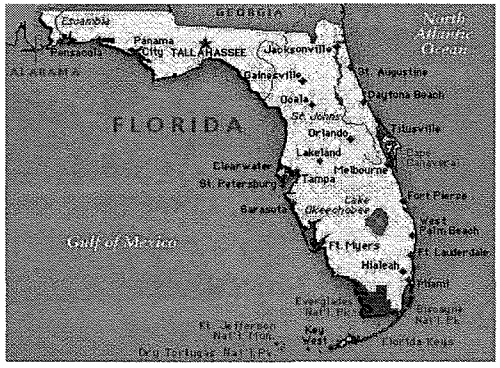
ACS Heritage
AllscriptsMisys
AlphaSante Group
Cerner
DAW Systems
Dental Associates
DrFirst
eHealth Solutions
Gold Standard
H2H
iMedX
InstantDx
iScribe
LighthouseMD
MedPlus
MediVoice
Navimedix
NetSmart Tech.
NewCrop
OA Systems
Prematics
RelayHealth
RxNT
Zix Corporation

Electronic Medical Record (EMR) Systems

4Medica
ABELSoft
Agastha
Allscripts
Altos Solutions
ASP.MD
Athenahealth
Axolotl
Bizmatics
BMA Enterprises
Cerner
ChartConnect
CliniPath
Clinitech
Clinx, LLC
ClinixMIS
CPSI
CureMD
Design Clinicals
digiChart
Doc-U-Chart
Doctations
e-MDs
eClinical Works
Eclipsys
EHS
EncounterPRO
Epic
EScribe EMR
Essence Group
Glenwood Systems
gloStream
gMed
Health Systems Research
Henry Schein Medical Systems
HealthPort
iMedica
Ingenix
Integrated Health Care Solutions
InteGreat
Integritas
iSALUS
Kryptiq
Leum Software
LSS Data Systems
Marshfield Clinic
MD Web Solutions
McKesson
MedAppz
MedComSoft
MedConnect
MEDENT
Medi-EMR
Medical Communication Systems
MedicaLinx
MedicSoft
Meditech
MedNet System
MedPlexus
NextGen
Nightingale
Noteworthy
Polaris Management
Practice Partner
Prime Clinical Systems
Pulse Systems
Purkinje
RxNT
SAGE Software
SmartEMR/VIPA Health
SOAPware/DOCs
Sonix Healthcare Solutions
SRS Software
SSIMED
STI Computer Services
Synamed
US Health Record Systems
Waiting Room Solutions
Wellogic
Wenatchee Valley Medical Center
Workflow

BOLD - Participant in production
ITALICS - Participant in certification

Florida e-Prescribe Landscape



Total Residents:	17,619,270
Children (0-18):	4,249,990
Adults (19-64):	10,523,070
Elderly (65+):	2,846,210
Medicaid:	12.6%
Medicare:	15.7%
Commercial:	51.8%
Uninsured:	19.9%

Source: Kaiser Commission on Medicaid and the Uninsured. Statehealthfacts.org

Network Connections	2008	2007
Payer Member Records	12.6 mil	10.4 mil
E-Prescribers	5,923	2,369
E-Pharmacies	3,343	3,128

Service Requests	2008	2007
Prescription Benefit	5.6 mil	1.4 mil
Prescription Routing – NewRx Request	1.4 mil	73,271

Certified Technology Partners	
ALLSCRIPTS-ERX NOW	MCKESSON
ALLSCRIPTS-HEALTHMATICS	MEDPLUS
ALLSCRIPTS-TOUCHWORKS	MISYS EMR
CAREGROUP-MASHARE	NEWCROP
CHART CONNECT	NEXTGEN
COMMUNITY COMPUTER SERV.	NEXTGEN-II
DAW SYSTEMS	OA SYSTEMS
DRFIRST	PRACTICE PARTNER
ECLINICALWORKS	PREMATICS
EHEALTH SOLUTIONS	REGENSTRIEF INPC
EPIC-UPMC	RELAYHEALTH
ERX NETWORKS	RXNT-DESKTOP
GOLD STANDARD	SSIMED
ICERX	SYNAMED, LLC
INSTANTDX	WAITING ROOM SOLUTIONS
ISCRIBE	ZIX CORP

Florida – Leveraging the existing Surescripts Network

Access to:

- The majority of Floridians (Medicaid to be added this year).
- The majority of the Pharmacies.
- Over 8,000 physicians and growing.
- Medication history that is dispensed 'outside of the state'.

Can support:

- The connection of physicians, payers, and pharmacies to the drug database if that is required.
- Access to all medication history from payers and pharmacies on the network, thus eliminating the need to create and maintain a drug database.

Gaps:

- Need to connect remaining pharmacies, payers, and physicians.

Florida – Leveraging the existing Surescripts Network

Options:

1. Full e-prescribing requirement statewide
2. Full e-prescribing requirement statewide, with permission for properly authenticated law enforcement to query the network according to legislated standards.
3. The State builds the prescription drug monitoring database which uses Surescripts network to provide connectivity between the database and the practitioners.

Florida – Leveraging the existing Surescripts Network

Suggestions:

- Do not create a separate database that collects retrospective data, which must be analyzed even further after the fact
  - Time lag is not helpful for enforcement purposes
  - Creates new bureaucracy
  - RATHER: leverage existing e-prescribing network that can provide the most up-to-date information within seconds
    - Significantly reduces costs for physicians and pharmacies to comply
    - Gives state and federal officials the most current data, helping speed identification and prosecution of illegal activities
- Help support the adoption of remaining physicians, pharmacies, and payers to connect for e-prescribing through ACHA/ePrescribe Florida.
- Create incentives through AHCA to physicians and pharmacies that adopt and use e-prescribing.

Florida – Leveraging the existing Surescripts Network

Suggestions (continued)

- Legislate the "process" to request medication history under defined circumstances

  Use existing e-prescribing network to provide the information
- Do not require biometrics or other devices that add cost and lock in technologies that will become quickly outdated

  RATHER: Use the existing e-prescribing standards or propose authentication in line with appropriate CCHIT or NIST standards
- Review this approach to proposed legislation

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For More Information

The E-Prescribing Resource Center

www.surescripts.com

A Comprehensive Resource Center for Payers, Prescribers and Pharmacists

Thank You!