



Health Care Regulation Policy Committee

**Tuesday, March 16, 2010
10:15 AM – 12:00 PM
Morris Hall (17 HOB)**

MEETING PACKET

**Larry Cretul
Speaker**

**Nick Thompson
Chair**



The Florida House of Representatives

Health Care Regulation Policy Committee

A G E N D A

**March 16, 2010
10:15 AM - 12:00 PM
Morris Hall (17 HOB)**

- I. Opening Remarks by Chair Thompson**
- II. Consideration of the following bill(s):**
 - HB 591 Health Insurance by Rep. Roberson, Y.**
 - HB 1071 Sale of Ephedrine or Related Compounds by Rep. Hays**
 - CS/HB 1337 Nursing by State Universities & Private Colleges Policy Committee, Grimsley**
- III. Status report of the implementation of Chapter 2009-82, Laws of Florida, related to the A.G. Holley State Hospital**
- IV. Closing Remarks by Chair**
- V. Adjournment**

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 591 Health Insurance

SPONSOR(S): Roberson and others

TIED BILLS: IDEN./SIM. BILLS:

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Care Regulation Policy Committee		Holt <i>[Signature]</i>	Calamas <i>[Signature]</i>
2) Insurance, Business & Financial Affairs Policy Committee			
3) Full Appropriations Council on Education & Economic Development			
4) General Government Policy Council			
5)			

SUMMARY ANALYSIS

The bill mandates that state regulated health plans include antiretroviral (ARV) drugs on their drug formulary or preferred drug list. The bill prohibits health plans from restricting access to ARVs by requiring prior authorization, step therapy, or any other limitation that limits access. Medicaid health plans, health insurance plans, and health maintenance organizations are required to comply with the provisions of the bill.

The bill will have a significant negative fiscal impact to the state and no fiscal impact to local governments (See Fiscal Analysis).

The bill takes effect July 1, 2010.

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:

The bill requires state-regulated health plans to include antiretroviral (ARV) drugs on their drug formulary or preferred drug list¹ (PDL). In addition the bill prohibits health plans from restricting access to ARVs by requiring prior authorization², step therapy³, or any other limitation that limits access.

HIV/AIDS

HIV stands for Human Immunodeficiency Virus. HIV is the virus that causes AIDS. A person with HIV is called HIV positive (HIV+).⁴ HIV weakens the immune system by killing "CD4 cells" or "T cells" which help protect the body from disease.⁵

Since the disease was first reported over 20 years ago, an estimated 944,306 people have developed AIDS in the United States.⁶ According to the Centers for Disease Control and Prevention (CDC), estimated 55,000 - 58,500 new HIV infections occur in the United States each year.⁷ In 2008, there were 7,111 reported new HIV cases in Florida.⁸

HIV/AIDS Life Expectancy, Treatment and Cost

The main drug treatment for people with HIV is Highly Active Antiretroviral Therapy (also called HAART). HAART drugs help to slow the growth of HIV in the body. HAART combines three or more

¹ A list in which an insurance company has categorized into prescription drugs into tiers.

² The process of obtaining advanced approval of coverage for a health care service or medication.

³ A treatment process that is designed to encourage utilization of select medication(s) before other medication(s) is used due to cost, safety and medical appropriateness. (e.g., first step use of generic drug; and second step use of name brand drug).

⁴ U.S. Food and Drug Administration, HIV and AIDS - Medicines to Help You, available at:

<http://www.fda.gov/ForConsumers/ByAudience/ForPatientAdvocates/HIVandAIDSactivities/ucm118966.htm> (last viewed March 6, 2010).

⁵ *Id.*

⁶ Centers for Disease Control and Prevention, National Prevention Information Network, HIV/AIDS Today, available at: <http://www.cdcnpi.org/scripts/hiv/hiv.asp> (last viewed March 2, 2010).

⁷ *Id.*

⁸ Florida Department of Health, Community Health Assessment Resource Tool Set (CHARTS), Communicable Diseases, HIV Cases (March 10, 2010).

ARVs in a daily regimen and is the recommended treatment for HIV infection.⁹ HAART is made up of seven different types of medicines:¹⁰

1. Nucleoside Reverse Transcriptase Inhibitors (NRTIs) are faulty versions of building blocks that HIV needs to replicate. When HIV uses an NRTI instead of a normal building block, reproduction of the virus is stalled. The U.S. Food and Drug Administration (FDA) has approved the following NRTIs for treatment of HIV:¹¹

Brand Name	Generic Name	Manufacturer Name	Approval Date
Combivir	lamivudine and zidovudine	GlaxoSmithKline	27-Sep-97
Emtriva	emtricitabine, FTC	Gilead Sciences	02-Jul-03
EpiVir	lamivudine, 3TC	GlaxoSmithKline	17-Nov-95
Epzicom	abacavir and lamivudine	GlaxoSmithKline	02-Aug-04
Hivid	zalcitabine, dideoxycytidine, ddC (no	Hoffmann-La Roche	19-Jun-92
Retrovir	zidovudine, azidothymidine, AZT,	GlaxoSmithKline	19-Mar-87
Trizivir	abacavir, zidovudine, and	GlaxoSmithKline	14-Nov-00
Truvada	tenofovir disoproxil fumarate and	Gilead Sciences, Inc.	02-Aug-04
Videx EC	enteric coated didanosine, ddl EC	Bristol Myers-Squibb	31-Oct-00
Videx	didanosine, dideoxyinosine, ddl	Bristol Myers-Squibb	9-Oct-91
Viread	tenofovir disoproxil fumarate, TDF	Gilead	26-Oct-01
Zerit	stavudine, d4T	Bristol Myers-Squibb	24-Jun-94
Ziagen	abacavir sulfate, ABC	GlaxoSmithKline	17-Dec-98

2. Nonnucleoside Reverse Transcriptase Inhibitors (NNRTIs) bind to and disable reverse transcriptase, a protein that HIV needs to replicate. The FDA has approved the following NNRTIs used in the treatment of HIV infection:¹²

Brand Name	Generic Name	Manufacturer Name	Approval Date
Intelligence	etravirine	Tibotec Therapeutics	18-Jan-08
Rescriptor	delavirdine, DLV	Pfizer	4-Apr-97
Sustiva	efavirenz, EFV	Bristol Myers-Squibb	17-Sep-98
Viramune	nevirapine, NVP	Boehringer Ingelheim	21-Jun-96

3. Protease Inhibitors disable protease, a protein that HIV needs to replicate. The FDA has approved the following protease inhibitors used in the treatment of HIV infection:¹³

Brand Name	Generic Name	Manufacturer Name	Approval Date
Agenerase	amprenavir, APV	GlaxoSmithKline	15-Apr-99
Aptivus	tipranavir, TPV	Boehringer Ingelheim	22-Jun-05
Crixivan	indinavir, IDV,	Merck	13-Mar-96
Fortovase	saquinavir (no longer marketed)	Hoffmann-La Roche	7-Nov-97

⁹ Agency for Health Care Administration, 2010 Bill Analysis & Economic Impact Statement, House Bill 591, March 1, 2010.

¹⁰ U.S. Food and Drug Administration, Antiretroviral drugs used in the treatment of HIV infection, available at: <http://www.fda.gov/ForConsumers/ByAudience/ForPatientAdvocates/HIVandAIDSactivities/ucm118915.htm> (last viewed March 9, 2010).

¹¹ *Id.*

¹² *Id.*

¹³ *Id.*

Invirase	saquinavir mesylate, SQV	Hoffmann-La Roche	6-Dec-95
Kaletra	lopinavir and ritonavir, LPV/RTV	Abbott Laboratories	15-Sep-00
Lexiva	Fosamprenavir Calcium, FOS-APV	GlaxoSmithKline	20-Oct-03
Norvir	ritonavir, RTV	Abbott Laboratories	1-Mar-96
Prezista	darunavir	Tibotec, Inc.	23-Jun-06
Reyataz	atazanavir sulfate, ATV	Bristol-Myers Squibb	20-Jun-03
Viracept	nelfinavir mesylate, NFV	Agouron Pharmaceuticals	14-Mar-97

4. Fusion Inhibitors block HIV entry into cells; these drugs require specialized laboratory testing in order to evaluate the appropriate use and efficacy of treatment. The FDA has approved the following fusion inhibitors used in the treatment of HIV infection:¹⁴

Brand Name	Generic Name	Manufacturer Name	Approval Date
Fuzeon	enfuvirtide, T-20	Hoffmann-La Roche & Trimeris	13-Mar-03

5. Integrase Inhibitors disable integrase, a protein that HIV uses to insert its viral genetic material into the genetic material of an infected cell. The FDA has approved the following integrase inhibitors used in the treatment of HIV infection:¹⁵

Brand Name	Generic Name	Manufacturer Name	Approval Date
Isentress	raltegravir	Merck & Co., Inc.	12-Oct-07

6. Entry Inhibitors block HIV entry into cells (similar function as fusion inhibitors). The FDA has approved the following entry inhibitors used in the treatment of HIV infection:¹⁶

Brand Name	Generic Name	Manufacturer Name	Approval Date
Selzentry	maraviroc	Pfizer	06-August-07

7. Combination Drugs combine two types of one class or two or more classes into one pill to help improve treatment adherence and tolerance. The FDA has approved the following combination used in the treatment of HIV infection:¹⁷

Brand Name	Generic Name	Manufacturer Name	Approval Date
Atripla	efavirenz, emtricitabine and tenofovir	Bristol-Myers Squibb and Gilead Sciences	12-July-06

Regulation of Health Plans

Health plans are regulated at both the state and federal level. At the federal level, the Employee Retirement Income and Security Act (ERISA) regulates the operation of voluntary employer-sponsored benefits including pension plans and health plans. ERISA provides an explicit exemption from state regulation for health plans that are self-funded. State regulations apply to health benefits purchased through private health insurance plans and health maintenance organizations (HMOs).

¹⁴ *Id.*

¹⁵ *Id.*

¹⁶ *Id.*

¹⁷ *Id.*

Health Insurance Mandates and Mandated Offerings

A health insurance mandate is a legal requirement that an insurance company or health plan cover services by particular health care providers, specific benefits, or specific patient groups. Mandated offerings do not mandate that certain benefits be provided. Rather, a mandated offering law can require that insurers offer an option for coverage for a particular benefit or specific patient groups, which may require a higher premium and which the insured is free to accept or reject.

Florida currently has at least 52 mandates.¹⁸ The Council for Affordable Health Insurance estimates that mandated benefits currently increase the cost of basic health coverage from a little less than 20 percent to perhaps 50 percent, depending on the number of mandates, the benefit design and the cost of the initial premium.¹⁹ Each mandate adds to the cost of a plan's premiums, in a range of less than 1 percent to 10 percent, depending on the mandate.²⁰ Higher costs resulting from mandates are most likely to be experienced in the small group market since these are the plans that are subject to state regulations. The national average cost of insurance for a family of four is \$13,375.²¹

Health Insurance Mandate Report

Florida enacted section 624.215, F.S., to take into account the impact of insurance mandates and mandated offerings on premiums when making policy decisions. That section requires that any proposal for legislation that mandates health benefit coverage or mandatorily offered health coverage must be submitted with a report to AHCA and the legislative committee having jurisdictions. The report must assess the social and financial impact of the proposed coverage to the extent information is available, shall include:

- To what extent is the treatment or service generally used by a significant portion of the population.²²
- To what extent is the insurance coverage generally available.²³
- If the insurance coverage is not generally available, to what extent does the lack of coverage result in persons avoiding necessary health care treatment.²⁴
- If the coverage is not generally available, to what extent does the lack of coverage result in unreasonable financial hardship.²⁵
- The level of public demand for the treatment or service.²⁶
- The level of public demand for insurance coverage of the treatment or service.²⁷
- The level of interest of collective bargaining agents in negotiating for the inclusion of this coverage in group contracts.²⁸
- To what extent will the coverage increase or decrease the cost of the treatment or service.²⁹
- To what extent will the coverage increase the appropriate uses of the treatment or service.³⁰

¹⁸ Office of Insurance Regulation list of state health insurance mandates on file with Health Care Regulation Policy Committee staff; and "Health Insurance Mandates in the States 2009," Council for Affordable Health Insurance; *available at*: http://www.cahi.org/cahi_contents/resources/pdf/HealthInsuranceMandates2009.pdf. (last viewed March 9, 2010)

¹⁹ "Health Insurance Mandates in the States 2009," Council for Affordable Health Insurance; *available at*: http://www.cahi.org/cahi_contents/resources/pdf/HealthInsuranceMandates2009.pdf. (last viewed March 9, 2010)

²⁰ *Id.*

²¹ Kaiser Family Foundation, Employer Health Benefits 2009 Annual Survey, *available at*: <http://ehbs.kff.org/?CFID=20695941&CFTOKEN=84763322&jsessionid=6030bac21268c605c7863526585a397e6175> (last viewed March 9, 2010).

²² s. 624.215(2)(a), F.S.

²³ s. 624.215(2)(b), F.S.

²⁴ s. 624.215(2)(c), F.S.

²⁵ s. 624.215(2)(d), F.S.

²⁶ s. 624.215(2)(e), F.S.

²⁷ s. 624.215(2)(f), F.S.

²⁸ s. 624.215(2)(g), F.S.

²⁹ s. 624.215(2)(h), F.S.

³⁰ s. 624.215(2)(i), F.S.

- To what extent will the mandated treatment or service be a substitute for a more expensive treatment or service.”³¹
- To what extent will the coverage increase or decrease the administrative expenses of insurance companies and the premium and administrative expenses of policyholders.”³²
- The impact of this coverage on the total cost of health care.”³³

HIV/AIDS Drug Coverage and Medicaid

Currently, ARVs are not listed on the Medicaid fee-for-service program’s preferred drug list (PDL), but are exempt from prior authorization or step therapy requirements as specified in s. 409.91195(5), F.S. Medicaid health plans are required to provide the same amount, duration, and scope of services available to recipients in the Medicaid fee-for-service program.³⁴

According to the Agency for Health Care Administration (AHCA), the 2009-2012 Health Plan Contract stipulates that the plans must provide “those products and services associated with the dispensing of medicinal drugs pursuant to a valid prescription, as defined in Chapter 465, F.S.”³⁵ Prescribed drug services generally include all prescription drugs listed in AHCA’s PDL.”³⁶ In addition, the contract states that “the Health Plan may place appropriate limits on prescriptions based on criteria such as medical necessity, or for the purpose of utilization control, provided the Health Plan reasonably expects said limits to achieve the purpose of the prescribed drug services set forth in the Medicaid State Plan.”³⁷ The contract further states that antiretroviral agents are not subject to the PDL.³⁸

Effects of the Bill

The bill mandates that state regulated health plans include ARV drugs on their drug formulary or preferred drug list. The bill prohibits health plans from restricting access to ARVs by requiring prior authorization, step therapy, or any other limitation that limits access. Medicaid health plans (s. 409.912, F.S.), all health insurance plans (ss. 627.6404, 627.6515, and 627.6572, F.S.), and health maintenance organizations (s.641.31093, F.S.) are required to comply with the provisions of the bill.

The health insurance mandate report³⁹ was submitted by the AIDS Healthcare Foundation, the proponent of House Bill 591.⁴⁰

Extent to which the treatment or service generally used by a significant portion of the population.⁴¹

According to proponents, the provisions in the bill will directly affect services provided to 30,000 HIV/AIDS patients. However, the proponents could not provide sufficient documentation to support this projection. In addition it is unclear what percentage of the 30,000 patients have been denied coverage for ARVs.

³¹ s. 624.215(2)(j), F.S.

³² s. 624.215(2)(k), F.S.

³³ s. 624.215(2)(l), F.S.

³⁴ Agency for Health Care Administration, 2010 Bill Analysis & Economic Impact Statement, House Bill 591, March 1, 2010.

³⁵ *Id.*

³⁶ *Id.*

³⁷ *Id.*

³⁸ *Id.*

³⁹ The Health insurance mandate report is on file with Health Care Regulation Policy Committee staff.

⁴⁰ The AIDS Healthcare Foundation is based in Los Angeles and is the nation’s largest provider of HIV/AIDS medical care. AHF offers cutting-edge medicine and advocacy, regardless of ability to pay to more than 27,000 people in the United States, Africa, Central America and Asia. Domestically, AHF operates 14 healthcare centers, 11 pharmacies, a disease management program in Florida serving the state’s HIV/AIDS Medicaid population (Positive Healthcare Florida) and the first capitated Medicaid managed care program for people with AIDS (Positive Healthcare California). See AIDS Healthcare Foundation, Organization, available at: <http://www.aidshealth.org/about-us/organization/> (last viewed March 10, 2010).

⁴¹ s. 624.215(2)(a), F.S.

Extent to which the insurance coverage generally available.⁴²

The proponent did not have adequate data to support a definite conclusion but believes that the majority of providers approve payment for ARVs without utilizing administrative procedures that impose delay or access to a particular ARV.

Extent to which the lack of insurance coverage results in persons avoiding necessary health care treatment, if insurance coverage is not generally available.⁴³

Documentation was not provided suggesting that patients are not being provided coverage outright. Thus, there is not any way to determine if persons are avoiding necessary health care treatment. Antidotal examples have been provided were a particular ARV was denied.

Extent to which insurance coverage is generally not available and results in an unreasonable financial hardship.⁴⁴

The proponents could not provide documentation showing that coverage is not generally available. The proponent provided examples were a particular ARV was denied. Under these situations, it is unclear if a patient paid for the drugs out-of-pocket, went without using the particular ARV, or whether an alternative drug was taken.⁴⁵ The proponents provided examples for eleven patients who utilized four different health plans⁴⁶ were ARVs were denied, later approved, or approved with limitations. The ARVs that were denied or later approved were: Isentress, Intelence, Prezista, and Truvada.⁴⁷ The ARVs that were approved with limitations were: Norvir, Lexiva, and Atripla.⁴⁸

The level of public demand for the treatment or service.⁴⁹

Insufficient documentation was provided to determine a level of public demand.

The level of public demand for insurance coverage of the treatment or service.⁵⁰

The proponent provides no data on the level of public demand for insurance coverage of all ARVs without utilization limits.

The level of interest of collective bargaining agents in negotiating for the inclusion of this coverage in group contracts.⁵¹

Insufficient documentation was provided to determine the interest of collective bargaining agents in negotiating for the inclusion of this coverage in group contracts.

Extent to which the coverage increase or decrease the cost of the treatment or service.⁵²

The provisions of the bill may increase the cost to health plans since they are restricted from using prior authorization or step therapy, which health plans commonly use to reduce utilization. In addition, a health plan might experience an increase in costs if the health plan's formulary does not currently

⁴² s. 624.215(2)(b), F.S.

⁴³ s. 624.215(2)(c), F.S.

⁴⁴ s. 624.215(2)(d), F.S.

⁴⁵ Schackman BR et al. The lifetime cost of current human immunodeficiency virus care in the United States. *Med Care* 2006 Nov; 44:990-7.

⁴⁶ The two health plans: Vista, Total Health Choice. The two Medicaid plans: Insurance Universal, Insurance Sunshine.

⁴⁷ Examples of health plan denials of ARVs on file with Health Care Regulation Policy Committee staff.

⁴⁸ *Id.*

⁴⁹ s. 624.215(2)(e), F.S.

⁵⁰ s. 624.215(2)(f), F.S.

⁵¹ s. 624.215(2)(g), F.S.

⁵² s. 624.215(2)(h), F.S.

contain all ARVs. However, according to the proponents, properly managed HIV/AIDS patients with appropriate ARVs can lead healthy, productive lives without risk of the complications that can result without treatment—in particular, opportunistic infections that result in increased hospitalizations. According to proponents, timely access to the correct ARV regimen reduces the likelihood that patient will develop a drug resistance that results in the need for newer and often more expensive ARVs. The projected life expectancy for HIV infected individual, if they remain in optimal HIV care, is 24.2 years, and the lifetime per person HIV care cost is \$618,900 per person.⁵³

Extent to which the coverage increase the appropriate uses of the treatment or service.⁵⁴

Since, the proponents could only provide a few examples where HIV/AIDS patients were denied coverage it is difficult to project the extent to which changes in coverage will increase the use of a treatment or service.

Extent to which the mandated treatment or service be a substitute for a more expensive treatment or service.⁵⁵

Insufficient information was provided to determine if more expensive treatment would be substituted. Depending upon what combination of ARVs a patient is prescribed would determine actual costs for service. Typically, newer drugs cost more.

Extent to which the coverage increases or decreases the administrative expenses of insurance companies and the premium and administrative expenses of policyholders.⁵⁶

Health plans should experience a decrease in administrative reviews and appeals associated with approving a particular drug therapy.

The impact of this coverage on the total cost of health care.⁵⁷

The actual impact to the cost of health care is unknown, since it is not known how many ARVs would have to be added to formularies, or the variety and value of utilization limits used by different plans. Based on the Department of Management Services fiscal analysis, two state employee health maintenance organizations that require prior authorization have projected an increase in cost of \$0.10 to \$0.90 per member per month.⁵⁸

The bill takes effect July 1, 2010.

B. SECTION DIRECTORY:

Section 1. Amending s. 409.912, F.S., relating to cost-effective purchasing of health care.

Section 2. Creating s. 627.6404, F.S., relating to HIV treatment.

Section 3. Amending s. 627.6515, F.S., relating to out-of-state groups.

Section 4. Creating s. 627.6572, F.S., relating to HIV treatment.

Section 5. Creating s. 641.31093, F.S., relating to HIV treatment

Section 6. Provides that the bill takes effect July 1, 2010.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

⁵³ Schackman BR et al. The lifetime cost of current human immunodeficiency virus care in the United States. *Med Care* 2006 Nov; 44:990-7.

⁵⁴ s. 624.215(2)(i), F.S.

⁵⁵ s. 624.215(2)(j), F.S.

⁵⁶ s. 624.215(2)(k), F.S.

⁵⁷ s. 624.215(2)(l), F.S.

⁵⁸ Department of Management Services, 2010 Bill Analysis & Economic Impact Statement, House Bill 591, March 3, 2010.

1. Revenues:

None.

2. Expenditures:

According to the Department of Management Services, the state contracts with two health maintenance organizations (HMOs) in the state employee group plan which require prior authorization for ARVs. Cost estimates provided by the two HMOs affected are:⁵⁹

Vendor 1: \$0.10 per member per month

Vendor 2: \$0.90 per member per month

Based on projected enrollment and the above estimates provided by the HMO vendors, the fiscal impact would be:⁶⁰

	<u>(FY 10-11)</u>	<u>(FY 11-12)</u>	<u>(FY 12-13)</u>
Vendor 1 cost:	\$9,152	\$9,510	\$9,865
Vendor 2 cost:	\$330,847	\$343,624	\$356,324
Total cost estimate:	\$339,999	\$353,134	\$366,189

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The provisions of the bill may increase the cost to health plans since they are restricted from using prior authorization or step therapy, which health plans commonly use to reduce utilization and cost. In addition, a health plan might experience an increase in costs if the health plan's formulary does not currently contain all ARVs. Usually, increases in cost are passed on to policyholders.

D. FISCAL COMMENTS:

According to AHCA, it is possible that the proposed language could be interpreted to restrict a Medicaid plan's ability to limit reimbursement for ARVs to those with a diagnosis of HIV. If the intent of the proposed language is to restrict the plan's ability to limit medication to those diagnosed with HIV and other approved uses, then this provision would have a fiscal impact to the AHCA.

This change may limit the Medicaid plan's ability to manage utilization of ARVs. A change in the utilization of ARVs would be reflected in the encounter data used for future rate setting and may result in a fiscal impact to AHCA. However, utilization data about the extent of prior authorization restrictions on the use of these ARVs by the plans is not available to determine the fiscal impact at this time. In the fee-for-service setting, the specified ARVs are currently covered and are not subject to prior authorization or step therapy requirements, so the bill's provisions would have no fiscal impact on expenditures for the drugs provided to those recipients. If there is any fiscal impact on the AHCA, the funding sources would be General Revenue and Medical Care Trust Fund at the currently expected 38.46 percent and 61.54 percent, respectively, for fiscal year 2010-2011.

⁵⁹ Department of Management Services, 2010 Bill Analysis & Economic Impact Statement, House Bill 591, March 3, 2010.

⁶⁰ *Id.*

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:

No additional rule making authority is necessary to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COUNCIL OR COMMITTEE SUBSTITUTE CHANGES

MEMORANDUM

To: The Honorable Garrett Richter, Chair; Senate Banking & Insurance Committee
The Honorable Pat Patterson, Chair; House Insurance, Business & Financial Affairs Policy Committee
The Honorable Don Gaetz, Chair; Senate Health Regulation Committee
The Honorable Nicholas R. Thompson, Chair; House Health Care Regulation Committee
Secretary Thomas W. Arnold, Agency for Health Care Administration

From: AIDS Healthcare Foundation

Re: HB 591/SB 1132 – Proposing Mandatory Health Benefit Coverage Related to Antiretroviral Medications

The AIDS Healthcare Foundation seeks legislation that will establish consistent policy with respect to health benefit coverage for individuals who are prescribed antiretroviral medications. The effect of the legislation is to extend to the private sector the same policy currently implemented by the Medicaid and Medicare programs. Specifically, the legislation proposes to prohibit prior authorization and other similar administrative requirements, thereby increasing patient access to medically necessary medications that have been prescribed by a physician. Because the legislation may be deemed a health benefit mandate, we are submitting the following as required by section 624.215, Florida Statutes.

1. To what extent is the treatment or service generally used by a significant portion of the population.

According to the Department of Health (DOH), there are almost 125,000 diagnosed cases of HIV in Florida. DOH estimates that Medicaid covers 50% of HIV infected persons, 25% have private, federal (Veterans Administration) or some other form of insurance, and 25% are indigent and receive care through the public health system. Because the effect of the proposed bill is to conform the practices of the commercial plans to the policies already implemented by Florida Medicaid and the Centers for Medicare and Medicaid Services with respect to patients receiving care through Medicare, we believe the bill will directly affect the services available to an estimated 30,000 patients with a diagnosis of HIV/AIDS.

2. To what extent is the insurance coverage generally available.

We do not have specific information regarding the practices of all providers, but believe, based on our direct experience, that the majority of providers approve payment for ARVs without utilizing administrative procedures that impose delay to access.

3. To what extent does the practice of limiting coverage of ARVs result in persons avoiding necessary healthcare treatment.

By definition, every instance when the prescription is delayed has the effect of denying a person necessary healthcare treatment. This is not purposeful conduct on the patient's part; rather a situation where the patient is being denied care that he or she has contracted for with the plan. AHF has encountered some instances in which the patient gives up before the final approval is received. We do not know, however, how frequently this happens in the market, generally.

Again, it is important to remember research confirms that proper treatment with ARVs enables an HIV infected person to lead a normal life with less of a risk of further transmitting the virus through sexual contact. Thus, as a matter of public health, even one instance where the delaying tactic causes an individual to miss treatment compounds the risk of further transmission of HIV.

4. To what extent does the practice of limiting coverage of ARVs result in unreasonable financial hardship.

ARV therapy, on average, costs \$2700 - \$3300/month. Thus, a patient who chooses to pay out-of-pocket versus fight with the plan for reimbursement could be required to pay approximately that amount. The more likely outcome, however, is that treatment is delayed or entirely missed.

5. What is the level of public demand for the treatment or service?

As indicated in response to question 1 above, the most recent surveillance report of the Department of Health indicates there are almost 125,000 diagnosed cases of HIV in Florida. According to numbers provided by the Department of Health, Medicaid covers 50% of HIV infected persons, 25% have private, VA or some other form of insurance and 25% are indigent and receive care through the public health system. Because the effect of the proposed bill is to conform the practices of the commercial plans to the policies already implemented by Florida Medicaid and the Centers for Medicare and Medicaid Services with respect to patients receiving care through Medicare, we believe the bill will directly affect the services available to an estimated 30,000 patients with a diagnosis of HIV/AIDS.

6. What is the level of public demand for insurance coverage of the treatment or service?

It is reasonable to assume that every patient with HIV who pays out of pocket for insurance coverage expects to have access to needed medications.

7. What is the level of interest of collective bargaining agents in negotiating for the inclusion of this coverage in group contracts.

We have no information related to this question.

8. To what extent will the coverage increase or decrease the cost of the treatment or service.

The legislation is estimated to affect coverage for not more than 30,000 Floridians. It may increase the cost to plans in the short term if the result is to require them to provide necessary ARVs and the plan's formulary does not currently contain a particular ARV. However, the result of this will be to reduce longer term costs since patients properly managed with ARVs can lead healthy, productive lives without risk of the complications that result without treatment—in particular, opportunistic infections that result in increased hospitalizations. In addition, timely access to the correct ARV regimen reduces the likelihood the patient will develop a drug resistance that results in the need for newer and often more expensive ARVs. Equally important is the reduced cost to Florida's public health system if HIV infected patients are properly managed and receive appropriate ARVs, thereby reducing the opportunity for them to transmit the virus to others. Lifetime treatment costs for a patient with HIV are approximately \$600,000.

8. To what extent will the coverage increase the appropriate uses of the treatment or service.

Please see our response to question 3 above. By definition, every instance when the prescription is delayed has the effect of denying a person necessary healthcare treatment. This

is not purposeful conduct on the patient's part; rather a situation where the patient is being denied care he or she has contracted for with the plan. AHF has encountered some instances in which the patient gives up before the final approval is received. We do not know, however, how frequently this happens in the market, generally. Again, it is important to remember research confirms that proper treatment with ARVs enables an HIV infected person to lead a normal life with less of a risk of further transmitting the virus through sexual contact. Thus, as a matter of public health, even one instance where the delaying tactic causes an individual to miss treatment compounds the risk of further transmission of HIV.

9. To what extent will the mandated treatment or service be a substitute for a more expensive treatment or service.

Please see our answer to question 8 above. The legislation may increase the cost to plans in the short term if the result is to require them to provide necessary ARVs. However, the result of this will be to reduce longer term costs since patients properly managed with ARVs can lead healthy, productive lives without risk of the complications that result without treatment—in particular, opportunistic infections that result in increased hospitalizations. In addition, timely access to the correct ARV regimen reduces the likelihood the patient will develop a drug resistance that results in the need for newer and often more expensive ARVs. Equally important is the reduced cost to Florida's public health system if HIV infected patients are properly managed and receive appropriate ARVs, thereby reducing the opportunity for them to transmit the virus to others. Lifetime treatment costs for a patient with HIV are approximately \$600,000.

10. To what extent will the coverage increase or decrease the administrative expenses of insurance companies and the premium and administrative expenses of policyholders.

The legislation should reduce the costs for both plans and policyholders because it will eliminate the opportunity for delaying tactics that result in extensive back and forth communications between both and unnecessary administrative reviews.

11. What is the impact of this coverage on the total cost of healthcare.

We do not have an estimate of this amount since the practices of individual providers vary. Some, and we believe the majority, approve payment for ARVs without interruption or delay; others challenge every prescription. We believe, however, that because the legislation affects the treatment costs of only a small percentage of the population, it should have a very limited impact on overall costs. In fact, we believe it will reduce the costs to the State of Florida by assisting in reducing the incidence of HIV transmission within the state.

1 A bill to be entitled
 2 An act relating to health insurance; amending s. 409.912,
 3 F.S.; requiring certain entities to include all
 4 antiretroviral agents on their formularies; prohibiting
 5 such entities from using access-limiting procedures to
 6 restrict antiretroviral agents prescribed to treat a
 7 person with HIV; creating ss. 627.6404, 627.6572, and
 8 641.31093, F.S.; requiring all antiretroviral agents to be
 9 included on health plan formularies; prohibiting access-
 10 limiting procedures used to restrict antiretroviral agents
 11 prescribed to treat a person with HIV; amending s.
 12 627.6515, F.S.; including reference to such requirements
 13 on policies issued by out-of-state groups; providing an
 14 effective date.

15
 16 Be It Enacted by the Legislature of the State of Florida:

17
 18 Section 1. Subsection (54) is added to section 409.912,
 19 Florida Statutes, to read:

20 409.912 Cost-effective purchasing of health care.—The
 21 agency shall purchase goods and services for Medicaid recipients
 22 in the most cost-effective manner consistent with the delivery
 23 of quality medical care. To ensure that medical services are
 24 effectively utilized, the agency may, in any case, require a
 25 confirmation or second physician's opinion of the correct
 26 diagnosis for purposes of authorizing future services under the
 27 Medicaid program. This section does not restrict access to
 28 emergency services or poststabilization care services as defined

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29 | in 42 C.F.R. part 438.114. Such confirmation or second opinion
30 | shall be rendered in a manner approved by the agency. The agency
31 | shall maximize the use of prepaid per capita and prepaid
32 | aggregate fixed-sum basis services when appropriate and other
33 | alternative service delivery and reimbursement methodologies,
34 | including competitive bidding pursuant to s. 287.057, designed
35 | to facilitate the cost-effective purchase of a case-managed
36 | continuum of care. The agency shall also require providers to
37 | minimize the exposure of recipients to the need for acute
38 | inpatient, custodial, and other institutional care and the
39 | inappropriate or unnecessary use of high-cost services. The
40 | agency shall contract with a vendor to monitor and evaluate the
41 | clinical practice patterns of providers in order to identify
42 | trends that are outside the normal practice patterns of a
43 | provider's professional peers or the national guidelines of a
44 | provider's professional association. The vendor must be able to
45 | provide information and counseling to a provider whose practice
46 | patterns are outside the norms, in consultation with the agency,
47 | to improve patient care and reduce inappropriate utilization.
48 | The agency may mandate prior authorization, drug therapy
49 | management, or disease management participation for certain
50 | populations of Medicaid beneficiaries, certain drug classes, or
51 | particular drugs to prevent fraud, abuse, overuse, and possible
52 | dangerous drug interactions. The Pharmaceutical and Therapeutics
53 | Committee shall make recommendations to the agency on drugs for
54 | which prior authorization is required. The agency shall inform
55 | the Pharmaceutical and Therapeutics Committee of its decisions
56 | regarding drugs subject to prior authorization. The agency is

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CODING: Words ~~stricken~~ are deletions; words underlined are additions.

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57 authorized to limit the entities it contracts with or enrolls as
58 Medicaid providers by developing a provider network through
59 provider credentialing. The agency may competitively bid single-
60 source-provider contracts if procurement of goods or services
61 results in demonstrated cost savings to the state without
62 limiting access to care. The agency may limit its network based
63 on the assessment of beneficiary access to care, provider
64 availability, provider quality standards, time and distance
65 standards for access to care, the cultural competence of the
66 provider network, demographic characteristics of Medicaid
67 beneficiaries, practice and provider-to-beneficiary standards,
68 appointment wait times, beneficiary use of services, provider
69 turnover, provider profiling, provider licensure history,
70 previous program integrity investigations and findings, peer
71 review, provider Medicaid policy and billing compliance records,
72 clinical and medical record audits, and other factors. Providers
73 shall not be entitled to enrollment in the Medicaid provider
74 network. The agency shall determine instances in which allowing
75 Medicaid beneficiaries to purchase durable medical equipment and
76 other goods is less expensive to the Medicaid program than long-
77 term rental of the equipment or goods. The agency may establish
78 rules to facilitate purchases in lieu of long-term rentals in
79 order to protect against fraud and abuse in the Medicaid program
80 as defined in s. 409.913. The agency may seek federal waivers
81 necessary to administer these policies.

82 (54) Any entity that provides Medicaid services on a
83 prepaid or fixed-sum basis shall include all antiretroviral
84 agents on its formulary and may not restrict antiretroviral

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85 agents prescribed to treat a person with HIV through a
 86 requirement for prior authorization, step therapy, or other
 87 limitation that limits access to any antiretroviral agent.

88 Section 2. Section 627.6404, Florida Statutes, is created
 89 to read:

90 627.6404 HIV treatment.—Antiretroviral agents prescribed
 91 to treat a person with HIV must be included on a health plan
 92 formulary and may not be restricted through a requirement for
 93 prior authorization, step therapy, or other limitation that
 94 limits access to any antiretroviral agent.

95 Section 3. Subsection (2) of section 627.6515, Florida
 96 Statutes, is amended to read:

97 627.6515 Out-of-state groups.—

98 (2) Except as otherwise provided in this part, this part
 99 does not apply to a group health insurance policy issued or
 100 delivered outside this state under which a resident of this
 101 state is provided coverage if:

102 (a) The policy is issued to an employee group the
 103 composition of which is substantially as described in s.
 104 627.653; a labor union group or association group the
 105 composition of which is substantially as described in s.
 106 627.654; an additional group the composition of which is
 107 substantially as described in s. 627.656; a group insured under
 108 a blanket health policy when the composition of the group is
 109 substantially in compliance with s. 627.659; a group insured
 110 under a franchise health policy when the composition of the
 111 group is substantially in compliance with s. 627.663; an
 112 association group to cover persons associated in any other

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113 common group, which common group is formed primarily for
 114 purposes other than providing insurance; a group that is
 115 established primarily for the purpose of providing group
 116 insurance, provided the benefits are reasonable in relation to
 117 the premiums charged thereunder and the issuance of the group
 118 policy has resulted, or will result, in economies of
 119 administration; or a group of insurance agents of an insurer,
 120 which insurer is the policyholder.†

121 (b) Certificates evidencing coverage under the policy are
 122 issued to residents of this state and contain in contrasting
 123 color and not less than 10-point type the following statement:
 124 "The benefits of the policy providing your coverage are governed
 125 primarily by the law of a state other than Florida".†~~and~~

126 (c) The policy provides the benefits specified in ss.
 127 627.419, 627.6572, 627.6574, 627.6575, 627.6579, 627.6612,
 128 627.66121, 627.66122, 627.6613, 627.667, 627.6675, 627.6691, and
 129 627.66911.

130 (d) Applications for certificates of coverage offered to
 131 residents of this state must contain, in contrasting color and
 132 not less than 12-point type, the following statement on the same
 133 page as the applicant's signature:

134
 135 "This policy is primarily governed by the laws of ...insert
 136 state where the master policy is filed.... As a result, all of
 137 the rating laws applicable to policies filed in this state do
 138 not apply to this coverage, which may result in increases in
 139 your premium at renewal that would not be permissible under a
 140 Florida-approved policy. Any purchase of individual health

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141 insurance should be considered carefully, as future medical
 142 conditions may make it impossible to qualify for another
 143 individual health policy. For information concerning individual
 144 health coverage under a Florida-approved policy, consult your
 145 agent or the Florida Department of Financial Services."

146
 147 This paragraph applies only to group certificates providing
 148 health insurance coverage which require individualized
 149 underwriting to determine coverage eligibility for an individual
 150 or premium rates to be charged to an individual except for the
 151 following:

152 1. Policies issued to provide coverage to groups of
 153 persons all of whom are in the same or functionally related
 154 licensed professions, and providing coverage only to such
 155 licensed professionals, their employees, or their dependents;

156 2. Policies providing coverage to small employers as
 157 defined by s. 627.6699. Such policies shall be subject to, and
 158 governed by, the provisions of s. 627.6699;

159 3. Policies issued to a bona fide association, as defined
 160 by s. 627.6571(5), provided that there is a person or board
 161 acting as a fiduciary for the benefit of the members, and such
 162 association is not owned, controlled by, or otherwise associated
 163 with the insurance company; or

164 4. Any accidental death, accidental death and
 165 dismemberment, accident-only, vision-only, dental-only, hospital
 166 indemnity-only, hospital accident-only, cancer, specified
 167 disease, Medicare supplement, products that supplement Medicare,
 168 long-term care, or disability income insurance, or similar

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169 supplemental plans provided under a separate policy,
 170 certificate, or contract of insurance, which cannot duplicate
 171 coverage under an underlying health plan, coinsurance, or
 172 deductibles or coverage issued as a supplement to workers'
 173 compensation or similar insurance, or automobile medical-payment
 174 insurance.

175 Section 4. Section 627.6572, Florida Statutes, is created
 176 to read:

177 627.6572 HIV treatment.—Antiretroviral agents prescribed
 178 to treat a person with HIV must be included on a health plan
 179 formulary and may not be restricted through a requirement for
 180 prior authorization, step therapy, or other limitation that
 181 limits access to any antiretroviral agent.

182 Section 5. Section 641.31093, Florida Statutes, is created
 183 to read:

184 641.31093 HIV treatment.—Antiretroviral agents prescribed
 185 to treat a person with HIV must be included on a health plan
 186 formulary and may not be restricted through a requirement for
 187 prior authorization, step therapy, or other limitation that
 188 limits access to any antiretroviral agent.

189 Section 6. This act shall take effect July 1, 2010.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1071

Sale of Ephedrine or Related Compounds

SPONSOR(S): Hays

TIED BILLS:

IDEN./SIM. BILLS:

	REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1)	Health Care Regulation Policy Committee		Holt <i>JA</i>	Calamas <i>CEC</i>
2)	Criminal & Civil Justice Policy Council			
3)	Full Appropriations Council on Education & Economic Development			
4)	Health & Family Services Policy Council			
5)				

SUMMARY ANALYSIS

The bill limits access to key ingredients (precursors) used in the manufacturing of methamphetamine. The bill defines "ephedrine or related compounds" to include ephedrine, pseudoephedrine, or phenylpropanolamine, or any of their salts, optical isomers, or salts of optical isomers

The bill restricts the quantity of ephedrine or related compounds that may be purchased during specific time periods. The bill requires retailers to adopt an electronic recordkeeping system (logbook) to track real-time point of sale transactions and block sales that exceed the legal limit of ephedrine and related compounds. However, any retailer who can provide the Florida Department of Law Enforcement reasonable showing of imposition of additional costs is exempt from electronic reporting. Furthermore, the bill provides an exemption for specific entities.

The bill may have an insignificant fiscal impact to the state and no fiscal impact to local governments (See Fiscal Analysis).

The bill takes effect July 1, 2010.

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:

Drug Schedules

Florida law divides controlled substances¹ into five categories ranging from Schedule I to Schedule V. The scheduling of a controlled substance is relevant to how it can be prescribed and to the severity of the criminal offense for its illicit possession, sale or purchase. A drug in Schedule I has a "high potential for abuse and has no currently accepted medical use in treatment in the United States."² Schedule II drugs have a high potential for abuse and a severely restricted medical use.³ Schedule III controlled substances have less potential for abuse than Schedule I or Schedule II substances and have some accepted medical use.⁴ A drug in Schedule V has a low potential for abuse relative to the substances in Schedule IV and has a currently accepted medical use in treatment in the United States, and abuse of such compound, mixture or preparation may lead to limited physical or psychological dependence relative to the substances in Schedule IV.⁵

Methamphetamine

Methamphetamine is a Schedule II controlled substance.⁶ The drug has limited medical uses in the treatment of narcolepsy, attention deficit disorders, and obesity.⁷ According to the 2008 National Survey on Drug Use and Health (NSDUH), approximately 12.6 million Americans aged 12 or older reported using methamphetamine at least once during their lifetimes, representing five percent of the population aged 12 or older.⁸ Commonly called "speed," "crank," "crystal," or "Poor Man's Cocaine," methamphetamine can be smoked, injected, snorted, or taken orally. It produces an initial "high," lasting between 15 and 30 minutes, that is difficult, if not impossible for the user to repeat, leading the user to ingest more and more of the drug and go on longer binges. Long-term methamphetamine abuse can cause addiction, anxiety, insomnia, mood disturbances, and violent behavior. Additionally, psychotic symptoms such as paranoia, hallucinations, and delusions (such as the sensation of bugs

¹ Controlled substances are classified into five schedules in order to regulate the manufacture, distribution, preparation, and dispensing of the substances. See s. 893.02(4), F.S.

² s. 893.03(1), F.S. LSD and heroin are examples of Schedule I controlled substances.

³ s. 893.03(2), F.S. Codeine and morphine are examples of Schedule I controlled substances.

⁴ s. 893.03(3), F.S. Butabarbital and anabolic steroids are examples of Schedule I controlled substances.

⁵ s. 893.03(5), F.S.

⁶ s. 893.03(2)(c), F.S.

⁷ Office of National Drug Control, Methamphetamine Facts & Figures, available at:

http://www.whitehousedrugpolicy.gov/drugfact/methamphetamine/methamphetamine_ff.html/ last viewed March 3, 2010)

⁸ *Id.*

crawling under the user's skin) can occur. The psychotic symptoms can last for months or years after methamphetamine use has ceased.⁹

Methamphetamine Production and Precursors

The ease with which methamphetamine can be manufactured is a major contributing factor to the increase in its use. Rural areas are popular sites for production because strong odors are produced during manufacturing. It is easily "cooked" up by anyone in a makeshift lab hidden in mobile homes, warehouses, motel rooms, or cars.¹⁰ Methamphetamine hydrochloride is produced using ephedrine, hydroiodic acid (both controlled substances), or over-the-counter pseudoephedrine or phenylpropanolamine found in cold medication.¹¹ Hydroiodic acid is a necessary ingredient in one of the major manufacturing processes. Recently, phenylpropanolamine has been used as a precursor chemical to produce amphetamine. Precursors are substances that, in nature, might be inactive. However, when combined with another chemical the result is a new product.¹²

There are literally thousands of recipes and information about making methamphetamine on the Internet.¹³ An investment of a few hundred dollars in over-the-counter medications and chemicals can produce thousands of dollars worth of methamphetamine.¹⁴

State and federal chemical restrictions of precursors, combined with sustained law enforcement pressure, have reduced domestic methamphetamine production over the past several years.¹⁵ Reported methamphetamine laboratory seizures have decreased sharply each year since 2004; the year that states began implementing strong, retail-level sales restrictions of ephedrine and pseudoephedrine products.¹⁶ Moreover, in September 2006 the federal Combat Methamphetamine Epidemic Act of 2005¹⁷ became effective nationwide, setting restrictions on the retail sale of pseudoephedrine, phenylpropanolamine and ephedrine products.¹⁸ However, purchasing legal quantities of pseudoephedrine at various locations (called "smurfing") circumventing purchasing limitations is common practice among methamphetamine producers.¹⁹

To address the issue of smurfing, a some states have mandated the use of a real-time electronic pseudoephedrine tracking system. Eleven states²⁰ have adopted laws requiring pseudoephedrine tracking systems.²¹ A tracking system usually includes a "stop sale" or "lead generating" program. In a stop sale program, the seller transmits information about an attempted purchase.²² The system then notifies the seller that the purchase would be in violation of federal or state over-the-counter sales restrictions.²³ The sale is not completed unless specific exceptions are satisfied. In a lead generating program, all sales are completed and the system analyzes the collected purchase information to identify apparent violations of law.²⁴

⁹ *Id.*

¹⁰ KCI, The Anti-Meth site, Manufacturing of Methamphetamine, *available* at: http://www.kci.org/meth_info/making_meth.htm (last viewed March 7, 2010).

¹¹ *Id.*

¹² KCI, The Anti-Meth site, FAQ About Methamphetamine, *available* at: http://www.kci.org/meth_info/faq_meth.htm (last viewed March 7, 2010).

¹³ *Id.*

¹⁴ *Id.*

¹⁵ *Id.*

¹⁶ *Id.*

¹⁷ Public Law 109-177.

¹⁸ KCI, The Anti-Meth site, FAQ About Methamphetamine, *available* at: http://www.kci.org/meth_info/faq_meth.htm (last viewed March 7, 2010).

¹⁹ Florida Department of Law Enforcement, Methamphetamine Briefing, December 7, 2009.

²⁰ Arkansas, Hawaii, Illinois, Indiana, Kansas, Kentucky, Oklahoma, Washington, Iowa, Louisiana, and West Virginia. See National Alliance for Model State Drug Laws (NAMSDL), Electronic Tracking Systems for Methamphetamine Precursors, Legislative & Policy Update to 2008 Report (October 2009); National Alliance for Model State Drug Laws (NAMSDL), Controlling Methamphetamine Precursor Chemicals: Factors and Considerations for Developing and Operating Effective Electronic Pseudoephedrine Tracking Systems, A Report to the Senate Appropriations Committee, Final Report (2008).

²¹ National Alliance for Model State Drug Laws (NAMSDL), Electronic Tracking Systems for Methamphetamine Precursors, Legislative & Policy Update to 2008 Report (October 2009).

²² *Id.*

²³ *Id.*

²⁴ *Id.*

In contrast, Oregon²⁵ requires a prescription for all drugs containing methamphetamine precursors, and Alabama²⁶, outlawed the sale of drugs containing ephedrine, pseudoephedrine, and phenylpropanolamine unless they are formulated so as to prevent their use in methamphetamine synthesis.²⁷ However, pharmaceutical companies thus far have not formulated "non-convertible" forms of ephedrine, pseudoephedrine, and phenylpropanolamine, but alternatives to these drugs are now available for some indications.²⁸

Federal Combat Methamphetamine Epidemic Act of 2005

Effective September 30, 2006, federal law requires sellers of nonprescription (over-the-counter) ephedrine, pseudoephedrine, or phenylpropanolamine to place items containing these ingredients where customers do not have direct access before the sale is made ("behind the counter" placement) or in a locked cabinet located in an area of the facility to which customers do not have direct access. The seller must deliver the product directly into the custody of the purchaser.

The seller is required to maintain a logbook (paper or electronic) that identifies: a products name; quantity sold; name and address of purchaser; and the date and time of the sale. The purchaser must present a photographic identification card issued by a state or the federal government (i.e. driver's license) and sign a logbook. The logbook must contain a notice to purchasers that entering false statements or misrepresentations in the logbook may subject the purchaser to criminal penalties under Title 18 U.S.C. § 1001 and such notice must specify the maximum fine (\$250,000.00) and term of imprisonment (5 years). The federal Combat Methamphetamine Epidemic Act of 2005 ("Act") authorizes disclosure of information contained in the logbook to the Attorney General and to State and local law enforcement agencies. The Act prohibits accessing, using, or sharing the logbook information for any purpose other than to comply with the Controlled Substances Act or to facilitate a product recall to protect public health and safety is prohibited. A seller who in good faith releases logbook information to Federal, State or local law enforcement authorities, is immune from civil liability for releasing the information unless the release constitutes gross negligence or intentional, wanton, or willful misconduct.

The Act sets daily sales limit of ephedrine base, pseudoephedrine base, or phenylpropanolamine base at 3.6 grams per purchaser, regardless of the number of transactions.²⁹ In addition, the act makes it unlawful for any person to knowingly or intentionally purchase at retail store more than 9 grams during a 30 day period (of which no more than 7.5 grams can be imported by private or commercial carrier or the Postal Service).³⁰

Table 1. Daily sales limit of ephedrine base, pseudoephedrine base, or phenylpropanolamine base is 3.6 grams per purchaser, regardless of number of transactions.

Ingredient	Number of Tablets (as base)
25 mg Ephedrine HCl	175
25 mg Ephedrine Sulfate	186
30 mg Pseudoephedrine HCl	146
60 mg Pseudoephedrine HCl	73
120 mg Pseudoephedrine HCl	36
30 mg Pseudoephedrine Sulfate	155
60 mg Pseudoephedrine Sulfate	77

²⁵ OR. REV. STAT. s.475.973 (2009).

²⁶ ALA.CODE s. 20-2-190 (2008).

²⁷ National Alliance for Model State Drug Laws (NAMSDL), Controlling Methamphetamine Precursor Chemicals: Factors and Considerations for Developing and Operating Effective Electronic Pseudoephedrine Tracking Systems, a Report to the Senate Appropriations Committee, Final Report (2008).

²⁸ National Alliance for Model State Drug Laws (NAMSDL), Electronic Tracking Systems for Methamphetamine Precursors, Legislative & Policy Update to 2008 Report (October 2009).

²⁹ 21 U.S.C. § 830.

³⁰ 21 U.S.C. § 844(a)

120 mg Pseudoephedrine Sulfate	38
Phenylpropanolamine	The Food and Drug Administration issued a voluntary recall of this ingredient as being unsafe for human consumption. Veterinary use is by prescription only.

US Department of Justice, Drug Enforcement Agency, Office of Drug Diversion

Table 2. Effective April 8, 2006, for mail-order sellers, sales are limited to 7.5 grams per customer during a 30-day period.

Ingredient	Number of tablets (as base)
25 mg Ephedrine HCl	366
25 mg Ephedrine Sulfate	389
30 mg Pseudoephedrine HCl	305
60 mg Pseudoephedrine HCl	152
120 mg Pseudoephedrine HCl	76
30 mg Pseudoephedrine Sulfate	324
60 mg Pseudoephedrine Sulfate	162
120 mg Pseudoephedrine Sulfate	81
Phenylpropanolamine	The Food and Drug Administration issued a voluntary recall of this ingredient as being unsafe for human consumption. Veterinary use is by prescription only.

US Department of Justice, Drug Enforcement Agency, Office of Drug Diversion

Florida Law

Section 893.1495, F.S., provides that no person shall knowingly deliver in any single over-the-counter retail sale:

- any number of packages of any drug containing a sole active ingredient that he or she knows to contain a combined total of more than 9 base grams of ephedrine, pseudoephedrine, phenylpropanolamine, or any of their salts, optical, isomers, or salts of optical isomers;³¹ or
- more than 3 packages, regardless of weight containing any such sole active ingredient.³²

Additionally, no person shall knowingly display and offer for retail sale packages of any drug having a sole active ingredient of ephedrine, pseudoephedrine, phenylpropanolamine, or any of their salts, optical, isomers, or salts of optical isomers other than behind a checkout counter where the public is not permitted.³³

Any person who violates these provisions commits a second degree misdemeanor³⁴ for a first offense, a first degree misdemeanor³⁵ for a second offense and a third degree felony³⁶ for a third or subsequent offense.

Moreover, current law prohibits a owner or primary operator of a retail outlet where ephedrine, pseudoephedrine or phenylpropanolamine products are available for sale shall knowingly allow an employee to engage in the retail sale of such products unless the employee has completed an

³¹ s. 893.1495(1), F.S.

³² *Id.*

³³ s. 893.1495(2), F.S.

³⁴ Second degree misdemeanors are punishable by up to 60 days in prison and/or up to \$500 fine. ss. 775.082, 775.083, F.S.

³⁵ First degree misdemeanors are punishable by up to 1 year in prison and/or up to \$1,000 fine. ss. 775.082, 775.083, F.S.

³⁶ Third degree felonies are punishable by up to 5 years in prison and/or up to a \$5,000 fine. ss. 775.082, 775.083, F.S.

employee training program that must include, at a minimum, basic instruction on state and federal regulations relating to the sale and distribution of such products.³⁷

The provisions in s. 893.1495, F.S., supersede any municipal ordinance or regulation passed on or after July 1, 2005, to the extent that such ordinance or regulation is more restrictive than the provisions of the section.³⁸

The Effects of the Bill

The bill provides the definition of "ephedrine or related compounds" as ephedrine, pseudoephedrine, or phenylpropanolamine, or any of their salts, optical isomers, or salts of optical isomers and conforms the change in terminology throughout the bill.

The bill specifically provides that a person may not knowingly obtain or delivery in any retail over-the-counter sale, in a single day, a nonprescription compound, mixture, or preparation that contains ephedrine or related compounds that:

- Contains a total of 3.6 grams per of ephedrine or related compounds.
- Consists of more than three packages (regardless of weight) that contain ephedrine or related compounds.

Additionally, the bill makes it unlawful for any person to knowingly or intentionally purchase at a retail store more than 9 grams of ephedrine or related compounds within a 30-day period.

The bill requires purchasers of ephedrine or related compounds to:

- be at least 18 years of age;
- present a government issued photo identification showing their name, date of birth, address, and photo identification number; and
- sign a log book (paper or electronic).

The bill requires retailers to use an electronic recordkeeping mechanism (or logbook) that provides real-time tracking of non-prescription over-the-counter ephedrine or related compound purchases. The electronic logbook must block sales in excess of legal quantities. The electronic logbook must be approved by the Florida Department of Law Enforcement (FDLE). Any retailer who can provide FDLE a reasonable showing of imposition of additional costs is exempt from electronic reporting. However, bill provides that a nonprescription compound, mixture, or preparation containing any quantity of ephedrine or related compounds cannot be sold over-the-counter unless the sale is reported to an FDLE approved electronic recordkeeping system.

The bill specifies that the electronic logbook must record:

- the date and time of the transaction;
- name, date of birth, address, type of photo identification presented and the identification number; amount and name of the compound, mixture or preparation purchased;
- signature of the purchaser or a unique number that is associated with a paper signature that is maintained on the premises.

Current law³⁹ requires owners or primary operator of retail stores to ensure that all employees that engage in the retail sale of ephedrine or related compounds must attend an employee training program that includes basic instruction on state and federal regulations. The bill provides, via a cross reference, that failure to provide this training to employees is a second degree misdemeanor (first offense); first degree misdemeanor (second offense) and a third degree felony (third offense).

The bill exempts the following entities from these provisions:

- licensed manufacturers who lawfully manufacture and distribute products;

³⁷ s. 893.1495(3), F.S.

³⁸ s. 893.1495(4), F.S.

³⁹ s. 893.1495(5), F.S.

- wholesalers who lawfully distribute products;
- hospitals licensed under ch. 395, F.S.;
- licensed long-term care facilities;
- government-operated health departments;
- physician offices;
- publicly operated prisons, jails, juvenile correctional facilities, or private adult/juvenile correctional facilities under contract with the state;
- public or private educational institutions that maintain health care programs; and
- government operated or industry operated medical facilities serving employees of the government.

The bill takes effect July 1, 2010.

B. SECTION DIRECTORY:

Section 1. Amends s. 893.1495, F.S., relating to retail sale of ephedrine and related compounds.

Section 2. Provides an effective date of July 1, 2010.

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:

Potentially there could be a cost to retailers for either creating an in-house or purchasing a real-time electronic logbook. There could be a cost associated with maintaining an electronic logbook and training of retail staff. Many of the major retail establishments already maintain electronic logbooks in an effort to comply with federal law. Retailers that do not already have computers equipped with card readers capable of scanning and capturing information from the magnetic strip on the back of driver's licenses may decide to purchase this equipment or have someone manually enter the required information into the electronic logbook.

However, the fiscal impact to retailers may be mitigated since the bill provides an exemption for retailers from electronic reporting if they can make "reasonable showing of imposition of additional costs".

D. FISCAL COMMENTS:

According to FDLE, there will be a workload impact to one full-time equivalent employee who will coordinate with law enforcement agencies and the (electronic recordkeeping system) vendor to provide access to law enforcement officers. FDLE will manage this increase in workload within existing resources. The provisions of the bill will require FDLE to use an electronic recordkeeping system. Currently there are electronic recordkeeping systems available at no cost to users (i.e. state law

enforcement agencies, retailers, or pharmacies). One such, electronic recordkeeping system is being offered by Apriss/MethCheck. This system is part of the National Precursor Log Exchange (NPLex). The Apriss/MethCheck electronic recordkeeping system is being paid for by manufacturers of ephedrine products and is managed by the National Association of Drug Diversion Investigators.⁴⁰

On February 23, 2010, the Criminal Justice Impact Conference met and concluded that the bill will have an insignificant impact on prison beds.

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:

The bill may not provide FDLE sufficient guidance to determine "reasonable showing of imposition of additional costs" or guidelines for approving electronic logbooks and so may implicate the non-delegation doctrine contained in Article II, Section 3 of the Florida Constitution.

B. RULE-MAKING AUTHORITY:

The bill does not provide FDLE rule-making authority, which is needed to promulgate rules for approving electronic logbooks and determining reasonable showing of imposition of additional costs.

C. DRAFTING ISSUES OR OTHER COMMENTS:

There are some inconsistencies in the bill. The bill mentions that retailers are required to use an electronic recordkeeping mechanism that provides real-time tracking and blocking of sales. However, the bill does not require the retailers to *report* to an electronic recordkeeping system. But (6) states that a retailer may not sell ephedrine or related compounds unless *reported*. It is unclear what and to whom the retailer is supposed to report. Furthermore, (6) appears to conflict with the intent of (7), which provides an exemption for electronic reporting if reasonable showing of imposition of additional costs is provided.

IV. AMENDMENTS/COUNCIL OR COMMITTEE SUBSTITUTE CHANGES

⁴⁰ Email correspondence with Florida Department of Law Enforcement on file with Health Care Regulation Policy Committee staff (March 13, 2010).

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1 A bill to be entitled
 2 An act relating to the sale of ephedrine or related
 3 compounds; amending s. 893.1495, F.S.; providing a
 4 definition; prohibiting obtaining or delivering to an
 5 individual in a retail sale any nonprescription compound,
 6 mixture, or preparation containing ephedrine or related
 7 compounds in excess of specified amounts; revising
 8 provisions relating to retail display of products
 9 containing ephedrine or related compounds; revising
 10 provisions relating to retail employee training; requiring
 11 a purchaser of a nonprescription compound, mixture, or
 12 preparation containing any detectable quantity of
 13 ephedrine or related compounds to meet specified
 14 requirements; requiring use of an electronic recordkeeping
 15 mechanism approved by the Department of Law Enforcement
 16 for such transactions to record specified information;
 17 providing for exemptions from the electronic recordkeeping
 18 requirement; revising language concerning local ordinances
 19 or regulations; providing exemptions for certain entities;
 20 conforming language concerning criminal penalties for
 21 violations; providing an effective date.

22
 23 Be It Enacted by the Legislature of the State of Florida:

24
 25 Section 1. Section 893.1495, Florida Statutes, is amended
 26 to read:

27 893.1495 Retail sale of ephedrine and related compounds.—
 28 (1) For purposes of this section, the term "ephedrine or

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29 related compounds" means ephedrine, pseudoephedrine,
30 phenylpropanolamine, or any of their salts, optical isomers, or
31 salts of optical isomers.

32 ~~(2)(1)~~ A No person may not shall knowingly obtain or
33 deliver to an individual in any single retail over-the-counter
34 sale any number of packages of any nonprescription compound,
35 mixture, or preparation drug containing a sole active ingredient
36 that contains a combined total of more than 9 base grams of
37 ephedrine or related compounds in excess of the following
38 amounts:

39 (a) In any single day, any number of packages that contain
40 a total of 3.6 grams of ephedrine or related compounds;

41 (b) In any single retail, over-the-counter sale, three
42 packages, regardless of weight, containing ephedrine or related
43 compounds; or

44 (c) In any 30-day period, in any number of retail, over-
45 the-counter sales, a total of 9 grams or more of ephedrine or
46 related compounds, pseudoephedrine, phenylpropanolamine, or any
47 of their salts, optical isomers, or salts of optical isomers, or
48 more than three packages in any single retail over the counter
49 sale, regardless of weight, containing any such sole active
50 ingredient.

51 ~~(3)(2)~~ A No person may not shall knowingly display and
52 offer for retail sale packages of any nonprescription compound,
53 mixture, or preparation containing drug having a sole active
54 ingredient of ephedrine or related compounds, pseudoephedrine,
55 phenylpropanolamine, or any of their salts or optical isomers
56 other than behind a checkout counter where the public is not

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57 permitted or other such location that is not otherwise
 58 accessible to the general public.

59 ~~(4)(3)~~ A ~~No~~ person who is the owner or primary operator of
 60 a retail outlet where any nonprescription compound, mixture, or
 61 preparation containing ephedrine or related compounds is,
 62 ~~pseudoephedrine, or phenylpropanolamine products~~ are available
 63 for sale may not shall knowingly allow an employee to engage in
 64 the retail sale of such compound, mixture, or preparation
 65 ~~products~~ unless the employee has completed an employee training
 66 program that shall include, at a minimum, basic instruction on
 67 state and federal regulations relating to the sale and
 68 distribution of such compounds, mixtures, or preparations
 69 ~~products~~.

70 (5)(a) Any person purchasing, receiving, or otherwise
 71 acquiring any nonprescription compound, mixture, or preparation
 72 containing any detectable quantity of ephedrine or related
 73 compounds must:

- 74 1. Be at least 18 years of age.
- 75 2. Produce a government-issued photo identification
 76 showing his or her name, date of birth, address, and photo
 77 identification number.
- 78 3. Sign his or her name on a record of the purchase,
 79 either on paper or on an electronic signature capture device.

80 (b) An electronic recordkeeping mechanism approved by the
 81 Department of Law Enforcement shall be used and shall record the
 82 following:

- 83 1. Date and time of the transaction.
- 84 2. Name, date of birth, address, and photo identification

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85 number of the purchaser, as well as the type of identification
 86 and the government of issuance.

87 3. The amount and name of the compound, mixture, or
 88 preparation containing ephedrine or related compounds.

89 4. The signature of the purchaser, or a unique number
 90 relating the transaction to a paper signature maintained at the
 91 retail premises.

92 (c) The electronic recordkeeping mechanism shall provide
 93 for:

94 1. Real-time tracking of nonprescription over-the counter
 95 sales under this section.

96 2. Blocking of nonprescription over-the-counter sales in
 97 excess of those allowed by the laws of this state or federal
 98 law.

99 (6) A nonprescription compound, mixture, or preparation
 100 containing any quantity of ephedrine or related compounds may
 101 not be sold over the counter unless reported to an electronic
 102 recordkeeping system approved by the Department of Law
 103 Enforcement.

104 (7) Any pharmacy or other retailer may request an
 105 exemption from electronic reporting from the Department of Law
 106 Enforcement. The department shall grant an exemption upon a
 107 reasonable showing of imposition of additional costs to the
 108 requester.

109 (8)-(4) The requirements of this section relating to the
 110 marketing, sale, or distribution of products containing
 111 ephedrine or related compounds supersedes, pseudoephedrine, or
 112 phenylpropanolamine products shall supersede any local ordinance

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113 or regulation passed by a county, municipality, or other local
 114 governmental authority.

115 (9) This section does not apply to:

116 (a) Licensed manufacturers manufacturing and lawfully
 117 distributing products in the channels of commerce.

118 (b) Wholesalers lawfully distributing products in the
 119 channels of commerce.

120 (c) Health care facilities licensed under chapter 395.

121 (d) Licensed long-term care facilities.

122 (e) Government-operated health departments.

123 (f) Physicians' offices.

124 (g) Publicly operated prisons, jails, or juvenile
 125 correctional facilities or private adult or juvenile
 126 correctional facilities under contract with the state.

127 (h) Public or private educational institutions maintaining
 128 health care programs.

129 (i) Government-operated or industry-operated medical
 130 facilities serving employees of the government or industry
 131 operating them.

132 (10)(5) Any individual who violates ~~subsection (1),~~
 133 subsection (2), ~~or~~ subsection (3), or subsection (4) commits:

134 (a) For a first offense, a misdemeanor of the second
 135 degree, punishable as provided in s. 775.083.

136 (b) For a second offense, a misdemeanor of the first
 137 degree, punishable as provided in s. 775.082 or s. 775.083.

138 (c) For a third or subsequent offense, a felony of the
 139 third degree, punishable as provided in s. 775.082, s. 775.083,
 140 or s. 775.084.

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141 | Section 2. This act shall take effect July 1, 2010.

Amendment No. 1

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 _____

1 Council/Committee hearing bill: Health Care Regulation Policy
2 Committee

3 Representative(s) Hays offered the following:

4
5 **Amendment (with title amendment)**

6 Remove everything after the enacting clause and insert:

7 Section 1. Section 893.1495, Florida Statutes, is amended
8 to read:

9 893.1495 Retail sale of ephedrine and related compounds.-

10 (1) For purposes of this section, the term "ephedrine or
11 related compounds" means ephedrine, pseudoephedrine,
12 phenylpropanolamine, or any of their salts, optical isomers, or
13 salts of optical isomers.

14 (2) ~~(1)~~ A ~~no~~ person ~~may not shall~~ knowingly obtain or

15 deliver to an individual in any ~~single~~ retail over-the-counter

16 ~~sale any number of packages of any nonprescription compound,~~

17 mixture, or preparation ~~drug~~ containing a ~~sole active ingredient~~

18 ~~that contains a combined total of more than 9 base grams of~~

Amendment No. 1

19 ephedrine or related compounds in excess of the following
20 amounts:

21 (a) In any single day, any number of packages that contain
22 a total of 3.6 grams of ephedrine or related compounds;

23 (b) In any single retail, over-the-counter sale, three
24 packages, regardless of weight, containing ephedrine or related
25 compounds; or

26 (c) In any 30-day period, in any number of retail, over-
27 the-counter sales, a total of 9 grams or more of ephedrine or
28 related compounds, pseudoephedrine, phenylpropanolamine, or any
29 of their salts, optical isomers, or salts of optical isomers, or
30 more than three packages in any single retail over-the-counter
31 sale, regardless of weight, containing any such sole active
32 ingredient.

33 ~~(3)-(2)~~ A No person may not shall knowingly display and
34 offer for retail sale ~~packages of any~~ nonprescription compound,
35 mixture, or preparation containing drug having a sole active
36 ingredient of ephedrine or related compounds, pseudoephedrine,
37 phenylpropanolamine, or any of their salts or optical isomers
38 other than behind a checkout counter where the public is not
39 permitted or other such location that is not otherwise
40 accessible to the general public.

41 ~~(4)-(3)~~ A No person who is the owner or primary operator of
42 a retail outlet where any nonprescription compound, mixture, or
43 preparation containing ephedrine or related compounds is,
44 pseudoephedrine, or phenylpropanolamine products are available
45 for sale may not shall knowingly allow an employee to engage in
46 the retail sale of such compound, mixture, or preparation

Amendment No. 1

47 ~~products~~ unless the employee has completed an employee training
48 program that shall include, at a minimum, basic instruction on
49 state and federal regulations relating to the sale and
50 distribution of such compounds, mixtures, or preparations
51 ~~products~~.

52 (5) (a) Any person purchasing, receiving, or otherwise
53 acquiring any nonprescription compound, mixture, or preparation
54 containing any detectable quantity of ephedrine or related
55 compounds must:

56 1. Be at least 18 years of age.

57 2. Produce a government-issued photo identification
58 showing his or her name, date of birth, address, and photo
59 identification number.

60 3. Sign his or her name on a record of the purchase,
61 either on paper or on an electronic signature capture device.

62 (b) Department of Law Enforcement shall approve an
63 electronic recordkeeping system for the purpose of recording and
64 monitoring the real time purchase of products containing
65 ephedrine or related compounds and for the purpose of monitoring
66 this information in order to prevent or investigate illegal
67 purchases of these products. The approved electronic
68 recordkeeping system shall be provided to a pharmacy or retailer
69 without any additional cost or expense. A pharmacy or retailer
70 may request an exemption from electronic reporting from the
71 Department of Law Enforcement if the pharmacy or retailer lacks
72 the technology to access the electronic recordkeeping system and
73 such pharmacy or retailer maintains a sales volume of less than
74 72 grams of ephedrine or related compounds in a thirty day

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75 period. The electronic recordkeeping system shall record the
76 following:

77 1. Date and time of the transaction.

78 2. Name, date of birth, address, and photo identification
79 number of the purchaser, as well as the type of identification
80 and the government of issuance.

81 3. The number of packages purchased, total grams per
82 package, and name of the compound, mixture, or preparation
83 containing ephedrine or related compounds.

84 4. The signature of the purchaser, or a unique number
85 relating the transaction to a paper signature maintained at the
86 retail premises.

87 (c) The electronic recordkeeping system shall provide for:

88 1. Real-time tracking of nonprescription over-the-counter
89 sales under this section.

90 2. Blocking of nonprescription over-the-counter sales in
91 excess of those allowed by the laws of this state or federal
92 law.

93 (6) A nonprescription compound, mixture, or preparation
94 containing any quantity of ephedrine or related compounds may
95 not be sold over the counter unless reported to an electronic
96 recordkeeping system approved by the Department of Law
97 Enforcement.

98 (7) Prior to completing a transaction a pharmacy or
99 retailer distributing products containing ephedrine or related
100 compounds to consumers in this state shall submit all required
101 data into an electronic recordkeeping system approved by the
102 Department of Law Enforcement either at the point of sale or

Amendment No. 1

103 through an interface with the electronic recordkeeping system,
104 unless granted an exemption by the Department of Law Enforcement
105 pursuant to subparagraph (5)(b).

106 (8) The data submitted to the electronic recordkeeping
107 system must be retained within the system for no less than two
108 years from the date of entry.

109 (9)-(4) The requirements of this section relating to the
110 marketing, sale, or distribution of products containing
111 ephedrine or related compounds supersedes, pseudoephedrine, or
112 phenylpropanolamine products shall supersede any local ordinance
113 or regulation passed by a county, municipality, or other local
114 governmental authority.

115 (10) This section does not apply to:

116 (a) Licensed manufacturers manufacturing and lawfully
117 distributing products in the channels of commerce.

118 (b) Wholesalers lawfully distributing products in the
119 channels of commerce.

120 (c) Health care facilities licensed under chapter 395.

121 (d) Licensed long-term care facilities.

122 (e) Government-operated health departments.

123 (f) Physicians' offices.

124 (g) Publicly operated prisons, jails, or juvenile
125 correctional facilities or private adult or juvenile
126 correctional facilities under contract with the state.

127 (h) Public or private educational institutions maintaining
128 health care programs.

COUNCIL/COMMITTEE AMENDMENT

Bill No. HB 1071 (2010)

Amendment No. 1

129 (i) Government-operated or industry-operated medical
130 facilities serving employees of the government or industry
131 operating them.

132 (11)(5) Any individual who violates subsection (1),
133 subsection (2), ~~or~~ subsection (3), or subsection (4) commits:

134 (a) For a first offense, a misdemeanor of the second
135 degree, punishable as provided in s. 775.083.

136 (b) For a second offense, a misdemeanor of the first
137 degree, punishable as provided in s. 775.082 or s. 775.083.

138 (c) For a third or subsequent offense, a felony of the
139 third degree, punishable as provided in s. 775.082, s. 775.083,
140 or s. 775.084.

141 (12) Information contained within the electronic
142 recordkeeping system shall be disclosed in a manner authorized
143 by state or federal law.

144 (13) A person who sells any product containing ephedrine
145 or related compounds who in good faith complies with the
146 requirements of this section is immune from civil liability for
147 the release of the information.

148 (14) The Department of Law Enforcement shall contract with
149 a private third party administrator to implement the electronic
150 recordkeeping system required by this section.

151 (15) The Department of Law Enforcement shall promulgate
152 rules necessary to implement this section.

153
154 Section 2. This act shall take effect July 1, 2010 and
155 shall be implemented by January 1, 2011.
156

Amendment No. 1

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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 sale of ephedrine or related compounds;
amending s. 893.1495, F.S.; providing a definition; prohibiting
obtaining or delivering to an individual in a retail sale any
nonprescription compound, mixture, or preparation containing
ephedrine or related compounds in excess of specified amounts;
revising provisions relating to retail display of products
containing ephedrine or related compounds; revising provisions
relating to retail employee training; requiring a purchaser of a
nonprescription compound, mixture, or preparation containing any
detectable quantity of ephedrine or related compounds to meet
specified requirements; requiring use of an electronic
recordkeeping mechanism approved by the Department of Law
Enforcement for such transactions to record specified
information; providing for exemptions from the electronic
recordkeeping requirement; revising language concerning local
ordinances or regulations; providing exemptions for certain
entities; conforming language concerning criminal penalties for
violations; providing an effective date.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 1337 Nursing
SPONSOR(S): State Universities & Private Colleges Policy Committee and Grimsley
TIED BILLS: IDEN./SIM. BILLS: SB 2530

Table with 4 columns: REFERENCE, ACTION, ANALYST, STAFF DIRECTOR. Row 1: State Universities & Private Colleges Policy Committee, 12 Y, 0 N, As CS, White, Tilton. Row 2: Health Care Regulation Policy Committee, Holt, Calamas. Row 3: Full Appropriations Council on Education & Economic Development. Row 4: Education Policy Council. Row 5: Empty.

SUMMARY ANALYSIS

To address the state's lack of nursing education program capacity, the 2009 Legislature took action to expedite and streamline the nursing education program approval and regulatory processes in Florida with the passage of House Bill 1209 (2009). This legislation repealed the Florida Board of Nursing's (BON's) authority to prescribe the nursing education program approval and regulation processes by rule and, instead, set forth these processes in statute.

Committee Substitute for House Bill 1337 builds upon the 2009 legislation by further streamlining these processes. Under the bill, a nursing education program that is accredited by one of the two specialized accrediting agencies that are nationally recognized by the United States Secretary of Education to accredit nursing education programs is no longer subject to BON regulation for as long as the program maintains its accreditation. The BON approval process for non-accredited programs, as adopted in last year's bill, is largely retained, but implementation issues identified by the Office of Program Policy and Government Accountability, Florida Center for Nursing, and stakeholders are addressed. The bill's changes include:

- Clarifying that the BON must approve or deny a nursing education program application within 90 days after receipt of a complete application.
Providing that faculty education requirements for a nursing program may be documented by an official transcript or a written statement from an educational institution verifying that it conferred a degree.
Providing that the graduate passage rate on the National Council Licensure Examination (NCLEX), which must be achieved by approved programs, is 10 percentage points, rather than 10 percent below, the national average passage rate.
Clarifying that the requirements for NCLEX graduate passage rates, as adopted in last year's legislation for approved programs, should only be applied prospectively beginning with the 2010 calendar year.
Specifying that approved programs placed on probation for inadequate NCLEX graduate passage rates shall be removed from probation after attaining the required passage rate for one calendar year.
Eliminating probation as a penalty for an approved program's failure to submit an annual report and, instead, requiring the program's director to appear before the BON to explain the delay.
Authorizing nursing program directors to receive information on the NCLEX exam date and pass/fail score for program graduates included in the program's graduate passage rate.

The bill does not appear to have a fiscal impact. Please see "Fiscal Analysis & Economic Impact Statement."

The bill takes effect July 1, 2010.

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.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

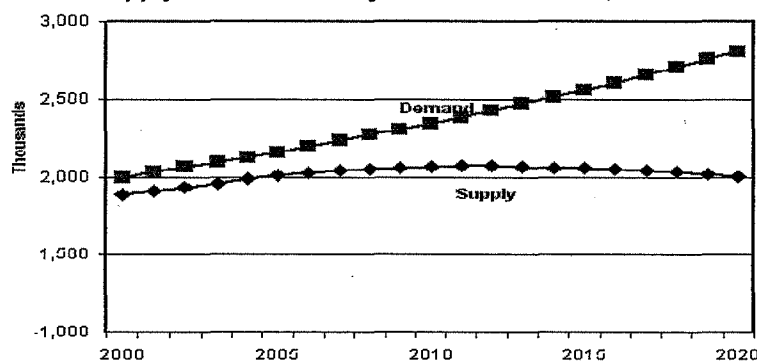
A. EFFECT OF PROPOSED CHANGES:

Present Situation

National Nursing Shortage

In 2007, the National Center for Health Workforce Analysis at Health Resource and Service Administration projected a growing shortage of Registered Nurses (RNs) over the next 15 years, with a 12% shortage by 2010 and a 20% shortage by 2015.¹

National Supply and Demand Projections for FTE RNs, 2000 to 2020



Since 2007, the economic recession has forced many nurses to return to the workforce and, as a result, the current demand for RNs has decreased somewhat. A national nursing shortage, however, remains on the horizon. According to a study published in the June 2009 edition of *Health Matters*, a peer-reviewed health policy journal, the shortage is projected to grow to 260,000 RNs by 2025. The primary cause is the aging nursing workforce.² By 2014, nearly 40% of the nation's RN population will be between the ages of 55 to 64 years and expected to retire from active nursing practice.³

¹U.S. Department of Health and Human Services, Bureau of Health Professions, National Center for Health Workforce Analysis, *Nursing Workforce Data Analysis: Methods for Identifying Facilities and Communities with Shortages of Nurses*, Technical Report. (February 2007). Available online at: http://bhpr.hrsa.gov/healthworkforce/nursingshortage/tech_report/default.htm (last viewed March 6, 2010).

²Buerhaus, P., Auerbach, D., & Staiger, D., (2009), *The Recent Surge In Nurse Employment: Causes And Implications*, *Health Matters*, 28, no. 4 (2009): w657-w668. Available online at: <http://content.healthaffairs.org/cgi/content/abstract/hlthaff.28.4.w657> (last viewed March 6, 2010).

³See *supra* note 1.

Florida Nursing Shortage

As of June 30, 2009, there were 62,254 active in-state licensed practical nurses (LPNs), 178,214 active in-state licensed RNs, and 11,829 active in-state licensed advanced registered nurse practitioners.⁴

According to reports prepared by the Florida Center for Nursing (FCN), there is a current shortage of RNs and LPNs in Florida, and this shortage is expected to grow significantly in the long-term. As of June 30, 2009, demand for RNs in Florida exceeded supply by 6,807 RNs and demand for LPNs exceeded supply by 1,417 LPNs.⁵ The FCN has projected that by 2020 the shortage of RNs will increase to 52,209 and the shortage of LPNs will increase to 7,018.^{6,7}

There is, however, no shortage of potential nurses in Florida. While Florida nursing programs produced 7,671 new RN graduates and 4,047 new LPN graduates in academic year 2008-2009, these programs also turned away 10,876 qualified RN program applicants and 2,755 qualified LPN program applicants in that same year because the programs were at capacity.⁸

To address the lack of nursing education program capacity, the 2009 Legislature took action to expedite and streamline the nursing education program approval and regulatory processes in Florida with the passage of House Bill 1209.⁹ As discussed in the section below, this legislation repealed the Florida Board of Nursing's (BON's) broad authority to prescribe the nursing education program approval and regulation processes by rule and, instead, set forth these processes in statute.

Nursing Education Program Approval and Regulation by the Florida Board of Nursing

Background: Part I, chapter 464, F.S., entitled the "Nurse Practice Act," (Act), provides for the regulation of the practice of nursing in Florida by the BON, which is established within the Department of Health (Department). The BON is comprised of 13 members appointed by the Governor and confirmed by the Senate who serve four year terms. Seven members must be RNs and three members must be LPNs. The remaining three members must be Florida residents who have never been licensed as nurses and who are in no way connected to the practice of nursing or to any health care facility, agency, or insurer.¹⁰ The BON meets six times per year and is staffed with 43 full-time positions.¹¹

Under the Act, an "approved program" means a nursing program conducted in a school, college, or university which is approved under s. 464.019, F.S., for the education of nurses.¹² Currently, there are 181 nursing education programs approved to operate in Florida. Of this number, 98 programs offer a LPN certificate, 58 programs offer an associate degree in nursing, and 25 programs offer a bachelor's degree in nursing.¹³ The Act requires individuals who seek licensure as a RN or LPN in Florida to, in relevant part, have graduated from an "approved program" or its equivalent, as determined by the BON, and to pass the Department's licensure exam.¹⁴ The exam utilized is the National Council Licensure Examination (NCLEX), developed by the National Council of State Boards of Nursing (NCSBN).

⁴ Florida Department of Health, Division of Medical Quality Assurance, Annual Report: July 1, 2008-June 30, 2009.

⁵ Florida Center for Nursing, *Workforce Demand in Nursing-Intensive Healthcare Settings, 2009 Vacancies and 2011 Growth Projections*, p. 8 (January 2010). Available at: <http://www.flcenterfornursing.org/workforce/researchreports.cfm> (last viewed March 6, 2010).

⁶ Florida Center for Nursing, *Forecasting Supply, Demand, and Shortage of RNs and LPNs in Florida, 2007-2020*, p. 5 (July 2008). Available at: <http://www.flcenterfornursing.org/workforce/researchreports.cfm> (last viewed March 6, 2010).

⁷ The projections were based on 2007 survey data. In a January 2010, report, the FCN noted that although the nationally economy has changed dramatically since the 2007 survey, the nursing shortage in Florida remains a critical issue. According to the FCN, "The nursing shortage, though perhaps temporarily eased by the increase in recession-related nursing employment, continues to be a looming problem for Florida. Drivers of the nursing shortage remain the same: older nurses who have returned to work will eventually retire, and an aging population will demand more healthcare. Once the recession eases, we will see the nursing shortage re-emerge. The Bureau of Labor Statistics (BLS) projects that demand for RNs will increase more than any other type of worker through 2016, with more than 587,000 new RN positions projected during this time in the United States. Hence, we expect long-term demand for nurses to increase in response to population trends." *Workforce Demand in Nursing-Intensive Healthcare Settings, 2009 Vacancies and 2011 Growth Projections*, supra note 5, at 4.

⁸ Florida Center for Nursing, *Florida Nursing Education Capacity and Nursing Faculty Supply/Demand 2007-2009 Trends*, pp. 8-9 (January 2010). Available at: <http://www.flcenterfornursing.org/nurseeducation/data.cfm> (last viewed March 6, 2010).

⁹ Chapter 2009-158, L.O.F.

¹⁰ Section 464.004, F.S.

¹¹ Office of Program Policy Analysis & Government Accountability, *Since Implementing Statutory Changes, the State Board of Nursing Has Approved More Nursing Programs; the Legislature Should Address Implementation Issues*, Report No. 10-14 at p. 2 (January 2010). Available at: <http://www.oppaqa.state.fl.us/Summary.aspx?reportNum=10-14> (last viewed March 6, 2010).

¹² Section 464.003(8), F.S.

¹³ See supra note 11.

¹⁴ Section 464.008, F.S.

Prior to July 1, 2009, the BON had extensive authority to establish the requirements applicable to nursing education program approval and regulation in Florida under s. 464.019, F.S. (2008). This section required the BON to adopt rules necessary to ensure that approved nursing programs graduated nurses capable of competent practice, including rules that addressed: program approval and oversight; site visits; requirements for educational objectives, faculty, curriculum, administrative procedures, and clinical training; and procedures for program probation, suspension, and termination.

During the 2009 Regular Session, the Legislature repealed the BON's rulemaking authority and, instead, prescribed the nursing education program approval and regulatory process in statute.¹⁵ This legislation specifically prohibited the BON from imposing any condition or requirement on an institution submitting a program application, an approved program, or a program on probationary status, except as expressly provided in s. 464.019, F.S. It further stated that the BON has no rulemaking authority to implement the section, except that the BON must adopt a rule that prescribes the format for submitting program applications and summary descriptions of program compliance, and it expressly directed the BON to repeal all rules in existence on July 1, 2009, that were inconsistent with the subsection.¹⁶

Existing Nursing Education Programs: Under the 2009 legislation, Florida nursing education programs in existence on June 30, 2009, were made subject to a "grandfathering clause" set forth in s. 464.019(2), F.S. This clause provides that a program approved by the BON as of June 30, 2009, notwithstanding whether that approval was full or provisional or whether the program was on probation, became an "approved program" on July 1, 2009, except for a program on probation due to inadequate graduate passage rates on the NCLEX. A program on such probation remains on probation until it achieves an average graduate passage rate for its first-time test takers on the NCLEX that is no more than 10 percent below the national average passage rate for first-time, U.S. educated test takers. This average graduate passage rate must be achieved by July 1, 2011, and, if not, the program must be terminated.¹⁷ As of June 30, 2009, six practical nursing programs and one professional associate degree nursing program were on probation for inadequate student performance on the NCLEX.¹⁸

New Program Approval: For an educational institution applying for approval of a prelicensure practical or professional nursing education program on or after July 1, 2009, the 2009 legislation amended s. 464.019(1), F.S., to require each program application to document that:

- At least 50 percent of the faculty and the program director are registered nurses in Florida who have, at a minimum, a bachelor's degree for a *practical* nursing program. For a *professional* nursing program, such faculty and program director must also have a master's degree in nursing or a related field.
- At least 50 percent of the curriculum consists of clinical training for a practical nursing program, professional associate's degree program, and professional diploma nursing program. For a bachelor's degree professional nursing program, at least 40 percent of the curriculum must consist of clinical training.
- No more than 25 percent of the program's clinical training consists of clinical simulation.
- The program has a signed agreement with each entity included in the curriculum plan as clinical training sites and community-based clinical experience sites.
- The program has written policies for direct supervision by faculty or clinical preceptors¹⁹ for students in clinical training consistent with specified standards.
- The curriculum plan documents clinical experience and theoretical instruction in specified subjects.

Within 90 days after receipt of a program application, s. 464.019(1), F.S., requires the BON to approve the application if it documents compliance with the standards above. If the program application is incomplete or does not document compliance, the BON is required to do the following:

¹⁵ Ch. 2009-168, L.O.F.

¹⁶ Section 464.019(7), F.S.

¹⁷ Ch. 2009-168, s. 2, L.O.F., *codified at s. 464.019(2) and (5)(a), F.S.*

¹⁸ Florida Center for Nursing, *Report of Findings and Recommendations – Ch. 2009-168, L.O.F., Florida Board of Nursing Education Program Approval & Oversight*, p. 2 (January 2010). Available at: <http://www.flcenterfornursing.org/nurseeducation/data.cfm> (last viewed March 6, 2010).

¹⁹ The term "clinical preceptor" is defined to mean, "a registered nurse employed by a clinical training facility who serves as a role model and clinical resource person for a specified period to an individual enrolled in an approved program." Section 464.003(10), F.S.

- For an incomplete application, the BON must notify the educational institution of any errors or omissions within 30 days after receipt and follow the procedures specified in s. 120.60, F.S., of the Administrative Procedure Act (APA). This section provides that an application is deemed complete upon receipt of an application that has corrected each identified error or omission and that the completed application must be approved or denied within 90 days after its receipt.²⁰
- For an application that does not document compliance, the BON must, within 90 days after receipt of the application, provide the educational institution with a notice of intent to deny that sets forth written reasons for the denial. The institution may request a hearing on such a notice pursuant to ch. 120, F.S., the APA.²¹

If the BON does not act on an application within the timeframes specified above, the application is deemed approved and the program becomes an approved program under s. 464.019, F.S.²²

BON Regulation of Approved Programs: In order to continue as an approved program, s. 464.019, F.S., as amended by the 2009 legislation, sets forth two requirements. First, all approved programs, including programs on probation, must submit a report to the BON by November 1 of each year. The annual report must include an affidavit certifying continued compliance with the requirements that must be documented in a new program application and provide a summary description of that compliance. The report must also document for the previous academic year: the number of student applications, qualified applicants, students accepted, and program graduates; the program's graduate passage rate on the NCLEX; the program's retention rates for students tracked from program entry to graduation; and the program's accreditation status, including identification of the accrediting body.²³ If a program fails to timely submit its annual report, the BON must place the program on probation. If the report is not submitted within six months following its due date, the BON must terminate the program.²⁴

Second, the BON is required to place an approved program on probation if the program's average graduate passage for first-time test takers on the NCLEX falls 10 percent or more below the national average passage rate for first-time NCLEX test takers educated in the United States, as annually published by the contract testing service of the NCSBN, for two consecutive years.²⁵ The program must remain on probationary status until it achieves compliance with the required passage rate and must be terminated by the BON if it does not achieve compliance within two calendar years.²⁶

A program placed on probation must disclose this status in writing to its students and applicants.²⁷

Data on Nursing Education Programs: In order to provide prospective students with greater access to information about nursing programs in Florida, the 2009 legislation requires the BON to have published the following information about Florida nursing programs on its website by December 31, 2009:

- The program application for each program approved on or after July 1, 2009.
- The summary description required to be submitted by each program in its annual report.
- A comprehensive list of nursing programs in the state.
- The accreditation status of each program, including identification of the accrediting body.
- Each program's approval or probationary status.
- Each program's graduate passage rate for the NCLEX.

²⁰ Section 120.60(1), F.S.

²¹ Section 464.019(1) and (3), F.S.

²² Section 464.019(1), F.S.

²³ Section 464.019(2)(b) and (c), F.S.

²⁴ Section 464.019(5)(b), F.S.

²⁵ Currently, s. 456.014, F.S., provides that all information required by the Department of any applicant for licensure is a public record with the exception of specified information that includes medical information, school transcripts, examination questions, answers, and grades. This information is confidential and exempt from s. 119.07(1), F.S., and may not be discussed with or made accessible to anyone except members of the relevant board, the department, and staff thereof. The Department has interpreted this section of law to mean that the NCLEX pass/fail results of an applicant for RN or LPN licensure may not be disclosed to the nursing education program from which the student graduated. Department of Health Bill Analysis for HB 1337, p. 2, March 4, 2010. Nursing education program stakeholders have expressed concerns that the non-disclosure of such data results in the program being unable to confirm whether the graduate passage rates are accurate.

²⁶ Section 464.019(5)(a), F.S.

²⁷ Section 464.019(5)(c), F.S.

- The national average passage rate for the NCLEX.
- Each program's student retention rates tracked from program entry to graduation.

The website must allow interactive searches and comparisons of specific nursing programs and must be updated at least quarterly.

Implementation Monitoring and Study: The 2009 legislation established a six-year monitoring process to evaluate the effectiveness of the changes made by the legislation in achieving quality nursing programs with a higher production of quality nursing graduates. To this end, the legislation required the Florida Center for Nursing (FCN) and the Office of Program Policy Analysis and Government Accountability (OPPAGA) to monitor the administration of the new nursing program approval process during its first year of implementation and to report their findings to the Governor and presiding officers of the Legislature by February 1, 2010.²⁸ These reports were submitted in January 2010 and are discussed below in the section entitled, "Implementation Monitoring."

The legislation also created s. 464.019(9), to require the FCN and OPPAGA to jointly study the bill's five-year implementation and to submit a report to the Governor and presiding officers of the Legislature on January 30, 2011, and annually thereafter through January 30, 2015. For this report, the OPPAGA is required to evaluate: the number of nursing education programs and student slots available; the number of applications submitted, qualified applicants, students accepted, and program graduates; program retention rates; graduate passage rates on the NCLEX; and the number of graduates who become employed in Florida as RNs or LPNs. The FCN is required to evaluate the BON's implementation of the program application approval process and program probation and termination processes.²⁹

Nursing Education Program State Regulation, Licensure, and Programmatic Accreditation

As discussed above there are currently 181 nursing education programs approved under s. 464.019, F.S., to operate in Florida. These programs are offered by: state-regulated public school districts, Florida colleges, and state universities; private institutions that must be licensed and regulated by the state Commission for Independent Education (CIE);³⁰ and private institutions that are not under the CIE pursuant to s. 1005.06(1)(c) and (e), F.S.^{31,32}

Some of Florida's nursing education programs are also accredited by specialized accrediting agencies that are nationally recognized by the United States (US) Secretary of Education to accredit nursing programs.³³ Accreditation is a private, nongovernmental review of the quality of educational programs. Approved programs in Florida are not required to be accredited.

The Secretary recognizes two agencies that provide specialized accreditation for prelicensure nursing education programs, the National League for Nursing Accreditation Commission (NLNAC) and the Commission on Collegiate Nursing Education (CCNE).³⁴ With regard to prelicensure nursing education programs, the NLNAC accredits certificate LPN programs and diploma, associate degree, and bachelor degree RN programs and the CCNE accredits bachelor degree RN programs.

²⁸ Section 464.019(8), F.S.

²⁹ Section 464.019(9), F.S.

³⁰ Chapter 1005, F.S., establishes the CIE to regulate independent postsecondary educational institutions, which are defined as, "any postsecondary educational institution that operates in this state or makes application to operate in this state, and is not provided, operated, and supported by the State of Florida, its political subdivisions, or the Federal Government." Section 1005.02(11), F.S.

³¹ Section 1005.06(1)(c), F.S., exempts a school from the CIE's licensure requirements if the institution: is under the jurisdiction of the Department of Education, eligible to participate in the William L. Boyd, IV, Florida Resident Access Grant Program and is a nonprofit independent college or university located and chartered in this state and accredited by the Commission on Colleges of the Southern Association of Colleges and Schools to grant baccalaureate degrees. Twenty-eight institutions in Florida are subject to this exemption.

³² Section 1005.06(1)(e), F.S., exempts a school from the CIE's licensure requirements if the institution: had been exempted prior to 2001; is incorporated in this state; the institution's credits or degrees are accepted for credit by at least three colleges that are accredited by an agency recognized by the USDOE; and the institution does not enroll any students who receive state or federal financial aid. Only two institutions in Florida, Pensacola Christian College and Landmark Baptist College, are subject to this exemption. Landmark Baptist College does not offer a nursing program.

³³ See *supra* note 18 at p. 3.

³⁴ United States Department of Education, *Specialized Accrediting Agencies*. Available at: http://www.ed.gov/admins/finaid/accred/accreditation_pg8.html#health (last viewed March 6, 2010).

Both accrediting agencies have extensive standards for the programs they accredit in order to ensure the quality of the education offered. These standards specify requirements that accredited programs must meet in areas that include the following: program administrator and faculty education qualifications; curriculum content and clinical experience requirements, which provide for periodic review of such content and experience to ensure rigor and currency; expectations for the use of best teaching practices; demonstration of sufficient fiscal, physical facility, and academic support services for the program; review of individual and aggregate student outcome data and graduate passage rates on the NCLEX; and review of student, alumni, and employer satisfaction.^{35,36}

According to NLNAC, initial and continuing accreditation is granted when the nursing program demonstrates compliance with all NLNAC Accreditation Standards. Initial accreditation is for a period of five years and continuing accreditation is for a period of eight years.³⁷ The NLNAC requires accredited programs to file annual reports containing specified data that is reviewed to determine whether the program is continuing to comply with accreditation standards. Additionally, site visits are conducted for the initial and continuing accreditation determinations.³⁸ The NLNAC may place conditions on a program's accreditation if it finds that a program is in non-compliance with one or two of the accrediting standards and may place an accredited program on warning status if it is in non-compliance with three or more standards. In both cases, the NLNAC requires the accredited program within a specified period of time to report on its efforts to attain compliance and the NLNAC conducts a follow-up site visit. If the program fails to achieve compliance with the standards, the NLNAC will deny continuing accreditation. Achievement of compliance for a LPN program must occur within 18 months and for a RN program must occur within two years.³⁹ A program may appeal the NLNAC's denial of initial or continuing accreditation status within 30 days of receipt of notice of denial. The appeal process must be completed within 90 days.⁴⁰

Similarly, initial and reaffirmed accreditation by the CCNE is granted to programs that demonstrate compliance with CCNE's standards. Initial accreditation may be for a period up to five years. Thereafter, the accreditation may be reaffirmed for a period up to 10 years. The CCNE requires accredited programs to file annual reports containing specified data that are reviewed to determine whether the program is continuing to comply with accreditation standards. Additionally, site visits are conducted for the initial and reaffirmed accreditation determinations.⁴¹ Accreditation will be withdrawn by the CCNE when a program pursuing reaffirmed accreditation fails to demonstrate its ability to meet the accreditation standards or if the program fails to submit reports or payment of fees as requested by the CCNE. A program may challenge an adverse action by the CCNE with regard to its accreditation by filing a notice of appeal within 10 business days of the adverse action. If the program fails to file a notice of appeal within 10 business days, the CCNE's decision becomes final.⁴²

Of the 181 nursing education programs approved in Florida, data from the FCN indicates that: eight of the 98 LPN programs (8.2%) are accredited by the NLNAC; 31 of the 58 associate degree RN programs (53.4%) are accredited by the NLNAC or CCNE; and 22 of the 25 bachelor degree RN programs (88%) are accredited by the NLNAC or CCNE.⁴³

Implementation Monitoring

As discussed above, the 2009 legislation required the FCN and OPPAGA to monitor the administration of the new nursing program approval process during its first year of implementation and to report their findings by February 1, 2010. Additionally, staff of the Joint Administrative Procedures Committee (JAPC) monitored the BON's implementation of the legislation's requirements relating to rulemaking.

³⁵ National League for Nursing Accrediting Commission, Inc., *Accreditation Manual*, pp. 76-98, (2008). Available at: <http://www.nlnac.org/manuals/Manual2008.htm> (last viewed March 7, 2010).

³⁶ Commission on Collegiate Nursing Education, *Standards for Accreditation of Baccalaureate and Graduate Degree Nursing Programs*, pp. 7-18 (April 2009). Available at: <http://www.aacn.nche.edu/accreditation/PubsBaccGrad.htm> (last viewed March 7, 2010).

³⁷ See *supra* note 35 at p. 32.

³⁸ See *supra* note 35 at p. 12, 61-62.

³⁹ See *supra* note 35 at pp. 32-34.

⁴⁰ See *supra* note 35 at pp. 42-44.

⁴¹ See *supra* note 36 at pp. 7-8 & 17.

⁴² See *supra* note 36 at pp. 13-14 & 21-24.

⁴³ See *supra* note 18 at p. 3

With regard to the new legislation's impact on increasing nursing education program capacity, the OPPAGA indicated in its report that:

New program applications submitted to the board have more than doubled in the six months since Ch. 2009-168, Florida Statutes, [sic] became effective compared to the previous year. As shown by Exhibit 3, since the new law went into effect, the board has considered 25 new applications for nursing programs, compared to 10 new applications considered in all of 2008. The board has approved 20 new nursing programs during this timeframe, compared to 9 new programs approved in 2008. In addition, the board has received seven new applications that will be considered at its February meeting.⁴⁴

The OPPAGA and FCN also identified a number of issues related to implementation. These included:

- *Program Application Timeframe:* The OPPAGA and FCN found that the program application timeframe implemented by the BON is inconsistent with the timeframe established in the Administrative Procedure Act.⁴⁵ The BON begins the 90-day time frame for approval or denial of a program application on the day the application is received notwithstanding whether the application is complete or incomplete. Section 464.019(3), F.S., however, with regard to incomplete applications, directs the BON to notify the educational institution of any errors or omissions within 30 days after receipt of the application and to follow the procedures specified in s. 120.60, F.S., of the Administrative Procedure Act (APA), which specifies that the 90-day time frame for approval or denial of an application does not begin until the application is complete. The OPPAGA stated:

As a result of this practice and the timing of board meetings, [department] staff must quickly review applications and notify programs to appear at the next board meeting, even when applications are incomplete. Since the board meets every other month, a program may only have one opportunity during the 90-day period to have their application go before the board; if all required documents are not yet filed the application will be denied unless the program waives the timeframe. If the applicant is denied, programs must submit a new application and begin the process anew.⁴⁶

The FCN and OPPAGA both recommended that the Legislature clarify the timeframe the BON should follow when it considers applications for nursing programs to ensure that the BON's practice is consistent with s. 120.60, F.S.⁴⁷

- *Program Application:* The OPPAGA found, and the FCN concurred in the finding, that the BON's application for new nursing programs is not yet finalized.⁴⁸ The OPPAGA also indicated that the application includes requirements beyond those specified in statute, such as curriculum vitae of faculty members, course descriptions, approval dates by the Department of Education, and nursing program length. The OPPAGA recommended that the BON finalize and publish a program application consistent with statute.⁴⁹ This issue, as discussed below, is currently being addressed by the JAPC and will be discussed by the BON at its March 12, 2010 teleconference.
- *Probation:* The OPPAGA found that the BON's method for placing programs on probation is not yet finalized. According to OPPAGA, the BON determined at its October meeting to use graduate passage rates beginning in January 2009 for purposes of determining whether a program has had two consecutive years of inadequate passage rates. OPPAGA indicated that stakeholders expressed concern that this decision resulted in utilizing data that predated the July 1, 2009 effective date of the law, i.e., retroactive application of the law.⁵⁰

⁴⁴ See *supra* note 11 at pp. 4-5.

⁴⁵ See *supra* note 11 at p. 5 and note 18 at p. 1.

⁴⁶ *Id.*

⁴⁷ See *supra* note 11 at p. 10 and note 18 at pp. 2 & 4.

⁴⁸ See *supra* note 11 at pp. 6-7 and note 18 at p. 1.

⁴⁹ See *supra* note 11 at pp. 6-7.

⁵⁰ See *supra* note 11 at pp. 7-8.

Additionally, OPPAGA found that the BON has not yet determined how programs will be placed on probation for failure to submit an annual report and affidavit or determined how programs will be removed from probationary status. The OPPAGA stated, "Statutory language states that programs shall remain on probation until they achieve compliance with the examination score requirement or submit their annual report. However, statutes do not specify the number of quarters that programs must maintain compliant scores before being removed from probation and the board has not yet addressed this issue."⁵¹

The OPPAGA recommended that the Legislature, "delineate the criteria and timeframe the board should use to place nursing education programs on probation and remove programs from probation."⁵²

- *Annual report:* The OPPAGA found that the BON's instructions for the 2009 Annual Report and Workforce Survey did not specify which items programs had to complete in order to comply with the statute. According to OPPAGA, the BON worked with the FCN to include the data elements required to be submitted to the BON by approved programs under s. 464.019(3)(c), F.S., in the FCN's annual electronic workforce survey. The instructions for the survey notified programs that they would be placed on probation if they failed to submit completed surveys by November 1, 2009. The survey, however, included items that were not required s. 464.019(3)(c), F.S., such as data on student demographics, changes to programs, and faculty information, which are used by the FCN to complete research reports. The OPPAGA indicated that the BON's survey instructions did not clearly indicate that these data were not statutorily mandated, creating the impression that programs could be placed on probation if they failed to include these additional data elements in their responses. The OPPAGA recommended that the BON clarify future directions for submitting the report.⁵³
- *BON Website:* The OPPAGA found, and the FCN concurred with the finding, that the BON's interactive website does not include all elements required by law.⁵⁴ OPPAGA indicated that the 2009 legislation required the BON to create an interactive website that enables the public to compare nursing programs using data points such as the program's approval status, retention, and examination scores; however, the website does not provide the accreditation status for all programs or retention rates for any programs. Additionally, the website does not allow users to readily compare all required data elements across programs.⁵⁵

The JAPC also monitored the BON's implementation of the 2009 legislation's rulemaking requirements. Since the bill took effect, JAPC staff notified BON legal counsel in writing of numerous concerns with the lack of rulemaking, but these issues were not addressed by the BON. As a result, JAPC staff presented a report on the BON's inaction at the committee's meeting held February 15, 2010. Two of the issues presented to the JAPC member related to s. 464.019(7), F.S., which directs BON to:

- Prescribe by rule the format for submitting program applications for new nursing programs. JAPC staff indicated that the BON has been using an "Application for New Nursing Program" without adopting it as a rule. JAPC staff also indicated that the application requires information that is not authorized by statute, and imposes a timeframe for granting or denying applications that is inconsistent with the APA.
- Prescribe by rule the format for submitting summary descriptions of program compliance for the annual report. JAPC staff indicated that the BON has not adopted this rule. According to JAPC staff, an "Affidavit" on the Board's website includes a section entitled "Summary Description." This affidavit is included in an annual report to be completed by programs, which appears to require information not authorized by statute.⁵⁶

⁵¹ *Id.*

⁵² See *supra* note 11 at p. 10.

⁵³ See *supra* note 11 at pp. 8, 10, & 14.

⁵⁴ See *supra* note 11 at p. 9 and note 18 at p. 1.

⁵⁵ See *supra* note 11 at pp. 9, 14, & 17.

⁵⁶ Joint Administrative Procedures Committee, Meeting Packet for February 15, 2010. Available at: http://www.leg.state.fl.us/cgi-bin/View_Page.pl?File=index_css.html&Directory=committees/joint/Japc&Tab=committees (last viewed March 7, 2010).

Since the JAPC hearing, the BON has noticed a teleconference meeting for March 12, 2010, which indicates that the BON will discuss the nursing education program application.⁵⁷

Effect of Proposed Changes

The bill builds upon the 2009 legislation's streamlining of the nursing education program regulation process by providing that a nursing education program that is accredited by one of the two specialized accrediting agencies that are nationally recognized by the US Secretary of Education to accredit nursing education programs is no longer subject to BON regulation for as long as the program maintains its accreditation. The BON approval process for non-accredited programs, as adopted in last year's bill, is retained, but implementation issues identified by the OPPAGA, FCN, and stakeholders are clarified. The following details the bill's proposed changes.

Nurse Practice Act

Definition Section: The bill makes technical amendments to s. 464.003, F.S., which sets forth definitions for the Act, to alphabetize section. It also amends existing definitions for two terms as follows:

- The definition for "approved program" is clarified to mean, "a program for the prelicensure education of practical or professional nurses that is conducted in the state at an educational institution and that is approved under s. 464.019." The definition also provides that, "the term includes a program placed on probationary status" so that the terms "approved program" and "program on probationary status" do not have to be separately and repeatedly stated throughout s. 464.019, F.S.
- The definition for "clinical preceptor" is amended to also authorize a LPN to act as a clinical preceptor. Current law only authorizes RNs to act as clinical preceptors. The bill also amends s. 464.019(1)(e), F.S., to specify that a clinical preceptor who supervises students in a professional nursing program must be a RN and that a clinical preceptor who supervises students in a practical nursing program must be a LPN.

The bill adds definitions for the following four new terms:

- "Accredited program" is defined to mean, "a program for the prelicensure education of professional or practical nurses that is conducted in the United States at an educational institution, whether in this state, another state, or the District of Columbia, and that is accredited by a specialized accrediting agency that is nationally recognized by the United States Secretary of Education to accredit nursing education programs." The NLNAC and CCNE are the only such accrediting agencies currently recognized by the Secretary.
- "Educational institution" is defined to mean, "a school, college, or university."
- "Graduate passage rate" is defined to mean, "the percentage of a program's graduates who, as first-time test takers, pass the National Council of State Boards of Nursing Licensing Examination during a calendar year, as calculated by the contract testing service of the National Council of State Boards of Nursing."
- "Required passage rate" is defined to mean, "the graduate passage rate required for an approved program pursuant to s. 464.019(6)(a)1., F.S." This subparagraph provides that the required passage rate is 10 percentage points, rather than 10 percent as in current law, below the national average passage rate on the NCLEX for U.S. educated, first-time test takers. It further specifies that the applicable national average passage rate is based on the type of program, i.e., an associate degree, a bachelor's degree, or a diploma professional nursing program or a practical nursing program.

Reorganization of s. 464.019, F.S.: The bill amends s. 464.019, F.S. to better organize the section by reordering and renumbering the existing subsections (1) through (9) to achieve the following order: (1) Program Applications; (2) Program Approval; (3) Status of Certain Programs; (4) Annual Report; (5) Internet Website; (6) Accountability; (7) Disclosure of Graduate Passage Rate Data; (8) Program Closure; (9) Rulemaking; (10) Applicability; and (11) Implementation Study.

⁵⁷ Florida Administrative Weekly, Board of Nursing Telephone Conference Meeting Notice for March 12, 2010, published February 26, 2010.

Accredited Programs

The bill amends s. 464.019(10), F.S., to provide that “accredited programs” conducted in this state are no longer subject to regulation by the BON for as long as the program maintains its accreditation. The only requirements an accredited program must comply with are those requiring a program that closes to notify the BON in writing of its arrangements for storage of permanent records and a program to respond to FCN and OPPAGA data requests.⁵⁸ The BON is specifically prohibited in s. 464.019(9), F.S., (formerly s. 464.019(7), F.S.) from imposing any condition or requirement on an accredited program except as expressly authorized in s. 464.019, F.S.

If an accredited program conducted in this state ceases to be accredited, it may apply to the BON to become an approved program.⁵⁹

Due to the bill’s recognition of accredited programs, the bill amends s. 464.008(1)(c), F.S., which sets forth the requirements an individual must meet to be eligible for licensure as a RN or LPN. Currently, this law specifies, in relevant part, that an individual must have graduated from an approved program, or its equivalent as determined by the BON. The bill retains these provisions, but adds that graduates of an accredited program on or after July 1, 2009, are also eligible, and further clarifies that persons who graduated from a prelicensure nursing education program before July 1, 2009, remain eligible for licensure if the program’s graduates were eligible to sit for the exam at the time they graduated.⁶⁰

Approved Programs

The bill substantially retains the BON approval process for non-accredited programs as established by the 2009 legislation, but makes changes, as described below, to address implementation issues identified by the OPPAGA, FCN, and stakeholders.

Program Applications: The bill amends s. 464.019(1), F.S., to:

- Reflect current practice that requires a program application and fee to be submitted for each prelicensure nursing education program to be offered at a main campus, branch campus, or other instructional site.
- Amend the faculty educational requirements that must be documented in a program application. Current law requires the program director and 50% of the faculty to have “a minimum” of a bachelor’s degree in nursing; however, some individuals may have a master’s or higher degree in nursing, but not a bachelor’s degree in nursing. Accordingly, the bill provides that the program director and 50% of the faculty members for a : (a) RN program must have a master’s or higher degree in nursing or a bachelor’s degree in nursing and a master’s or higher degree in a field related to nursing; and (b) LPN program must have a bachelor’s or higher degree in nursing.
- The bill adds a provision stating that the educational degree requirements for the program director or faculty may be documented by an official transcript or written statement by the educational institution verifying that it conferred the degree.

The bill also clarifies the timeframe for review of a program application. It specifies in s. 464.019(2), F.S. (formerly s. 464.019(3), F.S.) that the Department upon receiving an application and fee must review the application to determine if it is complete. If it is incomplete, the Department must notify the applicant in writing of any errors or omissions within 30 days. The bill further provides that an application is deemed complete upon the: (a) original date of receipt if the Department does not notify

⁵⁸ Section 464.019(8) and (11), F.S.

⁵⁹ Section 464.019(10), F.S.

⁶⁰ Prior to the July 1, 2009, effective date of ch. 2009-158, L.O.F., the BON recognized certain nursing education program graduates of Excelsior College (formerly Regents College) in New York as eligible for Florida RN licensure pursuant to a 1994 settlement agreement between the BON and the college. See *Regents College v. Florida Board of Nursing*, 2nd Judicial Circuit in Leon Co., Case No. 94-4314, Stipulation and Agreed Upon Order (1994). Subsequent to the 2009 legislation, the BON indicated that it would no longer automatically recognize these graduates as eligible for licensure; instead, the BON now individually determines whether each graduate is eligible by conducting a review of the individual’s professional medical experience and education. Currently, there are almost 1,200 Florida residents enrolled in the college’s nursing program. See Letter from Excelsior College dated November 4, 2009. Excelsior’s nursing program is accredited by the NLNAC. Thus, under the bill, graduates of the college or any other CCNE or NLNAC accredited program located in the U.S. will be eligible for licensure, if the graduate meets other eligibility requirements specified in current law.

the applicant of any errors or omissions within the 30-day period; or (b) date the Department receives a revised application that corrects each error and omission. As in current law, the BON must approve or deny a completed application within 90 days after receipt.

Annual Report: The bill amends s. 464.019(4), F.S. (formerly s. 464.019(2)(c), F.S.), to clarify that the annual report consists of an affidavit certifying continued compliance with paragraphs (1)(a) through (g), a summary description of that compliance, and other specified data. The bill amends the data requirements to specify that such data must be submitted to the "extent applicable" in order to recognize that newly approved programs may not yet have data available for submission. It also adds new data requirements. Under the bill, approved programs must also document the: (a) number of accepted applicants who enroll in program and the total number of students enrolled in program; and (b) program's accrediting agency, if it is accredited by an agency other than the NLNAC or CCNE.

In s. 464.019(9), F.S. (formerly s. 464.019(7), F.S.), the bill directs the BON to adopt a rule prescribing the format for the annual report. Current law only authorizes the BON to prescribe the format for the summary descriptions of program compliance.

Internet Website: The bill adds a requirement in s. 464.019(5), F.S. (formerly s. 464.019(4), F.S.) that the BON must publish on its website a list of each accredited program and the program's graduate passage rates for the two most recent calendar years. The accredited programs are not required to provide the BON with this data; rather, the Department is required to determine this information through the following sources: (a) the specialized accrediting agencies that are nationally recognized by the United States Secretary of Education to accredit nursing education programs; and (b) the contract testing service of the NCSBN.

The bill also makes technical conforming changes to s. 464.019(5)(b) & (c), F.S. (formerly s. 464.019(4)(a)-(h), F.S.), which relates to the data the BON must publish on its website for approved programs. The only substantive changes made by the bill are that: (a) approved program graduate passage rates and national average passage rates on the NCLEX must be published for two, rather than one, calendar years; and (b) the national average passage rate must be published for each individual program type.

BON Regulation of Approved Programs: For a program that was on probation on June 30, 2009, F.S., because it did not meet the BON's requirement for graduate passage rates, the bill clarifies s. 464.019(3), F.S. (formerly s. 464.019(2), F.S.) to provide that such program is an approved program, but that it shall remain on probation until it achieves the required passage rate for either the 2009 or 2010 calendar year. As in current law, the program must be terminated by the BON if it does not timely achieve the required passage rate. This provision will no longer apply to an accredited program as of the bill's July 1, 2010 effective date. See s. 464.019(10), F.S.

For other approved programs, the bill continues, as in current law, to require the BON to monitor the programs' compliance with NCLEX graduate passage rate and annual report requirements. Regarding the requirements for graduate passage rates, the only substantive changes made by the bill in s. 464.019(6)(a), F.S. (formerly s. 464.019(5), F.S.), are that:

- The bill provides that the required passage rate on the NCLEX for an approved program shall be 10 percentage points, rather than 10 percent, below the national average passage rate for the applicable program type.
- The bill clarifies that the requirements for graduate passage rates, which should have only been applied prospectively by the BON under the 2009 legislation, apply to graduate passage rates beginning with the 2010 calendar year.
- The bill clarifies that a program placed on probation for having had two consecutive calendar years of inadequate graduate passage rates must be removed from probation when the program achieves the required passage rate for one calendar year.

As in current law, the approved program must be terminated by the BON if it does not achieve the required passage rate within two calendar years.

Regarding the annual report requirements, the only substantive change made by the bill to s. 464.019(6)(b), F.S. (formerly s. 464.019(5)(b), F.S.), is that probation is eliminated as a penalty for an approved program's failure to timely submit the annual report. Instead, the bill requires the program director to appear before the BON to explain the delay. As in current law, the program must be terminated by the BON if it does not submit the report within six months after its due date.

Disclosure of Graduate Passage Rate Data

The bill amends s. 456.014, F.S., to provide that certain information relating to an applicant for licensure may be provided by the Department to a program director of an approved program or accredited program pursuant to s. 464.019(7), F.S. Subsection (7) states that a program director may make a written request to the Department for the disclosure of the following information relating to each program graduate included in the program's graduate passage rate: the graduate's name, the date the graduate took the NCLEX, and the determination of whether the graduate passed or failed the NCLEX. The program director must maintain the confidentiality of the information in the same manner as Department employees.

Conforming Changes and Effective Date

The bill amends ss. 464.015 and 464.033, F.S., to make conforming changes for the bill's recognition of accredited programs. The bill amends ss. 458.348, 459.025, 464.012, and 960.28, F.S., to conform cross-references to changes made by the bill. The bill provides an effective date of July 1, 2010.

B. SECTION DIRECTORY:

Section 1: Amends s. 456.014, F.S., relating to public inspection of information required by applicants for licensure by the Department.

Section 2: Amends s. 464.003, F.S., relating to definitions for the Nurse Practice Act.

Section 3: Amends s. 464.008, F.S., relating to licensure by examination.

Section 4: Amends s. 464.015, F.S., relating to titles and abbreviations for nurses.

Section 5: Amends s. 464.019, F.S., relating to approval of nursing education programs.

Section 6: Amends s. 464.022, F.S., relating to the practice of nursing pending NCLEX results.

Sections 7-10: Amending ss. 458.348, 459.025, 464.012, and 960.28, F.S., conforming cross-references to changes made by the bill.

Section 11: Providing an effective date of July 1, 2009.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

The Department and BON should incur a savings as a result of the bill's provisions that no longer require the Department or BON to regulate accredited programs.

2. Expenditures:

The Department indicates it will incur costs of \$78,795 because it will have to modify its existing list of approved schools on its website to accommodate the bill's requirement that it list accredited programs. The DOH was required to establish this website by the 2009 legislation and to provide specified data on all approved programs, including approved programs that are accredited.

Accordingly, this bill does not appear to create a fiscal impact, given that these requirements currently exist. Further, as indicated above, the Department should incur a savings a result of the bill's provisions that no longer require the Department or BON to regulate accredited programs.

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:

The bill provides that the BON shall adopt a rule that prescribes the format for the annual reports required under s. 464.019, F.S.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COUNCIL OR COMMITTEE SUBSTITUTE CHANGES

On March 10, 2010, the State Universities & Private Colleges Policy Committee adopted four amendments to HB 1337 and reported the bill favorably as a Committee Substitute (CS). These amendments technically clarified: (a) the definition of "accredited program" so that it reflects the terminology used by the federal Department of Education; and (b) that the bill applies to any prelicensure nursing program regardless of the credential awarded. This analysis is drafted to the CS.

1 A bill to be entitled
 2 An act relating to nursing; amending s. 456.014, F.S.;
 3 authorizing the disclosure of certain confidential
 4 information required of nursing license applicants to
 5 certain persons; amending s. 464.003, F.S.; providing and
 6 revising definitions; amending s. 464.008, F.S.; revising
 7 requirements for graduation from certain nursing education
 8 programs for nursing license applicants seeking to take
 9 the licensing examination; amending s. 464.015, F.S.;
 10 revising restrictions on nursing graduates who may use
 11 certain titles and abbreviations; amending s. 464.019,
 12 F.S.; revising requirements for the approval of nursing
 13 education programs by the Board of Nursing, including
 14 application requirements and procedures for the review and
 15 approval or denial of applications; revising requirements
 16 for the approval of nursing education programs meeting
 17 certain requirements before a specified date; providing
 18 for retroactive application; revising requirements for the
 19 submission of annual reports by approved programs;
 20 revising requirements for the information published on the
 21 board's Internet website; revising accountability
 22 requirements for an approved program's graduate passage
 23 rates on a certain licensing examination; revising
 24 procedures for placing programs on, and removing such
 25 programs, from probationary status; requiring termination
 26 of programs under certain circumstances; requiring certain
 27 representatives of programs that fail to submit annual
 28 reports to appear before the board; requiring the

29 Department of Health to disclose certain confidential
 30 information about a program's graduates to the program
 31 director under certain circumstances; requiring program
 32 directors to maintain the confidentiality of such
 33 information; providing penalties for unlawful disclosure
 34 of confidential information; revising the board's
 35 authority to adopt rules; exempting accredited programs
 36 from specified requirements; conforming provisions;
 37 deleting obsolete provisions; revising requirements for
 38 the Florida Center for Nursing's evaluation of the board's
 39 implementation of certain accountability provisions;
 40 conforming cross-references; amending s. 464.022, F.S.;
 41 conforming provisions; amending ss. 458.348, 459.025,
 42 464.012, and 960.28, F.S.; conforming cross-references;
 43 providing an effective date.

44

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

46

47 Section 1. Subsection (1) of section 456.014, Florida
 48 Statutes, is amended to read:

49 456.014 Public inspection of information required from
 50 applicants; exceptions; examination hearing.-

51 (1) All information required by the department of any
 52 applicant shall be a public record and shall be open to public
 53 inspection pursuant to s. 119.07, except financial information,
 54 medical information, school transcripts, examination questions,
 55 answers, papers, grades, and grading keys, which are
 56 confidential and exempt from s. 119.07(1) and shall not be

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57 | discussed with or made accessible to anyone except the program
 58 | director of an approved program or accredited program as
 59 | provided in s. 464.019(7), members of the board, the department,
 60 | and staff thereof, who have a bona fide need to know such
 61 | information. Any information supplied to the department by any
 62 | other agency which is exempt from the provisions of chapter 119
 63 | or is confidential shall remain exempt or confidential pursuant
 64 | to applicable law while in the custody of the department or the
 65 | agency.

66 | Section 2. Section 464.003, Florida Statutes, is reordered
 67 | and amended to read:

68 | 464.003 Definitions.—As used in this part, the term:

69 | (1) "Accredited program" means a program for the
 70 | prelicensure education of professional or practical nurses that
 71 | is conducted in the United States at an educational institution,
 72 | whether in this state, another state, or the District of
 73 | Columbia, and that is accredited by a specialized accrediting
 74 | agency that is nationally recognized by the United States
 75 | Secretary of Education to accredit nursing education programs.

76 | ~~(13)(1)~~ "Department" means the Department of Health.

77 | ~~(5)(2)~~ "Board" means the Board of Nursing.

78 | ~~(20)(3)(a)~~ "Practice of professional nursing" means the
 79 | performance of those acts requiring substantial specialized
 80 | knowledge, judgment, and nursing skill based upon applied
 81 | principles of psychological, biological, physical, and social
 82 | sciences which shall include, but not be limited to:

83 | ~~(a)1.~~ The observation, assessment, nursing diagnosis,
 84 | planning, intervention, and evaluation of care; health teaching

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85 and counseling of the ill, injured, or infirm; and the promotion
 86 of wellness, maintenance of health, and prevention of illness of
 87 others.

88 ~~(b)2.~~ The administration of medications and treatments as
 89 prescribed or authorized by a duly licensed practitioner
 90 authorized by the laws of this state to prescribe such
 91 medications and treatments.

92 ~~(c)3.~~ The supervision and teaching of other personnel in
 93 the theory and performance of any of the ~~above~~ acts described in
 94 this subsection.

95
 96 A professional nurse is responsible and accountable for making
 97 decisions that are based upon the individual's educational
 98 preparation and experience in nursing.

99 ~~(19)(b)~~ "Practice of practical nursing" means the
 100 performance of selected acts, including the administration of
 101 treatments and medications, in the care of the ill, injured, or
 102 infirm and the promotion of wellness, maintenance of health, and
 103 prevention of illness of others under the direction of a
 104 registered nurse, a licensed physician, a licensed osteopathic
 105 physician, a licensed podiatric physician, or a licensed
 106 dentist. ~~A The professional nurse and the practical nurse is~~
 107 ~~shall be~~ responsible and accountable for making decisions that
 108 are based upon the individual's educational preparation and
 109 experience in nursing.

110 ~~(7)(e)~~ "Clinical nurse specialist practice" means the
 111 delivery and management of advanced practice nursing care to
 112 individuals or groups, including the ability to:

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113 (a)1. Assess the health status of individuals and families
 114 using methods appropriate to the population and area of
 115 practice.

116 (b)2. Diagnose human responses to actual or potential
 117 health problems.

118 (c)3. Plan for health promotion, disease prevention, and
 119 therapeutic intervention in collaboration with the patient or
 120 client.

121 (d)4. Implement therapeutic interventions based on the
 122 nurse specialist's area of expertise and within the scope of
 123 advanced nursing practice, including, but not limited to, direct
 124 nursing care, counseling, teaching, and collaboration with other
 125 licensed health care providers.

126 (e)5. Coordinate health care as necessary and appropriate
 127 and evaluate with the patient or client the effectiveness of
 128 care.

129 (2)(d) "Advanced or specialized nursing practice" means,
 130 in addition to the practice of professional nursing, the
 131 performance of advanced-level nursing acts approved by the board
 132 which, by virtue of postbasic specialized education, training,
 133 and experience, are appropriately performed by an advanced
 134 registered nurse practitioner. Within the context of advanced or
 135 specialized nursing practice, the advanced registered nurse
 136 practitioner may perform acts of nursing diagnosis and nursing
 137 treatment of alterations of the health status. The advanced
 138 registered nurse practitioner may also perform acts of medical
 139 diagnosis and treatment, prescription, and operation which are
 140 identified and approved by a joint committee composed of three

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141 members appointed by the Board of Nursing, two of whom must be
 142 advanced registered nurse practitioners; three members appointed
 143 by the Board of Medicine, two of whom must have had work
 144 experience with advanced registered nurse practitioners; and the
 145 State Surgeon General or the State Surgeon General's designee.
 146 Each committee member appointed by a board shall be appointed to
 147 a term of 4 years unless a shorter term is required to establish
 148 or maintain staggered terms. The Board of Nursing shall adopt
 149 rules authorizing the performance of any such acts approved by
 150 the joint committee. Unless otherwise specified by the joint
 151 committee, such acts must be performed under the general
 152 supervision of a practitioner licensed under chapter 458,
 153 chapter 459, or chapter 466 within the framework of standing
 154 protocols which identify the medical acts to be performed and
 155 the conditions for their performance. The department may, by
 156 rule, require that a copy of the protocol be filed with the
 157 department along with the notice required by s. 458.348.

158 (17)~~(e)~~ "Nursing diagnosis" means the observation and
 159 evaluation of physical or mental conditions, behaviors, signs
 160 and symptoms of illness, and reactions to treatment and the
 161 determination as to whether such conditions, signs, symptoms,
 162 and reactions represent a deviation from normal.

163 (18)~~(f)~~ "Nursing treatment" means the establishment and
 164 implementation of a nursing regimen for the care and comfort of
 165 individuals, the prevention of illness, and the education,
 166 restoration, and maintenance of health.

167 (22)~~(4)~~ "Registered nurse" means any person licensed in
 168 this state to practice professional nursing.

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169 ~~(16)~~~~(5)~~ "Licensed practical nurse" means any person
 170 licensed in this state to practice practical nursing.

171 (6) "Clinical nurse specialist" means any person licensed
 172 in this state to practice professional nursing and certified in
 173 clinical nurse specialist practice.

174 ~~(3)~~~~(7)~~ "Advanced registered nurse practitioner" means any
 175 person licensed in this state to practice professional nursing
 176 and certified in advanced or specialized nursing practice,
 177 including certified registered nurse anesthetists, certified
 178 nurse midwives, and nurse practitioners.

179 ~~(4)~~~~(8)~~ "Approved program" means a ~~nursing~~ program for the
 180 prelicensure education of professional or practical nurses that
 181 is conducted in the state at an educational institution and that
 182 is in a school, college, or university which is approved under
 183 s. 464.019 for the education of nurses. The term includes such a
 184 program placed on probationary status.

185 ~~(10)~~~~(9)~~ "Clinical training" means direct nursing care
 186 experiences with patients or clients which offer the student the
 187 opportunity to integrate, apply, and refine specific skills and
 188 abilities based on theoretical concepts and scientific
 189 principles.

190 ~~(8)~~~~(10)~~ "Clinical preceptor" means a registered nurse or
 191 licensed practical nurse who is employed by a clinical training
 192 facility to serve ~~who serves~~ as a role model and clinical
 193 resource person for a specified period to students ~~an individual~~
 194 enrolled in an approved program.

195 ~~(9)~~~~(11)~~ "Clinical simulation" means a strategy used to
 196 replicate clinical practice as closely as possible to teach

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197 theory, assessment, technology, pharmacology, and skills.

198 (11)~~(12)~~ "Community-based clinical experience" means
 199 activities consistent with the curriculum and involving
 200 individuals, families, and groups with the intent of promoting
 201 wellness, maintaining health, and preventing illness.

202 (12)~~(13)~~ "Curriculum" means a planned sequence of course
 203 offerings and learning experiences that comprise a nursing
 204 education program.

205 (21)~~(14)~~ "Probationary status" means the status of an
 206 approved a nursing education program that is placed on such
 207 status pursuant subject to s. 464.019~~(2)(a)2. or (5)(a) or (b).~~

208 (14) "Educational institution" means a school, college, or
 209 university.

210 (15) "Graduate passage rate" means the percentage of a
 211 program's graduates who, as first-time test takers, pass the
 212 National Council of State Boards of Nursing Licensing
 213 Examination during a calendar year, as calculated by the
 214 contract testing service of the National Council of State Boards
 215 of Nursing.

216 (23) "Required passage rate" means the graduate passage
 217 rate required for an approved program pursuant to s.
 218 464.019(6)(a)1.

219 Section 3. Subsection (1) of section 464.008, Florida
 220 Statutes, is amended to read:

221 464.008 Licensure by examination.—

222 (1) Any person desiring to be licensed as a registered
 223 nurse or licensed practical nurse shall apply to the department
 224 to take the licensure examination. The department shall examine

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225 each applicant who:

226 (a) Has completed the application form and remitted a fee
 227 set by the board not to exceed \$150 and has remitted an
 228 examination fee set by the board not to exceed \$75 plus the
 229 actual per applicant cost to the department for purchase of the
 230 examination from the National Council of State Boards of Nursing
 231 or a similar national organization.

232 (b) Has provided sufficient information on or after
 233 October 1, 1989, which must be submitted by the department for a
 234 statewide criminal records correspondence check through the
 235 Department of Law Enforcement.

236 (c) Is in good mental and physical health, is a recipient
 237 of a high school diploma or the equivalent, and has completed
 238 the requirements for:

- 239 1. Graduation from an approved program;
- 240 2. Graduation from a prelicensure nursing education
 241 program that the board determines is, ~~or its~~ equivalent to an
 242 approved program;
- 243 3. Graduation on or after July 1, 2009, from an accredited
 244 program; or
- 245 4. Graduation before July 1, 2009, from a prelicensure
 246 nursing education program whose graduates at that time were
 247 eligible for examination as determined by the board, for the
 248 preparation of registered nurses or licensed practical nurses,
 249 whichever is applicable.

250
 251 Courses successfully completed in a professional nursing
 252 education program that ~~which~~ are at least equivalent to a

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253 practical nursing education program may be used to satisfy the
 254 education requirements for licensure as a licensed practical
 255 nurse.

256 (d) Has the ability to communicate in the English
 257 language, which may be determined by an examination given by the
 258 department.

259 Section 4. Subsections (3) and (4) of section 464.015,
 260 Florida Statutes, are amended to read:

261 464.015 Titles and abbreviations; restrictions; penalty.—

262 (3) Only persons who are graduates of prelicensure nursing
 263 education approved programs listed in s. 464.008(1)(c) ~~or the~~
 264 ~~equivalent~~ may use the term "Graduate Nurse" and the
 265 abbreviation "G.N.," pending the results of the first licensure
 266 examination for which they are eligible.

267 (4) Only persons who are graduates of prelicensure nursing
 268 education approved programs listed in s. 464.008(1)(c) ~~or the~~
 269 ~~equivalent~~ may use the term "Graduate Practical Nurse" and the
 270 abbreviation "G.P.N.," pending the results of the first
 271 licensure examination for which they are eligible.

272 Section 5. Section 464.019, Florida Statutes, is reordered
 273 and amended to read:

274 464.019 Approval of nursing education programs.—

275 (1) PROGRAM APPLICATIONS.—An educational institution that
 276 wishes to conduct a program in this state for the prelicensure
 277 education of professional or practical nurses must ~~shall~~ submit
 278 to the department a program application and ~~a program~~ review fee
 279 of \$1,000 for each prelicensure nursing education program to be
 280 offered at the institution's main campus, branch campus, or

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281 ~~other instructional site the department. Within 90 days after~~
 282 ~~receipt of a program application and program review fee, the~~
 283 ~~board shall approve the program application if it documents~~
 284 ~~compliance with the standards in paragraphs (a) (h). If the~~
 285 ~~program application is incomplete or does not document~~
 286 ~~compliance, the board shall follow the procedures in subsection~~
 287 ~~(3). a program application is deemed approved by the board if~~
 288 ~~the board does not act on the application within the timeframes~~
 289 ~~specified in subsection (3) or this subsection. Each program~~
 290 application must document that:

291 (a) 1. For a professional nursing education program, the
 292 program director and at least 50 percent of the program's
 293 faculty members are registered nurses who have, ~~at a minimum,~~ a
 294 master's or higher bachelor's degree in nursing or a bachelor's
 295 ~~and a master's~~ degree in nursing and a master's or higher degree
 296 in a field or a related to nursing field.

297 2. (b) For a practical nursing education program, the
 298 program director and at least 50 percent of the program's
 299 faculty members are registered nurses who have, ~~at a minimum,~~ a
 300 bachelor's or higher degree in nursing.

301
 302 The educational degree requirements of this paragraph may be
 303 documented by an official transcript or by a written statement
 304 from the educational institution verifying that the institution
 305 conferred the degree.

306 (b) ~~(e)~~ The program's nursing major curriculum consists of
 307 at least:

308 1. Fifty percent clinical training for a practical nursing

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309 education program, an associate degree professional nursing
 310 education program, or a professional diploma nursing education
 311 program.

312 2. Forty percent clinical training for a bachelor's degree
 313 professional nursing education program.

314 ~~(c)(d)~~ No more than 25 percent of the program's clinical
 315 training consists of clinical simulation.

316 ~~(d)(e)~~ The program has signed agreements with each agency,
 317 facility, and organization included in the curriculum plan as
 318 clinical training sites and community-based clinical experience
 319 sites.

320 ~~(e)(f)~~ The program has written policies for faculty which
 321 include provisions for direct or indirect supervision by program
 322 faculty or clinical preceptors for students in clinical training
 323 consistent with the following standards:

324 1. The number of program faculty members equals at least
 325 one faculty member directly supervising every 12 students unless
 326 the written agreement between the program and the agency,
 327 facility, or organization providing clinical training sites
 328 allows more students, not to exceed 18 students, to be directly
 329 supervised by one program faculty member.

330 2. For a hospital setting, indirect supervision may occur
 331 only if there is direct supervision by an assigned clinical
 332 preceptor, a supervising program faculty member is available by
 333 telephone, and such arrangement is approved by the clinical
 334 facility.

335 3. For community-based clinical experiences that involve
 336 student participation in invasive or complex nursing activities,

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337 students must be directly supervised by a program faculty member
338 or clinical preceptor and such arrangement must be approved by
339 the community-based clinical facility.

340 4. For community-based clinical experiences not subject to
341 subparagraph 3., indirect supervision may occur only when a
342 supervising program faculty member is available to the student
343 by telephone.

344

345 A program's policies established under this paragraph must
346 require a clinical preceptor, if supervising students in a
347 professional nursing education program, to be a registered nurse
348 or, if supervising students in a practical nursing education
349 program, to be a registered nurse or licensed practical nurse.

350 ~~(f)(g)~~ The professional or practical nursing curriculum
351 plan documents clinical experience and theoretical instruction
352 in medical, surgical, obstetric, pediatric, and geriatric
353 nursing. A professional nursing curriculum plan shall also
354 document clinical experience and theoretical instruction in
355 psychiatric nursing. Each curriculum plan must document clinical
356 training experience in appropriate settings that include, but
357 are not limited to, acute care, long-term care, and community
358 settings.

359 ~~(g)(h)~~ The professional or practical nursing education
360 program provides theoretical instruction and clinical
361 application in personal, family, and community health concepts;
362 nutrition; human growth and development throughout the life
363 span; body structure and function; interpersonal relationship
364 skills; mental health concepts; pharmacology and administration

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365 of medications; and legal aspects of practice. A professional
 366 nursing education program shall also provide theoretical
 367 instruction and clinical application in interpersonal
 368 relationships and leadership skills; professional role and
 369 function; and health teaching and counseling skills.

370
 371 ~~Upon the board's approval of a program application, the program~~
 372 ~~becomes an approved program under this section.~~

373 (3)-(2) STATUS OF CERTAIN PROGRAMS.-

374 ~~(a)~~ (a) A professional or practical nursing education program
 375 becomes an approved program if that, as of June 30, 2009, the
 376 program:

377 (a)1- Has full or provisional approval from the board or,
 378 except as provided in paragraph (b), is on probationary status,
 379 ~~except as provided in subparagraph 2., becomes an approved~~
 380 ~~program under this section. In order to retain approved program~~
 381 ~~status, such program shall submit the report required under~~
 382 ~~paragraph (c) to the board by November 1, 2009, and annually~~
 383 ~~thereafter.~~

384 (b)2- Is on probationary status because the program did
 385 not meet the board's requirement for ~~program~~ graduate passage
 386 rates. Such program on the National Council of State Boards of
 387 Nursing Licensing Examination, shall remain on probationary
 388 status until it the program achieves a graduate passage rate for
 389 calendar year 2009 or 2010 that equals or exceeds the required
 390 passage rate for the respective calendar year and compliance
 391 with the program graduate passage rate requirement in paragraph
 392 ~~(5) (a).~~ A program that is subject to this subparagraph must

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393 disclose its probationary status in writing to the program's
 394 students and applicants ~~submit the report required under~~
 395 ~~paragraph (c) to the board by November 1, 2009, and annually~~
 396 ~~thereafter and must comply with paragraph (5)(c).~~ If the program
 397 does not achieve the required passage rate ~~compliance by July 1,~~
 398 ~~2011,~~ the board shall terminate the program pursuant to chapter
 399 120 as provided in paragraph (5)(d).

400 ~~(b) Each professional or practical nursing program that~~
 401 ~~has its application approved by the board under subsection (1)~~
 402 ~~on or after July 1, 2009, shall annually submit the report~~
 403 ~~required under paragraph (c) to the board by November 1 of each~~
 404 ~~year following initial approval of its application.~~

405 (4) ANNUAL REPORT.—By November 1 of each year, each
 406 approved program shall submit to the board an

407 ~~(c) The annual report~~ comprised of required by this
 408 ~~subsection must include~~ an affidavit certifying continued
 409 compliance with paragraphs (1)(a)-(g) ~~subsection (1), must~~
 410 ~~provide~~ a summary description of the program's compliance with
 411 paragraphs (1)(a)-(g) ~~with subsection (1), and~~ documentation
 412 ~~must document~~ for the previous academic year that, to the extent
 413 applicable, sets forth ~~for each professional and practical~~
 414 ~~nursing program:~~

415 (a)1. The number of student applications received, ~~the~~
 416 ~~number of~~ qualified applicants, applicants ~~and the number of~~
 417 ~~students~~ accepted, accepted applicants who enroll in the
 418 program, students enrolled in the program, and

419 ~~2. the number of program graduates.~~

420 ~~3. The program's graduate passage rate on the National~~

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421 ~~Council of State Boards of Nursing Licensing Examination.~~

422 ~~(b)4.~~ The program's retention rates for students tracked
423 from program entry to graduation.

424 ~~(c)5.~~ The program's accreditation status, including
425 identification of the accrediting agency if such agency is not
426 an accrediting agency described in s. 464.003(1) body.

427 ~~(2)(3)~~ PROGRAM APPROVAL.-

428 (a) Upon receipt of a ~~If an institution's~~ program
429 application and review fee, the department shall examine the
430 application to determine whether it is complete. If a program
431 application is not complete ~~incomplete~~, the department board
432 shall notify the educational institution in writing of any
433 ~~apparent~~ errors or omissions within 30 days after the
434 department's receipt of the application ~~and follow the~~
435 ~~procedures in s. 120.60.~~ A program application is deemed
436 complete upon the department's receipt of:

437 1. The initial application, if the department does not
438 notify the educational institution of any errors or omissions
439 within the 30-day period; or

440 2. A revised application that corrects each error and
441 omission of which the department notifies the educational
442 institution within the 30-day period.

443 (b) Within 90 days after the department's receipt of a
444 complete program application, the board shall:

445 1. Approve the ~~If an institution's~~ program application if
446 it documents ~~does not document~~ compliance with paragraphs
447 (1)(a)-(g); or the standards in subsection (1), within 90 days
448 after the board's receipt of the program application, the board

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449 ~~shall~~

450 2. Provide the educational institution with a notice of
 451 intent to deny the program application if it does not document
 452 compliance with paragraphs (1)(a)-(g) that sets forth written
 453 reasons for the denial. The notice must set forth written
 454 reasons for the board's denial of the application. The board may
 455 not deny a program application because of an educational
 456 institution's failure to correct any error or omission of which
 457 the department does not notify the institution within the 30-day
 458 notice period under paragraph (a). The educational institution
 459 may request a hearing on the notice of intent to deny the
 460 program application pursuant to chapter 120.

461 (c) A program application is deemed approved if the board
 462 does not act within the 90-day review period provided under
 463 paragraph (b).

464 (d) Upon the board's approval of a program application,
 465 the program becomes an approved program.

466 ~~(5)(4)~~ INTERNET WEBSITE.—The board shall publish the
 467 following information on its Internet website:

468 (a) A list of each accredited program conducted in the
 469 state and the program's graduate passage rates for the most
 470 recent 2 calendar years, which the department shall determine
 471 through the following sources:

472 1. For a program's accreditation status, the specialized
 473 accrediting agencies that are nationally recognized by the
 474 United States Secretary of Education to accredit nursing
 475 education programs.

476 2. For a program's graduate passage rates, the contract

477 testing service of the National Council of State Boards of
 478 Nursing.

479 (b) The following data for each approved program, which on
 480 nursing programs located in the state. The data shall include,
 481 to the extent applicable:

482 1.(a) All documentation provided by the program in its
 483 applicant for each approved nursing program application if
 484 submitted on or after July 1, 2009.

485 2.(b) The summary description of the each program's
 486 compliance as submitted under subsection (4) paragraph (2)(c).

487 ~~(c) A comprehensive list of each practical and~~
 488 ~~professional nursing program in the state.~~

489 3.(d) The program's accreditation status for each program,
 490 including identification of the accrediting agency if such
 491 agency is not an accrediting agency described in s. 464.003(1)
 492 body.

493 4.(e) The Each program's approval or probationary status.

494 5.(f) The Each program's graduate passage rates for the
 495 most recent 2 calendar years rate on the National Council of
 496 State Boards of Nursing Licensing Examination.

497 ~~(g) The national average for passage rates on the National~~
 498 ~~Council of State Boards of Nursing Licensing Examination.~~

499 6.(h) Each program's retention rates for students tracked
 500 from program entry to graduation.

501 (c) The average passage rates for United States educated
 502 first-time test takers on the National Council of State Boards
 503 of Nursing Licensing Examination for the most recent 2 calendar
 504 years, as calculated by the contract testing service of the

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505 National Council of State Boards of Nursing. The average passage
 506 rates shall be published separately for each type of comparable
 507 degree program listed in sub-subparagraphs (6)(a)1.a.-d.

508
 509 The information ~~data~~ required to be published under this
 510 subsection shall be made available in a manner that allows
 511 interactive searches and comparisons of individual specific
 512 nursing education programs selected by the website user. The
 513 board shall ~~publish the data by December 31, 2009,~~ and update
 514 the Internet website at least quarterly with the available
 515 information data.

516 ~~(6)(5)~~ ACCOUNTABILITY.-

517 (a) 1. An approved program must achieve a graduate passage
 518 rate that is not lower than 10 percentage points less than the
 519 average passage rate for graduates of comparable degree programs
 520 who are United States educated first-time test takers on the
 521 National Council of State Boards of Nursing Licensing
 522 Examination during a calendar year, as calculated by the
 523 contract testing service of the National Council of State Boards
 524 of Nursing. For purposes of this subparagraph, an approved
 525 program is comparable to all degree programs of the same program
 526 type from among the following program types:

527 a. Professional nursing education programs that terminate
 528 in a bachelor's degree.

529 b. Professional nursing education programs that terminate
 530 in an associate degree.

531 c. Professional nursing education programs that terminate
 532 in a diploma.

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533 d. Practical nursing education programs.
534 2. Beginning with graduate passage rates for calendar year
535 2010, if an approved a professional or practical nursing
536 program's average graduate passage rates do not equal or exceed
537 the required passage rates rate for first time test takers on
538 the National Council of State Boards of Nursing Licensing
539 Examination falls 10 percent or more below the national average
540 passage rate for first time test takers educated in the United
541 States, as annually published by the contract testing service of
542 the National Council of State Boards of Nursing, for 2
543 consecutive calendar years, the board shall place the program on
544 probationary status pursuant to chapter 120 probation and the
545 program director must shall be required to appear before the
546 board to present a plan for remediation. The program shall
547 remain on probationary status until it achieves a compliance
548 with the graduate passage rate that equals or exceeds the
549 required passage rate for any one calendar year.

550 3. Upon the program's achievement of a graduate passage
551 rate that equals or exceeds the required passage rate,
552 requirement and shall be terminated by the board, at its next
553 regularly scheduled meeting following release of the program's
554 graduate passage rate by the National Council of State Boards of
555 Nursing, shall remove the program's probationary status.
556 However, under paragraph (d) if the program, during the 2
557 calendar years following its placement on probationary status,
558 does not achieve the required passage rate for any one
559 compliance within 2 calendar year, the board shall terminate the
560 program pursuant to chapter 120 years.

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561 (b) If an approved a program fails to submit the annual
 562 report required in subsection (4) ~~(2)~~, the board shall notify
 563 the program director and president or chief executive officer of
 564 the educational institution in writing within 15 days after the
 565 due date of the annual report. The program director must appear
 566 before the board at the board's next regularly scheduled meeting
 567 to explain the reason for the delay ~~place the program on~~
 568 ~~probation.~~ The board ~~program~~ shall terminate the program
 569 pursuant to chapter 120 ~~remain on probationary status until it~~
 570 ~~submits the annual report and shall be terminated by the board~~
 571 ~~under paragraph (d)~~ if it does not submit the annual report
 572 within 6 months after the ~~report's~~ due date.

573 (c) An approved A program ~~placed~~ on probationary status
 574 shall disclose its probationary status in writing to the
 575 program's students and applicants.

576 ~~(d) The board shall terminate a program that fails to~~
 577 ~~comply with subparagraph (2)(a)2., paragraph (a), or paragraph~~
 578 ~~(b) pursuant to chapter 120.~~

579 (7) DISCLOSURE OF GRADUATE PASSAGE RATE DATA.-

580 (a) For each of an approved program's or accredited
 581 program's graduates included in the calculation of the program's
 582 graduate passage rate, the department shall disclose to the
 583 program director, upon his or her written request, the name,
 584 examination date, and determination of whether each graduate
 585 passed or failed the National Council for State Boards of
 586 Nursing Licensing Examination, to the extent that such
 587 information is provided to the department by the contract
 588 testing service of the National Council for State Boards of

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589 Nursing. The written request must specify the calendar years for
 590 which the information is requested.

591 (b) A program director to whom confidential information
 592 exempt from public disclosure pursuant to s. 456.014 is
 593 disclosed under this subsection must maintain the
 594 confidentiality of the information and is subject to the same
 595 penalties provided in s. 456.082 for department employees who
 596 unlawfully disclose confidential information.

597 (8)(6) PROGRAM CLOSURE.—Each approved program and
 598 accredited ~~a nursing~~ program conducted in the state that closes
 599 shall notify the board in writing and advise the board of the
 600 arrangements for storage of permanent records.

601 (9)(7) RULEMAKING.—The board does not have any rulemaking
 602 authority to administer this section, except that the board
 603 shall adopt a rule that prescribes the format for submitting
 604 program applications under subsection (1) and annual reports
 605 ~~submitting summary descriptions of program compliance~~ under
 606 subsection (4) ~~paragraph (2)(c)~~. The board may not impose any
 607 condition or requirement on an educational institution
 608 submitting a program application, an approved program, or an
 609 accredited program, ~~a program on probationary status~~ except as
 610 expressly provided in this section. The board shall repeal all
 611 rules, or portions thereof, in existence on July 1, 2009, that
 612 are inconsistent with this subsection.

613 (10) APPLICABILITY.—Subsections (1)-(4), paragraph (5)(b),
 614 and subsection (6) do not apply to an accredited program. An
 615 accredited program on probationary status before July 1, 2010,
 616 ceases to be subject to the probationary status. If an

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617 accredited program ceases to be accredited, the program may
 618 apply under this section to become an approved program.

619 ~~(8) The Florida Center for Nursing and the Office of~~
 620 ~~Program Policy Analysis and Government Accountability shall~~
 621 ~~each:~~

622 ~~(a) Monitor the administration of this section and~~
 623 ~~evaluate the effectiveness of this section in achieving quality~~
 624 ~~nursing programs with a higher production of quality nursing~~
 625 ~~graduates.~~

626 ~~(b) Report its findings and make recommendations, if~~
 627 ~~warranted, to improve the effectiveness of this section to the~~
 628 ~~Governor, the President of the Senate, and the Speaker of the~~
 629 ~~House of Representatives by February 1, 2010.~~

630 (11)~~(9)~~ IMPLEMENTATION STUDY.—The Florida Center for
 631 Nursing and the education policy area of the Office of Program
 632 Policy Analysis and Government Accountability shall study the 5-
 633 year administration of this section and submit reports to the
 634 Governor, the President of the Senate, and the Speaker of the
 635 House of Representatives by January 30, 2011, and annually
 636 thereafter through January 30, 2015. The annual reports shall
 637 address the previous academic year; set forth data on the
 638 measures specified in paragraphs (a) and (b) ~~for each~~
 639 ~~prelicensure practical and professional nursing program in the~~
 640 ~~state~~, as such data becomes available; and include an evaluation
 641 of such data for purposes of determining whether this section is
 642 increasing the availability of nursing education programs and
 643 the production of quality nurses. The department and each
 644 approved program or accredited program shall comply with

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645 requests for data from the Florida Center for Nursing and the
 646 education policy area of the Office of Program Policy Analysis
 647 and Government Accountability.

648 (a) The education policy area of the Office of Program
 649 Policy Analysis and Government Accountability shall evaluate
 650 program-specific data for each approved program and accredited
 651 program conducted in the state, including, but not limited to:

652 1. The number of ~~nursing education~~ programs and student
 653 slots available.

654 2. The number of student applications submitted, the
 655 number of qualified applicants, and the number of students
 656 accepted.

657 3. The number of program graduates.

658 4. Program retention rates of students tracked from
 659 program entry to graduation.

660 5. Graduate passage rates on the National Council of State
 661 Boards of Nursing Licensing Examination.

662 6. The number of graduates who become employed as
 663 practical or professional nurses in the state.

664 (b) The Florida Center for Nursing shall evaluate the
 665 board's implementation of the:

666 1. Program application approval process, including, but
 667 not limited to, the number of program applications submitted
 668 under subsection (1); the number of program applications
 669 approved and denied by the board under subsection (2)
 670 ~~subsections (1) and (3);~~ the number of denials of program
 671 applications reviewed under chapter 120; and a description of
 672 the outcomes of those reviews.

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673 2. Accountability ~~Probation and termination~~ processes,
 674 including, but not limited to, the number of programs ~~placed~~ on
 675 probationary status, the number of approved programs for which
 676 the program director is required to appear before the board
 677 under subsection (6), the number of approved programs terminated
 678 by the board ~~under paragraph (5)(d)~~, the number of terminations
 679 reviewed under chapter 120, and a description of the outcomes of
 680 those reviews.

681 Section 6. Subsection (4) of section 464.022, Florida
 682 Statutes, is amended to read:

683 464.022 Exceptions.—No provision of this part shall be
 684 construed to prohibit:

685 (4) The practice of nursing by graduates of prelicensure
 686 nursing education approved programs listed in s. 464.008(1)(c)
 687 ~~or the equivalent~~, pending the result of the first licensing
 688 examination for which they are eligible following graduation,
 689 provided they practice under direct supervision of a registered
 690 professional nurse. The board shall by rule define what
 691 constitutes direct supervision.

692 Section 7. Paragraph (a) of subsection (1) and subsection
 693 (2) of section 458.348, Florida Statutes, are amended to read:

694 458.348 Formal supervisory relationships, standing orders,
 695 and established protocols; notice; standards.—

696 (1) NOTICE.—

697 (a) When a physician enters into a formal supervisory
 698 relationship or standing orders with an emergency medical
 699 technician or paramedic licensed pursuant to s. 401.27, which
 700 relationship or orders contemplate the performance of medical

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701 acts, or when a physician enters into an established protocol
 702 with an advanced registered nurse practitioner, which protocol
 703 contemplates the performance of medical acts identified and
 704 approved by the joint committee pursuant to s. 464.003(2)~~(3)~~~~(d)~~
 705 or acts set forth in s. 464.012(3) and (4), the physician shall
 706 submit notice to the board. The notice shall contain a statement
 707 in substantially the following form:

708 I, ...(name and professional license number of
 709 physician)..., of ...(address of physician)... have hereby
 710 entered into a formal supervisory relationship, standing orders,
 711 or an established protocol with ...(number of persons)...
 712 emergency medical technician(s), ...(number of persons)...
 713 paramedic(s), or ...(number of persons)... advanced registered
 714 nurse practitioner(s).

715 (2) ESTABLISHMENT OF STANDARDS BY JOINT COMMITTEE.—The
 716 joint committee created under s. 464.003(2)~~(3)~~~~(d)~~ shall
 717 determine minimum standards for the content of established
 718 protocols pursuant to which an advanced registered nurse
 719 practitioner may perform medical acts identified and approved by
 720 the joint committee pursuant to s. 464.003(2)~~(3)~~~~(d)~~ or acts set
 721 forth in s. 464.012(3) and (4) and shall determine minimum
 722 standards for supervision of such acts by the physician, unless
 723 the joint committee determines that any act set forth in s.
 724 464.012(3) or (4) is not a medical act. Such standards shall be
 725 based on risk to the patient and acceptable standards of medical
 726 care and shall take into account the special problems of
 727 medically underserved areas. The standards developed by the
 728 joint committee shall be adopted as rules by the Board of

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729 Nursing and the Board of Medicine for purposes of carrying out
 730 their responsibilities pursuant to part I of chapter 464 and
 731 this chapter, respectively, but neither board shall have
 732 disciplinary powers over the licensees of the other board.

733 Section 8. Paragraph (a) of subsection (1) of section
 734 459.025, Florida Statutes, is amended to read:

735 459.025 Formal supervisory relationships, standing orders,
 736 and established protocols; notice; standards.—

737 (1) NOTICE.—

738 (a) When an osteopathic physician enters into a formal
 739 supervisory relationship or standing orders with an emergency
 740 medical technician or paramedic licensed pursuant to s. 401.27,
 741 which relationship or orders contemplate the performance of
 742 medical acts, or when an osteopathic physician enters into an
 743 established protocol with an advanced registered nurse
 744 practitioner, which protocol contemplates the performance of
 745 medical acts identified and approved by the joint committee
 746 pursuant to s. 464.003(2)~~(3)~~~~(d)~~ or acts set forth in s.
 747 464.012(3) and (4), the osteopathic physician shall submit
 748 notice to the board. The notice must contain a statement in
 749 substantially the following form:

750 I, ...(name and professional license number of osteopathic
 751 physician)..., of ...(address of osteopathic physician)... have
 752 hereby entered into a formal supervisory relationship, standing
 753 orders, or an established protocol with ...(number of
 754 persons)... emergency medical technician(s), ...(number of
 755 persons)... paramedic(s), or ...(number of persons)... advanced
 756 registered nurse practitioner(s).

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757 Section 9. Paragraph (c) of subsection (3) of section
758 464.012, Florida Statutes, is amended to read:

759 464.012 Certification of advanced registered nurse
760 practitioners; fees.—

761 (3) An advanced registered nurse practitioner shall
762 perform those functions authorized in this section within the
763 framework of an established protocol that is filed with the
764 board upon biennial license renewal and within 30 days after
765 entering into a supervisory relationship with a physician or
766 changes to the protocol. The board shall review the protocol to
767 ensure compliance with applicable regulatory standards for
768 protocols. The board shall refer to the department licensees
769 submitting protocols that are not compliant with the regulatory
770 standards for protocols. A practitioner currently licensed under
771 chapter 458, chapter 459, or chapter 466 shall maintain
772 supervision for directing the specific course of medical
773 treatment. Within the established framework, an advanced
774 registered nurse practitioner may:

775 (c) Perform additional functions as may be determined by
776 rule in accordance with s. 464.003(2)~~(3)~~~~(d)~~.

777 Section 10. Subsection (2) of section 960.28, Florida
778 Statutes, is amended to read:

779 960.28 Payment for victims' initial forensic physical
780 examinations.—

781 (2) The Crime Victims' Services Office of the department
782 shall pay for medical expenses connected with an initial
783 forensic physical examination of a victim of sexual battery as
784 defined in chapter 794 or a lewd or lascivious offense as

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785 defined in chapter 800. Such payment shall be made regardless of
 786 whether the victim is covered by health or disability insurance
 787 and whether the victim participates in the criminal justice
 788 system or cooperates with law enforcement. The payment shall be
 789 made only out of moneys allocated to the Crime Victims' Services
 790 Office for the purposes of this section, and the payment may not
 791 exceed \$500 with respect to any violation. The department shall
 792 develop and maintain separate protocols for the initial forensic
 793 physical examination of adults and children. Payment under this
 794 section is limited to medical expenses connected with the
 795 initial forensic physical examination, and payment may be made
 796 to a medical provider using an examiner qualified under part I
 797 of chapter 464, excluding s. 464.003(16)~~(5)~~; chapter 458; or
 798 chapter 459. Payment made to the medical provider by the
 799 department shall be considered by the provider as payment in
 800 full for the initial forensic physical examination associated
 801 with the collection of evidence. The victim may not be required
 802 to pay, directly or indirectly, the cost of an initial forensic
 803 physical examination performed in accordance with this section.

804 Section 11. This act shall take effect July 1, 2010.

Status Report
A.G. Holley State
Hospital

Chapter 2009-82, Laws of Florida

Section 14. In order to implement Specific Appropriations 448, 450, 456,458, and 459 of the 2009-2010 General Appropriations Act:

- (1) The Department of Health shall issue a request for proposals, as defined in s. 287.012, Florida Statutes, and shall enter into a contract no later than March 1, 2010, for a replacement facility for the A.G. Holley State Hospital and for the provision of inpatient hospital services and other operations currently provided by the A.G. Holley State Hospital.
- (2) The request for proposals shall specify that responses may include proposals to design and construct a new hospital, to move the location of the hospital, or to co-locate the hospital with existing state, public, or private facilities. The request for proposals shall specify that any proposals to construct a new hospital on the existing A.G. Holley State Hospital campus shall be limited to using no more than 15 acres of the existing campus. Proposals may not address future uses for the existing campus, other than the portion of the campus which may be used for a replacement facility.
- (3) The request for proposals shall specify that qualified respondents shall have experience in the administration of inpatient services and shall document a plan for securing staff having expertise in the treatment of patients who have active tuberculosis. Hospital operations may not include public health functions related to tuberculosis control and prevention. Such functions shall remain the responsibility of the Department of Health. The provision of hospital services shall commence upon the availability of the replacement facility. The request for proposals shall require that the number of beds for the replacement facility be limited to the highest average census for the last 5 fiscal years. A qualified respondent shall submit an application for accreditation to the Joint Commission on Accreditation of Healthcare Organizations within 6 months after commencing the operation of its facility and must receive accreditation within 18 months after commencing the operation of its facility.
- (4) The request for proposals shall specify that the treatment and all other hospital operations may not exceed \$9 million annually. Qualifying proposals must identify one or more methods for financing the costs of relocation or new construction, which may include, but are not limited to, sponsoring the issuance of tax-exempt certificates of participation or other securities, or a lease-purchase agreement with the state.
- (5) This section expires July 1, 2010.

TITLE PAGE

REQUEST FOR PROPOSALS

FOR

INPATIENT HOSPITAL SERVICES AND OTHER OPERATIONS HOUSED
WITHIN A REPLACEMENT FACILITY CURRENTLY PROVIDED FOR AND
LOCATED AT A.G. HOLLEY STATE HOSPITAL, LANTANA, FLORIDA

RFP DOH09-006

Issued by:

The Florida Department of Health

Proposer Name _____

Proposer Mailing Address _____

City-State-Zip _____

Telephone Number _____

Email Address _____

Federal Employer Identification Number (FEID) _____

Authorized Signature (Manual) _____

Authorized Signature (Typed) and Title _____

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Timeline
DOH09-006

EVENT	DUE DATE	LOCATION
RFP Advertised - Released	November 4, 2009	Vendor Bid System: http://vbs.dms.state.fl.us/vbs/main_menu
Questions submitted in writing.	Prior to 5:00 PM EST November 23, 2009	Submit to: Florida Department of Health Purchasing – Janice Brown, Suite 310 4052 Bald Cypress Way, Bin B07 Tallahassee, FL 32399-1749 Fax: (850) 412-1188 E-mail: janice_brown@doh.state.fl.us
Pre-Proposal Conference	November 30, 2009 9:00 am – 12:00 pm	Florida Department of Health 4052 Bald Cypress Way, Room 301 Tallahassee, Florida 32399
Answers to Questions	December 10, 2009	Posted electronically via the following Internet site: http://vbs.dms.state.fl.us/vbs/main_menu
Sealed Proposals Due and Opened	Shall be received PRIOR to: 2:30 PM EST January 19, 2010	Florida Department of Health Purchasing – Janice Brown, Suite 310 4052 Bald Cypress Way, Bin B07 Tallahassee, FL 32399-1749
Anticipated Evaluation of Proposals	Beginning January 19, 2010	Individual Evaluation of proposals – Note: any Evaluation Team Meetings will be publicly noticed.
Anticipated Posting of Intent to Award	February 1, 2010	Vendor bid system: http://vbs.dms.state.fl.us/vbs/main_menu

SECTION 1.0 – GENERAL INSTRUCTIONS TO PROPOSERS

This section explains the General Instructions to Proposers (PUR 1001) of the solicitation process. These General Instructions to Proposers are hereby incorporated by reference. Attachment: This is a downloadable document. Please download and save this document to your computer for further review. There is no need to return this document back to the Department of Health.

<http://dms.myflorida.com/content/download/2934/11780>

SECTION 2.0 - GENERAL CONTRACT CONDITIONS

This section explains the General Contract Conditions (PUR 1000) for this solicitation. These General Contract Conditions are hereby incorporated by reference. Attachment: This is a downloadable document. Please download and save this document to your computer for further review. There is no need to return this document back to the Department of Health.

<http://dms.myflorida.com/content/download/2933/11777>

SECTION 3.0 – INTRODUCTORY MATERIALS

3.1 OVERVIEW

The A.G. Holley State Hospital, established in 1950, is located in Lantana, Florida. A.G. Holley State Hospital's mission, as a public health institute, is to care for medically complex as well as noncompliant tuberculosis patients who, if not confined, treated and subsequently cured, would cause a threat to public health.

Chapter 392, Florida Statutes requires the State of Florida, Department of Health, (hereafter referred to as "Department") to exercise its police powers for the control of tuberculosis for those persons who are posing a public health threat. Only the Department of Health may seek an order for hospitalization, patient isolation, or placement of a non-compliant patient with active TB. Circuit courts in Florida, on petition of the Department and after hearing, may order a sheriff to take custody of a patient and deliver them to A.G. Holley State Hospital. Tuberculosis is the only communicable disease which, under Florida law, may subject a person to involuntary hospitalization for up to 180 days. See admission Criteria for State Tuberculosis Hospital for additional background related to TB care in the State of Florida, Attachment VIII.

The Department hereby solicits proposals from qualified Proposers to implement the legislative directive contained in Chapter 2009-82 Laws of Florida. This legislation states:

(1) The Department of Health shall issue a request for proposals, as defined in s. 287.012, Florida Statutes, and shall enter into a contract no later than March 1, 2010, for a replacement facility for the A.G. Holley State Hospital and for the provision of inpatient hospital services and other operations currently provided by the A.G. Holley State Hospital.

(2) The request for proposals shall specify that responses may include proposals to design and construct a new hospital, to move the location of the hospital, or to co-locate the hospital with existing state, public, or private facilities. The request for proposals shall specify that any proposals to construct a new hospital on the existing A.G. Holley State Hospital campus shall be limited to using no more than 15 acres of the existing campus. Proposals may not address future uses for the existing campus, other than the portion of the campus which may be used for a replacement facility.

(3) The request for proposals shall specify that qualified respondents shall have experience in the administration of inpatient services and shall document a plan for securing staff having expertise in the treatment of patients who have active tuberculosis. Hospital operations may not include public health functions related to tuberculosis control and prevention. Such functions shall remain the responsibility of the Department of Health. The provision of hospital services shall commence upon the availability of the replacement facility. The request for proposals shall require that the number of beds for the replacement facility be limited to the highest average census for the past 5 fiscal years¹. A qualified respondent shall submit an application for accreditation to the Joint Commission on Accreditation of Healthcare Organizations² within 6 months after commencing the operation of its facility and must receive accreditation within 18 months after commencing the operation of its facility.

(4) The request for proposals shall specify that the treatment and all other hospital operations may not exceed \$9 million annually. Qualifying proposals must identify one or more methods for financing the costs of relocation or new construction, which may include, but are not limited to sponsoring the issuance of tax-exempt certificates of participation or other securities, or a lease-purchase agreement with the State.

(5) This section expires July 1, 2010.

3.2 DEFINITIONS

The following abbreviations and terms used in this RFP are defined as follows:

- A.G. Holley Advisory Board: Section 392.69 (4), Florida Statutes. The Department shall appoint an advisory board, which shall meet quarterly to review and make recommendations relating to patient care at A. G. Holley State Hospital. Members shall be appointed for terms of 3 years, with such appointments being staggered so that terms of no more than two members expire in any one year. Members shall serve without compensation, but they are entitled to be reimbursed for per diem and travel expenses under s. 112.061.
- A.G. Holley State Hospital (AGH Hospital): The hospital established in Lantana, Florida for the treatment of tuberculosis patients
- AHCA: The Agency for Health Care Administration
- ASHRAE: American Society of Heating, Refrigeration and Air-Conditioning Engineers
- CON: Certificate of Need as issued by AHCA, sections 408.031 – 408.035, F.S
- Department of Health (DOH): The Florida Department of Health
- DOT: Directly observed therapy
- Facility: All land, buildings, supporting infrastructure and space, whether natural or constructed or renovated, dedicated to accomplish the purpose of service provision for the hospital. Depending on the specific context, it may refer to the current hospital or the replacement facility.
- MDR/XDR/CDR strains: Multi-drug resistant, extensively drug resistant, and completely drug resistant TB strains.
- NSF - Net Square Feet: Unit of measure for size of functional spaces listed in the facility space program.
- Proposer: Any qualified private sector business entity, other governmental entity, not-for-profit or for-profit organization that has timely responded to all of the applicable provisions of this request for proposals and met the qualification criteria set forth in

¹ The AG Holley State Hospitals daily census averages approximately 45 beds patients .

² The Joint Commission on Accreditation of Healthcare Organizations is now called The Joint Commission, TJC

Attachment I.

- RFP: Request for Proposals
- Standard of Cure: Completion of therapy for tuberculosis as determined by the Florida Department of Health, Bureau of Tuberculosis.
- TJC: The Joint Commission responsible for accreditation of hospitals and its operations
- Tuberculosis (TB): means a disease caused by an organism belonging to the *Mycobacterium tuberculosis* complex.

3.3 PRIMARY OBJECTIVE

For this RFP and any contract that may result from it, the Department's primary objective is to assure that individuals with complex cases of tuberculosis meet Florida Department of Health, Bureau of Tuberculosis standard of cure before discharge. The replacement facility shall be designed to fully integrate treatment and security in an environment that ensures the safety and health of patients, staff, and the public.

All Proposers shall demonstrate at least five (5) years of experience operating an in-patient hospital since the year 2000 and how the Proposer will assist the Department in the attainment of these objectives.

Since the Department intends to award to a single Proposer, all proposals shall address the full scope of services delineated in this RFP in order to be determined responsive. The award of any contract that may result from this RFP shall be made to the responsive, responsible Proposer whose submission is determined the most advantageous to the State.

3.4 STATEMENT OF PURPOSE

To implement Chapter 2009-82 Laws of Florida, the Department seeks proposals for a replacement facility to perform inpatient hospital services and other operations currently being provided by the A.G. Holley State Hospital in Lantana, Florida.

3.5 POTENTIAL SCENARIOS

The Department seeks a phased approach to transition the existing A.G. Holley State Hospital and its operations to a replacement facility.

A Proposer may propose any or all of the following scenarios, however each scenario shall be a separate and independent submission:

1. To design, finance, construct, operate, manage, and maintain a replacement facility on the existing A.G. Holley State Hospital campus. Any proposals to construct a replacement hospital on the existing A.G. Holley State Hospital Campus shall be limited to using no more than 15 acres of the existing campus. Proposals may not address future uses for the remaining existing campus. As a specialty TB hospital located on the A.G. Holley State Hospital site, the replacement 45-bed hospital may maintain the existing Certificate of Need for 100 specialty TB beds;

2., To design, finance, construct, operate, manage, and maintain a replacement facility on a site other than A.G. Holley State Hospital campus, subject to the Department's site approval;

3. To relocate the A.G. Holley State Hospital to an existing facility and to design, finance and construct any renovations, operate, manage and maintain the existing facility, for the use of A.G. Holley State Hospital patients, subject to the Department's site approval;

The tasks described in 2 and 3 above will require the successful Proposer to successfully obtain a Certificate of Need for the proposed site.

3.6 BROAD OBJECTIVES

The successful Proposer shall meet a number of broad objectives, including, but not limited to the following:

1. Provide quality treatment, through comprehensive, inpatient care necessary to assure the cure of complex TB patients
2. Provide care in an environment that is conducive to the treatment goals defined in the document and that ensures the safety of patients, staff, and the public.
3. Comply with federal, state and local laws and regulations and maintain full accreditation by TJC throughout the term of the contract.
4. Provide a replacement facility that is licensed as a specialty TB hospital and consistent with best practices in secure tuberculosis hospital architecture. Demonstrate efficient site utilization along with all other requirements of this RFP.
5. Establish and maintain professional organizational responsibility and accountability.
6. As the Department's main service provider of tuberculosis inpatient care in Florida, the successful Proposer shall show how its performance under any contract that may result from this RFP will support and further the Department's efforts to meet its commitment to these objectives.
7. In the event of default by the successful Proposer, the Department must be able to continue care of patients. Proposer shall submit a plan to enable the Department to continue care of the patients in the replacement facility.
8. The Proposer shall submit a plan describing the disposition of the land, facility, furnishings, and equipment at the end of the contract term and/or default.

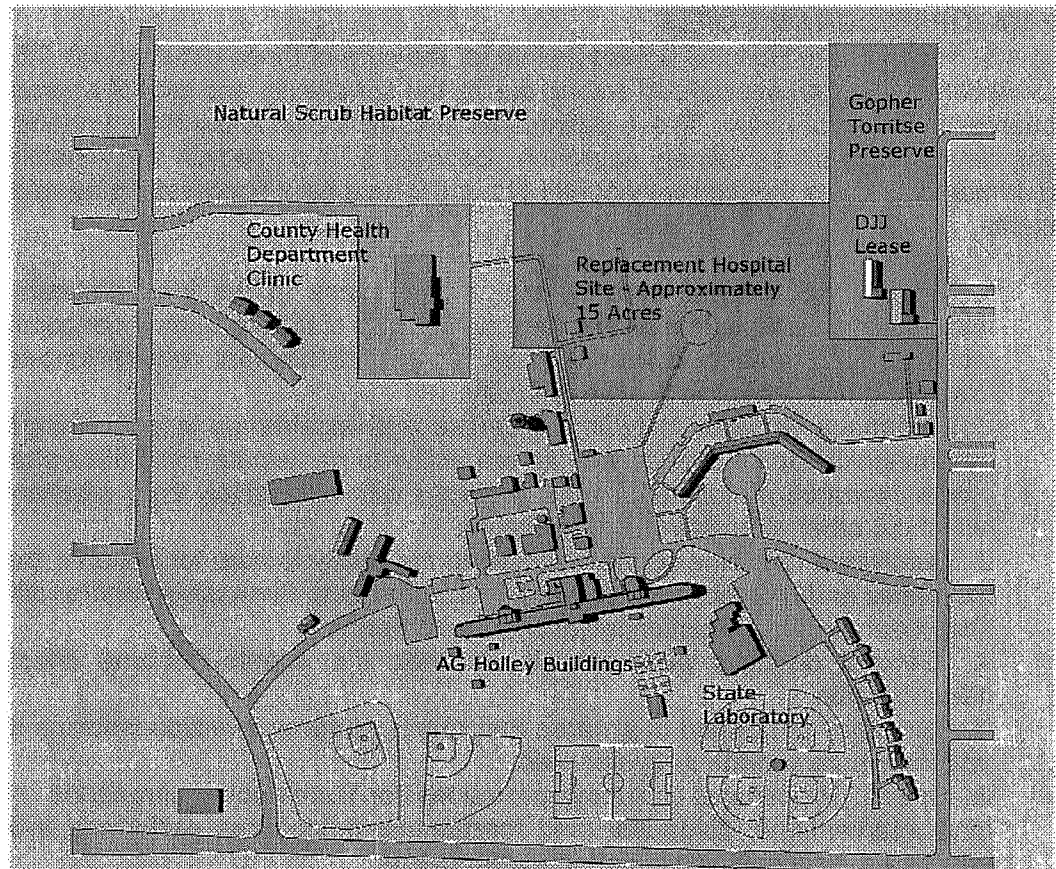
3.7 SUMMARY OF TERMS OF AGREEMENT

The contract period for the design, financing, construction, operation, management, and maintenance of the replacement facility shall be for a total of no more than fifty (50) years including renewals.

The Department may enter into a contract with the successful Proposer for the replacement facility, contingent upon their ability to secure a suitable site, and to obtain financing consistent with the terms and conditions specified in Section 3.1. The acquisition, design, construction, and equipping of the replacement facility shall be in accordance with plans and specifications approved by the Department and meeting the objectives listed, and consistent with all other contractual obligations.

The Department considers the personnel listed in Section 4.6 and their qualifications critical to the success of the A.G. Holley State Hospital replacement facility and its operations. The credentials of the proposed staff shall be evaluated as a part of the proposal. Current A.G. Holley State Hospital staff may be proposed and their resumes will be available upon request. Such request should be sent to the person listed in Section 5.4. Proposers may not contact or receive any communications with current A.G. Holley State Hospital employees in accordance with Section 5.4. The successful Proposer shall comply with the requirements of this RFP, including maintaining hospital licensure and accreditation of the executive team members and complying with all applicable Department of Health criteria. The Department's decision on patients to be served at the hospital is final and binding on all parties.

Any proposals to construct a new hospital on the existing A.G. Holley State Hospital campus shall be limited to using no more than fifteen (15) acres of the existing campus. The following diagram illustrates the intended approximate boundaries of the potential site on the existing A.G. Holley State Hospital campus. The Department will make the final determination of the new hospital boundaries.



Approximate Location of fifteen (15) acre site area on A.G. Holley State Hospital property indicating maximum site utilization

3.8 TERM

In accordance with Chapter 2009-82 Laws of Florida, the Department of Health shall enter into a contract no later than March 1, 2010 with the successful Proposer. The term of any contract resulting from this RFP shall not exceed fifty (50) years, including renewals.

The payment terms of any contract resulting from this RFP shall be paid upon the delivery of the deliverables contemplated by this Request for Proposals. Payments from the State of Florida shall not commence until the replacement facility is fully operational with all the necessary initial operational licenses.

SECTION 4.0 – TECHNICAL SPECIFICATIONS

4.1 PROGRAMMATIC AUTHORITY

The Department of Health is authorized by Chapter 2009-82 Laws of Florida to issue this RFP. The A.G. Holley State Hospital is part of the Department of Health, Division of Disease Control. Chapter 392, Florida Statutes provides legislative authority for the delivery of TB control services at the A.G. Holley State Hospital. The funds available from the State for this project are limited to use for TB treatment and all other hospital operations as currently being performed at and by the A.G. Holley State Hospital.

4.2 MAJOR PROGRAM GOALS

The A.G. Holley State Hospital is responsible for the cure of those patients with TB that can not be accomplished in a non specialized setting due to the complexity and lack of appropriate expertise and resources in the community. These patients have complicated and intricate needs, which require a highly developed multidisciplinary approach. Below is a list of medical and rehabilitative departments/services that currently contribute to the hospital's successful cure rate of complex TB patients.

1. Specialized medical care by expert physicians in the inpatient care of complex tuberculosis patients that allows for the provision of care including concomitant illnesses such as HIV, renal and liver disease for all patients that require long-term inpatient treatment no matter the degree of acuity.
2. Pharmacy services including expertise and experience in performing the required pharmacokinetic studies as well as the ability to participate and utilize pharmaceuticals under research protocols for those patients with extensively drug resistant disease for which no other alternatives are available.
3. Behavioral medicine services including the ability to care for patients that are acutely psychotic and/or pose a significant physical threat to themselves and/or others in rooms that meet airborne infection isolation requirements.
4. General dentistry performed in an area that meets airborne infection isolation requirements.
5. Radiology performed in an area that meets airborne infection isolation requirements, at a minimum provide x-ray services.
6. Special Procedures including provisions for fluoroscopy, ultrasound, bronchoscopy and interventional diagnostic and therapeutic procedures performed in an area that meets airborne infection isolation requirements.
7. Physical therapy performed in an area that meets airborne infection isolation requirements.
8. Patient activities including patient education, occupational therapy, TV, internet, phone, library, chapel.
9. Nutritional services including assessment and assurance that patients receive appropriate nutritional treatment.
10. Infection Control Services including necessary facilities, procedures and monitoring
11. Services to provide Medical and Educational Services to the Community.
12. Access to and accommodation for legal including consultative legal and educational services.
13. Quality Improvement Department.
14. Risk Management Department.
15. Patient Transport Services.
16. Respiratory Services.

17. Security Staff and Facilities that ensure the ability to successfully confine patients that have been court ordered until they have completed required therapy.
18. Availability of expert specialized surgical services and other tertiary care for those patients (e.g. those with extensively drug resistant disease for which medications are not fully effective) that require interventions in other facilities that meet airborne infection isolation requirements.
19. Availability of nearby clinical laboratory services for contract analysis of patient specimens.
20. Laundry and linen services.

4.3 HEALTH CARE PROVIDER REQUIREMENTS

The following are minimum requirements for the provision of inpatient healthcare services:

1. Shall demonstrate at least five (5) years of experience operating an in-patient hospital since the year 2000 and how the Proposer will assist the Department in the attainment of these objectives.
2. Shall demonstrate expertise and capabilities of the medical team necessary to provide in-patient care for the most difficult cases of TB that cannot otherwise be treated in the community. The medical team includes physicians, physician assistants, nurses, and other professionals involved directly with patient medical care.
3. Shall demonstrate a reasonable plan to provide tertiary medical care to any patient on an as-needed basis by using other nearby medical providers, including assuming cost of care in other facilities if transfer is necessary. This care includes but is not limited to the following services: surgical, psychological, specialized diagnostic imaging, medical records, laboratory, and transport of patients.
4. Shall consult with and abide by Bureau of TB/DOH physician decisions concerning admissions, discharges and subsequent community care coordination. Shall admit all tuberculosis patients that meet admissions criteria as set forth by the Bureau of TB/DOH (see Attachment VIII), regardless of reimbursement for care. The successful Proposer will keep patients as in-patients until cured. As part of its proposal, and to be deemed qualified, the Proposer shall certify it agrees to abide by the Bureau of TB/DOH decisions regarding patient eligibility and referral (see Attachment VIII).
5. Shall maintain all medical and operational licensure requirements required for TJC certification. Any changes in standards by TJC will apply to the successful Proposer; however, if TJC lowers its standards, the successful Proposer will be bound to the standards in effect at the effective date of the contract. It is the Department's intent that the TJC standards will be used as the basis for assessing a Proposer's understanding of the Department's expectations regarding the operation and management of the hospital.
6. Shall provide medical malpractice and general liability insurance for the operations of the hospital. The successful Proposer will not be granted sovereign immunity that is available to state operated hospitals.
7. Shall have the ability to provide necessary TB training, education and consultation (24 hours, 365 days a year) to medical professionals and willingness to continue the obligations of the grants and studies if available that have been procured by A.G. Holley State Hospital and its partners.

4.4 TASK LIMITS

The successful Proposer shall not perform any tasks related to the project other than those described herein without the express written consent of the Department.

4.5 STAFFING LEVELS

The successful Proposer shall include their proposed staffing for technical, administrative, and clerical support. The successful Proposer shall maintain an adequate administrative organizational structure and support staff sufficient to discharge its contractual responsibilities. In the event the Department determines that the successful Proposer's staffing levels do not conform to the contract, it shall advise the successful Proposer in writing who shall have thirty (30) days to remedy the identified staffing deficiencies. The successful Proposer shall replace any employee whose continued presence would be detrimental to the success of the project as determined by the Department with an employee of equal or superior qualifications. The Department's contract manager will exercise exclusive judgment in this matter.

4.6 PROFESSIONAL QUALIFICATIONS

Each Proposer shall have experience in the medical administration of inpatient hospital services and shall document a plan for securing staff having expertise in the treatment of patients who have active tuberculosis. Hospital operations may not include public health functions related to tuberculosis control and prevention. Such functions shall remain the responsibility of the Department of Health.

1. The Department considers the following key personnel and their qualifications, critical to the success of the A.G. Holley State Hospital replacement facility and its operations. The credentials of the proposed staff shall be evaluated as a part of the proposal. Current A.G. Holley State Hospital staff may be proposed and their resumes will be available upon request. Such requests should be sent to the person listed in Section 5.4. Proposers may not contact or receive any communications with current A.G. Holley State Hospital employees in accordance with Section 5.4. The successful Proposer shall comply with the requirements of this RFP, including maintaining hospital licensure and accreditation of the executive team members and complying with all applicable Department of Health criteria. The Department's decision on patients to be served at the hospital is final and binding on all parties.

Minimum qualifications for the duration of the contract and any extensions or renewals of either shall include the following:

- A. Hospital Administrator: Management or supervisory experience providing inpatient services to persons with TB, including at least ten years in a management position comparable to an executive staff level role in an inpatient center, research institute or developmental center. Appropriate professional degree or minimum educational level attained will be a Master's degree in any health care management or administrative discipline. Florida license or certification is required where applicable. At least three of the ten years of inpatient management/supervisory experience shall have been in a TB treatment setting.
- B. Assistant Hospital Administrator: Management or supervisory experience providing in-patient services to persons with TB, including at least five years in a management position comparable to an executive staff level role in an inpatient center, research institute or developmental center. Appropriate professional degree or minimum educational level attained will be a Master's degree in any health or administrative discipline. Florida license or certification is required where applicable.
- C. Medical Director: A valid Florida license to practice medicine with ten or more years experience in providing inpatient services to persons with complex tuberculosis, five years of which shall have been at the medical director level - assistant director or its equivalent

- D. **Nursing Director:** Licensed to practice as a Registered Nurse in the State of Florida, including at least two years of post-licensure clinical nursing experience working with individuals diagnosed with tuberculosis in an inpatient facility. In addition, the Director shall have a Master's degree in Nursing and two years of managerial experience or a Master's degree in a related health care or medical services, and three years managerial experience. The managerial work experience shall come from performing those duties typically associated with an Assistant or Associate Director of Nursing, or Director of Nursing.
- E. **Chief Financial Officer:** At least five years of progressively responsible financial management experience within a healthcare system or hospital setting is required. A degree in healthcare administration, finance, or related field is required. A Master's degree is preferred.
- F. **Security Chief:** A Bachelor's degree, a minimum of ten years experience in a healthcare, correctional or secure forensic health facility with at least five years of managerial level experience.
- G. **Facility Manager:** An engineering, construction or business-related Bachelor's degree (Masters preferred) and at least ten years of facilities management experience, five of which shall be in an environment of comparable size and complexity to the hospital. Experience in a healthcare and/or institutional setting is desirable and experience in a secure facility is preferred. Demonstrated skills in life-safety systems, computerized work order management and preventive maintenance systems are required.
- H. **Nutritional Services Director/Licensed Dietician:** A licensed dietician, licensed food service manager and sufficient staff to provide meals for 45 patients and maintain licensure.
- I. **Pharmacy Director:** A valid Florida license as both a pharmacist and pharmacy consultant with at least 5 years experience as a hospital pharmacy director. At least 3 years of experience in compounding, repackaging and dispensing tuberculosis medications, monitoring for adverse drug reactions and drug interactions, and experience with serum TB drug pharmacokinetics.

2. The Proposer shall identify the individuals it intends to employ as the management team by name in its proposal and attach a resume for each, including employment history for all relevant and related experience, all education and degrees (including specific dates, names of employers, and educational institutions), description of the work duties and how they will perform the objectives, and expertise relevant to the work required.

4.7 REFERENCES

Proposers are required to submit with their proposal, references that have been provided for services of a similar size and parameters of those requested in this solicitation. Proposers shall include three (3) references for design/construction team and three (3) references for hospital operations and maintenance. Proposers shall use Attachment VII. The Department reserves the right to contact any and all references in the course of this solicitation evaluation and make a fitness determination, not subject to review or challenge.

4.8 PATIENT GENERAL DESCRIPTION

All persons that have been diagnosed with tuberculosis who can not be successfully treated in the community as indicated in Attachment VIII, Admission Criteria for State Tuberculosis Hospital are eligible to be patients. Patients are referred through one of the sixty-seven (67) County Health Departments (CHDs) and/or the Department of Health, Division of Disease Control, Bureau of TB.

All TB patients admitted may have co-morbid medical conditions that shall be addressed during the hospitalization. Demographics of patients currently served by the hospital include:

- 35% of patients are HIV infected;
- 70% of patients admitted have been diagnosed with major psychiatric conditions;
- 75% of patients have significant drug and/or alcohol abuse issues;
- Approximately 30% of patients have drug resistant strains, including 15% that are infected with the most deadly MDR/XDR/CDR strains.

The hospital's daily census averages approximately 45 patients. A.G. Holley State Hospital is currently operationally funded for 50 beds, although it is licensed through an existing Certificate of Need for 100 beds. A.G. Holley State Hospital admits an average of 80 patients a year, with an average length of stay of 170 days. Approximately 65% of A.G. Holley State Hospital's patients are court ordered through county health departments to the hospital for the purpose of being cured, due to the threat to the public's health that they pose when non-adherent to treatment and proven inability to complete therapy in the community. The other 35% of A.G. Holley State Hospital's patients are referred by other hospitals through County Health Departments, due to the complex nature of the illness as well as the referring facilities' inability, lack of expertise and resources to treat and cure them.

4.9 PATIENT ELIGIBILITY

The successful Proposer agrees to admit all patients requested by the medical staff designated by the Department's Division of Disease Control, Bureau of TB (regardless of reimbursement or complexity of care required) who have either failed outpatient therapy for TB or such therapy is deemed not feasible as an outpatient (including those court ordered to treatment). The successful Proposer agrees to continue to treat all admitted patients until they are deemed to have completed a therapeutic course of TB therapy by the Department, Bureau of TB, unless alternative outpatient therapy is deemed possible by the Bureau of TB.

4.10 PATIENT DETERMINATION

In the event of any disputes regarding the eligibility of clients, the determination made by the Department is final and binding on all parties. Criteria for admission of patients is located in Attachment VIII of this RFP.

4.11 TASK LIST

The following tasks shall be performed, at a minimum, by the successful Proposer:

1. Recruit, select and hire a management team that meets the requirements specified in the RFP, whose members are fully capable of carrying out the requirements and intent of the RFP.
2. Provide integrated treatment and security to ensure the safety of patients, staff, and the public.
3. If the current location is not utilized, acquire property for the location of the replacement facility, subject to Departmental approval.
4. Design, finance, construct, operate, manage and maintain a replacement state-of-

the-art, tuberculosis treatment hospital that supports the integration of security and treatment and that meets the requirements specified in the RFP, by implementing one of the scenarios in Section 3.5.

5. Provide a comprehensive active treatment program and all services necessary to support the twenty-four (24) hours a day, seven (7) days a week inpatient care of persons with complex cases of TB.

6. Assure that the replacement facility is fully accredited by TJC within eighteen (18) months of occupancy.

7. Provide a plan for successful transition of services to the replacement facility as outlined in Section 4.14.

8. Maintain staff records in accordance with TJC standards and shall include: the results of background screening; resumes and completed job application forms; documentation of education; documentation of current licensure, registration, or certification; reference checks; results of required medical examinations, tests, and immunizations; time and attendance records; awards; disciplinary reports; training completed; and performance evaluations.

4.12 REPLACEMENT SPACE REQUIREMENTS

The form, scope, and size of the proposed replacement facility space are based upon the following assumptions:

1. A.G. Holley State Hospital's current patient census (mid to high 40's).
2. Most difficult and complicated TB patients will occupy most beds.
3. Admission of non-TB respiratory illnesses will be on an emergency basis only. No beds will be held in reserve. In case of a declared emergency, some non-emergency TB patients will be discharged into the community for follow-up or to another facility until the emergency ends.
4. Below is a list of medical and rehabilitative spaces that will be needed in a replacement facility in order to provide the appropriate medical services.
 - Inpatient medical care (45 isolation beds). The replacement facility will continue to meet the current demand for inpatient TB care and have some capacity to admit other cases of infectious airborne disease that pose a public health threat. The design of 45 isolation rooms brings more flexibility to the facility so that a variety of cases with different diagnoses can be housed without risk of spread to other vulnerable patients and/or staff in the facility.
 - Specimen Processing and Storage Area. The facility will have adequate space available for the processing, storage, and preparation to transport biological specimens, including centrifuge, refrigerator, -80 F degree freezer, incubator, computer terminal, and specimen processing unit.
 - Pharmacy. The dual role of the pharmacy includes compounding, repackaging, and dispensing.
 - Behavioral medicine. This department plays a vital role in addressing emotional, mental, and behavioral issues that may have led to the patient's TB infection and/or complicate the patient's treatment and cure. The department also works to humanely control patients who are admitted to A.G. Holley State Hospital involuntarily while maintaining the patient's dignity and rights.
 - Dentistry. TB is a disease which causes devastating nutritional deficiencies. The need for good dentition is essential to replenish the nutritional demands of the patient. The suite will be equipped with the necessary infection control precautions

to protect the staff and other patients.

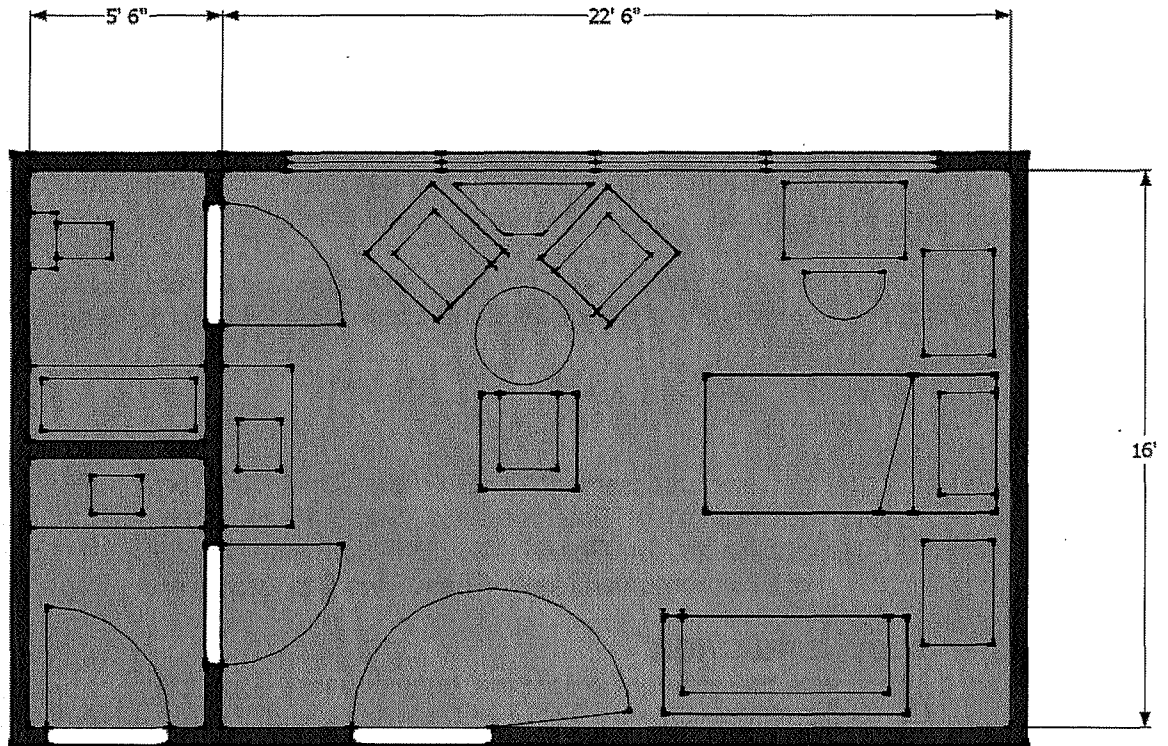
- Radiology. Diagnostic and therapeutic imaging is an essential requirement for the care of TB patients. The radiology suite should have the ability to perform routine radiographic studies.
- Bronchoscopy. This procedure is often required to diagnose TB as well as to rule out and treat other TB complications (malignancies and hemoptysis). This procedure is performed by hospital staff and will be available for inpatient use.
- Physical therapy. TB patients with their concomitant conditions often arrive at A.G. Holley State Hospital debilitated, requiring physical therapy to restore them to be functioning members of society. By providing such services, patients are able to leave A.G. Holley State Hospital with the ability to be self-sufficient.
- Patient activities. An indoor and outdoor recreational facility is a necessity. Moreover, an outdoor facility may be used to manage the more contagious patients. Many of A.G. Holley State Hospital's patients have a long length of stay (6 months to 2 years) required to treat and cure their TB. Given this, patient activities shall be provided to keep patients active and to control/prevent behavioral problems.
- Nutritional services. TB is a "consumptive disease". Nutritional therapy is an essential component in the treatment of TB. The need for nutrition is magnified in various states of disease.
- Hospital support. This includes departments such as administrative services, finance, housekeeping, quality improvement, risk management, legal, IT, medical records and other functions required to adequately operate a hospital. Most of these supports are not only essential to provide adequate care but are mandated by AHCA and/or TJC to maintain A.G. Holley State Hospital's licensure and to maintain professional accreditations.
- Security. This includes configuration of space to allow secure operations of the hospital and prevention of unauthorized elopement of court mandated patients.

5. The replacement facility should include the functional areas as outlined in the table on the following page. The square footage listed on the table is provided for informational purposes only and represents the space contained in the existing facility.

Department / Room	Function	No Rooms	NSF / Room	Total NSF	NSF / Bed
Respiratory Hospital (45 Bed)					
Admissions	Administrative			400	7
Employee Health Services	Administrative			400	7
Finance and Accounting	Administrative			936	17
General Services	Administrative			3,316	60
Legal Counsel Services	Administrative			300	5
Medical Administration	Administrative			2,500	45
Medical Records	Administrative			3,080	56
Nursing Administration	Administrative			1,394	25
Patient's Benefits	Administrative			200	4
Risk Management	Administrative			1,426	26
Interfaith Chapel	Administrative			400	7
QA/QI	Administrative			300	5
PIO/Library/Volunteers	Administrative			6,360	116
	Subtotals			21,012	382
Communications	Building Support			446	8
Engineering	Building Support			8,000	145
Environmental Services	Building Support			2,820	51
Information Technology	Building Support			2,836	52
Safety and Disaster Prep	Building Support			180	3
Security	Building Support			670	12
Stores	Building Support			10,000	182
Superintendent	Building Support			1,865	34
	Subtotals			26,817	488
Patient Care					
Isolation Rooms	Patient Care	45	360	16,200	295
Ante Rooms	Patient Care	45	40	1,800	33
Patient Toilets	Patient Care	45	40	1,800	33
Nurse Stations	Patient Care	2	1000	2,000	36
Nurse Storage	Patient Care	2	500	1,000	18
Dental Clinic	Patient Care			1,000	18
Clean/Dirty Linen	Patient Care	4	50	200	4
Short Term Equip Stg	Patient Care	4	500	2,000	36
Forensics Rooms	Patient Care	2	250	500	9
	Subtotals			26,500	482
Patient Amenities					
Recreation Room	Patient Amenities	3	500	1,500	27
Vocational Room	Patient Amenities	2	500	1,000	18
Exercise Room	Patient Amenities	3	500	1,500	27
Movie / Study / Meeting Rm	Patient Amenities	1	800	800	15
Barber Shop	Patient Amenities	1	750	750	14
Hair Salon	Patient Amenities	1	750	750	14
Patient Store	Patient Amenities	1	2000	2,000	36
Thrift Shop	Patient Amenities	1	1500	1,500	27
Physical Therapy	Patient Amenities	2	1000	2,000	36
Horticulture	Patient Amenities	1	500	500	9
	Subtotals			11,800	224
Patient Support					
Behavioral Medicine	Patient Support			4,240	77
Infection Control	Patient Support			960	17
Nutritional Services	Patient Support			10,824	197
Pharmacy/Specimen Storage	Patient Support			4,000	73
Respiratory	Patient Support			600	11
X-Ray	Patient Support			4,000	73
	Subtotals			24,624	448
Educational					
Classrooms	Educational	4	800	3,200	58
Pre Function	Educational	2	500	1,000	18
Offices	Educational			2,000	36
Educational Support	Educational			1,500	27
	Subtotals			7,700	140
Plus secured exterior space for patients					
				TOTAL NET AREA (45 Beds)	118,453

6. Provide a safe environment with the required specialized environmental protections and maintenance to ensure the safety of the patients, staff and public. Any proposed replacement facility, new or existing, shall have the ability to be an airborne infection isolation facility and will require compliance with TJC, AHCA and compliance with prevailing industry standards for a 50 year building and subject to the Department's approval.
7. Provide specialized facilities and grounds security to ensure prevention of elopement of patients and to avoid compromising the safety of the patients, staff and public.
8. All new building(s) will be constructed to sustainability standards as described in accordance with section 255.252 (3), Florida Statutes.
9. Each proposal to use existing space will be carefully evaluated against current design requirements and local building codes.
10. Any new or renovated building(s) shall meet or exceed all applicable hurricane requirements and shall be able to function during and after such an event (i.e., backup generators, etc.).
11. The typical patient room should have the following features:
 - a. Hospital bed
 - b. Adequate space and access to hospital bed by medical imaging systems
 - c. Large windows of adequate quality for negative air pressure rooms
 - d. Shades or blinds
 - e. Negative air pressure
 - f. Varied and soothing lighting
 - g. Room to move large imaging systems
 - h. Normal room furniture (chairs, end tables, sofas)
 - i. Safe and easy access to adjacent toilet
 - j. Safe and easy access to Ante Room that leads to Corridor
 - k. Flooring – Vinyl
 - l. Base – Vinyl
 - m. Walls – Paint in variable color schemes
 - n. Ceiling – Acoustical Tile

Occupancy times in these rooms can be several months therefore the interior design shall make the spaces as livable as possible. See Figure below



Typical patient isolation room layout

12. Facility Site Proposal. Any proposed site under Scenario 2 or 3 shall be located in the State of Florida on acreage sufficient in size and configuration to build a structure not to exceed three stories and all necessary ancillary buildings.

The Proposer shall provide a detailed narrative of the land including:

- Requirements for perimeter security
- Property description, boundaries, and potential for future expansion
- Size and location of the land
- Aerial or satellite photograph
- Types of facilities on adjacent properties and whether the land is near a school, playground, neighborhood, etc.
- Roadways and travel times to population centers
- Elevation, drainage and other environmental issues (including whether it is in the 100-year flood zone or county emergency management Category 3 surge inundation zone)
- Types of visual or physical buffers around the land

- Status of site plan approval or plat approval
- Evidence of site control. Proposer shall demonstrate site control by providing a fully executed contract for purchase and sale, fully executed option contract, fully executed lease or recorded deed for the subject property
- Evidence of infrastructure availability. Proposer shall demonstrate that all utilities and road access are available to accomplish the proposed design for the replacement facility
- Furnish evidence of appropriate zoning
- Environmental site assessment. For Phase One ESA, provide the properly completed verification of Environmental Safety-Phase One Site Assessment Form. If applicable for Phase Two ESA, provide the properly completed verification of Environmental Safety-Phase Two Site Assessment Form

4.13 DESIGN AND CONSTRUCTION

The design shall incorporate the optimum in function, security, aesthetics, efficiency and energy conservation, and execution of construction activities that are economical and sound. Perimeter and other fencing as well as other design features devoted to security shall provide a secure environment for patients, staff, and the public. The Proposer is encouraged to make use of landscaped buffers and barriers, wherever possible, to delineate the replacement facility's boundaries. Well-sloped roofs, hardened exterior design, secure and impact-resistant windows, and natural light shall be incorporated to soften the institutional look of this secure treatment facility.

1. The hospital design shall be for a structure(s) not to exceed three (3) stories, and shall incorporate areas for recreation, treatment, training, and administration. Sightlines shall permit a direct view of supervision on units, recreation spaces, and corridors. Control shall be both direct and indirect. Controlling movement of patients to program spaces shall be direct, and simultaneous movement shall be possible.
2. The design shall provide a minimum of forty-five (45) individual airborne isolation patient rooms, with an individual sink and toilet for each room, as illustrated in the Typical Isolation Room Layout in Section 4.12.
3. The design shall incorporate private living spaces for patients, yet facilitate contact between patients and staff. Staff offices shall be located adjacent to living areas to enhance opportunities for therapeutic interactions. The design shall show how patients will be able to have private but secure space, various types of common space, and frequent and easy access to outdoor space.
4. The design shall permit multiple activities to be conducted at the same time. Large group recreation spaces are to be convenient and well-placed. Overall, there should be a good balance among competency training rooms, recreation, and treatment spaces to reduce scheduling difficulties. Program spaces shall be adequately sized and shall be capable of close supervision. Recreation spaces shall be easily and safely accessible.
5. There shall be a security center that is able to monitor all facility cameras, communicate with the secure perimeter and all other control rooms and staff stations, monitor perimeter security features, control all remote and electronic door locks, and communicate with and receive alerts from staff. Perimeter security, and visitor access shall meet standards for a secure facility with interior and exterior patrol and emergency response capability. Public and staff parking and access shall be well-zoned. Perimeter

security shall be provided and internal security features shall enhance rather than diminish the provision of treatment.

6. The HVAC system shall be a central chilled water system designed to optimize dehumidification and to maximize cost-efficient operation. There shall not be individual room units for HVAC. Isolation rooms shall maintain a negative air pressure relative to room entries in accordance with ASHRAE requirements.

7. The Proposer's proposal shall provide sufficient information to permit a full understanding of the physical setting in which it proposes to serve patients and how its conceptual design will support the achievement and integration of therapeutic and security goals outlined above. The Proposer shall demonstrate that the proposed design will meet TJC and hospital licensure standards.

8. The Proposer shall include a narrative description and overview of the facility as it is intended to look upon completion. While the Department does not require the Proposer to submit completed architectural drawings or plans, the Proposer shall include conceptual design drawings, prepared by a registered Florida architect, and supporting narrative for the replacement facility. These drawings shall indicate the proposed style, exterior arrangement of building(s) and internal organization of space. The Proposer is encouraged to submit supporting illustrations, photographs from similar buildings, and sketches. The Proposer's required conceptual design and narrative submission are considered binding on the Proposer; however, deviations required by circumstances beyond the Proposer's foreseeable control may be permitted with the prior written approval of the Department. The narrative shall include the following:

- The soil and ground water conditions, contours, accessibility, utilities, Florida zoning and governing codes, etc. The topographic information shall include significant terrain features that will impact the siting and orientation of buildings. The one-hundred (100) year flood elevation should be determined with reference to the site, and the probability of water overrunning the site shall be reported.
- A site plan indicating site use, location and orientation of building(s), building construction, circulation and parking.
- The general location and orientation of buildings associated with possible future expansion.
- Natural and constructed recreation areas.
- Block diagrams (floor plans) for each level of each building.
- Larger scale (1/4"=1'-0") drawings of repetitive modules such as patient rooms, individual offices, medical examination rooms, etc.
- Larger scale drawings of complicated rooms such as control rooms, kitchen/dining, etc.
- Proposed accommodations for patients, staff, or visitors with disabilities.
- A general description of the architectural, engineering, construction, and security concepts, and the architectural, structural, plumbing, fire protection, mechanical HVAC, communications, electronics and electrical systems to be used.
- A listing of codes with which the design complies.

- A statement that the Department of State has been contacted and that any conflicts between the project and the conservation or historical interests of the Department of State have been or are being resolved.
- Cost and area analyses correlated to the program requirements.
- Phase 1 environmental site assessment including endangered species report for the gopher tortoise.

9. Architect Services. The Proposer shall select its architectural firm prior to submitting a proposal. The Proposer shall retain the services of an architectural firm that has members registered in the disciplines of architecture and engineering in the State of Florida and has a Florida-based office. The design shall incorporate the optimum in function, aesthetics, security, efficiency and energy conservation, as well as an execution of construction activities that are both economical and sound. The architectural firm's contributions are expected to include, at a minimum, planning, design, construction documents, cost estimates, reports, and construction administration.

- The architectural firm will be solely responsible for secure hospital facility design in terms of quality, technical accuracy, cost control and effective coordination of all services rendered to it. In this regard, the responsibility for professional decisions made pursuant to review documents or questions shall remain with the design professionals. All services shall be accomplished in accordance with current criteria, guides, and applicable codes, and shall conform to the best professional practices. The architectural firm shall ensure the completeness of its own work and that of all sub-consultants, and shall ensure that all disciplines are fully coordinated from the design process through construction administration and final completion. The architectural team shall include, but not be limited to, representation from the architectural, civil/structural engineering, mechanical engineering, and electrical engineering disciplines. The architect shall coordinate all building warranty issues through the first year of occupancy.
- The Proposer shall indicate the specific services the architectural firm will perform, as well as provide any supporting information that indicates the architectural firm's expertise and unique qualifications for participation in a project of this type, including but not limited to demonstrated experience in designing facilities for the health and safety in which medical treatment is provided.
- The Proposer shall submit the following evidence of the proposed design professional's qualifications:
 - Standard Form 330. This form may be obtained from U.S. Superintendent of Documents, Government Printing Office (GPO), Washington, DC 20402; or from federal regional offices; or from the Office of Construction Management, General Services Administration (GSA), 18th and F Streets, N.W., Washington, DC 20402.
 - Professional Registration Certificates. A copy of a current and active Florida professional registration certificate from the governing board of each

professional discipline in which services are offered shall be submitted for the business entity, for each individual to be assigned to the project, and for any other individuals qualifying as a corporation to practice in any such discipline(s) in the State of Florida.

- Business or Government Entity Registration. If the firm providing professional design services is a corporation, PA, or LLC, it shall provide proof of registration with the Florida Department of State.

10. Building Program. The Proposer's design and construction management plan shall be included in the submission of its proposal. The program will list the major space categories and requirements of each space in the construction. In addition, the schematic design management plan shall include a project schedule showing how the Proposer intends to manage design activities. The following sample schedule, which assumes a building committee approach, includes activities and milestone completion dates or due dates starting from construction proposal submission with schematic design documents. Proposers shall submit their design and construction management plan with a project schedule illustrating the milestones below.

SAMPLE PROJECT SCHEDULE:

Activity	Anticipated Due date
Schematic design drawings/narrative and program	_/_/_
Building committee reviews schematic design	_/_/_
A/E prepares advanced schematic design documents	_/_/_
Building committee reviews advanced schematic design	_/_/_
A/E prepares design development documents	_/_/_
Building committee reviews design documents	_/_/_
A/E prepares 50 percent Construction Documents (CDs)	_/_/_
Building committee review of 50 percent CDs	_/_/_
A/E prepares 100 percent CDs	_/_/_
Building committee review of 100 percent CDs	_/_/_
Environmental and other permit applications	_/_/_
Road/utility easements or right-of-way acquisitions	_/_/_
Construction contracting	_/_/_
Local building permit applications	_/_/_
Shop drawing submittal & approval	_/_/_
Construction administration	_/_/_
Substantial completion	_/_/_
Punch list items, final completion	_/_/_

11. Design and Construction Methodology. The Proposer shall submit with its proposal a design and construction management plan describing how it intends to fast-track the project including planning and design phases while involving the Department in the design process. The plan shall include the Proposer's approach to involving the Department, the hospital staff, and community leaders in the design process, such as using focus groups or a building committee. All submissions for review and all final plans will become property of the Department. Three (3) complete sets of each submission will be provided for the Department's review.

The successful Proposer shall address the following:

- **Program Verification and Schematic Design Documents:** Schematic Design development documents shall comply with the Professional Services Guide of the Bureau of General Services - Office of Design and Construction, Department of Health, State of Florida. This guide will be made available upon request, such requests should be sent to the person listed in Section 5.4. The Department shall have 30 days to review the advanced schematic design and respond with comments.
- **Design Development Documents:** Design development documents shall comply with the Professional Services Guide of the Bureau of General Services - Office of Design and Construction, Department of Health, State of Florida. The Department shall have 30 days to review the advanced schematic design and respond with comments.
- **Construction Documents:** Shall include both 50 percent construction documents and 100 percent construction documents. The Department shall have 30 days for each submittal to review and respond with comments.
- **Construction Administration:** The architect of record is responsible for review of shop drawings and the monthly pay requests from the contractor. The architect, in his approval of these items, shall certify that the contractor's representation of work completed is accurate and that the architect has personally reviewed the work for compliance with the approved construction documents. The architect will then turn the items for review over to the successful Proposer for submittal to the Department for approval. The Architect shall provide Complete As Built documents for the finished project to the Department in an electronic media storage using a compatible Auto CADD software.

12. **Surveys.** The Proposer is responsible for defining barrier, egress and land use requirements for the replacement building(s). Prior to and as a part of the Department's approval of proposed site boundaries, the Proposer shall furnish a proposed site boundaries. In addition, the Proposer will be responsible for coordinating utility service and obtaining documents depicting utility easements across the property.

13. **Code Compliance.** The replacement facility will be subject to local building code review and shall comply with latest adopted edition of local ordinances regarding zoning, landscaping, drainage, fire protection, and utility provision. The successful Proposer shall construct the replacement facility in accordance with the statutes, codes, rules, regulations, TJC standards, and the standards listed directly below. The Proposer must verify and provide an complete list of authorities having jurisdiction on the proposed site with a plan addressing code compliance with each.

- Life Safety Code, NFPA 101, is adopted by Rule 69A-53.004, F.A.C., under authority of Section 633.022, F.S. as the "Uniform Fire Safety Standards for Hospitals and Nursing Homes".
- Florida Building Code is adopted as the State Minimum Building Code in accordance with Section 553.73, F.S.
- Hospital Licensure, Rule 59A-3, F.A.C., promulgated under authority of Section 395.0163, F.S., defines minimum construction standards for facilities seeking to obtain or maintain licensure as a hospital facility in Florida.
- American Institute of Architects Guideline Design and Construction of Hospital

and Health Care Facilities

- Uniform Fire Safety Standards, adopted by the State Fire Marshal by Rule 69A-3.012, F.A.C., under authority of Section 633.022, F.S.
- Handicapped Accessibility Guidelines, defined by Section 553.503, F.S., adopting the federal Americans with Disabilities Act Accessibility Guidelines (Title II of Public Law 101-336, as published in 28 CFR 36, Subparts A and D), subject to the exceptions of Section 553.504 (Chapter 11 in the Florida Building Code.)
- Florida Energy Efficiency Code for Building Construction, promulgated by the Florida Department of Community Affairs pursuant to Section 553.901, F.S.
- Florida Energy Conservation Standards, promulgated by the Florida Department of Community Affairs pursuant to Section 553.954, F.S.

14. Code Compliance Authorities. The following agencies, in addition to the local building permit enforcement agency, will review and approve plans, specifications and construction. The Proposer shall meet the requirements of the authorities listed below and any other applicable code compliance authorities:

- Office of State Fire Marshal. It is the duty of the State Fire Marshal and agents to inspect, or cause to be inspected, on a recurring basis established by rule, each state-owned building or any building leased (directly or indirectly) by the state. All replacement construction shall comply with the uniform fire-safety standards of the State Fire Marshal. Compliance with these standards shall be determined by a review of the plans for the proposed construction, to be submitted by the successful Proposer or design professional to the Division of State Fire Marshal for review and approval prior to commencement of construction. The Division of State Fire Marshal may inspect state-owned space and state-leased space as necessary prior to occupancy or during construction, renovation, or alteration to ascertain compliance with the uniform fire-safety standards. Whenever the Division of State Fire Marshal determines by such inspection or by review of plans that construction, renovation, or alteration of state-owned or state-leased space is not in compliance with the uniform fire-safety standards, it shall issue an order to cease construction, renovation, or alteration, or to preclude occupancy, of a building until compliance is obtained, except for those activities required to achieve such compliance.
- Agency for Health Care Administration (AHCA). As required by Rule 59A-3.080, F.A.C., under authority of Section 395.0163, F.S.(2009), no construction work (including demolition) may be started on a hospital until prior written approval has been given by the AHCA Office of Plans and Construction.
- Department of Health, General Services Design and Construction will provide programmatic evaluation and technical advice for the project. The Department's Office of Design and Construction concurrence shall be obtained at each stage of the design process.
- The Joint Commission (TJC). The successful Proposer will maintain TJC accreditation of the existing hospital program and will obtain and maintain TJC accreditation of the replacement hospital facility within 18 months of occupancy. Information on TJC accreditation may be obtained from: Joint Commission on Accreditation of Healthcare Organizations, One Renaissance Boulevard, Oakbrook Terrace, Illinois 60181, Telephone: (630) 792-5000.
- Florida Department of Environmental Protection (FDEP). Under authority of Chapter 403, F.S., and the rules and regulations adopted pursuant thereto (Chapter 62, F.A.C.), FDEP and the associated local environmental program in

the county where the facility is built will have jurisdiction with regard to pollution and environmental protection issues.

15. Building Materials. The Department strongly supports the use of high-quality building materials that are sustainable, durable, and easy to maintain. Because maintenance costs throughout the life of the building usually exceed original construction costs, the architectural firm shall select the most maintenance-free materials that the budget will allow. The planning and design of the building(s) shall be based on the use of permanent and protective construction materials that extend the life of the building. All drawings and specifications shall clearly establish such a standard of quality for all materials.

4.14 TRANSITION TO A REPLACEMENT FACILITY

The Department will maintain operation of the existing facility including inpatient care until the replacement facility is completed. Upon completion of the replacement hospital facility, the successful Proposer shall be responsible for the safe and secure transition of patients from the existing A.G. Holley State Hospital location to the replacement hospital facility. In addition, the successful Proposer will be responsible for the transition of new and current staff to the replacement facility. Transition shall occur with no interruption in patient care, admissions and no delays in performance.

The Proposer shall propose a detailed transition plan, which demonstrates a safe and orderly transition from the current hospital facility to the replacement facility. The plan shall include timeframes, tasks, and responsible parties.

The plan shall include how the Proposer will establish basic hospital infrastructure services such as building systems and support operations prior to relocating any patients to the new facility. Proposer will ensure new facility is ready to provide patient care in the preparation and execution of this transition plan.

The plan shall include how the Proposer will physically transfer patients, how it will ensure safety and security at both facilities during the transfer/transition period and how they will staff both facilities until all transfers have occurred.

The Department will conduct a readiness review prior to transition to verify compliance with the successful Proposer's proposal and requirements contained in the RFP. The Department reserves sole discretion to extend the commencement of the contract pending implementation of the successful Proposer's proposal, until readiness is achieved.

Once the transition to the replacement facility is complete, all state owned property will be retained by the Department.

4.15 FACILITY MANAGEMENT, OPERATION AND MAINTENANCE

The successful Proposer shall be fully responsible for the operation, maintenance and repair of the replacement hospital facility, including the structures and associated building operating systems as well as the surrounding campus and supporting utility systems.

1. Maintenance Inspections: The facility shall be subject to inspections by the State Fire Marshal, Agency for Health Care Administration, Department of Health, Department of Financial Services and any other governmental agency having jurisdiction where the replacement facility is located. The successful Proposer shall ensure that corrective actions are completed within the required time frames for identified deficiencies. The Proposer shall provide a plan with its proposal that outlines a regular maintenance and inspection schedule.

2. **Maintenance Tasks:** Maintenance includes all preventive, predictive and repair maintenance, including major repairs. The Proposer shall provide a plan with its proposal that outlines all managerial, administrative and technical support necessary for the efficient and timely accomplishment of all facility management functions including the following:
 - Facilities administration and supervision.
 - Annual facilities operations, including emergency stand alone operations.
 - Operation, maintenance and repair of mechanical, HVAC, refrigeration, electrical, and utility equipment and systems.
 - Elevator maintenance and repair, if applicable.
 - Fire and life safety systems repair and maintenance.
 - Architectural and structural maintenance and repair.
 - Cleaning, laundry and janitorial services.
 - Pest control.
 - Waste removal, including bio-hazardous waste, and recycling.
 - Grounds maintenance, including storm water and irrigation systems.
 - Recreational facilities and related equipment maintenance and repair.
 - Medical equipment maintenance and repair.
 - Kitchen/dining and laundry equipment maintenance and repair.
 - Television, VCR, and related equipment maintenance and repair.
 - Personal care equipment maintenance and repair.
 - Motor vehicle maintenance and repair.
 - Water and air distribution equipment and systems.
 - Domestic water equipment and systems maintenance and repair.
 - Interior and exterior lighting maintenance and repair.
 - Sanitary sewage equipment and systems.
 - Electronic and mechanical security access, surveillance and alarm systems maintenance and repair.
 - Emergency generator maintenance and repair.
 - Roofing maintenance and repair.
 - Program furniture, fixtures and equipment.
 - Hazardous materials storage and handling.
 - Inventories of all tools, equipment, materials and supplies/furnishings.
 - Communications and IT services.
3. **Facility Management Services:** The Proposer shall provide with its proposal a plan for annual facility management services. Including the following:
 - Capability to operate as a stand alone facility in emergency situations
 - Compiling and maintaining permanent records of maintenance and repair activities
 - Quality Initiative committee review of facility operations
 - Quality Assurance inspections of maintenance , repair, custodial activities
4. **Quality Control:** The Proposer shall include with its proposal a detailed description of its proposed Quality Control program. At a minimum, the Proposer shall delineate the methods it will use to encourage personnel to promote patient safety and comfort, preserve the facility for future use, prevent maintenance defects, reduce utility costs and control the processes that are crucial to performing quality maintenance service.
5. **Emergency Management/Continuous Operations Plans:** The Proposer shall submit a plan to manage the facility (existing and replacement) during all emergency situations

such as fires, accidents, strikes, civil disturbances, natural disasters and military contingency operations, including the identification of alternative care sites if necessitated by conditions. The successful Proposer is expected to take all necessary actions to ensure the facility it occupies is maintained and protected for any contingency. A comprehensive emergency operations plan shall be developed in conjunction with the Department and approved by AHCA, the State Fire Marshal, and the local disaster management/emergency services agency. This plan shall address the issues of staffing, transportation, sheltering arrangements, emergency equipment and supplies, etc. The successful Proposer shall be an active participant in the development or amendment of the emergency operations plan, as it is integral to safeguarding the buildings and protecting the safety of the patients at the facility. The plans should include listings of actions, items necessary to protect patients, staff and property during and after each type of emergency situation. If an emergency situation occurs, the successful Proposer will be required to assist the Department and other state entities as necessary. This assistance might include providing staff to work in other facilities or relief centers, housing for displaced individuals, and other resources deemed necessary by the Department.

6. HVAC Operation: The successful Proposer shall maintain HVAC equipment in accordance with manufacturers' recommended preventive maintenance procedures. The successful Proposer shall perform preventive maintenance services as required and applicable to keep systems operating properly. The central HVAC system shall be operated in an energy efficient manner, to provide the following environmental conditions:
 - Negative Pressure- Patient isolation rooms and medical procedure rooms requiring isolation of airborne pathogens shall maintain and monitor continuous negative pressure in relation to adjacent spaces or corridors. These rooms shall not use re-circulated air and exhaust air using high efficiency particulate air filters to the outside.

4.16 EQUIPMENT

Upon availability of the replacement facility, the successful Proposer will be responsible for supplying, at its own expense, all equipment necessary to perform hospital operations under any contract resulting from this RFP, including but not limited to medical equipment, computers, telephones, copier and fax machines, supplies and maintenance, and needed office supplies.

4.17 SERVICE TIMES

Hospital services for inpatient care require continuous operations 365 days a year, 24 hours a day.

4.18 FLORIDA LOCATION

The replacement facility shall be located within the geographic area of the State of Florida.

4.19 CHANGES IN LOCATION

The successful Proposer shall notify the Department in writing a minimum of one week prior to making changes in location that will affect the Department's ability to contact the successful Proposer by telephone or facsimile.

4.20 REPORTS

Where the resulting contract requires the delivery of reports to the Department, mere receipt by the Department shall not be construed to mean or imply acceptance of those reports. It is specifically intended by the parties that acceptance of required reports shall constitute a separate act. The

Department reserves the right to reject reports as incomplete, inadequate, or unacceptable according to the parameters set forth in the resulting contract. The Department, at its option, may allow additional time where the successful Proposer may remedy the objections noted by the Department. The Department may, after having given the successful Proposer a reasonable opportunity to complete, make adequate, or acceptable, declare the contract to be in default.

4.21 RECORDS AND DOCUMENTATION

To the extent that information is utilized in the performance of the resulting contract or generated as a result of it, and to the extent that information meets the definition of "public record" as defined in subsection 119.011(1), F.S., said information is hereby declared to be and is hereby recognized by the parties to be a public record and absent a provision of law or administrative rule or regulation requiring otherwise, shall be made available for inspection and copying by any interested person upon request as provided in Chapter 119, F.S., or otherwise. It is expressly understood that the successful Proposer's refusal to comply with Chapter 119, F.S., shall constitute an immediate breach of the contract that results from this RFP and entitles the Department to unilaterally cancel the contract. The successful Proposer will be required to promptly notify the Department of any requests made for public records.

Unless a greater retention period is required by state or federal law, all documents pertaining to the program contemplated by this RFP shall be retained by the successful Proposer for a period of six years after the termination of the resulting contract or longer as may be required by any renewal or extension of the contract. During the records retention period, the successful Proposer agrees to furnish, when requested to do so, all documents required to be retained. Submission of such documents shall be in the Department's standard word processing format (currently Microsoft Word 6.0). If this standard should change, it will be at no cost incurred to the Department. Data files will be provided in a format readable by the Department.

The successful Proposer agrees to maintain the confidentiality of all records required by law or administrative rule to be protected from disclosure. The successful Proposer further agrees to hold the Department harmless from any claim or damage including reasonable attorney's fees and costs or from any fine or penalty imposed as a result of an improper disclosure by the successful Proposer of confidential records whether public record or not and promises to defend the Department against the same at its expense.

The successful Proposer shall maintain all records required to be maintained pursuant to the resulting contract in such manner as to be accessible by the Department upon demand. Where permitted under applicable law, access by the public shall be permitted without delay.

By submitting a proposal, the Proposer agrees to furnish, in an expeditious manner, all documents required by the provisions contained in this RFP upon the Department's demand. Full compliance with this provision means that the documents are supplied in the Department's standard electronic format and at no cost to the Department. Data files shall be provided in a format readable by the Department.

4.22 OUTCOMES AND OUTPUTS (PERFORMANCE MEASURES)

The Department will require the successful Proposer to submit monthly reports showing progress toward meeting the following performance measures. The Department will provide the report format.

Elements of the report may include:

- Adherence to the construction schedule
- Successful transition and patient migration to replacement facility
- Status of TJC accreditation the replacement facility
- A successful cure rate in excess of 90% in complex TB cases
- Successful performance in working with the oversight of the existing A.G. Holley

- Advisory Board as established by section 392.69(4) Florida Statutes
- Successful operations and maintenance of the replacement facility

4.23 MONITORING AND PERFORMANCE EVALUATION METHODOLOGY

The Contract Manager shall be responsible for the approval and acceptance of all deliverables identified in any contract resulting from this RFP and approval of any change in project scope or objectives. The Contract Manager shall determine the successful Proposer's compliance with performance measures and conformance with the contract terms and conditions.

The successful Proposer shall comply with all Department quality assurance activities and processes, in addition to maintaining its own quality assurance functions in compliance with TJC standards. The successful Proposer shall permit the Department access to the facility, staff, patients, and records at all times. The successful Proposer agrees to cooperate fully with the Department in the conduct of performance audits and financial audits.

This section of the RFP is intended to be in addition to other audit requirements found in other documents incorporated by reference in the resulting contract and is not to be construed as a limitation upon them. The successful Proposer agrees to include these audit and record-keeping requirements in all approved subcontracts and assignments that result from this RFP.

By execution of the contract resulting from this RFP, the successful Proposer hereby acknowledges and agrees that its performance under the contract shall meet the standards set forth in the RFP document and will be bound by the conditions set forth in the contract. If the successful Proposer fails to meet these standards, the Department, at its exclusive option, may allow up to six months for the successful Proposer to achieve compliance with the standards. If the performance deficiencies are not resolved to the satisfaction of the Department within the prescribed time, and if no extenuating circumstances can be documented by the successful Proposer to the Department's satisfaction, the Department shall terminate the contract with the successful Proposer. The determination of the extenuating or mitigating circumstances is the exclusive determination of the Department.

4.24 PERFORMANCE REMEDIES

The successful Proposer shall achieve full TJC accreditation within 18 months of occupying the replacement facility or pay the Department a performance remedy equivalent to 5 percent of the annual payment from the State anticipated to be paid under the provisions of the contract, assessed annually until accreditation is achieved. Provisional accreditation, conditional accreditation or preliminary non-accreditation will not meet this requirement.

If at any time, the successful Proposer ceases to have or fails to attain good standing with TJC, it will face an additional performance remedy. For the first 90-day period in which it did not have good standing, this performance remedy will be equivalent to 5 percent of the annual payment anticipated to be paid under the provisions of the contract, assessed for that period. For each consecutive 90-day period thereafter, the performance remedy shall increase by an additional 5 percent assessed each 90 day period until it attains good standing. As used herein, good standing means accreditation with commendation or basic accreditation. It will be the successful Proposer's responsibility to contact the Department's Contract Manager within 24 hours of any notification by TJC that it has either lost accreditation or received conditional accreditation. All performance remedies shall be paid from the successful Proposer's corporate or private funds and result in no reduction in the contracted level of service.

Failure to comply with performance remedies may result in termination of the contract. Performance remedies are not to be considered penalties or to act in place of any other form of liquidated damages or performance bond(s) entered into as a result of this RFP and any contract which may result from

this RFP. Moreover, the performance remedies shall be in addition to any other remedies the Department has in equity or at law. Election of one remedy shall not preclude the use of another.

4.25 PROVIDER UNIQUE ACTIVITIES

The successful Proposer is solely and uniquely responsible for the satisfactory performance of the tasks described in Section 4.11 Task List. By execution of the resulting contract the successful Proposer recognizes its singular responsibility for the tasks, activities, and deliverables described therein and warrants that it has fully informed itself of all relevant factors affecting accomplishment of the tasks, activities, and deliverables and agrees to be fully accountable for the performance thereof.

4.26 DEPARTMENT OBLIGATIONS

The Department may provide technical support and assistance to the successful Proposer within the resources of the Department to assist the successful Proposer in meeting the required tasks in Section 4.11 Task List. The support and assistance, or lack thereof shall not relieve the successful Proposer from full performance of contract requirements. Public Health functions related to tuberculosis control and prevention will remain the responsibility of the Department of Health.

4.27 DEPARTMENT DETERMINATIONS

The Department has reserved the exclusive right to make certain determinations in these specifications. The absence of the Department setting forth a specific reservation of rights does not mean that all other areas of the resulting contract are subject to mutual agreement. The Department reserves the exclusive right to make any and all determinations that it deems necessary to protect the best interests of the State of Florida and the health, safety, and welfare of the clients who are served by the Department either directly or through any one of its contracted Providers.

4.28 INSURANCE REQUIREMENTS

The successful Proposer, as an independent contractor, is neither covered by the state's Risk Management Trust Fund for liability nor does it have sovereign immunity. Under no circumstances will the state's risk management insurance coverage extend to indemnify an independent contractor. Therefore, as a condition of obtaining a contract with the Department, the successful Proposer shall produce confirmation of comprehensive general liability insurance coverage (broad form coverage), specifically including premises, fire and legal liability. The Department shall be listed as an additional named insured on this policy. In addition, the successful Proposer shall obtain comprehensive automobile liability insurance. Policies for both bodily injury and property damage shall provide coverage on a per-occurrence basis.

Further, the successful Proposer shall secure workers' compensation insurance for all of its employees associated with the work of this project. If any work is subcontracted, the subcontract shall similarly require the subcontractor to provide such insurance for all its employees unless those employees are covered by the protection afforded by the successful Proposer. This insurance shall comply fully with Florida's Workers' Compensation Law.

In addition, the successful Proposer shall obtain and provide proof of professional liability insurance coverage, including medical malpractice liability and errors and omissions coverage, to cover all professional services to be provided by the successful Proposer.

The successful Proposer shall be solely responsible for identifying and determining the extent of any insurance coverage necessary to provide full financial protection for the Department. It shall not commence any work arising from any contract/s that may result from this RFP until it has obtained all of the required forms of insurance delineated herein, and the existence of such insurance has been submitted to and confirmed by the Contract Manager. All insurance policies shall be with Florida licensed insurance companies.

The Department shall be exempt from, and in no way liable for, any sums of money that may represent a deductible in any commercial insurance policy. The payment of any deductible shall be the sole responsibility of the successful Proposer or subcontractor providing the insurance.

For the purposes of responding to this RFP, the Proposer is not required to purchase the forms of insurance indicated above, but shall show the ability to provide such insurance if its proposal is selected. Ability to provide such insurance shall include sample insurance policies (including the cost of the policies) and endorsements with a certified statement from the insurance carriers issuing the policies that such policies are available to the Proposer.

4.29 FINANCIAL SPECIFICATIONS

The Proposer shall submit with their proposal audited financial statements for the last three years.

The provision of hospital services and other operations shall commence upon the availability of the proposed replacement facility. Payments from the State of Florida shall not commence until the replacement facility is fully operational with all the necessary initial operational licenses.

Funding Sources: Annual funding for patient treatment and all other operations of the 45 bed replacement facility may not exceed \$9 million annually. The existing hospital facility and campus operates with approximately \$9.7 million per year. The State expects the operations of the replacement hospital can be performed more efficiently than the current operations budget of the A.G. Holley State Hospital.

Design and Construction Financial Plan: The Proposer shall submit with their proposal a plan that includes the detailed budget associated with the development of a project of this scope.

Management, Operational, and Maintenance Financial Plan: The Proposer shall submit with their proposal a plan that includes the budget associated with the management, operations, and maintenance of the replacement facility within the limitation of state funding.

Continuance of Patient Care in the Replacement Facility: The Proposer shall submit with their proposal a plan to ensure that the State will be able to continue care for patients in the event of default, early termination, or on the ending date of the contract.

Disposition of Property: The Proposer shall submit with their proposal a plan to transition the Replacement Facility back to the State including the disposition of the land, facility, furnishings, and equipment at the end of the contract term.

Capital Financing Proposals: The Proposer shall submit with their proposal a plan that provides a complete description of financing options that would enable the desired program to be developed. Those options may include but are not limited to:

- a. Lease-Purchase agreement with the State
- b. Tax Exempt Certificates of Participation (COPS) or other securities

4.30 EVALUATION OF PROPOSAL

Each proposal will be evaluated to determine if it meets the qualifying criteria in Attachment I. These are considered Qualified Proposals.

Each Qualified Proposer's Proposal will be evaluated and scored based on the criteria defined in Attachment II. Evaluation sheets will be used by the evaluation team to designate the point value assigned to each proposal. The scores of each member of the evaluation team will be averaged within

each section to determine the final scoring. The Proposer receiving the highest score will be selected for award.

The Department reserves the right to reject all proposals resulting in no contract and the right to waive any minor irregularities.

4.31 REQUIRED DOCUMENTATION

The following documentation shall be submitted by Proposers participating in this solicitation:

- Qualifying Criteria as indicated in Attachment I
- Required Certifications - Attachment IV
- Reference Forms - Attachment VII (A) and Attachment VII (B)

4.32 TITLE PAGE

Each copy of the proposal shall include a title page that contains the following information:

1. RFP number;
2. Title of proposal;
3. Proposer's name;
4. Name, title, phone number and address of person who can respond to inquiries regarding the proposal; and,
5. Name of Proposer's project director (if known).

4.33 DESCRIPTION OF APPROACH TO PERFORMING TASK

The proposal shall include a section to provide insight into the Proposer's approach to providing the services as specified in this solicitation. The Proposer will address all areas of work within the Section 4.11 Task List. The Proposer's technical approach will demonstrate a thorough understanding and insight into this project. The Proposer's demonstrated technical knowledge, expertise and ability to meet the specifications stated in this RFP. At a minimum, this section should address the following factors:

- Medical and Operational
- Financial Plans
- Design and Construction
- Facility Maintenance and Operations

4.34 DESCRIPTION OF STAFFING AND ORGANIZATIONAL CAPACITY

To ensure that competent and capable staff will be hired or retained to perform the work described, the Proposer shall describe how its project and hospital management teams will be organized to best accomplish the requirements of this RFP. The Proposer shall identify the individual who will be responsible for the overall management and operation and describe the qualifications and duties that are defined in the individual's job description.

The Proposer's proposal should include:

1. A description of the staff that will provide the service, their qualifications and the number of staff that will work on the project.
2. A synopsis of the Proposer's business entity and its qualifications, indicating ability to manage and complete the proposed project.
3. Table of organization
4. Resumes of critical project/program staff, including documented certifications and significant experience in the inpatient long term care of complex tuberculosis patients (including extensively resistant strains).
5. Proposer's capacity to accomplish tasks related to this project and information showing evidence of capability to perform.
6. Documentation which shows a proven ability to recruit and retain qualified staff

- particularly for specialized TB medical and technical positions, as shown by competitive salary and benefit structure.
7. Information that will provide the Department with a basis for determining the Proposer's organizational abilities to perform the work described in this RFP and whether it has the staff skills needed to successfully complete the work. The Proposer shall describe its staffing pattern for all staff, how it will recruit and maintain adequate numbers of competent staff, and methods used to orient, train and educate staff; and assess, maintain and improve staff competence.
 8. Proposer shall show the ability to provide insurance as indicated in Section 4.28
 9. The Proposer shall identify the following members of its project team: (1) financial advisor and/or accounting firm, (2) bond counsel, if applicable (3) legal counsel, (4) architectural firm, and (5) construction manager, if applicable. In addition, the Proposer shall indicate the specific services each member will provide, as well as provide any supporting information that indicates the member's expertise and qualifications for participation in a project of this type. The Proposer shall describe all previous projects where any of the project team members have worked together, which of the entities proposed were involved, and the type and extent of the interaction. Specific information regarding design professional's services, expertise and qualifications shall be submitted.
 10. The Proposer shall demonstrate that it will have on staff a sufficient number of administrative and clinical personnel to provide effective in-patient services as described in this RFP and the Proposer's proposal. Program policies and procedures shall define the types and numbers of clinical and managerial staff needed to provide the hospital treatment services in a safe and therapeutic environment.
 11. The Proposer shall describe an organizational chart that assures sufficient supervisory staff on all shifts for both security staff and direct clinical care staff. There shall be provisions for overlap at shift changes to allow for good communication and information-sharing about individual patient progress, behavior and needs and general facility or program conditions. The Proposer shall establish a clear line of accountability and oversight to ensure that staff at all levels and on all shifts are following procedures and good practice in the care and treatment of patients.
 12. The Proposer shall provide information concerning its proposed staffing patterns and modules by discipline, anticipated salary structure and benefits package, and copies of its proposed administrative and clinical organizational charts. These documents shall be accompanied by an explanation as to why these choices or levels would be appropriate for this particular facility.
 13. The Proposer shall provide a policy on recruitment and selection using both objective and subjective principles. Recruitment and selection shall be done without regard to age, race, color, sex, religious creed, national origin, political opinions or affiliations, marital status, or handicap except when such requirement constitutes a bona fide occupational qualification necessary to perform the tasks associated with the position, equal opportunity practices relating to recruitment, appointment, training, promotion, or other employment practices.
 14. The Proposer shall describe how it will provide quality, timely and ongoing training of and supervision for the hospital staff, including those under subcontracts. The plan shall include providing timely and comprehensive orientation to replacement staff. The Proposer shall describe how it will assure that all staff are trained in, and that staff performance is regularly evaluated on, knowledge of the laws, policies, regulations and procedures governing the facility's program and operation that are relevant to their responsibilities.

15. The Proposer shall indicate its intent to cooperate in recruiting and retaining sufficient numbers of competent staff throughout the transition from the existing A.G. Holley State Hospital to the replacement facility.

4.35 CROSS REFERENCE TABLE

In order to assist the Proposer(s) in the development of a responsive proposal and to facilitate proposal evaluation by the Department, the Proposer may provide a table, which cross references the contents of the offer with the following sections of the RFP. There is no specified or standard format for this table; however the following sample is provided as a suggestion.

RFP Section	Subject	Proposal Page
4.32	Title Page	
4.33	Description of Approach to Performing Tasks	
4.29	Financial Proposal and Budget Narrative	
4.34	Description of Staffing and Organizational Capacity	
4.31	Required Documentation	

SECTION 5.0 - SPECIAL INSTRUCTIONS TO PROPOSERS

These "Special Instructions" shall take precedence over form PUR 1001 unless the conflicting term in PUR 1001 is statutorily required, in which case the term contained in the form PUR 1001 shall take precedence.

5.1 INSTRUCTIONS FOR SUBMITTING PROPOSALS

Electronic submission of proposals is not required and will not be accepted for this solicitation. This Special Instruction takes precedence over General Instruction #3.

- Proposals may be sent by U.S. Mail, Courier, Overnight, or Hand-Delivered to the location as identified in the Timeline.
- Proposers are required to complete, sign, and return the "Title Page" with their proposals.
- Proposals shall be submitted in a sealed envelope/package and shall be clearly marked on the outside with the proposal number, date and time of opening, as identified in the Timeline.
- It is the responsibility of the Proposer to assure their proposal is submitted at the place and time indicated in the Timeline.
- The State of Florida's performance and obligation to pay under this contact is contingent upon annual appropriation by the Legislature.
- Late proposals/offers will not be accepted.

5.2 PUBLIC RECORDS AND TRADE SECRETS

Article I, Section 24, Florida Constitution, guarantees every person access to all public records, and Section 119.011, Florida Statutes, provides a broad definition of public record. As such, all responses to a competitive solicitation are public records unless exempt by law. Any Proposer claiming that its response contains information that is exempt from the public records law shall clearly segregate and mark that information "**CONFIDENTIAL**" and provide the specific statutory citation for such exemption. Failure to comply with this section will result in the complete disclosure of all submitted materials not in compliance with this section. The Department of Health will not defend the Proposer's claim of public record exemption, but will notify the Proposer of receipt of a public records request so that the Proposer may defend its claim in court.

5.3 INSTRUCTIONS FOR FORMATTING PROPOSALS

- The proposal should be single-spaced. Include written narrative and tables to describe how the tasks would be performed, references with contact information, and other support materials.
- The pages must be numbered and with one-inch margins used.
- The font size and type is at the discretion of the Proposer but shall be at least as large as the font type you are currently reading (Arial 11).
- One (1) original proposal, ten (10) hard copies of the proposal, and one electronic copy of the proposal on either CD or disk, which includes all supporting documents.

Materials submitted will become the property of the State of Florida. The state reserves the right to use any concepts or ideas contained in the response.

5.4 PROPOSERS INQUIRIES

Questions related to this RFP shall be received in writing directed to the contact person listed below by the time indicated in the Timeline. The questions may be sent U.S. mail, overnight, courier, e-mail, fax, or hand-delivered. During an active competitive solicitation, communications are restricted to those submitted in writing during the period identified in the Timeline. Inquiries submitted after the period specified in the Timeline will not be addressed. Answers to questions submitted in accordance with the Timeline will be posted on the MyFlorida.com Vendor Bid System web site, http://vbs.dms.state.fl.us/vbs/main_menu.

Proposers to this solicitation or persons acting on their behalf may not contact, between the release of the solicitation and the end of the 72-hour period following the agency posting the notice of intended award, excluding Saturdays, Sundays, and state holidays, any employee or officer of the executive or legislative branch concerning any aspect of this solicitation, except in writing to the procurement officer as provided in the solicitation documents. **Violation of this provision may be grounds for rejecting a proposal.**

Florida Department of Health
 Attention: Janice Brown, Suite 310
 4052 Bald Cypress Way, Bin B07
 Tallahassee, FL 32399-1749
 Fax: 850-412-1188
 Email: janice_brown@DOH.state.fl.us

5.5 PRE-PROPOSAL CONFERENCE

A pre-proposal conference will be held at the time and location indicated in the Timeline. The pre-proposal conference is the only open forum available during this competitive bid process for answering questions and making clarifications.

5.6 SPECIAL ACCOMMODATIONS

Any person requiring special accommodations at DOH Purchasing because of a disability should call DOH Purchasing at (850) 245-4199 at least five (5) work days prior to any pre-proposal conference, proposal opening, or meeting. If you are hearing or speech impaired, please contact Purchasing by using the Florida Relay Service, which can be reached at 1-800-955-8771 (TDD).

5.7 SUBCONTRACTORS

The successful Proposer may, only with prior written approval of the Department, enter into written subcontracts for performance of specific services under the contract resulting from this solicitation. Anticipated subcontract agreements known at the time of proposal submission and the amount of the subcontract shall be identified in the proposal. If a subcontract has been identified at the time of proposal submission, a copy of the proposed subcontract shall be submitted to the Department. No subcontract that the Proposer enters into with respect to performance under the contract shall in any way relieve the Proposer of any responsibility for performance of its contract responsibilities with the Department. The Department reserves the right to request and review information in conjunction with its determination regarding a subcontract request.

The successful Proposer shall provide a monthly Subcontract Report summarizing all subcontracting/material suppliers performed during the prospective contract period. This report shall include the name and address, Federal Employment Identification number and dollar amount expended for any subcontractor. A copy of this form shall be submitted to the Contract Manager of the Department of Health. The Department of Health encourages the use of MWBE and SDVBE vendors for subcontracting opportunities. For assistance locating a certified MWBE or a SDVBE, contact the Department of Health's Minority Coordinator (850-245-4198) or the Office of Supplier Diversity (850-487-0915), as needed.

SECTION 6.0 - SPECIAL CONDITIONS

6.1 COST OF PREPARATION

Neither the Department of Health nor the State is liable for any costs incurred by a Proposer in responding to this solicitation.

6.2 VENDOR REGISTRATION

Each vendor doing business with the State for the sale of commodities or contractual services as defined in Section 287.012, F.S., shall register in the MyFloridaMarketPlace system, unless exempted under subsection 60A-1.030(3), F.A.C. Also, an agency shall not enter into an agreement for the sale of commodities or contractual services as defined in Section 287.012 F.S. with any vendor not registered in the MyFloridaMarketPlace system, unless exempted by rule. A vendor not currently registered in the MyFloridaMarketPlace system shall do so within 5 days after posting of intent to award. Information about the registration is available, and registration may be completed, at the MyFloridaMarketPlace website

http://dms.myflorida.com/business_operations/state_purchasing/myflorida_marketplace/vendors.

Those lacking internet access may request assistance from the MyFloridaMarketPlace Customer Service at 866-352-3776 or from State Purchasing, 4050 Esplanade Drive, Suite 300, Tallahassee, Florida 32399.

For vendors located outside of the United States, please contact Vendor Registration Customer Service at 866-352-3776 (8:00 AM - 5:30 PM Eastern Time) to register.

6.3 IDENTICAL TIE PROPOSALS

When evaluating Proposer's responses to solicitations where there is identical pricing or scoring from multiple Proposers, the Department shall determine the order of award in accordance with Rule 60A-1.011 F.A.C.

6.4 ADDENDA

If the Department of Health finds it necessary to supplement, modify or interpret any portion of the specifications or documents during the solicitation period a written addendum will be posted on the MyFlorida.com Vendor Bid System, http://vbs.dms.state.fl.us/vbs/main_menu. It is the responsibility of the Proposer to be aware of any addenda that might have bearing on their proposal.

6.5 VERBAL INSTRUCTIONS PROCEDURE

No negotiations, decision, or actions shall be initiated or executed by the Proposer as a result of any DISCUSSIONS WITH ANY State employee. Only those communications, which are in writing from Department of Health's Purchasing Office, may be considered as a duly authorized expression on behalf of the State. Also, only communications from Proposers in writing, will be recognized by the State as duly, authorized expressions on behalf of the Proposer.

6.6 UNAUTHORIZED ALIENS

NOTICE TO CONTRACTOR: The employment of unauthorized aliens by any contractor is considered a violation of section 274A(e) of the Immigration and Nationality Act. If the contractor knowingly employs unauthorized aliens, such violation shall be cause for unilateral cancellation of this contract.

6.7 CERTIFICATE OF AUTHORITY

All corporations, limited liability companies, corporations not for profit, and partnerships seeking to do business with the State shall be registered with the Florida Department of State in accordance with the provisions of Chapter 607, 608, 617, and 620, Florida Statutes, respectively.

6.8 MINORITY AND SERVICE-DISABLED VETERAN BUSINESS PARTICIPATION

The Department of Health encourages minority and women-owned business (MWBE) and service-disabled veteran business enterprise (SDVBE) participation in all its solicitations. Proposers are encouraged to contact the Office of Supplier Diversity at 850/487-0915 or visit their website at <http://osd.dms.state.fl.us> for information on becoming a certified MWBE or SDVBE or for names of existing businesses who may be available for subcontracting or supplier opportunities.

6.9 SURETIES - PROPOSAL GUARANTEE

All proposals shall be accompanied by a surety bond in the amount of ten percent (10%) of the annual contract value and conditioned upon the successful Proposer submitting the specified performance bond within ten (10) calendar days following notice of award. Failure by a Proposer to provide the required proposal guarantee in the manner stated shall cause the proposal to be considered non-responsive to this solicitation. The proposal guarantee will be returned after the opening of proposals to all non-responsive Proposers, and the remainder will be returned after the contract is executed. The cost of the proposal guarantee shall be borne by the Proposer.

6.10 SURETIES - PERFORMANCE BOND

Within ten (10) days after notification of award, the awarded Proposer shall be required to submit a performance bond in the amount of 100% of the annual contract value and both a Performance Bond and a Labor and Material Payment Bond each for 100% of replacement facility project cost. Proposals shall indicate how the State's interests are protected through performance bonds based on the scenario proposed. Failure by the awarded Proposer to provide the required performance bond within the time designated shall cause the proposal guarantee submitted with the proposal to be forfeited as

liquidated damages because of such failure and shall cause the Department to withdraw the award and proceed with the next lowest responsive proposal. The bond shall be renewed each subsequent year before the preceding year expires. The bond shall be issued by a surety company licensed to do business in the State of Florida. The cost of the performance bond shall be borne by the Proposer.

6.11 CONFLICT OF INTEREST

Section 287.057(18), Florida Statutes, provides, "A person who receives a contract that has not been procured pursuant to subsections (1) through (5) to perform a feasibility study of the potential implementation of a subsequent contract, who participates in the drafting of a solicitation or who develops a program for future implementation, is not eligible to contract with the agency for any other contracts dealing with that specific subject matter, and any firm in which such person has any interest in not eligible to receive such contract. However, this prohibition does not prevent a proposer who responds to a request for information from being eligible to contract with an agency." The Department of Health considers participation through decision, approval, disapproval, recommendation, preparation of any part of a purchase request, influencing the content of any specification or procurement standard, rendering of advice investigation, or auditing or any other advisory capacity to constitute participation in drafting of the solicitation.

6.12 STANDARD CONTRACT/PURCHASE ORDER

Each Proposer shall review and become familiar with the Department's Standard Contract and/or Purchase Order (Attachment III & Attachment VI) which contains administrative, financial and non-programmatic terms and conditions mandated by federal or state statute and policy of the Department of Financial Services. Use of one of these documents is mandatory for departmental contracts as they contain the basic clauses required by law. The terms and conditions contained in the Standard Contract or Purchase Order are non-negotiable. The standard contract/purchase order terms and conditions are included as Attachment III & Attachment VI.

6.13 LICENSES, PERMITS, AND TAXES

Proposer shall pay for all licenses, permits and taxes required to operate in the State of Florida. Also, the Proposer shall comply with all Federal, State & Local codes, laws, ordinances, regulations and other requirements at no cost to the Florida Department of Health.

6.14 TERMINATION

Termination shall be in accordance with Department of Health Standard Contract, Attachment III, Section III B or Department of Health Purchase Order Terms and Conditions, Attachment VI. In the event of termination, or because of lack of funds, the state will take control of the facility to ensure continuous patient care in order to fulfill statutory duties under Chapter 392.

**ATTACHMENT I
QUALIFYING CRITERIA**

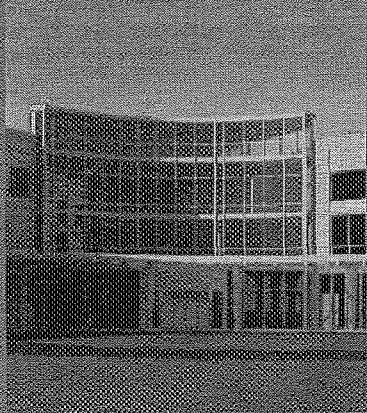
QUALIFYING CRITERIA REQUIREMENTS: The initial screening requirements are described below. Failure to comply shall render a proposal non-responsive and ineligible for further evaluation.

CRITERIA ITEM	Y/N
i) Does the proposal include the proposal guarantee as required by section 6.9?	
ii) Does the proposal include the signed Required Certifications, Attachment IV?	
iii) Does the proposal provide Proposer's audited financial statements as required in section 4.29?	
iv) Does the proposal provide resumes and an organization chart of key staff as required in section 4.6, & 4.34?	
v) Does the proposal provide evidence of at least 5 years of operating an inpatient hospital as required by section 3.3 & 4.3?	
vi) Does the proposal include a financial plan to operate 45 beds for no more than \$9 million per year as required in section 4.29?	
vii) Does the proposal include the design and construction management plan as required by section 4.13?	
viii) Does the proposal include the Capital Financing Plan as required by section 4.29?	
ix) If the proposal indicates a site other than the A.G. Holley State Hospital site does the proposal include the required site description as required by section 4.12?	
x) Does the proposal include the facility design professional's qualifications required by section 4.13?	

Proposer Name: _____ Evaluator Name: _____



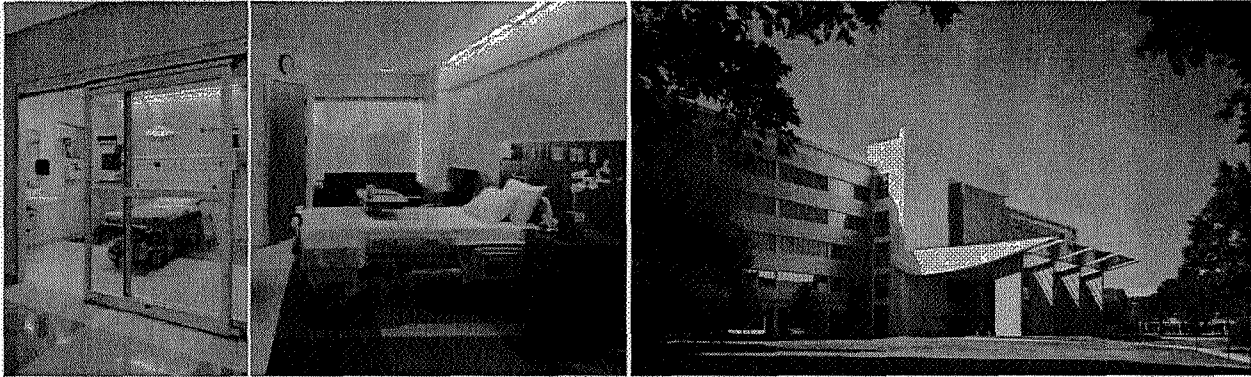
**A.G. Holley State
Hospital
Replacement
Facility Proposal**



A.G. Holley State Hospital Replacement Facility Proposal



UNIVERSITY OF FLORIDA • FLORIDA ATLANTIC UNIVERSITY • JUPITER MEDICAL CENTER • PERKINS+WILL •
PHASE 3 PROPERTIES • CBRE LIFE SCIENCES • ROBINS & MORTON • GEORGE K BAUM



Mayo Hospital Replacement,
Jacksonville Florida
(Perkins+Will)

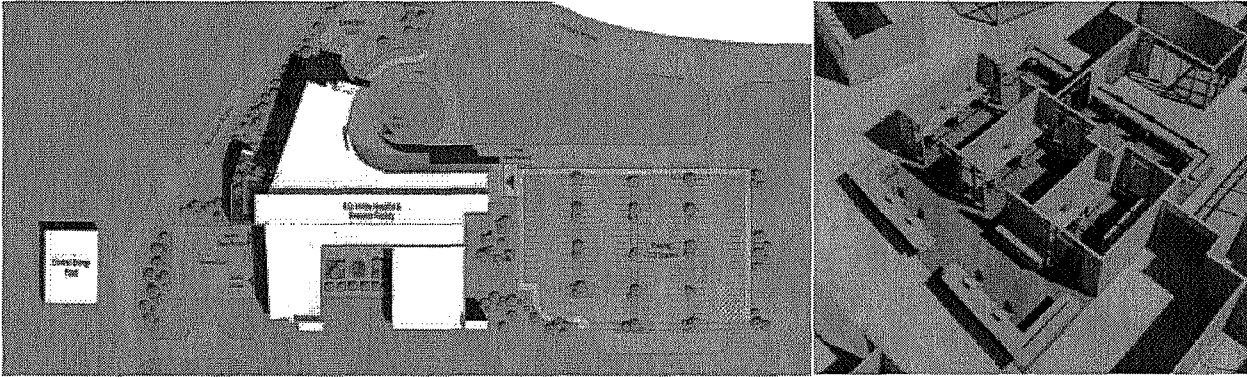
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A.G. Holley State Hospital Replacement Facility Proposal

Section 02 Executive Summary

Executive Summary



A.G. Holley, Proposed Site Plan and Central Nursing Hub. For more diagrams, please refer to Section 05.

Introduction

The University of Florida (“UF”), is pleased to submit this response to the Request for Proposal (“RFP”) issued November 4, 2009, by the State of Florida, Bureau of Tuberculosis and the Florida Department of Health (“DOH”) for the replacement of the existing A.G. Holley State Hospital in Lantana, Florida. In collaboration with Florida Atlantic University (“FAU”), we propose to relocate the hospital to a new site on the FAU campus in Jupiter or on a site now owned by The Rendina Companies (“Rendina”) immediately adjacent to the FAU campus. Each will be in close proximity to the Scripps Florida Institute and the Max Planck Florida Institute. Both potential sites offer the opportunity for the development of an efficient state-of-the-art TB hospital as well as opportunities for cooperation and collaboration with the physicians, scientists and researchers at the hospital, UF, Scripps, Max Planck and FAU. Site selection will be made by UF in cooperation with DOH, FAU and Rendina.

We propose the development, construction, financing and operation of a new state-of-the-art hospital and research facility (the Florida Infectious Diseases Research and Education Center) containing an aggregate of approximately 150,000 square feet. This includes a 45-bed hospital unit; approximately 30,000 square feet of integrated research facilities; an auditorium and meeting rooms for conferences and training; and other common facilities. Certain non-essential functions will be outsourced to Jupiter Medical Center (“JMC”). UF will assume responsibility for operation of the research and training components of the Center, and will provide physician coverage for the hospital through collaborative agreements with DOH. Ownership of the facility, and responsibility of its hospital component, will remain with DOH. Total Project Cost for the new facility will be approximately \$77 million as detailed in the project budget in Section 10, Appendix, and will be financed by the issuance of tax-exempt bonds. The new facility will meet and exceed all of the goals and objectives of the RFP.



A.G. Holley State Hospital
Replacement Facility Proposal
Section 02 Executive Summary

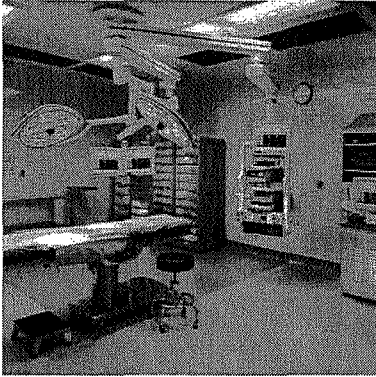


*Tift Regional Medical Center
Tifton, Georgia*

We understand that the primary objective of the RFP is to assure that individuals with complex cases of tuberculosis meet Florida Department of Health, Bureau of Tuberculosis standard of care before discharge. The replacement facility shall be designed to fully integrate treatment and security in an environment that ensures the safety and health of patients, staff and the public. However, the current proposal is predicated on the vision that reconstruction of this facility provides an “once-in-a-lifetime” opportunity to create an internationally recognized Center for research and training in tuberculosis and other infectious diseases. Such a Center, while going beyond the facility described in the RFP, will serve as a strong base for further research activity in the area, with significant high-level job creation for Florida and leveraging of the already substantial state biotech investment at this location. The project as currently designed has the opportunity to not only deliver a state-of-the-art TB hospital but also to successfully provide a world-class medical research asset designed to spawn life saving research technologies within Florida’s burgeoning health science industry.

Our team has toured the existing A.G. Holley State Hospital and has a clear understanding of the current operational procedures. Accordingly, we are familiar with the challenges, project constraints and realize the significant potential that exists within this redevelopment opportunity. As requested, our proposed development plan generously provides an efficient and well-appointed replacement hospital consistent with and accommodating to the growing demands of the patient population. Our proposal delivers an efficient operational plan and an economically viable development concept for the requested replacement facility. Further, our planning process has included the possibility of a second, linked building at some point in the future. We envision a second phase that could serve as a research, innovation, technology, or expanded treatment facility that will complement and enhance the operations and reputation of the hospital as well as provide significant opportunities for collaboration and cooperation with the neighboring research institutions of Scripps Florida, Max Planck and Florida Atlanta University, creating a leading world-center for TB healthcare and both TB and life science research alike.

This proposal has broad support from all sectors of the health sciences industry, the scientific, research and academic communities, adjacent land owners and other stakeholders including FAU, Scripps, Max Planck, Jupiter Medical Center, Palm Beach County, the Business Development Board of Palm Beach County and the Rendina Companies. Copies of letters expressing support, excitement and enthusiasm for the Project are included at the end of Section 01. This support is an important factor in enabling the DOH to achieve its goals and fulfill its mission for the new facility and in providing the State of Florida with its anticipated return on its significant investment in the FAU Jupiter campus.



South Georgia Medical Center
Valdosta, Georgia

This formal response to the November 4, 2009 Request for Proposal is viewed as an important first step in aligning strengths with the State of Florida and the DOH as a complete team, working together to determine the optimal development plan and operational plan for the project. The terms set forth herein are flexible and we welcome any comments or questions in how to best integrate this exciting development and operational strategy into the health sciences fabric of Florida

Background / Rationale

In the 1950s when A.G. Holley State TB hospital opened its doors, tuberculosis was well entrenched in its place among the top ten killers of Americans. In 1950 alone almost 35,000 people died in the US because of TB. In the first half of the twentieth century, effective medical therapy for TB did not exist and the afflicted were subjected to various concoctions, questionable procedures, and dubious strategies that, at first glance, reminded one of medical practices in the Middle Ages.

When the contagious aspects of TB were realized in the early twentieth century, thoughts turned to isolating patients away from the uninfected; thus was born the sanitarium movement, of which A.G. Holley was a part. However, shortly after A.G. Holley was constructed, advances in medical science made it possible to treat TB with specific antibiotics, decreasing the need for the prolonged hospitalizations for which sanitariums were designed. During the 1960's and 70's all but two of the former sanitariums in the US closed: one was the institution that would eventually become the Texas Center for Infectious Diseases and the other was A.G. Holley Hospital. Both of these institutions underwent a transformation from sanitariums to TB hospital to meet the changing realities of the TB epidemic, and have emerged as leaders in their field because of this transformation.

This reflects the fact that, in contrast to the initial hopes that arose after discovery that TB could be cured by antibiotics, TB has not disappeared. Instead, it has assumed new and increasingly troublesome guises: internationally, it is the leading cause of death associated with HIV, and efforts to treat infected patients are increasingly hampered by the rapid emergence of high-level resistance to most, if not all, standard antibiotics, including the emergence of what are now referred to as XDR ("extensively drug resistant") TB strains. In this setting, increasing dollars are being committed to TB research by the U.S. Government, the World Health Organization, and private foundations such as the Bill and Melinda Gates Foundation: in 2008, total grant dollars available for work with TB were in the range of \$500 million. Above and beyond that, substantial resources are being committed by pharmaceutical and biotech companies to TB, including development of a series of new antibiotics.



*John B. Amos Cancer Center
Columbus, Georgia*

A.G. Holley currently provides state-of-the-art clinical care for some of the most difficult to treat TB patients anywhere in the world and does so effectively and efficiently. In collaboration with UF, A.G. Holley is also a core component of the Southeastern National Tuberculosis Center, one of four such CDC-funded Centers in the United States, placing it in a national leadership role in TB education and training. We understand the financial issues that drive the desire for privatization of A.G. Holley. However, complete privatization, within the strict constraints of the RFP, has the potential for reducing the quality of care for Florida TB patients, and for causing significant job loss: this includes both immediate loss of jobs associated with closure of the current hospital, and failure to take advantages of the unique opportunities posed by the hospital in terms of new job creation in research and biotech. Rather than dismantling the current hospital and its highly trained staff, we shall build on the expertise present at A.G. Holley to maintain and enhance the quality of clinical care available to patients; and provide a venue that will attract additional research and biotech funding to Florida. Creation of an innovative and economically viable alternative role for A.G. Holley will capitalize on what is great about A.G. Holley and the DOH, and provide a model for public private collaborations for the public good in these difficult financial times.

Four Points of Strength

Prior to presenting the detailed concept for our flexible development program of the site, we would like to delineate and describe members of our development and project design team. The individual strengths of each entity, as well as their combined experience in planning, developing and operating large scale and diverse healthcare and research projects is a key strength of this proposal.

Point One - The Team

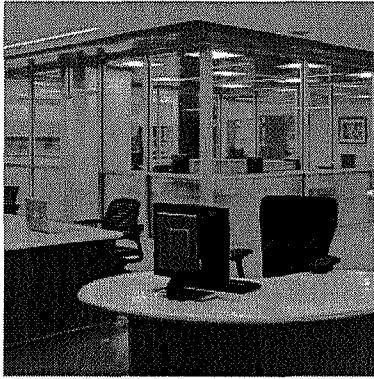
The University of Florida leads the overall team. For this project, we have assembled an outstanding team of seasoned institutional professionals whose expertise in delivering first class full-service healthcare, life science research and clinical care medical facilities will provide the State with the experience necessary to implement this ambitious replacement project. Our members of the team include:

- | | |
|-----------------------------|---------------------|
| University of Florida | Project Leader |
| Phase 3 Properties | Developer |
| Perkins+Will | Architect |
| George K. Baum | Financial Advisor |
| CBRE | Real Estate Advisor |
| Florida Atlantic University | Research Partner |
| Jupiter Medical Center | Service Provider |



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A.G. Holley State Hospital
Replacement Facility Proposal
Section 02 Executive Summary



*Halifax Medical Center, France Tower
Daytona Beach, Florida*

Phase 3 Properties, Inc. (P3P) will be the developer of the Project. P3P's principals oversee the successful design, construction, development, leasing, operations and financing of a broad portfolio of complex, public/private mixed-use health science development projects containing residential, retail, life sciences and medical technology projects. P3P is one of the country's leading private developers and managers of quality life sciences facilities.

Our design, construction and technical team is led by one of the world's most accomplished and expansive firms, Perkins+Will, Inc. Their reputation for healthcare design excellence in a broad range of design specialties and the insights developed through successfully executing large-scale and highly collaborative projects will prove invaluable to this effort. Their deep knowledge of the State of Florida and their leadership of many of its most significant and complex public/private development efforts over the last three decades is a long list of accomplishments that has earned the respect and admiration of private, institutional and public clients throughout the country and the world. Their design leadership will ensure a thoughtful, informed and high performing adaptive replacement facility of the existing A.G. Holley State Hospital.

Every consultant on this team has a long history of accomplishments with state of Florida, has the design excellence and technical skills essential for successful project implementation, an outstanding track record of successful collaborations and we welcome the opportunity to introduce this team to the State of Florida and DOH:

- Planning, Design, Architecture, Interior Design and Landscape Architecture – Perkins+Will
- Construction and Costing - Robins & Morton
- Structural Engineer – Walter P Moore
- MEP Engineers – TLC Engineering for Architecture
- Civil Engineers: Kimley Horn

An Organizational Chart showing the members of the team is included at the end of this Executive Summary.

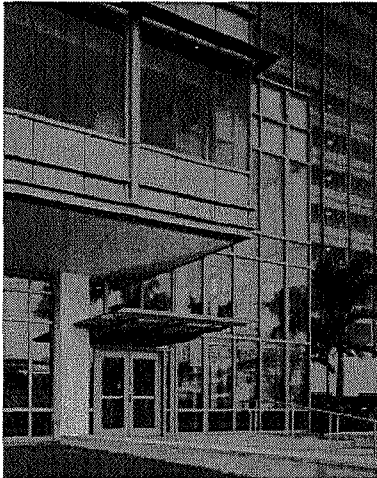
Point Two – Financing and Development Creativity

George K. Baum & Company (GKB) understands the uniqueness of this transaction, the scope of the project and the related complexities. Attention to detail is of paramount importance. Every detail matters from the participants, legal and corporate structure to funding mechanisms. Every decision has implications which will affect the organization's structure, flexibility, access to capital and ability to achieve future goals and objectives. GKB is mindful of these aspects of the transaction and will strive to achieve maximum flexibility for the organization while successfully securing efficient, low interest cost financing for the new state-of-the-art replacement facility for A.G. Holley State Hospital.



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A.G. Holley State Hospital
Replacement Facility Proposal
Section 02 Executive Summary



*University of Miami Clinical Research
Building
Miami, Florida*

GKB has extensive experience working with replacement hospitals, new campuses and first-time borrowers. This experience will prove to be invaluable to A.G. Holley State Hospital. Our bankers' hands-on approach, industry knowledge and expertise will assist in the project development and ensure successful financing of the project.

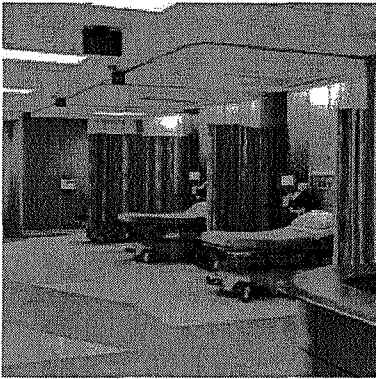
The recommended capital financing plan was carefully crafted based on information available and designed to maximize flexibility, minimize costs and balance risks. GKB's recommendation utilizes a 63-20 lease-back structure and Build America Bonds financing. Our recommended structure contemplates a project ground lease between Florida's Board of Trustees of the Internal Improvement Trust Fund (TIITF) and the Borrower who is a Nonprofit Corporation. The Nonprofit Corporation may be an existing entity or corporation formed for this specific project. The nonprofit status of the Borrower allows them to issue Build America Bonds. Build America Bonds are taxable bonds created under the American Recovery and Reinvestment Act of 2009. Build America Bonds are an attractive form of financing because the Borrower receives a tax credit equal to 35% of the interest cost of the bonds, effectively reducing the Borrower's all-inclusive cost of capital. In today's market, Build America Bonds are the most efficient form of fixed rate financing.

The capital finance plan is an important component of the overall transaction. GKB is aware there are numerous financing options. If fortunate to work with the Florida Department of Health and A.G. Holley State Hospital, we will evaluate all possible financing options in greater detail. GKB will strive to achieve the lowest possible cost of capital and maximum flexibility with the proper balance of risk for A.G. Holley State Hospital and the Florida Department of Health.

Point Three – The Creative Approach

Understanding the State's vision for a world-class replacement TB hospital and considering the proximity of the site to research and medical facilities, and applying detailed financial analysis for a variety of approaches, it is clear that the optimal development program should consider the inclusion of an expansion phase. The reasons for including this unique use are clear. As the patient populations are studied by world-renowned institutions like Scripps, Max Planck, the University of Florida, and Florida Atlantic University, the research that spins out of these institutions will, simply put, save lives. Further, the technologies that are spawned will all be Florida-based life science technologies, which will create a major economic impact for the state by creating successful health science companies.

This strategy of providing a phased development plan that will also have a second phase enhances and sustains the major investments the State has made into the health sciences industry. The complex hospital design



*Mayo Clinic Replacement Hospital
 Jacksonville, Florida*

adapts well to the proposed development plan by providing a central lobby, from which access to the second phase will be provided. This proximity will promote and encourage cooperation and collaboration by and among the leading scientists and researchers at the hospital, Scripps, Max Planck, and FAU. Not only will the State be achieving the goals of the RFP, but will also be setting a research engine in motion that will deliver growth to the State's economy. When the project is delivered under this development program, it will immediately enhance Florida's existing reputation as one of the leading destinations for advanced infectious disease care and research in the United States and provide a further quality TB care for the residents of Florida and the surrounding geographical region.

Point Four – The Design and Engineering Philosophy

Our team recognizes that each institution has its specific culture, challenges and goals. While this proposal attempts to convey our understanding of the unique needs of the institution, a successful design will be a collaboration of team members that includes user-groups on an ongoing basis as the design is conceived and developed.

The redevelopment of A.G. Holley provides unique opportunities to create a state of the art facility that combines clinical and research components. Perkins+Will believes there are several planning and design elements critical to the success of the project.

1. Integration

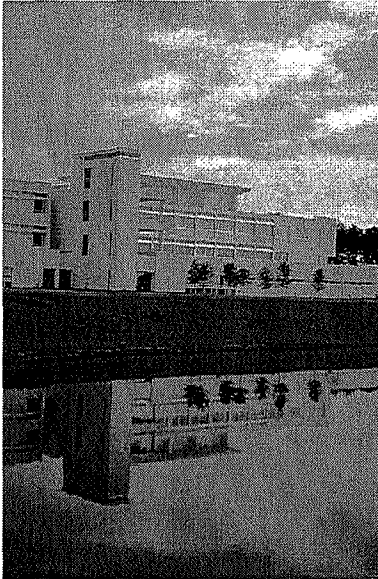
The A.G. Holley Hospital and Research Project provides a unique opportunity to develop a collaborative environment for research, education and patient treatment, resulting in a true center of excellence. Integrating each of these program components into a single building while maintaining appropriate separation of spaces allows extraordinary benefits to both the patients and research.

2. State of the art facilities and equipment

Advances in our understanding of TB allows us to rethink how we provide a built environment to best meet the unique needs of the TB patient, providing the negative air pressure necessary for patients while not completely restricting interaction. And development of world-class lab and research space can be achieved by drawing from our vast experience with similar, cutting edge projects.

3. Sustainability

Perkins+Will is an industry leader in sustainable design, understanding the importance of creating energy efficient, sustainable buildings. Developing the new facility to meet LEED qualifications will allow the institution to operate at substantially less cost and impact to the environment over the life of the facility.



*Florida Hospital Heartland
Sebring, Florida*

4. Adaptable and flexible spaces

Flexibility to respond to changes in the healthcare market is essential in any project of this magnitude. Flexibility for the future is achieved through a variety of elements including wide structural bays, use of materials, and development of clear organized circulation with consideration for future growth patterns.

5. Unique Patient Needs

The unique needs of the TB patient often involve far more than just the TB infection. The facility design responds to the infectious disease requirements, psychological challenges and security demands while promoting healing and rehabilitation. This is achieved through facility layout, choice of materials, and development of both indoor and outdoor therapy spaces, creating patient rooms that can respond to the necessary level of security.

6. Cost-effective design

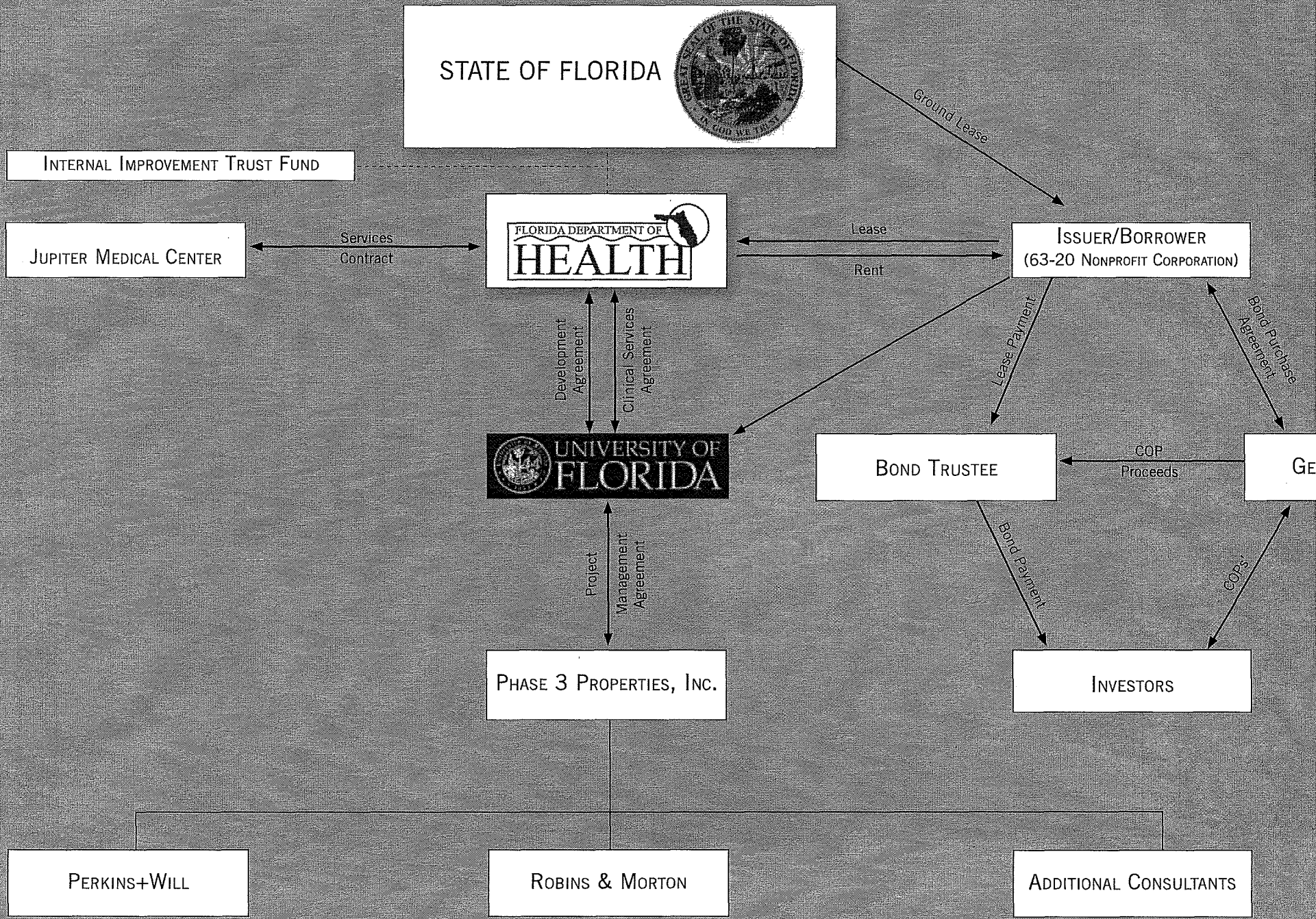
Developing cost effective buildings considers not only choice of durable yet economical materials, but also involves planning a facility that is space-efficient and has the ability to minimize staffing and operational costs over the course of the building. This can be accomplished in a variety of ways, including by sharing nurse stations and support spaces, using flexible-use offices, planning buildings to minimize staff circulation and maximize visual control capabilities of staff.

7. Safety

Patient and staff safety must be considered at all times, as well as the safety of the surrounding public. The proposed facility develops site security with appropriate fencing, landscape, and controlled exterior recreation spaces. The interior of the building provides the ability to have a locked unit for a portion of the patients needing a higher level of security, while giving more flexibility to other patients. Control stations are located to monitor entrances and exits and security systems provide yet further security capability.

8. Healthy, professional, productive work environments

Staff retention and recruitment is vital to sustaining a viable healthcare and research facility. The introduction of natural light into the work areas, efficient space configurations, and spaces designed to foster collaboration help create a healthy work



A.G. Holley State Hospital
Replacement Facility Proposal

Section 03

Medical and Operations Plan



1 Statement of ability to meet program goals/ Organizational Structure

The University of Florida team is committed to providing optimal medical care for patients in the relocated A.G. Holley hospital (Florida Infectious Diseases Research and Education Center), in a setting that will also facilitate research and training. We are proposing the following organizational structure: (Please also refer to the chart on the following page).

Hospital Management:

This proposal anticipates that DOH will retain ownership of the proposed facility, with management of the hospital component of the facility to be undertaken by DOH or its designee. The intent is to retain the current highly trained staff at A.G. Holley, placing them within an environment that will facilitate their ability to provide optimal patient care.

In preparing this proposal, the UF Team extensively investigated the possibility of bringing in an "outside" hospital management company to operate the hospital. Three different management companies were approached, including both local and national firms. All conducted comprehensive reviews of hospital operation, and, ultimately, all three indicated that they were not willing to assume management of the hospital because of significant concerns about its financial viability, particularly when the need to provide optimal care was balanced against the conditions and criteria in the RFA. Key elements in this decision included the specification that sovereign immunity would not transfer to the new hospital, and the \$9 million cap on the hospital budget.

Despite these circumstances, we have elected to proceed with the proposal, with the proviso, as outlined above, that DOH would retain ownership of the facility. Under this scenario, administration of the hospital would, at least initially, remain with DOH; should DOH subsequently elect to identify an outside management firm, that firm would need to be selected in a separate series of negotiations.

Physician Coverage, Clinical and Laboratory Research, Training:

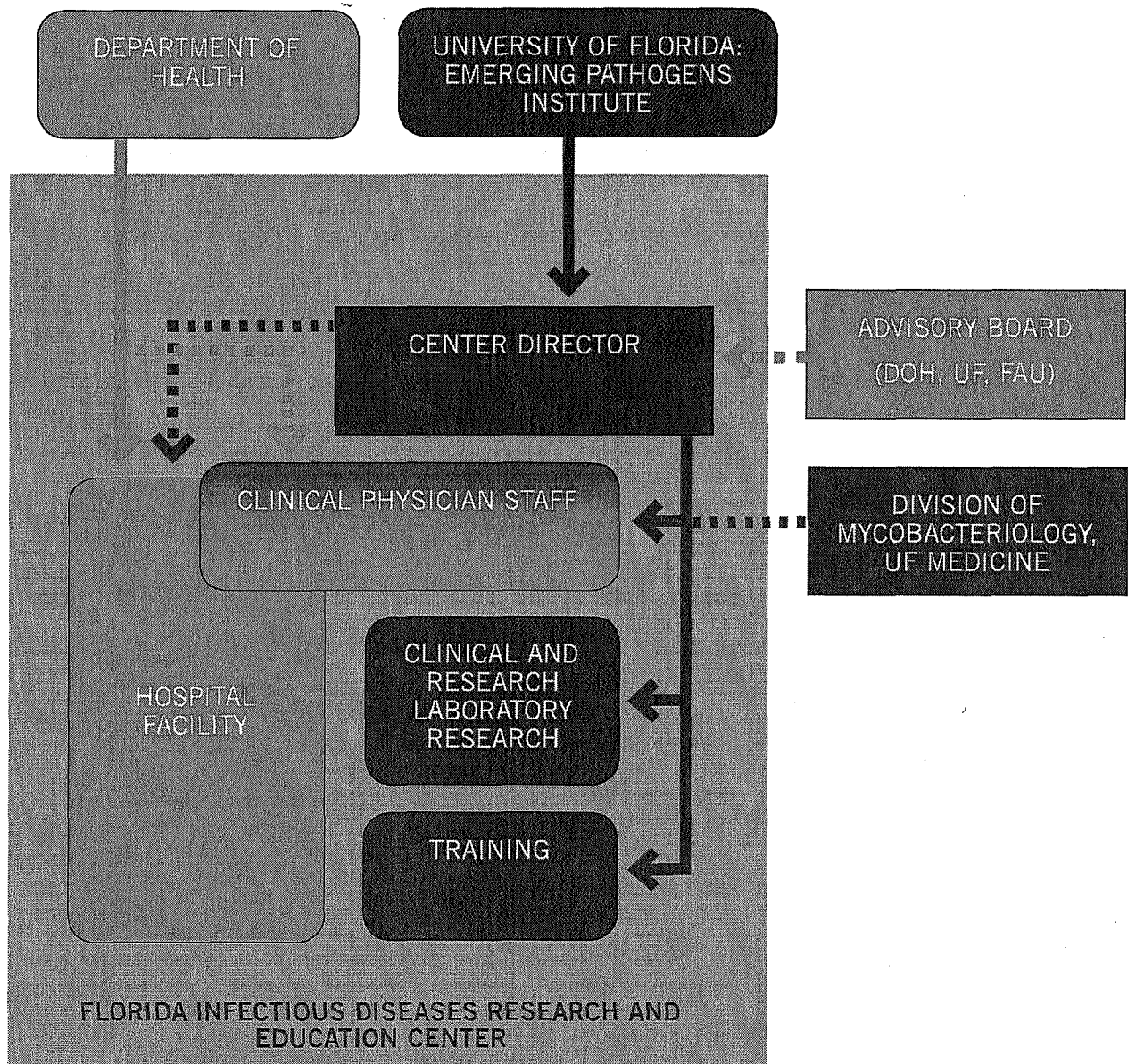
Physician clinical coverage, clinical and laboratory research, and training components of the facility will be under the supervision of a Center Director, working in consultation with the Center Advisory Board

Center Advisory Board

The Board will consist of five members, two appointed by the Department of Health, two appointed by the University of Florida, and one by Florida Atlantic University.



Organizational Structure





A.G. Holley State Hospital Replacement Facility Proposal Section 03 Medical and Operations Plan

Center Director

The Center Director will hold a full-time faculty appointment at the University of Florida, and will be appointed by the Director of the University of Florida Emerging Pathogens Institute, in consultation with the Center Advisory Board.

Physician Clinical Staff

Physicians constituting the medical staff of the facility will be supervised by a Medical Director, who will answer to the Center Director. Physician clinical staff will hold faculty appointments in the Division of Mycobacteriology, Department of Medicine, University of Florida College of Medicine, with dual appointments with the Bureau of TB and Refugee Health, DOH.

2 Demonstrated inpatient healthcare services experience

Nursing and administrative staff within the hospital facility will be directly employed by DOH. We anticipate that this staff will be drawn primarily from the existing staff at A.G. Holley Hospital, building on over 50 years of experience in managing complex TB patients.

3 Professional Qualifications for Medical Administration of New Hospital

The team assembled by the University of Florida has the necessary experience and is exceptionally well-qualified to manage complex TB cases. Home to the Southeastern National Tuberculosis Center (SNTC), a Centers for Disease Control and Prevention funded center, it is one of four National TB Centers that works in close collaboration with the state of Florida's TB Program as well as the CDC and state TB Programs around the country particularly in the Southeast. It is recognized as a national and international leader in TB education, training and medical consultation for the most difficult cases of tuberculosis in the country. Key team members include:

- **Dr. Michael Lauzardo**, the Director of the SNTC, has over twelve years experience in the clinical management of tuberculosis and has an equal amount of experience in the programmatic aspects of TB having served as the Deputy Health Officer for Tuberculosis for the State of Florida. He is one of the most experienced clinical TB physicians in the country.



A.G. Holley State Hospital
Replacement Facility Proposal
Section 03 Medical and Operations Plan

- **Dr. Kevin Fennelly** is a recent addition to the UF team. Dr. Fennelly has extensive experience in managing the most difficult and complex cases of TB including multi-drug resistant cases. He was part of the Global Tuberculosis Institute in Newark New Jersey, one of the other four CDC funded National TB Centers, and was Division Chief of the Division of Pulmonary and Critical Care Medicine at the University of Medicine and Dentistry, New Jersey. He has over 15 years experience in TB including working with multi-drug resistant TB cases in Uganda.
- **Dr. Charles Peloquin** is also a relatively new addition to the UF team having been recruited to Florida from the National Jewish Respiratory Health Center in Denver Colorado last year. Dr. Peloquin has been a global leader in the study and practice of TB pharmacokinetics for over 20 years and has published extensively on the topic. His research capabilities are un-paralleled and he brings a huge potential for extramural funding to our program.
- **Dr. Glenn Morris** is Director of the UF Emerging Pathogens Institute; prior to coming to UF in 2007, he served as interim Dean of the University of Maryland, Baltimore, School of Public Health. Board certified in Infectious Diseases, with training as a CDC EIS officer, he has 25 years experience in working with patients with TB as an infectious diseases consultant; he also has extensive administrative experience in management of complex research and clinical activities of this type.

While UF has a strong leadership group with extensive experience in work with TB, the intent would be to build on the existing, nationally-recognized expertise in TB case management already existent at A.G. Holley. This would be accomplished in two ways:

1. Physician staff:

Strong efforts would be made to recruit/retain the current physician staff at A.G. Holley. Physicians will hold faculty positions at UF, in the newly created Division of Mycobacteriology, Department of Medicine, College of Medicine, with anticipated dual appointments in the Bureau of TB and Refugee Health, DOH. Compensation for services provided by these and other TB physicians will need to be separately negotiated by DOH and UF if this proposal is accepted.

2. Nursing and other hospital staff:

Nursing and other hospital staff: This proposal anticipates that DOH will retain ownership of the proposed facility, with management of the hospital component of the facility to be undertaken by DOH or its designee. Again, the intent is to retain the current highly trained staff at A.G. Holley, placing them within an environment that will facilitate their ability to provide optimal patient care.



4 Staff Recruitment and Retention

Staff physicians will be members of the Division of Mycobacteriology, Department of Medicine, University of Florida College of Medicine. Recruitment will follow standard University procedures for recruitment of new faculty. Appointment through the University system will facilitate retention, as physicians will be eligible for College of Medicine benefits, will have greater flexibility in salary, and will have the opportunity to work within an academic teaching environment.

5 Delivery of Care

Care Delivery

All current A.G. Holley patient care protocols/policies will be retained, including policies relating to patient admission and discharge. Admission and discharge criteria will follow current guidelines. With anticipated retention of current clinical staff, decisions will be sound from a public health perspective.

Patient Eligibility and Reimbursement

The eligibility criteria used for admission will be the same that is used today. Those patients who, because of either medical, social, or other circumstances, are unable to be cared for in the community will be admitted and provided comprehensive care regardless of their ability to pay. By making the new A.G. Holley a state facility, the hospital will have at its disposal several other financial resources that would not be available if the facility were privatized (negotiated pharmacy contracts to ensure access to lower cost medications, disproportionate share, etc).

However, to offset some of the financial shortcomings in the past, other revenue streams must be considered. One, the lifting of the Medicare cap to allow patients who are hospitalized for more than 45 days to be eligible for continued payment. Second, careful selection of patients from out of state whose states would be willing to pay for their care in Florida because of higher costs to treat in their home state could add to the bottom line and regionalizing the services of the facility. Due regard will be taken to ensure that patients from outside Florida will not take beds from Florida residents.



6 Operational Organization

As mentioned previously, the operational and public health aspects of the new A.G. Holley will remain within the Department and will thus employ the expertise already possessed by the Department. No other institution has more experience than the Department in managing the most difficult and complex TB patients from a medical or public health perspective. We seek to complement that by introducing a strong research and educational component both of which will bring new resources to the Department through grants and other programs.

7 Patient Admission and Discharge

Please see above. Admission and discharge criteria will remain the same as previous and any changes will be made with the Bureau of TB and Refugee Health as a collaborator and partner. The goal shall remain to treat patients until cured.

8 Patient and Operations Transition to the new facility

The new facility will be completed prior to any transfer of patients to the new facility. Any contingency plans that may be necessary in the event of fiscal emergencies that may arise before the facility is completed will be developed with the Department.

9 Licensure and Operational Certificates

This proposal calls for the Department to maintain the current licensure and other operational certificates by TJC and other agencies. UF will insure that the physicians are credentialed appropriately and possess the appropriate skills necessary to perform their duties.



10 Approach to Obtain CON

The Agency for Healthcare Administration has indicated that it will work closely with the Department and the successful Proposer to obtain the CON (please refer to the Department response to submitted questions). As a specialty hospital with no overlap with surrounding facilities, the CON from the current A.G. Holley should transfer without difficulty.

11 Monthly Progress Reports

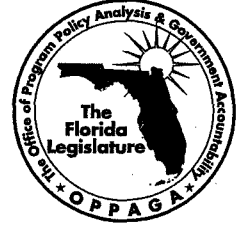
Monthly Progress Reports will be submitted to the Department regarding the clinical and medical aspects of the facility. Patient outcomes and discharges will be reviewed by the Medical Director and Center Director and quarterly Morbidity and Mortality conferences will be continued. Medical quality assurance evaluations will be shared with the Bureau of TB and Refugee Health on a monthly basis. Content of the monthly reports will include the following. The reader should bear in mind that if the Department wishes that other information be included in monthly reports, the UF team will be as accommodating as possible.

- Number of Admissions
- Number of Discharges
- Adverse outcomes
- Reason for admission
- Reason for discharge
- Number court ordered admissions
- Number and types of active research protocols
- Number of trainees involved in patient care
- Copies of consent forms for active research protocols



The Florida Legislature

OFFICE OF PROGRAM POLICY ANALYSIS AND GOVERNMENT ACCOUNTABILITY



RESEARCH MEMORANDUM

Tuberculosis Hospitalization in Other States

March 11, 2010

Summary

The Department of Health's A.G. Holley State Hospital provides long-term in-patient care for individuals with the most difficult, resistant, complex, and dangerous cases of tuberculosis in Florida. Patients admitted to A.G. Holley are difficult to treat and cure because they have other serious medical conditions that complicate treatment, such as HIV/AIDS or Hepatitis C, or have forms of tuberculosis that are resistant to antibiotics.¹ These patients may also be considered high risk for not complying with treatment regimens, often because of substance abuse and mental health issues, homelessness, or other social issues.

During Fiscal Year 2008-09, the department admitted 105 patients to A.G. Holley State Hospital. Admissions originate from county health departments, which refer patients to the state hospital. The hospital screens patients for a history of failing outpatient treatment or having medical or psychosocial conditions that make outpatient treatment inappropriate. According to Department of Health managers, individuals admitted to A.G. Holley State Hospital during Fiscal Year 2008-09 had the following characteristics:

- 100% had serious medical conditions in addition to tuberculosis;
- 26% had drug resistant forms of the disease;
- 63% were admitted based on orders by circuit courts because they had been determined to be public health threats;² and
- 22% were foreign-born individuals.³

The department also reports that the average length of stay in the hospital is 170 days and less than 5% of patients are readmitted.

The Legislature appropriated \$11 million to fund 50 beds at A.G. Holley in Fiscal Year 2009-10. Of this amount, \$5.6 million is from state general revenue, \$5.4 million is from state trust funds,

¹ Drug-resistant tuberculosis occurs when the medications typically used can no longer kill the tuberculosis bacteria. Multidrug-resistant tuberculosis is resistant to at least two of the medications considered the best treatment options, isoniazid and rifampicin. These drugs are considered first-line drugs and are used to treat all individuals with tuberculosis.

² Section 392.56(1), *F.S.*, authorizes the Department of Health to petition the circuit court to order an individual who has active tuberculosis to be hospitalized, placed in another health care facility or residential facility, or isolated from the general public in the home as a result of the probable spread of tuberculosis, until they are no longer infectious to the general public or the risk of infection can be reduced so that they are no longer a public health threat.

³ In 2008, 59% of the tuberculosis cases nationwide occurred in foreign-born individuals.

Gary R. VanLandingham, Ph.D., Director

111 West Madison Street ■ Room 312 ■ Claude Pepper Building ■ Tallahassee, Florida 32399-1475
850/488-0021 ■ FAX 850/487-9083
www.oppaga.state.fl.us

Re: Tuberculosis Hospitalization in Other States

March 11, 2010

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including Disproportionate Share Hospital funds and revenues from third-party reimbursements, and \$59,321 is from federal trust funds.

To determine how other states treat medically complex tuberculosis patients with similar conditions to those at A.G. Holley State Hospital, we contacted tuberculosis program managers in seven of the largest states' public health agencies. We found that only one other state (Texas) besides Florida operates a state-run infectious disease hospital that treats tuberculosis patients. For the remaining six states, the local health departments use local or regional hospitals to treat medically complex patients. States vary as to whether state funds or the local health departments reimburse the hospitals. See Exhibit 1 for detailed information on each state.

Exhibit 1

States Vary in How They Place and Fund Treatment for Complex Tuberculosis Patients

State (Website for more information)	2008 Rate per 100,000 Population (Total Cases)	State-Run Hospital	Treatment Settings	Funding Sources
Florida http://www.doh.state.fl.us/AGHolley/index.html	5.2 (954)	YES	A.G. Holley State Hospital provides long-term in-patient care for individuals with the most difficult, resistant, complex, and dangerous cases of tuberculosis in Florida. Admissions originate from county health departments, which refer patients to the state hospital. The hospital screens patients for a history of failing outpatient treatment or having medical or psychosocial conditions that make outpatient treatment inappropriate.	The state funds patient care provided at the center for patients that do not have health insurance or other health care coverage, such as Medicaid.
California http://www.cdph.ca.gov/programs/tb/Pages/default.aspx	7.3 (2,695)	NO	Local health departments admit medically complex patients to local or regional acute care hospitals.	The funds used to pay for services vary according to the patient's medical and legal circumstances. Funding sources include private payer sources, state Medi-Cal, state tuberculosis funds (for civil detention of persistently non-adherent patients), city and county funds, and uncompensated care funds. The state will reimburse local health departments on a per diem basis for hospital charges if patients meet specific criteria.
Illinois http://www.idph.state.il.us/public/hb/hbtb.htm	3.6 (469)	NO	Local health departments admit medically complex patients to local or regional hospitals.	While some counties have a tuberculosis or public health tax that could be used to fund these services, hospitals typically absorb the cost of treating these patients and have not charged the local health departments for these services.
Michigan http://www.michigantb.org/	1.9 (188)	NO	Local health departments admit medically complex patients to local or regional hospitals.	The local health department primarily covers the cost of care. The state may contribute as the payer of last resort if patients meet specific criteria. Reimbursements are based on Medicaid inpatient hospital rates and availability of funding.

Re: Tuberculosis Hospitalization in Other States

March 11, 2010

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State (Website for more information)	2008 Rate per 100,000 Population (Total Cases)	State-Run Hospital	Treatment Settings	Funding Sources
New York http://www.health.state.ny.us/diseases/communicable/tuberculosis/fact_sheet.htm	6.2 (1,200)	NO	Local health departments admit medically complex patients to acute care hospitals.	If the patient does not have health insurance or other health care coverage, the state contributes funding to the local health departments to reimburse hospitals. Hospital rates are set at the Medicaid inpatient hospital rates.
North Carolina http://www.epi.state.nc.us/epi/tb/	3.6 (335)	NO ¹	Local health departments admit medically complex patients to acute care hospitals.	The state provides funding to the local health departments for patient care that occurs on an out-patient basis. Hospitals absorb the cost of treating patients requiring in-patient services.
Ohio http://www.odh.ohio.gov/odhPrograms/idc/tcont/tcont1.aspx	1.9 (213)	NO	Local health departments admit medically complex patients to local hospitals.	The state does not provide funds, and 100% of care is funded by the local health departments.
Texas http://www.dshs.state.tx.us/tcid/default.shtm	6.2 (1,501)	YES	The Texas Department of State Health Services operates a 72-bed tuberculosis hospital, the Texas Center for Infectious Disease. The facility hospitalizes tuberculosis patients who are not compliant with treatment, homeless, or have complications that require constant care. Patients are admitted by their attending physician who coordinates with the hospital's nurse case manager. The case manager evaluates the need for hospitalization. The Texas Department of Health is currently constructing a 75-bed tuberculosis hospital and will contract with Texas' university system to manage it.	The state funds patient care provided at the center for patients that do not have health insurance or other health care coverage, such as Medicaid.

¹ North Carolina has three beds available in a state mental health hospital that it uses for patients that are considered infectious, but cannot be housed in the community. However, these patients must be compliant with treatment and do not have the same medical complexity as those treated at A. G. Holley State Hospital.

Source: U.S. Centers for Disease Control, OPPAGA internet research, and OPPAGA interviews with public health officials in other states.