

# **Health Innovation Subcommittee**

Monday, January 25, 2016 12:30 PM - 3:30 PM 306 HOB

# Committee Meeting Notice HOUSE OF REPRESENTATIVES

# **Health Innovation Subcommittee**

Start Date and Time:

Monday, January 25, 2016 12:30 pm

**End Date and Time:** 

Monday, January 25, 2016 03:30 pm

Location:

306 HOB

**Duration:** 

3.00 hrs

# Consideration of the following bill(s):

HB 421 Reimbursement of Medicaid Providers by Trumbull

HB 543 Small Group Health Insurance by Stark

HB 1241 Ordering of Medication by Plasencia

HB 1245 Medicaid Provider Overpayments by Peters

HB 1269 Adult Cardiovascular Services by Pigman

HB 1335 Long-term Care Prioritization by Magar

Pursuant to rule 7.12, the deadline for amendments to bills on the agenda by non-appointed members is 6:00 p.m., Friday, January 22, 2016.

By request of the chair, all committee members are asked to have amendments to bills on the agenda submitted to staff by 6:00 p.m., Friday, January 22, 2016.

# HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #:

HB 421

Reimbursement of Medicaid Providers

SPONSOR(S): Trumbull

**TIED BILLS:** 

IDEN./SIM. BILLS: SB 526

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Innovation Subcommittee		McElroy M	Poche My
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

### **SUMMARY ANALYSIS**

In the Medicaid program, to determine the appropriate reimbursement to a provider for services rendered to a recipient, the Agency for Health Care Administration (AHCA) pays the amount billed by the provider, the provider's usual and customary charge, or the maximum allowable fee established by AHCA, whichever amount is less. AHCA is required to make timely payment for services or goods to a provider upon receipt of a claim form from the provider. Among other requirements, the claim form certifies that the services or goods were completely furnished to the recipient and that the amount billed does not exceed the provider's usual and customary charge for the same services or goods.

"Usual and customary" is a common payment methodology utilized in various sections of Florida law, including the Medicaid statutes. However, despite its prevalent use, the term is not defined in law. This potentially creates uncertainty of interpretation of the term and, as least in the Medicaid program, has resulted in litigation.

HB 421 amends s. 409.901, F.S., to define "usual and customary", for the purposes of the Medicaid program, as the amount routinely billed by a provider or supplier to an uninsured consumer for services or goods before application of any discount, rebate, or supplemental plan. The term does not include free or discounted charges for services or goods based upon a person's insured or financial status. The bill expressly states that the definition is remedial in nature and, based on existing case law, demonstrates the intent for retroactive application of the definition.

The bill does not appear to have a fiscal impact on state or local governments.

The bill provides an effective date of July 1, 2016.

This document does not reflect the intent or official position of the bill sponsor or House of Representatives. STORAGE NAME: h0421.HIS.DOCX

**DATE**: 1/11/2016

### **FULL ANALYSIS**

#### I. SUBSTANTIVE ANALYSIS

#### A. EFFECT OF PROPOSED CHANGES:

#### **Present Situation**

### Medicaid

Medicaid is the health care safety net for low-income Floridians. Medicaid is a partnership of the federal and state governments established to provide coverage for health services for eligible persons. The program is administered by the Agency for Health Care Administration (AHCA) and financed by federal and state funds. AHCA delegates certain functions to other state agencies, including the Department of Children and Families, the Agency for Persons with Disabilities, and the Department of Elderly Affairs.

The structure of each state's Medicaid program varies and what states must pay for is largely determined by the federal government, as a condition of receiving federal funds. Federal law sets the amount, scope, and duration of services offered in the program, among other requirements. These federal requirements create an entitlement that comes with constitutional due process protections. The entitlement means that two parts of the Medicaid cost equation – people and utilization – are largely predetermined for the states: some populations are entitled to enroll in the program and enrollees are entitled to certain benefits.

The federal government sets the minimum mandatory benefits to be covered in every state Medicaid program. These benefits include physician services, hospital services, home health services, and family planning. States can add benefits, with federal approval. Florida has added many optional benefits, including prescription drugs, dental services, and dialysis.<sup>2</sup>

# Statewide Medicaid Managed Care<sup>3</sup>

In 2011, the Legislature established the Statewide Medicaid Managed Care (SMMC) program as Part IV of Chapter 409, F.S. The SMMC program is an integrated managed care program which provides all mandatory and optional Medicaid benefits to enrollees. Within the SMMC program, the Managed Medical Assistance (MMA) program provides primary and acute medical assistance and related services, including dental services. In the SMMC program, each Medicaid recipient has one managed care organization to coordinate all health care services, rather than various entities.<sup>5</sup>

In December 2012, AHCA released an Invitation to Negotiate (ITN) to competitively procure managed care plans on a regional basis for the MMA program.<sup>6</sup> AHCA selected 19 managed care plans and executed 5-year contracts in February 2014. The MMA program was fully implemented statewide as of August 1, 2014.

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<sup>&</sup>lt;sup>1</sup> S. 409.905, F.S.

<sup>&</sup>lt;sup>2</sup> S. 409.906, F.S.

<sup>&</sup>lt;sup>3</sup> The delivery of Medicaid services through managed care is not expressly authorized by federal law. If a state wants to use a managed care delivery system, it must seek a waiver of certain requirements of Title XIX of the Social Security Act (Medicaid). To implement the SMMC program, AHCA applied for and obtained section 1115 waiver authority.

The other component of the SMMC program is the Long-Term Care Managed Care Program.

<sup>&</sup>lt;sup>5</sup> This comprehensive coordinated system of care was successfully implemented in the 5-county Medicaid reform pilot program, 2006-2014.

<sup>&</sup>lt;sup>6</sup> AHCA Invitation to Negotiate, *Statewide Medicaid Managed Care*, *Addendum 2*, Solicitations Number: AHCA ITN 017-12/13; dated February 26, 2013 http://www.govcb.com/Statewide-Medicaid-Managed-Care-ADP13619273520001182.htm (last visited on January 4, 2016); AHCA Invitation to Negotiate, Statewide Medicaid Managed Care, Solicitation Number: AHCA ITN 017-12/13; dated December 28, 2012 http://www.govcb.com/Statewide-Medicaid-Managed-Care-ADP13619273520001182.htm (last visited on January 4, 2016). STORAGE NAME: h0421.HIS.DOCX

# Medicaid Provider Reimbursement- Usual and Customary

AHCA is required to reimburse Medicaid providers in accordance with state and federal law.<sup>7</sup> Requirements for reimbursement are established according to methodologies set forth in AHCA's administrative rules and in policy manuals and handbooks incorporated by reference.<sup>8</sup>

Medicaid reimbursement methodologies differ based upon what type of services or goods are being provided; however, these methodologies often include a prohibition against reimbursement in excess of the provider's usual and customary rate for the service or good. In fact, with some exceptions, for each allowable service or good furnished in accordance with applicable law, the reimbursement is the amount billed by the provider, the provider's usual and customary charge, or the Medicaid maximum allowable fee, whichever is less. Further, in order to be eligible to receive payment from AHCA, a provider must certify that the service or good has been completely furnished to the Medicaid recipient and that the amount billed does not exceed the provider's usual and customary charge. However, despite its prevalent use, the term is not defined in Florida law.

Reimbursement for Laboratory Services- Qui Tam Action against Certain Providers<sup>12</sup>

"Qui tam" is a Latin abbreviation for "he who sues in this matter for the king as well as for himself". 13 Qui tam actions are commonly referred to as whistle blower lawsuits and involve a private citizen suing a person or corporation on behalf of the federal or state government. The private citizen plaintiff is authorized to prosecute the lawsuit from start to finish; however, the government may intervene and assume primary responsibility for the lawsuit. The private citizen plaintiff is entitled to a percentage of any amount recovered for the government.

In 2007, Hunter Labs and Chris Riedel filed a qui tam action under the Florida False Claims Act in the circuit court in Leon County, alleging that LabCorp and Quest Diagnostics (LabCorp/Quest) defrauded the state by overcharging the Medicaid program for laboratory services provided to recipients. In 2013, the Attorney General (AG) intervened in the above lawsuit alleging that LabCorp/Quest defrauded the state by failing to charge the Medicaid program its lowest charge to any other third party payer for providing laboratory services.<sup>14</sup>

LabCorp/Quest filed an administrative petition with the Division of Administrative Hearings (DOAH) against AHCA challenging the validity of the "lowest charge" rule. <sup>15</sup> Ultimately, AHCA agreed that the rule was invalid and a Consent Order was entered in March 2014, formally striking down the rule. This litigation, although related to the circuit court case, was separate and distinct from the qui tam action.

In light of the Consent Order entered into in the DOAH hearing, the AG is pursuing an alternative legal theory against LabCorp/Quest in the qui tam action. The AG alleges that LabCorp/Quest defrauded the state by charging more than their usual and customary charge. For purposes of the litigation, it is the

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<sup>7</sup> S. 409.908, F.S. Reimbursement is subject to specific appropriations.

ld; see also s. 409.912(8)(a), F.S.; s. 409.9128(5), F.S.; s. 409.967, F.S.; 42 C.F.R. 447.512; Florida Medicaid Provider General Handbook, as promulgated in Rule 59G-5.020, F.A.C.; and Florida Medicaid Prescribed Drug Services Handbook, as promulgated in Rule 59G-4.250, F.A.C.,

<sup>&</sup>lt;sup>10</sup> S. 409.907(5)(a), F.S.

<sup>11</sup> Usual and customary is identified as a payment methodology in chapters 394, 400, 409, 440, 627, 641, and 817; however, the term is

<sup>&</sup>lt;sup>12</sup> <u>State of Florida ex rel. Hunter Laboratories, LLC and Chris Riedel v. Quest Diagnostics, Incorporated, et al</u>, in the Circuit Court for the Second Judicial Circuit in and for Leon County, case number 2007-CA-003549.

<sup>&</sup>lt;sup>13</sup> Qui Tam: An Abbreviated Look at the False Claims Act and Related Federal Statutes, Congressional Research Service, Charles Doyle, August 6, 2009, available at:

http://webcache.googleusercontent.com/search?q=cache:INZp35Nhq5EJ:https://www.fas.org/sgp/crs/misc/R40786.pdf+&cd=5&hl=en&ct=clnk&gl=us (last viewed January 7, 2016).

<sup>&</sup>lt;sup>4</sup> Rule 59G-5.110(2), F.A.C.

<sup>&</sup>lt;sup>15</sup> The petition was filed against AHCA because AHCA developed and adopted the rule.

AG's position that the term "usual and customary" is defined as any amount accepted by LabCorp/Quest as payment from any other third-party payer.

In August 2014, AHCA proposed a rule that would have codified the AG's interpretation of usual and customary charge. Medicaid providers objected to the rule and the interpretation, arguing that the proposed definition was contrary to the long understood meaning of the term, and the term had never been interpreted in that manner. LabCorp/Quest filed an administrative petition with DOAH, challenging the proposed rule as an invalid exercise of delegated legislative authority. This litigation, although related the circuit court case, was separate and distinct from the qui tam action, AHCA subsequently withdrew the proposed rule and stipulated that it had never previously interpreted "usual and customary charge" according to the "accepted payment" standard in the proposed rule and that it would not rely on that interpretation moving forward.

Although litigation of the administrative petitions with DOAH has resolved, the gui tam action against LabCorp/Quest is currently ongoing.

# Retroactive and Remedial Application of Law

Newly enacted legislation is presumed to apply prospectively absent clear legislative intent to the contrary. 16 However, the intent for retrospective application of enacted legislation can be established through the express language of the statute or by analyzing the practical effect of the statute. If the intent for retrospective application is established, then it must be determined whether such application of the statute is constitutionally permissible. 17 Retroactive application is unconstitutional, and thereby prohibited, if:18

- Vested rights are adversely affected or destroyed;<sup>19</sup>
- A new obligation or duty is created or imposed; or
- An additional disability is established.

The Florida Supreme Court previously ruled that retroactive application of a remedial statute is constitutionally permissible and should occur to achieve the intended purpose of the statute.<sup>20</sup> Remedial statutes operate to further a remedy or confirm existing rights and do not create new obligations or adversely affect vested rights.<sup>21</sup> Further, when an amendment to a statute is enacted soon after controversies as to the interpretation of the original statute arise, a court may consider that amendment as legislative interpretation of the original law and not a substantive change of the law.<sup>22</sup>

# **Effect of Proposed Changes**

The term "usual and customary" is not defined for purposes of determining reimbursement of Medicaid providers in Florida. HB 421 amends s. 409.901, F.S., and defines "usual and customary" as the amount routinely billed by a provider or supplier to an uninsured consumer for services or goods before application of any discount, rebate, or supplemental plan. The term does not include free or discounted charges for services or goods based upon a person's insured or financial status. The definition applies to the entire Medicaid program, through sections 409.901 through 409.920, F.S., unless expressly stated otherwise. The bill expressly states that the definition is remedial in nature and, based upon existing case law, demonstrates intent for retrospective application of the definition.

<sup>&</sup>lt;sup>16</sup> See Metropolitan Dade County v. Chase Federal Housing Corp., 737 So.2d 494 (Fla. 1999).

<sup>&</sup>lt;sup>18</sup> ld.

<sup>&</sup>lt;sup>19</sup> For example, a law which retroactively criminalizes a vested legal right, such as the right to marriage, would be considered unconstitutional. Similarly, a zoning law which retroactively prohibits the use of real property is unconstitutional if the right to that particular use had previously vested in the owner.

See City of Lakeland v. Cantinella, 129 So.2d 133 (Fla. 1961); see also Smiley v. State, 966 So.2d 330 (Fla. 2007); City of Orlando v. Desjardins, 493 So.2d 1027 (Fla. 1986).

<sup>&</sup>lt;sup>22</sup> See Lowry v. Parole and Probation Commission, 473 So.2d 1248 (Fla. 1985).

#### **B. SECTION DIRECTORY:**

**Section 1:** Amends s. 409.901, F.S., relating to definitions; ss. 409.901-409.920.

Section 2: Creates an unnumbered section of law stating that changes made by the act to s. 409.901,

F.S., are intended to clarify existing law and are remedial in nature.

Section 3: Provides an effective date of July 1, 2016.

#### II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

### A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

None.

#### B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

#### C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

If a provider has a system in place to calculate the usual and customary charge for Medicaid billing which applies a definition of "usual and customary" which is different from the definition in the bill, then the provider may need to change the way they calculate billing rates.

D. FISCAL COMMENTS:

None.

# III. COMMENTS

### A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable. The bill does not appear to affect county or municipal governments.

2. Other:

None.

**B. RULE-MAKING AUTHORITY:** 

None.

# C. DRAFTING ISSUES OR OTHER COMMENTS:

The bill contains an unnumbered section of law which states, "The changes made by this act to s. 409.901, Florida Statutes, are intended to clarify existing law and are remedial in nature." It is unclear whether a statement of remedial intent in an unnumbered section of law in pending legislation has the

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same impact as a statement of remedial intent contained within a statute. Existing statutes that expressly intend for remedial application of the law include such statements within the statute itself.<sup>23</sup> Thus, it is recommended that the statement of remedial intent contained within the bill be placed within s. 409.901, F.S.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

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<sup>&</sup>lt;sup>23</sup> For example, the remedial statement is contained within the statute itself in ss. 553.73 (14), 655.851 and 222.21(2)(c), F.S. **STORAGE NAME**: h0421.HIS.DOCX

HB 421 2016

1 2

A bill to be entitled

An act relating to reimbursement of Medicaid providers; amending s. 409.901, F.S.; defining the term "usual and customary charge" for purposes of Medicaid billing; providing applicability; providing an effective date.

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

Section 1. Subsection (29) is added to section 409.901, Florida Statutes, to read:

409.901 Definitions; ss. 409.901-409.920.—As used in ss. 409.901-409.920, except as otherwise specifically provided, the term:

- consumer for services or goods before application of any discount, rebate, or supplemental plan. The term does not include free or discounted charges for services or goods based upon a person's uninsured or indigent status or other financial hardship.
- Section 2. The changes made by this act to s. 409.901, Florida Statutes, are intended to clarify existing law and are remedial in nature.
  - Section 3. This act shall take effect July 1, 2016.

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Amendment No.

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COMMITTEE/SUBCOMMIT	TTEE AC	TION
ADOPTED	(Y	/N)
ADOPTED AS AMENDED	(Y	/N)
ADOPTED W/O OBJECTION	(Y	/N)
FAILED TO ADOPT	(Y	/N)
WITHDRAWN	(Y	/N)
OTHER	4044	

Committee/Subcommittee hearing bill: Health Innovation Subcommittee

Representative Trumbull offered the following:

# Amendment (with title amendment)

Remove everything after the enacting clause and insert: Section 1. Subsection (11) of section 409.908, Florida Statutes, is amended to read:

409.908 Reimbursement of Medicaid providers.—Subject to specific appropriations, the agency shall reimburse Medicaid providers, in accordance with state and federal law, according to methodologies set forth in the rules of the agency and in policy manuals and handbooks incorporated by reference therein. These methodologies may include fee schedules, reimbursement methods based on cost reporting, negotiated fees, competitive bidding pursuant to s. 287.057, and other mechanisms the agency considers efficient and effective for purchasing services or

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goods on behalf of recipients. If a provider is reimbursed based on cost reporting and submits a cost report late and that cost report would have been used to set a lower reimbursement rate for a rate semester, then the provider's rate for that semester shall be retroactively calculated using Medicaregranted extensions for filing cost reports, if applicable, shall also apply to Medicaid cost reports. Payment for Medicaid compensable services made on behalf of Medicaid eligible persons is subject to the availability of moneys and any limitations or directions provided for in the General Appropriations Act or chapter 216. Further, nothing in this section shall be construed to prevent or limit the agency from adjusting fees, reimbursement rates, lengths of stay, number of visits, or number of services, or making any other adjustments necessary to comply with the availability of moneys and any limitations or directions provided for in the General Appropriations Act, provided the adjustment is consistent with legislative intent.

(11) A provider of independent laboratory services shall be reimbursed on the basis of competitive bidding or for the least of the amount billed by the provider, the provider's usual and customary charge, or the Medicaid maximum allowable fee established by the agency. For purposes of ss. 409.901-409.9201 and with respect to a provider of independent laboratory services, "usual and customary charge" means the amount routinely billed by the provider to an uninsured consumer for services or goods before the application of any discount,

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rebate, or supplemental plan. Free or discounted charges for services or goods based on a person's uninsured or indigent status or other financial hardship are not usual and customary charges. This subsection is intended to be remedial in nature and to clarify existing law, and shall apply retroactively.

 $\verb|T I T L E A M E N D M E N T | \\$ 

Remove everything before the enacting clause and insert:

A bill to be entitled

An act relating to Medicaid providers of independent laboratory services; amending s. 409.908, F.S.; providing a definition of "usual and customary charge" for providers of independent laboratory services; providing an effective date.

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Amendment No.

	COMMITTEE/SUBCOMM	ITTEE 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		<del></del>
1	Committee/Subcommittee	hearing bill: Health Innovation
1 2	Committee/Subcommittee Subcommittee	hearing bill: Health Innovation
	Subcommittee	hearing bill: Health Innovation
2	Subcommittee	-
2	Subcommittee Representative Trumbul	-
2 3 4	Subcommittee Representative Trumbul  Amendment to Amendment	l offered the following:

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#### HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #:

HB 543

Small Group Health Insurance

SPONSOR(S): Stark

TIED BILLS:

**IDEN./SIM. BILLS:** 

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Innovation Subcommittee		Tuszynski	Poche MW
2) Insurance & Banking Subcommittee			
3) Health & Human Services Committee			

### **SUMMARY ANALYSIS**

The federal Patient Protection and Affordable Care Act (PPACA) was signed into law on March 23, 2010. PPACA imposes many insurance requirements including required benefits, rating and underwriting standards, required review of rate increases, reporting of medical loss ratios and payment of rebates, covering adult dependents, internal and external appeals of adverse benefit determinations, and other requirements.

The Florida Employee Health Care Access Act (EHCAA) was enacted in 1992 to promote the availability of health insurance coverage to small employers with fifty or less employees, regardless of claims experience or employee health status. The EHCAA requires small employer health insurers (carriers) in the small group market to offer and issue all small employer health benefit plans on a guaranteed-issue basis to every eligible small employer.

A small employer carrier that offers coverage to a small employer must offer to all of the employer's eligible employees and their dependents. A small employer carrier may not offer coverage limited to certain persons in a group or to part of a group, except with respect to late enrollees. While the EHCAA requires a *small employer carrier* to offer both employee and dependent coverage to small employers, no federal or state laws require a *small employer* to provide insurance to its employees or dependents.

Under PPACA, if the cost of an employee-sponsored plan would cover an employee for 9.66% or less of household income, the employee and his or her dependents are not eligible for premium tax credits to purchase a health insurance plan on the Health Insurance Marketplace, nor are they eligible for cost-sharing reductions to lower their out-of-pocket payments for health services. This may make the cost of coverage unaffordable.

HB 543 amends s. 627.6699(5)(e)5., F.S., to provide a small employer with the option to offer employee-only coverage to all eligible employees. The bill clarifies that a small employer may offer coverage to the spouse and dependents of an eligible employee, but is not required to offer such coverage.

By clarifying that a small employer is not required to offer dependent coverage, dependents would not have an offer of affordable employer-based coverage, which should allow them to qualify for premium tax credits or other cost-sharing reductions to offset the cost of an insurance plan through the Marketplace. Such coverage through the Marketplace may be cheaper than the cost of the family coverage through employer-sponsored insurance.

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

The bill provides for an effective date of July 1, 2016.

This document does not reflect the intent or official position of the bill sponsor or House of Representatives. STORAGE NAME: h0543.HIS.DOCX

#### **FULL ANALYSIS**

#### I. SUBSTANTIVE ANALYSIS

# A. EFFECT OF PROPOSED CHANGES:

#### **Present Situation**

# Patient Protection and Affordable Care Act

The federal Patient Protection and Affordable Care Act (PPACA) was signed into law on March 23, 2010. PPACA imposes many insurance requirements including required benefits, rating and underwriting standards, required review of rate increases, reporting of medical loss ratios and payment of rebates, covering adult dependents, internal and external appeals of adverse benefit determinations, and other requirements.<sup>2</sup>

Many of the changes outlined in PPACA apply to individual and small group markets, except those plans that have grandfathered status under the law.<sup>3</sup> For example, PPACA requires coverage offered in the individual and small group markets to provide the following categories of services (essential health benefits package):<sup>4</sup>

- Ambulatory patient services
- Emergency services
- Hospitalization
- Maternity and newborn care
- Mental health and substance abuse disorder services, including behavioral health treatment
- Prescription drugs
- Rehabilitative and habilitative services and devices
- Laboratory services
- Preventive and wellness services and chronic disease management
- Pediatric services, including oral and vision care

PPACA prohibits an insurer from establishing rules for eligibility based on any of the following health status-related factors: health status, medical condition, claims experience, receipt of health care, medical history, genetic information, disability, evidence of insurability (including conditions arising out of domestic violence), or any other health-status related factor deemed appropriate by the U.S. Department of Health and Human Services.<sup>5</sup>

# PPACA - Limited Preemption of State Law

Under the U.S. Constitution's Supremacy Clause, a federal law may preempt state law.<sup>6</sup> Preemption occurs when Congress intentionally enacts legislation that is intended to supersede state law on the same subject.<sup>7</sup> In PPACA, Congress expressed that the federal law preempts state law only to the extent that it prevents the application of a provision of PPACA.<sup>8</sup>

<sup>&</sup>lt;sup>1</sup> P.L. 111-148. On March 30, 2010, PPACA was amended by P.L. 111-152, the Health Care and Education Reconciliation Act of 2010. <sup>2</sup> Most of the insurance regulatory provisions in PPACA amend Title XXVII of the Public Health Service Act (PHSA) (42 U.S.C. 300gg et seg.)

<sup>&</sup>lt;sup>3</sup> For an insured plan, grandfathered health plan coverage is group or individual coverage in which an individual was enrolled on March 23, 2010, subject to conditions for maintaining grandfathered status as specified by law and rule. See 42 U.S.C. s. 18011.

<sup>&</sup>lt;sup>4</sup> 42 U.S.C. 300gg-6.

<sup>&</sup>lt;sup>5</sup> 42 U.S.C. s. 300gg-4.

<sup>&</sup>lt;sup>6</sup> U.S. Const. art. VI, cl. 2.

<sup>&</sup>lt;sup>7</sup> See West Florida Regional Medical Center v. See, 79 So.3rd 1, at 15 (Fla. 2012).

<sup>&</sup>lt;sup>8</sup> PPACA s. 1321(d).

Title I of PPACA, which includes the requirements related to health insurance regulation, contains the following provision:

No Interference With State Regulatory Authority – Nothing in this title shall be construed to preempt any State law that does not prevent the application of the provisions of this title.<sup>9</sup>

Though expressed in the negative, PPACA preempts any state law that prevents the application of a provision of PPACA. PPACA effectively allows states to adopt and enforce laws that do not directly conflict with PPACA, but any state law that does conflict will be preempted.<sup>10</sup>

# Health Insurance Marketplaces

The Health Insurance Marketplace (Marketplace) is an online shopping platform for people to purchase insurance if they do not have insurance through employment, Medicare, Medicaid, the Children's Health Insurance Program (CHIP), or another source that provides qualifying coverage. An individual may purchase insurance through the Marketplace even if they have access to employer-sponsored insurance. However, an individual with access to employer-sponsored insurance will not be eligible for premium tax credits unless the employer's insurance option does not meet certain standards. 12

# Health Insurance Premium Tax Credits in the Marketplace

Under PPACA, individuals and families with incomes between 100% and 400% of the Federal Poverty Level (\$11,700 for an individual and \$24,500 for a family of 4)<sup>13</sup> who purchase coverage through the Marketplace are eligible for a tax credit to reduce the cost of coverage. The amount of the tax credit varies based on income such that the premium a person would have to pay for the second cheapest silver plan<sup>14</sup> on the Marketplace would not exceed a percentage of their income, as follows:<sup>15</sup>

Income Level	Premium as a Percent of Income
Up to 133% FPL	2.03% of income
133 – 150% FPL	3.05 – 4.07% of income
150 – 200% FPL	4.07 – 6.41% of income
200 – 250% FPL	6.41 – 8.18% of income
250 – 300% FPL	8.18 – 9.66% of income
300 – 400% FPL	9.66% of income

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<sup>9</sup> Id.

National Association of Insurance Commissioners, "Preemption and State Flexibility in PPACA" available at: <a href="http://www.naic.org/documents/index">http://www.naic.org/documents/index</a> health reform general preemption and state flex ppaca.pdf (last viewed January 23, 2016).

11 U.S. Department of Health & Human Services, Centers for Medicare & Medicaid Services, A quick guide to the Health Insurance Marketplace, available at: <a href="https://www.healthcare.gov/quick-guide/">https://www.healthcare.gov/quick-guide/</a> (last viewed January 23, 2016).

<sup>&</sup>lt;sup>13</sup> U.S. Department of Health & Human Services, Office of the Assistant Secretary For Planning and Evaluation, *2015 Poverty Guidelines*, available at: <a href="https://aspe.hhs.gov/2015-poverty-guidelines">https://aspe.hhs.gov/2015-poverty-guidelines</a> (last viewed January 23, 2016).

<sup>&</sup>lt;sup>14</sup> PPACA designates required coverage levels as bronze, silver, gold, or platinum. Each of these tiers corresponds to an actuarial value of the qualified health plans within that tier. The actuarial value corresponds to the percentage of total average costs for covered benefits that a plan will cover. For example, if a plan has an actuarial value of 70%, on average, an individual would be responsible for 30% of the costs of all covered benefits through co-pays and other cost-sharing mechanisms. The corresponding actuarial values to the PPACA tiers are: Bronze – 60%; Silver – 70%; Gold – 80%; and Platinum – 90%.

<sup>&</sup>lt;sup>15</sup> Internal Revenue Service, *Internal Revenue Bulletin: 2014-50*, December 8, 2014, available at: <a href="https://www.irs.gov/irb/2014-50">https://www.irs.gov/irb/2014-50</a>, available at: <a href="https://www.irs.gov/irb/2

# Florida Employee Heath Care Access Act

The Employee Health Care Access Act (EHCAA)<sup>16</sup> was enacted in 1992 to promote the availability of health insurance coverage to small employers with fifty or less employees, regardless of claims experience or employee health status.<sup>17</sup> The EHCAA requires small employer health insurers (carriers) in the small group market to offer and issue all small employer health benefit plans on a guaranteedissue basis to every eligible small employer.<sup>18</sup>

A small employer carrier that offers coverage to a small employer must offer to all of the employer's eligible employees<sup>19</sup> and their dependents.<sup>20</sup> A small employer carrier may not offer coverage limited to certain persons in a group or to part of a group, except with respect to late enrollees.<sup>21</sup> While the EHCAA requires a small employer carrier to offer both employee and dependent coverage to small employers, <sup>22</sup> no federal or state laws require a small employer to provide insurance to its employees or dependents.23

# Employer-Sponsored Insurance Offered to Dependents

Eligibility for federal premium tax credits to purchase health insurance from the Marketplace is not solely determined by income. Whether a family has access to affordable employer-sponsored insurance is also used to determine eligibility. 24 The problem is the definition of "affordable" as for both an individual employee and a family, it is defined based on the cost of individual-only coverage and does not take into consideration the often significantly higher cost of a family plan.<sup>25</sup>

Under PPACA, if the cost of an employee-sponsored plan would cover an employee for less than 9.66% of household income, the employee and his or her dependents are not eligible for premium tax credits to reduce the cost of a Marketplace plan or for cost-sharing reductions to lower their out-ofpocket payments for health services, regardless of the ability to afford coverage otherwise. 26 For example, if an employee can purchase an employee-only plan and the cost is only 9.5% of his or her household income, yet the family option costs 13% of his or her household income, which is unaffordable for the family, they do not qualify for premium tax credits. This is referred to as the "family glitch" in PPACA - the family is priced out of the Marketplace because they have been offered an affordable employee-sponsored plan and are not eligible for premium tax credits, yet the employerbased family option is out of the family's budget.

# Florida Health Insurance Advisory Board

The Florida Health Insurance Advisory Board (Board) was established in 1992 as the Small Employer Health Reinsurance Program.<sup>27</sup> Its purpose was to promote the availability of health care coverage to

<sup>&</sup>lt;sup>16</sup> S. 627.6699, F.S.

<sup>&</sup>lt;sup>17</sup> Ch. 92-33, Laws of Fla.

<sup>&</sup>lt;sup>18</sup> S. 627.6699(5)(b), F.S.

<sup>19</sup> S. 627.6699(3)(g), F.S., defines an "eligible employee" as an employee who works full time, having a normal workweek of 25 or more hours, and who has met any applicable waiting-period requirements or other requirements of this act. The term includes a selfemployed individual, a sole proprietor, a partner of a partnership, or an independent contractor, if the sole proprietor, partner, or independent contractor is included as an employee under a health benefit plan of a small employer, but does not include a part-time, temporary, or substitute employee.

<sup>&</sup>lt;sup>20</sup> S. 627.6699(5)(e)5., F.S.

<sup>&</sup>lt;sup>21</sup> ld.

<sup>&</sup>lt;sup>23</sup> Office of Insurance Regulation, *Agency Analysis of 2016 House Bill* 543, p. 2, Dec. 18, 2015.

<sup>&</sup>lt;sup>24</sup> Health Affairs, Health Policy Briefs, The Family Glitch, available at:

http://www.healthaffairs.org/healthpolicybriefs/brief.php?brief\_id=129 (last viewed January 23, 2016).

ld. <sup>26</sup> ld.

<sup>&</sup>lt;sup>27</sup> Florida Office of Insurance Regulation, *Florida Health Insurance Advisory Board*, available at: http://www.floir.com/sections/landh/fhiab.aspx (last viewed January 23, 2016).

small employers.<sup>28</sup> At that time, Board members were primarily representatives of health insurers licensed under chapter 624 or 641 of the Florida Statutes.<sup>29</sup> In 2005, the Legislature expanded the composition of the Board to include representatives of employers, an individual policyholder, and a representative from the Agency for Health Care Administration (AHCA).<sup>30</sup> The Board's responsibilities were expanded to include an advisory role on health insurance issues to the Office of Insurance Regulation (OIR), AHCA, the Department of Financial Services, other executive departments and the Legislature.<sup>31</sup>

In its legislative recommendations for 2014, <sup>32</sup> 2015, <sup>33</sup> and 2016<sup>34</sup> the Board has recommended that small group employers be specifically allowed the option to offer employee-only coverage to allow spouses and dependents to obtain coverage in the Marketplace, where they may qualify for a premium tax credit.

OIR has also stated that it has received comment that there is confusion in the insurance market as to whether a small employer has the option to offer employee-only coverage.<sup>35</sup>

# **Effect of the Proposed Changes**

HB 543 amends s. 627.6699(5)(e)5., F.S., to provide a small employer with the option to offer employee-only coverage to all eligible employees. The bill clarifies that a small employer may offer coverage to the spouse and dependents of an eligible employee, but is not required to offer such coverage.

This clarification allows employers to inform small group carriers that they have made the choice to offer employee-only coverage. This, in turn, allows the small group carrier to offer such coverage and not extend an offer of coverage to dependents of an eligible employee.

By clarifying that a small employer is not required to offer dependent coverage, dependents will not have an offer of affordable employer-based coverage, which should allow them to qualify for premium tax credits to offset the cost of an insurance plan through the Marketplace, which may be cheaper than the cost of the family coverage through employer-sponsored insurance.

### **B. SECTION DIRECTORY:**

**Section 1:** Amends s. 627.6699, F.S., relating to the Employee Health Care Access Act.

**Section 2:** Provides for an effective date of July 1, 2016.

#### II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

#### A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

<sup>5</sup> Supra. at FN 23, pg. 4.

PAGE: 5

<sup>&</sup>lt;sup>28</sup> ld.

<sup>&</sup>lt;sup>29</sup> ld.

<sup>&</sup>lt;sup>30</sup> Ch. 2005-231, Laws of Fla.

<sup>ຶ່</sup> ld.

<sup>&</sup>lt;sup>32</sup>Florida Office of Insurance Regulation, Florida Health Insurance Advisory Board, *2014 Legislative Recommendations*, available at: http://www.floir.com/siteDocuments/FHIABLegRecommendations2014.pdf (last viewed January 23, 2016).

http://www.floir.com/siteDocuments/FHIABLegRecommendations2014.pdf (last viewed January 23, 2016).

33 Florida Office of Insurance Regulation, Florida Health Insurance Advisory Board, 2015 Legislative Recommendations, available at: http://www.floir.com/siteDocuments/FHIABLegRecommendations2015.pdf (last viewed January 23, 2016).

<sup>&</sup>lt;sup>34</sup> Florida Office of Insurance Regulation, Florida Health Insurance Advisory Board, *2016 Legislative Recommendations*, available at: <a href="http://www.floir.com/siteDocuments/FHIABLegRecommendations2016.pdf">http://www.floir.com/siteDocuments/FHIABLegRecommendations2016.pdf</a> (last viewed January 23, 2016).

	2. Expenditures:
	None.
C.	DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:
	For low to moderate-income families that qualify for premium tax credits to purchase health insurance through the Marketplace, dependents of employees of a small employer may have access to less expensive coverage as compared to the cost of family coverage through the employer.
D.	FISCAL COMMENTS:
	None.
	III. COMMENTS
A.	CONSTITUTIONAL ISSUES:
	1. Applicability of Municipality/County Mandates Provision:
	Not Applicable. This bill does not appear to affect county or municipal governments.
	2. Other:
	None.
В.	RULE-MAKING AUTHORITY:
	None.
C.	DRAFTING ISSUES OR OTHER COMMENTS:
	None.
	IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES
	IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

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2. Expenditures:

**B. FISCAL IMPACT ON LOCAL GOVERNMENTS:** 

None.

1. Revenues: None.

HB 543 2016

A bill to be entitled

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An act relating to small group health insurance; amending s. 627.6699, F.S.; revising health benefit plan requirements relating to small employers;

providing an effective date.

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

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Section 1. Paragraph (e) of subsection (5) of section 627.6699, Florida Statutes, is amended to read:

627.6699 Employee Health Care Access Act.-

- (5) AVAILABILITY OF COVERAGE.
- (e) All health benefit plans issued under this section must comply with the following conditions:
- 1. For employers who have fewer than two employees, a late enrollee may be excluded from coverage for no longer than 24 months if he or she was not covered by creditable coverage continually to a date not more than 63 days before the effective date of his or her new coverage.
- 2. Any requirement used by a small employer carrier in determining whether to provide coverage to a small employer group, including requirements for minimum participation of eligible employees and minimum employer contributions, must be applied uniformly among all small employer groups having the same number of eligible employees applying for coverage or receiving coverage from the small employer carrier, except that

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HB 543 2016

a small employer carrier that participates in, administers, or issues health benefits pursuant to s. 381.0406 which do not include a preexisting condition exclusion may require as a condition of offering such benefits that the employer has had no health insurance coverage for its employees for a period of at least 6 months. A small employer carrier may vary application of minimum participation requirements and minimum employer contribution requirements only by the size of the small employer group.

- 3. In applying minimum participation requirements with respect to a small employer, a small employer carrier shall not consider as an eligible employee employees or dependents who have qualifying existing coverage in an employer-based group insurance plan or an ERISA qualified self-insurance plan in determining whether the applicable percentage of participation is met. However, a small employer carrier may count eligible employees and dependents who have coverage under another health plan that is sponsored by that employer.
- 4. A small employer carrier shall not increase any requirement for minimum employee participation or any requirement for minimum employer contribution applicable to a small employer at any time after the small employer has been accepted for coverage, unless the employer size has changed, in which case the small employer carrier may apply the requirements that are applicable to the new group size.
  - 5. If a small employer carrier offers coverage to a small

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employer, it must offer coverage to all the small employer's eligible employees and their dependents. A small employer carrier may not offer coverage limited to certain persons in a group or to part of a group, except with respect to late enrollees. If a small employer offers coverage to its employees, the coverage must be offered to all eligible employees. The small employer may also offer coverage to the spouses and dependents of eligible employees.

- 6. A small employer carrier may not modify any health benefit plan issued to a small employer with respect to a small employer or any eligible employee or dependent through riders, endorsements, or otherwise to restrict or exclude coverage for certain diseases or medical conditions otherwise covered by the health benefit plan.
- 7. An initial enrollment period of at least 30 days must be provided. An annual 30-day open enrollment period must be offered to each small employer's eligible employees and their dependents. A small employer carrier must provide special enrollment periods as required by s. 627.65615.
  - Section 2. This act shall take effect July 1, 2016.

Page 3 of 3

#### HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #:

HB 1241

Ordering of Medication

SPONSOR(S): Plasencia

TIED BILLS:

IDEN./SIM. BILLS:

SB 152

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF	
1) Health Innovation Subcommittee		Siples 75	Poche (Mi)	
2) Health & Human Services Committee				

#### **SUMMARY ANALYSIS**

Florida law authorizes a supervising physician to delegate to a physician assistant (PA), the authority to order medicinal drugs for the physician's patient who is in a hospital, ambulatory surgical center, or mobile surgical facility. However, there is no authority under Florida law for a physician to delegate an equivalent authority to an advanced registered nurse practitioner (ARNP).

The bill expressly authorizes an ARNP to order any medication for administration to a patient in a hospital, ambulatory surgical center, mobile surgical center, or nursing home, within the framework of an established protocol. The bill expands the current ability of a physician to delegate authority to a PA to order medicinal drugs, to allow a PA to order medicinal drugs for a patient in a nursing home.

The bill amends the Florida Comprehensive Drug Abuse Prevention and Control Act to expressly provide that a licensed practitioner may authorize a licensed PA or ARNP, who he or she supervises, to order controlled substances for administration to a patient in a hospital, ambulatory surgical center, mobile surgical facility, or nursing home.

The bill amends the definition of "prescription" to clarify that an order for the administration of a drug is not included in its definition.

The bill may have an indeterminate, negative fiscal impact on the Department of Health and no fiscal impact on local governments.

The bill provides an effective date of July 1, 2016.

This document does not reflect the intent or official position of the bill sponsor or House of Representatives. STORAGE NAME: h1241.HIS.DOCX

#### **FULL ANALYSIS**

#### I. SUBSTANTIVE ANALYSIS

# A. EFFECT OF PROPOSED CHANGES:

#### **Present Situation**

# Physician Assistants

Licensure and Regulation

A physician assistant (PA) is a person who has completed a medical training program approved by the Florida Board of Medicine (Board of Medicine) or the Board of Osteopathic Medicine (Osteopathic Board), and is licensed to perform medical services, as delegated by a supervising physician. The licensure of PAs in Florida is governed by ss. 458.347(7) and 459.022(7), F.S. The Department of Health (DOH) licenses PAs, and the Florida Council on Physician Assistants (Council) regulates the practice of PAs in conjunction with either the Board of Medicine for PAs licensed under ch. 458, F.S., or the Osteopathic Board for PAs licensed under ch. 459, F.S. There are approximately 7,987 PAs who hold active licenses in Florida.<sup>2</sup>

To be licensed as a PA in Florida, an applicant must demonstrate to the Council that he or she has met the following requirements:

- Satisfactory passage of the proficiency examination administered by the National Commission on Certification of Physician Assistants;
- Completion of an application and remittance of the applicable fees to the DOH;<sup>3</sup>
- Completion of a board-approved PA training program;
- Submission of a sworn statement of any prior felony convictions;
- Submission of a sworn statement of any revocation or denial of licensure or certification in any state:
- Submission of two letters of recommendation; and
- If the applicant is seeking prescribing authority, a submission of a copy of course transcripts and the course description from a PA training program describing the course content in pharmacotherapy.<sup>4</sup>

Licenses are renewed biennially.<sup>5</sup> At the time of renewal, a PA must demonstrate that he or she has met the continuing medical education requirements of 100 hours and must submit a sworn statement that he or she has not been convicted of any felony in the previous two years.<sup>6</sup> If a PA is licensed as a prescribing PA, an additional 10 hours of continuing medical education in the specialty areas of his or her supervising physician must be completed.<sup>7</sup>

Supervision of PAs

A PA may only practice under the delegated authority of a supervising physician. A supervising physician may only delegate tasks and procedures to the PA that are within the supervising physician's

<sup>&</sup>lt;sup>1</sup> Sections 458.347(2)(e) and 459.022(2)(e), F.S.

<sup>&</sup>lt;sup>2</sup> Email correspondence with the Department of Health on November 9, 2015. The number of active-licensed PAs include both in-state and out-of-state licensees, as of November 9, 2015.

<sup>&</sup>lt;sup>3</sup> The application fee is \$100 and the initial license fee is \$200. Applicants must also pay an unlicensed activity fee of \$5. See Rules 64B8-30.019 and 64B15-6.013, F.A.C.

<sup>&</sup>lt;sup>4</sup> Sections 458.347(7) and 459.022(7), F.S.

<sup>&</sup>lt;sup>5</sup> For timely renewed licenses, the renewal fee is \$275 and the prescribing registration fee is \$150. Additionally, at the time of renewal, the PA must pay an unlicensed activity fee of \$5. See Rules 64B8-30.019 and 64B15-6.013, F.A.C.

<sup>&</sup>lt;sup>6</sup> Sections 458.347(7)(c)-(d) and 459.022(7)(c)-(d), F.S.

<sup>&</sup>lt;sup>7</sup> Rules 64B8-30.005(6) and 64B15-6.0035(6), F.A.C.

scope of practice.<sup>8</sup> Supervision is defined as responsible supervision and control that requires the easy availability or physical presence of the licensed physician for consultation and direction of the PA.<sup>9</sup> A physician may not supervise more than four PAs at any time.<sup>10</sup>

The Board of Medicine and the Osteopathic Board have prescribed by rule what constitutes adequate responsible supervision. Responsible supervision is the ability of a supervising physician to reasonably exercise control and provide direction over the services or tasks performed by the PA.<sup>11</sup> Whether the supervision of the PA is adequate is dependent on the:

- Complexity of the task;
- Risk to the patient;
- Background, training, and skill of the PA;
- Adequacy of the direction in terms of its form;
- Setting in which the tasks are performed;
- Availability of the supervising physician;
- Necessity for immediate attention; and
- Number of other persons that the supervising physician must supervise.

The decision to permit a PA to perform a task or procedure under direct or indirect supervision is made by the supervising physician based on reasonable medical judgment regarding the probability of morbidity and mortality to the patient.<sup>13</sup> Direct supervision refers to the physical presence of the supervising physician so that the physician is immediately available to the PA when needed.<sup>14</sup> Indirect supervision refers to the reasonable physical proximity of the supervising physician to the PA or availability by telecommunication.<sup>15</sup>

# Delegable Tasks

Rules of both the Board of Medicine and the Osteopathic Board place limitations on a supervising physician's ability to delegate certain tasks. The following tasks are not permitted to be delegated to a PA, except when specifically authorized by statute:

- Prescribing, dispensing, or compounding medicinal drugs; and
- Final diagnosis.<sup>16</sup>

A supervising physician may delegate to a PA the authority to:

- Prescribe or dispense any medicinal drug used in the supervising physician's practice, except controlled substances, general anesthetics, and radiographic contrast materials;<sup>17</sup>
- Order medicinal drugs for a hospitalized patient of the supervising physician; 18 and
- Administer a medicinal drug under the direction and supervision of the physician.

<sup>8</sup> Sections 458.347(4)(g), and 459.022(4)(f), F.S., provides that an order is not a prescription.

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<sup>&</sup>lt;sup>8</sup> Rules 64B8-30.012(1) and 64B15-6.010(1), F.A.C. The term "scope of practice" refers to those tasks and procedures that the supervising physician is qualified by training or experience to support.

<sup>&</sup>lt;sup>9</sup> Sections 458.347(2)(f) and 459.022(2)(f), F.S. <sup>10</sup> Sections 458.347(3) and 459.022(3), F.S.

<sup>&</sup>lt;sup>11</sup> Rules 64B8-30.001(3) and 64B15-6.001(3), F.A.C.

<sup>&</sup>lt;sup>12</sup> ld.

<sup>&</sup>lt;sup>13</sup> Rules 64B8-30.012(2) and 64B15-6.010(2), F.A.C.

<sup>&</sup>lt;sup>14</sup> Rules 64B8-30.001(4) and 64B15-6.001(4), F.A.C.

<sup>&</sup>lt;sup>15</sup> Rules 64B8-30.001(5) and 64B15-6.001(5), F.A.C.

<sup>&</sup>lt;sup>16</sup> Supra, note 11.

<sup>&</sup>lt;sup>17</sup> Sections 458.347(4)(f)1., F.S., and 459.022(4)(e), F.S., direct the Council to establish a formulary listing of the medicinal drugs that a PA may not prescribe. The formulary in Rules 64B8-30.008 and 64B15-6.0038, F.A.C., prohibits PAs from prescribing controlled substances, as defined in Chapter 893, F.S., general, spinal, or epidural anesthetics, and radiographic contrast materials.

# Advanced Registered Nurse Practitioners

# Licensure and Regulation

Part I of ch. 464, F.S. (Nurse Practice Act), governs the licensure and regulation of advanced registered nurse practitioners (ARNPs) in Florida. Nurses are licensed by the DOH and are regulated by the Board of Nursing. 19 There are 22,003 actively licensed ARNPs in Florida. 20

In Florida, an ARNP is a licensed nurse who is certified in advanced or specialized nursing practice.<sup>21</sup> Section 464.003(2), F.S., defines "advanced or specialized nursing practice" to include the performance of advanced-level nursing acts approved by the Board of Nursing, which by virtue of postbasic specialized education, training, and experience are appropriately performed by an ARNP.<sup>22</sup>

Florida recognizes three types of ARNPs: nurse anesthetist, certified nurse midwife, and nurse practitioner. The Board of Nursing, created by s. 464,004, F.S., establishes the eligibility criteria for an applicant to be certified as an ARNP and the applicable regulatory standards for ARNP nursing practices.<sup>23</sup> To be certified as an ARNP, the applicant must:

- Have a registered nurse license;
- Have earned, at least, a master's degree; and
- Submit proof to the Board of Nursing of holding a current national advanced practice certification obtained from a board-approved nursing specialty board.<sup>24</sup>

All ARNPs must carry malpractice insurance or demonstrate proof of financial responsibility.<sup>25</sup> An applicant for certification is required to submit proof of coverage or financial responsibility within sixty days of certification and with each biennial renewal.<sup>26</sup> An ARNP must have professional liability coverage of at least \$100,000 per claim with a minimum annual aggregate of at least \$300,000, or an unexpired irrevocable letter of credit, which is payable to the ARNP as the beneficiary, in the amount of at least \$100,000 per claim with a minimum aggregate availability of at least \$300,000.

# Supervision of ARNPs

Pursuant to s. 464.012(3), F.S., ARNPs may only perform nursing practices delineated in an established protocol filed with the Board of Nursing. 28 Florida law allows a primary care physician to supervise ARNPs in up to four offices, in addition to the physician's primary practice location.<sup>29</sup> If the

<sup>&</sup>lt;sup>19</sup> Pursuant to s. 464.004, F.S., the Board of Nursing is comprised of 13 members appointed by the Governor and confirmed by the Senate who serve 4-year terms. The Board is comprised of three licensed practical nurses who have practiced for at least four years; three Florida residents who have never been licensed as nurses, are not connected to the practice of nursing, and have no financial interest in any health care facility, agency, or insurer; and seven members who are registered nurses who have practiced at least four years. Among the seven members who are registered nurses, there must be at least one ARNP, one nurse educator of an approved program, and one nurse executive.

E-mail correspondence with the Department of Health (Nov. 9, 2015) (on file with committee staff). This number includes all active licenses, including out of state practitioners.

Section 464.003(3), F.S.

<sup>&</sup>lt;sup>22</sup> Section 464.003(2), F.S.

<sup>&</sup>lt;sup>23</sup> Section 464.012(2), F.S.

<sup>&</sup>lt;sup>24</sup> Section 464.012(1), F.S., and Rule 64B9-4.002, F.A.C. A nursing specialty board must attest to the competency of nurses in a clinical specialty area, require nurses to take a written examination prior to certification, require nurses to complete a formal program prior to eligibility of examination, maintain program accreditation, and identify standards or scope of practice statements appropriate for each nursing specialty.

Section 456.048, F.S.

<sup>&</sup>lt;sup>26</sup> Rule 64B9-4.002(5), F.A.C.

<sup>&</sup>lt;sup>27</sup> ld.

<sup>&</sup>lt;sup>28</sup> The protocol must be filed within 30 days of entering into a supervisory relationship with a physician and upon each biennial license renewal. Physicians are also required to provide notice of the written protocol and the supervisory relationship to the Board of Medicine or Board of Osteopathic Medicine, respectively. See ss. 458.348 and 459.025, F.S.

Sections 458.348(4) and 459.025(3), F.S.

physician provides specialty health care services, then only two medical offices, in addition to the physician's primary practice location, may be supervised.

The supervision limitations do not apply in the following facilities:

- Hospitals:
- Colleges of medicine or nursing:
- Nonprofit family-planning clinics;
- Rural and federally qualified health centers;
- Nursing homes:
- Assisted living facilities;
- Student health care centers or school health clinics; and
- Other government facilities.30

To ensure appropriate medical care, the number of ARNPs a physician may supervise is limited based on consideration of the following factors:

- Risk to the patient:
- Educational preparation, specialty, and experience in relation to the supervising physician's protocol;
- Complexity and risk of the procedures:
- Practice setting; and
- Availability of the supervising physician or dentist.31

Delegable Tasks

Within the framework of a written physician protocol, an ARNP may:

- Monitor and alter drug therapies;
- Initiate appropriate therapies for certain conditions:
- Order diagnostic tests and physical and occupational therapy:
- Perform certain acts within his or her specialty:
- Perform medical acts authorized by a joint committee; and
- Perform additional functions determined by rule. 32

Florida law does not authorize ARNPs to prescribe, independently administer, or dispense controlled substances.<sup>33</sup> Certified registered nurse anesthetists are permitted to order certain controlled substances "to the extent authorized by an established protocol approved by the medical staff of the facility in which the anesthetic service is performed."34

ARNP Petition for Declaratory Statement

On January 22, 2014, a petition for declaratory statement<sup>35</sup> was filed with the Board of Nursing that asked, in substance, whether an ARNP can legally order narcotics for patients treated within an institution with written protocols from an attending physician. 36 The petition noted that prior to January

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<sup>&</sup>lt;sup>30</sup> Sections 458.348(4)(e), and 459.025(3)(e), F.S.

<sup>&</sup>lt;sup>31</sup> Rule 64B9-4.010, F.A.C.

<sup>&</sup>lt;sup>32</sup> Section 464.012(3), F.S. Pursuant to s. 464.012(4), F.S., certified registered nurse anesthetists, certified nurse midwives, and certified nurse practitioners are authorized to perform additional acts that are within their specialty and authorized under an established supervisory protocol.

Sections 893.02(21) and 893.05(1), F.S. The definition of practitioner does not include ARNPs.

<sup>34</sup> Section 464.012(4), F.S.

<sup>&</sup>lt;sup>35</sup> Pursuant to s. 120.565(1), F.S., a declaratory statement is an agency's opinion regarding the applicability of a statutory provision, rule, or agency order to a petitioner's set of circumstances.

In Re: Petition for Declaratory Statement of Carolann Robley, ARNP, 40 Fla. Admin. Reg. 81 (Apr. 25, 2014).

2014, ARNPs ordered controlled substances for patients.<sup>37</sup> Effective January 2014, the hospital disallowed the practice and required all ARNPs to get an order from a physician. The hospital cited passage of legislation in 2013,<sup>38</sup> which clarified the authority of PAs to order controlled substances for patients in institutions, but did not address the authority of ARNPs. 39 The Board of Nursing dismissed the petition, finding that it failed to comply with the requirements of Chapter 120, F.S., and that it sought an opinion regarding the scope of practice of a category of licensees based on an employer's policies. 40

# Florida Comprehensive Drug Abuse Prevention and Control Act

Controlled substances are drugs with the potential for abuse. Chapter 893, F.S., sets forth the Florida Comprehensive Drug Abuse Prevention and Control Act (Act) and classifies controlled substances into five categories, known as schedules. 41 The distinguishing factors between the different drug schedules are the "potential for abuse" of the substance and whether there is a currently accepted medical use for the substance. Schedules are used to regulate the manufacture, distribution, preparation and dispensing of the substances. The Act provides requirements for the prescribing and administering of controlled substances by health care practitioners and proper dispensing by pharmacists and health care practitioners.42

### **Drug Enforcement Administration**

The Drug Enforcement Administration (DEA), housed within the U.S. Department of Justice, enforces the controlled substances laws and regulations of the United States, including preventing and investigating the diversion of controlled pharmaceuticals.<sup>43</sup>

A health care professional wishing to prescribe controlled substances must apply for a registration number from the DEA. Registration numbers are linked to state licenses and may be suspended or revoked upon any disciplinary action taken against a licensee.<sup>44</sup> The DEA will grant registration numbers to a wide range of health care professionals, including physicians, nurse practitioners, physician assistants, optometrists, dentists, and veterinarians, but such professionals may only engage in those activities authorized under state law for the jurisdiction in which their practice is located. 45

The DEA exempts certain agents and employees from registration with the agency, including an individual practitioner<sup>46</sup> who is an agent or an employee of a hospital or other institution. Such practitioner may, when acting in the normal course of business or employment, administer, dispense, or prescribe controlled substances under the registration of the hospital or institution, provided that:

- Such dispensing, administering, or prescribing is done in the usual course of his or her professional practice;
- Such practitioner is authorized to do so by the jurisdiction in which he or she is practicing;
- The hospital or institution employing the practitioner has verified that the practitioner is authorized to dispense, administer, or prescribe drugs within the jurisdiction:

<sup>&</sup>lt;sup>37</sup> For a copy of the petition for declaratory statement and the final order disposing the petition, please see http://www.floridahealth.gov/licensing-and-regulation/declaratory/ documents/nursing/DOH-14-0732-DS-MQA.pdf#page=1&zoom=auto,-10,795 (last visited Jan. 11, 2016).

See ch. 2013-127, Laws of Fla.

<sup>&</sup>lt;sup>39</sup> Supra, note 37.

<sup>&</sup>lt;sup>40</sup> In Re: Petition for Declaratory Statement of Carolann Robley, ARNP, 40 Fla. Admin. Reg. 103 (May 28, 2014).

<sup>&</sup>lt;sup>41</sup> See s. 893.03, F.S.

<sup>&</sup>lt;sup>42</sup> Sections 893.04 and 893.05, F.S.

<sup>&</sup>lt;sup>43</sup>Drug Enforcement Administration, *About Us*, available at <a href="http://www.deadiversion.usdoj.gov/Inside.html">http://www.deadiversion.usdoj.gov/Inside.html</a> (last visited Jan. 12, 2016). 44 Registration numbers must be renewed every three years. Drug Enforcement Administration, *Practitioners Manual*, 7(2006), available at <a href="http://www.deadiversion.usdoj.gov/pubs/manuals/pract/pract\_manual012508.pdf">http://www.deadiversion.usdoj.gov/pubs/manuals/pract/pract\_manual012508.pdf</a> (last visited Jan. 12, 2016).

<sup>&</sup>lt;sup>46</sup> An individual practitioner is defined as a physician, dentist, veterinarian, or other individual licensed, registered, or otherwise permitted by the United States of the jurisdiction in which he or she practices, to dispense a controlled substance in the course of professional practice, but does not include a pharmacist, a pharmacy, or an institutional practitioner. (21 C.F.R. s. 1300.01(b)). STORAGE NAME: h1241.HIS.DOCX

- Such individual is acting only within the scope of his or her employment in the hospital or institution;
- The hospital or institution authorizes the practitioner to administer, dispense, or prescribe under the hospital registration and designates a specific internal code number for each individual practitioner so authorized; and
- The hospital or institution maintains a current list of internal codes and the corresponding individual practitioners that is available at all times to other registrants and law enforcement agencies for the purpose of verifying the prescribing authority of the individual practitioners.<sup>47</sup>

An individual practitioner who is an agent or employee of another practitioner (other than a mid-level practitioner)<sup>48</sup> registered to dispense controlled substances may, when acting in the normal course of business or employment, administer or dispense (other than by issuance of a prescription)<sup>49</sup> controlled substances if and to the extent authorized by state law, under the registration of the employer or principal practitioner in lieu of being registered himself or herself.<sup>50</sup>

# **Effect of Proposed Changes**

The bill clarifies that a PA may order any medication for administration to a patient of his or her supervising physician in a hospital, ambulatory surgical center, or mobile surgical facility, and adds authority for a PA to order medication for administration in a nursing home.

The bill authorizes an ARNP to order any medication, including a controlled substance, for administration to a patient, within the framework of an established protocol, in a facility licensed under ch. 395, F.S. (a hospital, ambulatory surgical center, or mobile surgical facility), or part II of ch. 400, F.S. (a nursing home).

The bill amends the Florida Comprehensive Drug Abuse Prevention and Control Act to expressly provide that a licensed practitioner may authorize a licensed PA or ARNP, who he or she supervises, to order controlled substances for administration to a patient in a hospital, ambulatory surgical center, mobile surgical facility, or nursing home.

The bill amends the definition of "prescription" to exclude an order for medication that is dispensed for administration by an authorized, licensed practitioner, and makes conforming changes that clarify the difference between a prescription and an order for administration. The bill also amends the definition of "administer" to include the term "administration."

The bill reenacts several sections of Florida law for the purpose of incorporating amendments made by the bill.

The bill provides an effective date of July 1, 2016.

# **B. SECTION DIRECTORY:**

**Section 1.** Amends s. 458.347, F.S., relating to physician assistants.

Section 2. Amends s. 459.022, F.S., relating to physician assistants.

**Section 3.** Amends s. 464.012, F.S., relating to certification of advanced registered nurse practitioners; fees.

**Section 4.** Amends s. 465.003, F.S., relating to definitions.

Section 5. Amends s. 893.02, F.S., relating to definitions.

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<sup>&</sup>lt;sup>47</sup> 21 C.F.R. s. 1301.22(c).

<sup>&</sup>lt;sup>48</sup> Examples of mid-level practitioners include nurse practitioners, nurse midwives, nurse anesthetists, clinical nurse specialists, and physician assistants.

<sup>49</sup> The DEA defines "\*\*receptables" as a result of the property of the prope

<sup>&</sup>lt;sup>49</sup> The DEA defines "prescription" as an order for medication which is dispensed to or for an ultimate user, but is not an order for a medication dispensed for immediate administration to the user, such as an order to dispense a drug to a patient in a hospital setting. See 21 C.F.R. s. 1300.01(b).

<sup>&</sup>lt;sup>50</sup> 21 C.F.R. s. 1301.22(b).

- **Section 6.** Amends s. 893.04, F.S., relating to pharmacist and practitioner.
- Section 7. Amends s. 893.05, F.S., relating to practitioners and persons administering controlled substances in their absence.
- Section 8. Reenacts s. 400.462, F.S., relating to definitions.
- Section 9. Reenacts s. 409.906, F.S., relating to optional Medicaid services.
- Section 10. Reenacts s. 401.445, F.S., relating to emergency examination and treatment of incapacitated persons.
- Section 11. Reenacts s. 766.103, F.S., relating to the Florida Medical Consent Law.
- Section 12. Reenacts s. 409.9201, F.S., relating to Medicaid fraud.
- Section 13. Reenacts s. 465.014, F.S., relating to pharmacy technician.
- **Section 14.** Reenacts s. 465.1901, F.S., relating to the practice of orthotics and pedorthics.
- Section 15. Reenacts s. 499.003, F.S., relating to definitions of terms used in this part.
- Section 16. Reenacts s. 831.30, F.S., relating to medicinal drugs; fraud in obtaining.
- Section 17. Reenacts s. 458.331, F.S., relating to grounds for disciplinary action; action by the board and department.
- Section 18. Reenacts s. 459.015, F.S., relating to grounds for disciplinary action; action by the board and department.
- **Section 19.** Reenacts s. 465.015, F.S., relating to violations and penalties.
- Section 20. Reenacts s. 465.016, F.S., relating to disciplinary actions.
- Section 21. Reenacts s. 465.022, F.S., relating to pharmacies; general requirements; fees.
- Section 22. Reenacts s. 465.023, F.S., relating to pharmacy permittee; disciplinary action.
- Section 23. Reenacts s. 112.0455, F.S., relating to the Drug-Free Workplace Act.
- **Section 24.** Reenacts s. 381.986, F.S., relating to the compassionate use of low-THC cannabis.
- Section 25. Reenacts s. 440.102, F.S., relating to drug-free workplace requirements.
- Section 26. Reenacts s. 499.0121, F.S., relating to storage and handling of prescription drugs; recordkeeping.
- Section 27. Reenacts s. 768.36, F.S., relating to alcohol or drug defense.
- Section 28. Reenacts s. 810.02, F.S., relating to burglary.
- Section 29. Reenacts s. 812.014, F.S., relating to theft.
- Section 30. Reenacts s. 856.015, F.S., relating to open house parties.
- Section 31. Reenacts s. 944.47, F.S., relating to introduction, removal, or possession of certain articles unlawful: penalty.
- Section 32. Reenacts s. 951.22, F.S., relating to county detention facilities; contraband articles.
- Section 33. Reenacts s. 985.711, F.S., relating to introduction, removal, or possession of certain articles unlawful; penalty.
- Section 34. Reenacts s. 1003.57, F.S., relating to exceptional students instruction.
- Section 35. Reenacts s. 1006.09, F.S., relating to duties of school principal relating to student discipline and school safety.
- **Section 36.** Reenacts s. 893.0551, F.S., relating to public records exemption for the prescription drug monitoring program.
- Section 37. Provides an effective date of July 1, 2016.

### II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

# A. FISCAL IMPACT ON STATE GOVERNMENT:

Revenues:

None.

# 2. Expenditures:

The bill may have an indeterminate, negative fiscal impact on the DOH due to a possible increase in practitioner complaints associated with the ARNPs' and PAs' new authority to order medications for administration in new settings.

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B.	FIS	SCAL IMPACT ON LOCAL GOVERNMENTS:
	1.	Revenues: None.
	2.	Expenditures: None.
C.	DII	RECT ECONOMIC IMPACT ON PRIVATE SECTOR:
	ho	lysicians or institutions who use ARNPs or PAs to order the administration of medications for spitalized patients or those in nursing homes may realize cost savings associated with increased iciencies of using such practitioners. Additionally, patients may be better served by ARNPs and PAs

# D. FISCAL COMMENTS:

None.

# **III. COMMENTS**

who can order medications for administration under a supervisory protocol, without the direct

# A. CONSTITUTIONAL ISSUES:

Applicability of Municipality/County Mandates Provision:

Not applicable. This bill does not appear to affect county or municipal governments.

2. Other:

None.

**B. RULE-MAKING AUTHORITY:** 

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

C. DRAFTING ISSUES OR OTHER COMMENTS:

involvement of the supervising physician.

None.

# IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

STORAGE NAME: h1241.HIS.DOCX DATE: 1/23/2016

HB 1241 2016

1 A bill to be entitled 2 An act relating to the ordering of medication; 3 amending ss. 458.347 and 459.022, F.S.; revising the 4 authority of a licensed physician assistant to order 5 medication under the direction of a supervisory 6 physician for a specified patient; amending s. 7 464.012, F.S.; authorizing an advanced registered 8 nurse practitioner to order medication for 9 administration to a specified patient; amending s. 10 465.003, F.S.; revising the term "prescription" to 11 exclude an order for drugs or medicinal supplies 12 dispensed for administration; amending s. 893.02, 13 F.S.; revising the term "administer" to include the 14 term "administration"; revising the term 15 "prescription" to exclude an order for drugs or 16 medicinal supplies dispensed for administration; 17 amending s. 893.04, F.S.; conforming provisions to 18 changes made by the act; amending s. 893.05, F.S.; 19 authorizing a licensed practitioner to authorize a 20 licensed physician assistant or advanced registered 21 nurse practitioner to order controlled substances for 22 a specified patient under certain circumstances; 23 reenacting ss. 400.462(26) and 409.906(18), F.S., 24 relating to the definition of the term "physician 25 assistant" for purposes of the Home Health Services 26 Act and physician assistant services under the

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HB 1241 2016

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Medicaid program, respectively, to incorporate the amendments made by the act to ss. 458.347 and 459.022, F.S., in references thereto; reenacting ss. 401.445(1) and 766.103(3), F.S., relating to emergency examination and treatment of incapacitated persons and the Florida Medical Consent Law, respectively, to incorporate the amendments made by the act to ss. 458.347, 459.022, and 464.012, F.S., in references thereto; reenacting ss. 409.9201(1)(a), 465.014(1), 465.1901, 499.003(43), and 831.30(1), F.S., relating to the definition of "prescription drug" for purposes of Medicaid fraud, the supervision of registered pharmacy technicians, applicability of provisions regulating the practice of orthotics or pedorthics to pharmacists, the definition of the term "prescription drug" for purposes of the Florida Drug and Cosmetic Act, and criminal penalties related to the fraudulent obtaining of medicinal drugs, respectively, to incorporate the amendment made by the act to s. 465.003, F.S., in references thereto; reenacting ss. 458.331(1)(pp), 459.015(1)(rr), 465.015(2)(c) and (3), 465.016(1)(s), 465.022(5)(j), and 465.023(1)(h), F.S., relating to grounds for disciplinary action by the Board of Medicine or the Board of Osteopathic Medicine, unlawful acts and penalties related to the practice of pharmacy, grounds for denial of a pharmacy

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permit or disciplinary action against a pharmacy permittee, respectively, to incorporate the amendments made by the act to ss. 465.003 and 893.02, F.S., in references thereto; reenacting ss. 112.0455(5)(i), 381.986(7)(b), 440.102(1)(1), 499.0121(14), 768.36(1)(b), 810.02(3)(f), 812.014(2)(c), 856.015(1)(c), 944.47(1)(a), 951.22(1), 985.711(1)(a), 1003.57(1)(i), and 1006.09(8), F.S., relating to the Drug-Free Workplace Act, the compassionate use of low-THC cannabis, drug-free workplace program requirements, reporting of prescription drug distribution, the definition of the term "drug" for purposes of defenses from civil actions related to alcohol or drugs, burglary offenses, penalties for grand theft, the definition of the term "drug" for purposes of offenses related to open house parties, unlawful introduction of certain articles into correctional institutions, county detention facilities, or juvenile detention facilities, the definition of the term "controlled substance" for purposes of exceptional student instruction, and duties of school principals related to student discipline, respectively, to incorporate the amendment made by the act to s. 893.02, F.S., in references thereto; reenacting s. 893.0551(3)(d) and (e), F.S., relating to disclosure by the Department of Health of

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confidential information in prescription drug monitoring program records, to incorporate the amendments made by the act to ss. 893.04 and 893.05, F.S., in references thereto; providing an effective date.

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

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Section 1. Paragraph (g) of subsection (4) of section 458.347, Florida Statutes, is amended to read:

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458.347 Physician assistants.—

90 91 (4) PERFORMANCE OF PHYSICIAN ASSISTANTS.-

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physician assistant the authority to, and the licensed physician assistant acting under the direction of the supervisory physician may, order any medication medications for

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administration to the supervisory physician's patient during his or her care in a facility licensed under chapter 395 or part II

(q) A supervisory physician may delegate to a licensed

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of chapter 400, notwithstanding any provisions in chapter 465 or chapter 893 which may prohibit this delegation. For the purpose

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of this paragraph, an order is not considered a prescription. A licensed physician assistant working in a facility that is

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licensed under chapter 395 may order any medication under the direction of the supervisory physician.

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Section 2. Paragraph (f) of subsection (4) of section 459.022, Florida Statutes, is amended to read:

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459.022 Physician assistants.-

- (4) PERFORMANCE OF PHYSICIAN ASSISTANTS.-
- (f) A supervisory physician may delegate to a licensed physician assistant the authority to, and the licensed physician assistant acting under the direction of the supervisory physician may, order any medication medications for administration to the supervisory physician's patient during his or her care in a facility licensed under chapter 395 or part II of chapter 400, notwithstanding any provisions in chapter 465 or chapter 893 which may prohibit this delegation. For the purpose of this paragraph, an order is not considered a prescription. A licensed physician assistant working in a facility that is licensed under chapter 395 may order any medication under the direction of the supervisory physician.
- Section 3. Paragraph (e) is added to subsection (3) of section 464.012, Florida Statutes, to read:
- 464.012 Certification of advanced registered nurse practitioners; fees.—
- (3) An advanced registered nurse practitioner shall perform those functions authorized in this section within the framework of an established protocol that is filed with the board upon biennial license renewal and within 30 days after entering into a supervisory relationship with a physician or changes to the protocol. The board shall review the protocol to ensure compliance with applicable regulatory standards for protocols. The board shall refer to the department licensees

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submitting protocols that are not compliant with the regulatory standards for protocols. A practitioner currently licensed under chapter 458, chapter 459, or chapter 466 shall maintain supervision for directing the specific course of medical treatment. Within the established framework, an advanced registered nurse practitioner may:

(e) Order any medication for administration to a patient in a facility licensed under chapter 395 or part II of chapter 400.

Section 4. Subsection (14) of section 465.003, Florida Statutes, is amended to read:

465.003 Definitions.—As used in this chapter, the term:

medicinal supplies written or transmitted by any means of communication by a duly licensed practitioner authorized by the laws of this the state to prescribe such drugs or medicinal supplies and intended to be dispensed by a pharmacist, except for an order that is dispensed for administration. The term also includes an orally transmitted order by the lawfully designated agent of such practitioner; The term also includes an order written or transmitted by a practitioner licensed to practice in a jurisdiction other than this state, but only if the pharmacist called upon to dispense such order determines, in the exercise of her or his professional judgment, that the order is valid and necessary for the treatment of a chronic or recurrent illness; and. The term "prescription" also includes a pharmacist's order

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for a product selected from the formulary created pursuant to s. 465.186. Prescriptions may be retained in written form or the pharmacist may cause them to be recorded in a data processing system, provided that such order can be produced in printed form upon lawful request.

Section 5. Subsections (1) and (22) of section 893.02, Florida Statutes, are amended to read:

- 893.02 Definitions.—The following words and phrases as used in this chapter shall have the following meanings, unless the context otherwise requires:
- (1) "Administer" or "administration" means the direct application of a controlled substance, whether by injection, inhalation, ingestion, or any other means, to the body of a person or animal.
- drugs or medicinal supplies which is written, signed, or transmitted by any word of mouth, telephone, telegram, or other means of communication by a duly licensed practitioner authorized licensed by the laws of this the state to prescribe such drugs or medicinal supplies, is issued in good faith and in the course of professional practice, is intended to be filled, compounded, or dispensed by a another person authorized licensed by the laws of this the state to do so, and meets meeting the requirements of s. 893.04.
- (a) The term also includes an order for drugs or medicinal supplies so transmitted or written by a physician, dentist,

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veterinarian, or other practitioner licensed to practice in a state other than Florida, but only if the pharmacist called upon to fill such an order determines, in the exercise of his or her professional judgment, that the order was issued pursuant to a valid patient-physician relationship, that it is authentic, and that the drugs or medicinal supplies so ordered are considered necessary for the continuation of treatment of a chronic or recurrent illness.

- (b) The term does not include an order that is dispensed for administration by a licensed practitioner authorized by the laws of this state to administer such drugs or medicinal supplies.
- (c) However, If the physician writing the prescription is not known to the pharmacist, the pharmacist shall obtain proof to a reasonable certainty of the validity of the said prescription.
- (d) A prescription order for a controlled substance may shall not be issued on the same prescription blank with another prescription order for a controlled substance that which is named or described in a different schedule or with another, nor shall any prescription order for a controlled substance be issued on the same prescription blank as a prescription order for a medicinal drug, as defined in s. 465.003(8), that is which does not fall within the definition of a controlled substance as defined in this act.
  - Section 6. Paragraphs (a), (d), and (f) of subsection (2)

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of section 893.04, Florida Statutes, are amended to read: 893.04 Pharmacist and practitioner.—

- (2)(a) A pharmacist may not dispense a controlled substance listed in Schedule II, Schedule III, or Schedule IV to any patient or patient's agent without first determining, in the exercise of her or his professional judgment, that the prescription order is valid. The pharmacist may dispense the controlled substance, in the exercise of her or his professional judgment, when the pharmacist or pharmacist's agent has obtained satisfactory patient information from the patient or the patient's agent.
- (d) Each written prescription written prescribed by a practitioner in this state for a controlled substance listed in Schedule II, Schedule III, or Schedule IV must include both a written and a numerical notation of the quantity of the controlled substance prescribed and a notation of the date in numerical, month/day/year format, or with the abbreviated month written out, or the month written out in whole. A pharmacist may, upon verification by the prescriber, document any information required by this paragraph. If the prescriber is not available to verify a prescription, the pharmacist may dispense the controlled substance, but may insist that the person to whom the controlled substance is dispensed provide valid photographic identification. If a prescription includes a numerical notation of the quantity of the controlled substance or date, but does not include the quantity or date written out in textual format,

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the pharmacist may dispense the controlled substance without verification by the prescriber of the quantity or date if the pharmacy previously dispensed another prescription for the person to whom the prescription was written.

- (f) A pharmacist may not knowingly <u>dispense</u> fill a prescription that has been forged for a controlled substance listed in Schedule II, Schedule III, or Schedule IV.
- Section 7. Subsection (1) of section 893.05, Florida Statutes, is amended to read:
- 893.05 Practitioners and persons administering controlled substances in their absence.—
- (1) (a) A practitioner, in good faith and in the course of his or her professional practice only, may prescribe, administer, dispense, mix, or otherwise prepare a controlled substance, or the practitioner may cause the controlled substance same to be administered by a licensed nurse or an intern practitioner under his or her direction and supervision only.
- (b) Pursuant to s. 458.347(4)(g), s. 459.022(4)(f), or s. 464.012(3), as applicable, a practitioner who supervises a licensed physician assistant or advanced registered nurse practitioner may authorize the licensed physician assistant or advanced registered nurse practitioner to order controlled substances for administration to a patient in a facility licensed under chapter 395 or part II of chapter 400.
  - (c) A veterinarian may so prescribe, administer, dispense,

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mix, or prepare a controlled substance for use on animals only, and may cause the controlled substance it to be administered by an assistant or orderly under the veterinarian's direction and supervision only.

(d) A certified optometrist licensed under chapter 463 may not administer or prescribe a controlled substance listed in Schedule I or Schedule II of s. 893.03.

Section 8. For the purpose of incorporating the amendments made by this act to sections 458.347 and 459.022, Florida Statutes, in references thereto, subsection (26) of section 400.462, Florida Statutes, is reenacted to read:

400.462 Definitions.—As used in this part, the term:

(26) "Physician assistant" means a person who is a graduate of an approved program or its equivalent, or meets standards approved by the boards, and is licensed to perform medical services delegated by the supervising physician, as defined in s. 458.347 or s. 459.022.

Section 9. For the purpose of incorporating the amendments made by this act to sections 458.347 and 459.022, Florida Statutes, in references thereto, subsection (18) of section 409.906, Florida Statutes, is reenacted to read:

409.906 Optional Medicaid services.—Subject to specific appropriations, the agency may make payments for services which are optional to the state under Title XIX of the Social Security Act and are furnished by Medicaid providers to recipients who are determined to be eligible on the dates on which the services

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were provided. Any optional service that is provided shall be provided only when medically necessary and in accordance with state and federal law. Optional services rendered by providers in mobile units to Medicaid recipients may be restricted or prohibited by the agency. Nothing in this section shall be construed to prevent or limit the agency from adjusting fees, reimbursement rates, lengths of stay, number of visits, or number of services, or making any other adjustments necessary to comply with the availability of moneys and any limitations or directions provided for in the General Appropriations Act or chapter 216. If necessary to safeguard the state's systems of providing services to elderly and disabled persons and subject to the notice and review provisions of s. 216.177, the Governor may direct the Agency for Health Care Administration to amend the Medicaid state plan to delete the optional Medicaid service known as "Intermediate Care Facilities for the Developmentally Disabled." Optional services may include:

(18) PHYSICIAN ASSISTANT SERVICES.—The agency may pay for all services provided to a recipient by a physician assistant licensed under s. 458.347 or s. 459.022. Reimbursement for such services must be not less than 80 percent of the reimbursement that would be paid to a physician who provided the same services.

Section 10. For the purpose of incorporating the amendments made by this act to sections 458.347, 459.022, and 464.012, Florida Statutes, in references thereto, subsection (1)

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of section 401.445, Florida Statutes, is reenacted to read:
401.445 Emergency examination and treatment of
incapacitated persons.—

- (1) No recovery shall be allowed in any court in this state against any emergency medical technician, paramedic, or physician as defined in this chapter, any advanced registered nurse practitioner certified under s. 464.012, or any physician assistant licensed under s. 458.347 or s. 459.022, or any person acting under the direct medical supervision of a physician, in an action brought for examining or treating a patient without his or her informed consent if:
- (a) The patient at the time of examination or treatment is intoxicated, under the influence of drugs, or otherwise incapable of providing informed consent as provided in s. 766.103;
- (b) The patient at the time of examination or treatment is experiencing an emergency medical condition; and
- (c) The patient would reasonably, under all the surrounding circumstances, undergo such examination, treatment, or procedure if he or she were advised by the emergency medical technician, paramedic, physician, advanced registered nurse practitioner, or physician assistant in accordance with s. 766.103(3).

Examination and treatment provided under this subsection shall be limited to reasonable examination of the patient to determine

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the medical condition of the patient and treatment reasonably necessary to alleviate the emergency medical condition or to stabilize the patient.

Section 11. For the purpose of incorporating the amendments made by this act to sections 458.347, 459.022, and 464.012, Florida Statutes, in references thereto, subsection (3) of section 766.103, Florida Statutes, is reenacted to read:

766.103 Florida Medical Consent Law.-

- (3) No recovery shall be allowed in any court in this state against any physician licensed under chapter 458, osteopathic physician licensed under chapter 459, chiropractic physician licensed under chapter 460, podiatric physician licensed under chapter 461, dentist licensed under chapter 466, advanced registered nurse practitioner certified under s. 458.347 or s. 459.022 in an action brought for treating, examining, or operating on a patient without his or her informed consent when:
- (a)1. The action of the physician, osteopathic physician, chiropractic physician, podiatric physician, dentist, advanced registered nurse practitioner, or physician assistant in obtaining the consent of the patient or another person authorized to give consent for the patient was in accordance with an accepted standard of medical practice among members of the medical profession with similar training and experience in the same or similar medical community as that of the person treating, examining, or operating on the patient for whom the

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consent is obtained; and

- 2. A reasonable individual, from the information provided by the physician, osteopathic physician, chiropractic physician, podiatric physician, dentist, advanced registered nurse practitioner, or physician assistant, under the circumstances, would have a general understanding of the procedure, the medically acceptable alternative procedures or treatments, and the substantial risks and hazards inherent in the proposed treatment or procedures, which are recognized among other physicians, osteopathic physicians, chiropractic physicians, podiatric physicians, or dentists in the same or similar community who perform similar treatments or procedures; or
- (b) The patient would reasonably, under all the surrounding circumstances, have undergone such treatment or procedure had he or she been advised by the physician, osteopathic physician, chiropractic physician, podiatric physician, dentist, advanced registered nurse practitioner, or physician assistant in accordance with the provisions of paragraph (a).

Section 12. For the purpose of incorporating the amendment made by this act to section 465.003, Florida Statutes, in a reference thereto, paragraph (a) of subsection (1) of section 409.9201, Florida Statutes, is reenacted to read:

409.9201 Medicaid fraud.

- (1) As used in this section, the term:
- (a) "Prescription drug" means any drug, including, but not

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limited to, finished dosage forms or active ingredients that are subject to, defined in, or described in s. 503(b) of the Federal Food, Drug, and Cosmetic Act or in s. 465.003(8), s. 499.003(52), s. 499.007(13), or s. 499.82(10).

The value of individual items of the legend drugs or goods or services involved in distinct transactions committed during a single scheme or course of conduct, whether involving a single person or several persons, may be aggregated when determining the punishment for the offense.

Section 13. For the purpose of incorporating the amendment made by this act to section 465.003, Florida Statutes, in a reference thereto, subsection (1) of section 465.014, Florida Statutes, is reenacted to read:

465.014 Pharmacy technician.

intern may not engage in the practice of the profession of pharmacy, except that a licensed pharmacist may delegate to pharmacy technicians who are registered pursuant to this section those duties, tasks, and functions that do not fall within the purview of s. 465.003(13). All such delegated acts must be performed under the direct supervision of a licensed pharmacist who is responsible for all such acts performed by persons under his or her supervision. A registered pharmacy technician, under the supervision of a pharmacist, may initiate or receive communications with a practitioner or his or her agent, on

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behalf of a patient, regarding refill authorization requests. A licensed pharmacist may not supervise more than one registered pharmacy technician unless otherwise permitted by the guidelines adopted by the board. The board shall establish guidelines to be followed by licensees or permittees in determining the circumstances under which a licensed pharmacist may supervise more than one pharmacy technician.

Section 14. For the purpose of incorporating the amendment made by this act to section 465.003, Florida Statutes, in a reference thereto, section 465.1901, Florida Statutes, is reenacted to read:

465.1901 Practice of orthotics and pedorthics.—The provisions of chapter 468 relating to orthotics or pedorthics do not apply to any licensed pharmacist or to any person acting under the supervision of a licensed pharmacist. The practice of orthotics or pedorthics by a pharmacist or any of the pharmacist's employees acting under the supervision of a pharmacist shall be construed to be within the meaning of the term "practice of the profession of pharmacy" as set forth in s. 465.003(13), and shall be subject to regulation in the same manner as any other pharmacy practice. The Board of Pharmacy shall develop rules regarding the practice of orthotics and pedorthics by a pharmacist. Any pharmacist or person under the supervision of a pharmacist engaged in the practice of orthotics or pedorthics is not precluded from continuing that practice pending adoption of these rules.

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Section 15. For the purpose of incorporating the amendment made by this act to section 465.003, Florida Statutes, in a reference thereto, subsection (43) of section 499.003, Florida Statutes, is reenacted to read:

499.003 Definitions of terms used in this part.—As used in this part, the term:

(43) "Prescription drug" means a prescription, medicinal, or legend drug, including, but not limited to, finished dosage forms or active pharmaceutical ingredients subject to, defined by, or described by s. 503(b) of the federal act or s. 465.003(8), s. 499.007(13), subsection (32), or subsection (52), except that an active pharmaceutical ingredient is a prescription drug only if substantially all finished dosage forms in which it may be lawfully dispensed or administered in this state are also prescription drugs.

Section 16. For the purpose of incorporating the amendment made by this act to section 465.003, Florida Statutes, in a reference thereto, subsection (1) of section 831.30, Florida Statutes, is reenacted to read:

831.30 Medicinal drugs; fraud in obtaining.-Whoever:

(1) Falsely makes, alters, or forges any prescription, as defined in s. 465.003, for a medicinal drug other than a drug controlled by chapter 893;

with intent to obtain such drug commits a misdemeanor of the second degree, punishable as provided in s. 775.082 or s.

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775.083. A second or subsequent conviction constitutes a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

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Section 17. For the purpose of incorporating the amendments made by this act to sections 465.003 and 893.02, Florida Statutes, in references thereto, paragraph (pp) of subsection (1) of section 458.331, Florida Statutes, is reenacted to read:

458.331 Grounds for disciplinary action; action by the board and department.—

- (1) The following acts constitute grounds for denial of a license or disciplinary action, as specified in s. 456.072(2):
- (pp) Applicable to a licensee who serves as the designated physician of a pain-management clinic as defined in s. 458.3265 or s. 459.0137:
- 1. Registering a pain-management clinic through misrepresentation or fraud;
- 2. Procuring, or attempting to procure, the registration of a pain-management clinic for any other person by making or causing to be made, any false representation;
- 3. Failing to comply with any requirement of chapter 499, the Florida Drug and Cosmetic Act; 21 U.S.C. ss. 301-392, the Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq., the Drug Abuse Prevention and Control Act; or chapter 893, the Florida Comprehensive Drug Abuse Prevention and Control Act;
  - 4. Being convicted or found guilty of, regardless of

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adjudication to, a felony or any other crime involving moral turpitude, fraud, dishonesty, or deceit in any jurisdiction of the courts of this state, of any other state, or of the United States;

- 5. Being convicted of, or disciplined by a regulatory agency of the Federal Government or a regulatory agency of another state for, any offense that would constitute a violation of this chapter;
- 6. Being convicted of, or entering a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction of the courts of this state, of any other state, or of the United States which relates to the practice of, or the ability to practice, a licensed health care profession;
- 7. Being convicted of, or entering a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction of the courts of this state, of any other state, or of the United States which relates to health care fraud;
- 8. Dispensing any medicinal drug based upon a communication that purports to be a prescription as defined in s. 465.003(14) or s. 893.02 if the dispensing practitioner knows or has reason to believe that the purported prescription is not based upon a valid practitioner-patient relationship; or
- 9. Failing to timely notify the board of the date of his or her termination from a pain-management clinic as required by s. 458.3265(2).
  - Section 18. For the purpose of incorporating the

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amendments made by this act to sections 465.003 and 893.02, Florida Statutes, in references thereto, paragraph (rr) of subsection (1) of section 459.015, Florida Statutes, is reenacted to read:

459.015 Grounds for disciplinary action; action by the board and department.—

- (1) The following acts constitute grounds for denial of a license or disciplinary action, as specified in s. 456.072(2):
- (rr) Applicable to a licensee who serves as the designated physician of a pain-management clinic as defined in s. 458.3265 or s. 459.0137:
- 1. Registering a pain-management clinic through misrepresentation or fraud;
- 2. Procuring, or attempting to procure, the registration of a pain-management clinic for any other person by making or causing to be made, any false representation;
- 3. Failing to comply with any requirement of chapter 499, the Florida Drug and Cosmetic Act; 21 U.S.C. ss. 301-392, the Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq., the Drug Abuse Prevention and Control Act; or chapter 893, the Florida Comprehensive Drug Abuse Prevention and Control Act;
- 4. Being convicted or found guilty of, regardless of adjudication to, a felony or any other crime involving moral turpitude, fraud, dishonesty, or deceit in any jurisdiction of the courts of this state, of any other state, or of the United States;

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5. Being convicted of, or disciplined by a regulatory agency of the Federal Government or a regulatory agency of another state for, any offense that would constitute a violation of this chapter;

- 6. Being convicted of, or entering a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction of the courts of this state, of any other state, or of the United States which relates to the practice of, or the ability to practice, a licensed health care profession;
- 7. Being convicted of, or entering a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction of the courts of this state, of any other state, or of the United States which relates to health care fraud;
- 8. Dispensing any medicinal drug based upon a communication that purports to be a prescription as defined in s. 465.003(14) or s. 893.02 if the dispensing practitioner knows or has reason to believe that the purported prescription is not based upon a valid practitioner-patient relationship; or
- 9. Failing to timely notify the board of the date of his or her termination from a pain-management clinic as required by s. 459.0137(2).

Section 19. For the purpose of incorporating the amendments made by this act to sections 465.003 and 893.02, Florida Statutes, in references thereto, paragraph (c) of subsection (2) and subsection (3) of section 465.015, Florida Statutes, are reenacted to read:

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465.015 Violations and penalties.-

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- (2) It is unlawful for any person:
- (c) To sell or dispense drugs as defined in s. 465.003(8) without first being furnished with a prescription.
- It is unlawful for any pharmacist to knowingly fail to report to the sheriff or other chief law enforcement agency of the county where the pharmacy is located within 24 hours after learning of any instance in which a person obtained or attempted to obtain a controlled substance, as defined in s. 893.02, or at the close of business on the next business day, whichever is later, that the pharmacist knew or believed was obtained or attempted to be obtained through fraudulent methods or representations from the pharmacy at which the pharmacist practiced pharmacy. Any pharmacist who knowingly fails to make such a report within 24 hours after learning of the fraud or attempted fraud or at the close of business on the next business day, whichever is later, commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083. A sufficient report of the fraudulent obtaining of controlled substances under this subsection must contain, at a minimum, a copy of the prescription used or presented and a narrative, including all information available to the pharmacist concerning the transaction, such as the name and telephone number of the prescribing physician; the name, description, and any personal identification information pertaining to the person who presented the prescription; and all other material information,

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such as photographic or video surveillance of the transaction.

Section 20. For the purpose of incorporating the amendments made by this act to sections 465.003 and 893.02, Florida Statutes, in references thereto, paragraph (s) of subsection (1) of section 465.016, Florida Statutes, is reenacted to read:

465.016 Disciplinary actions.-

- (1) The following acts constitute grounds for denial of a license or disciplinary action, as specified in s. 456.072(2):
- (s) Dispensing any medicinal drug based upon a communication that purports to be a prescription as defined by s. 465.003(14) or s. 893.02 when the pharmacist knows or has reason to believe that the purported prescription is not based upon a valid practitioner-patient relationship.

Section 21. For the purpose of incorporating the amendments made by this act to sections 465.003 and 893.02, Florida Statutes, in references thereto, paragraph (j) of subsection (5) of section 465.022, Florida Statutes, is reenacted to read:

465.022 Pharmacies; general requirements; fees.-

- (5) The department or board shall deny an application for a pharmacy permit if the applicant or an affiliated person, partner, officer, director, or prescription department manager or consultant pharmacist of record of the applicant:
- (j) Has dispensed any medicinal drug based upon a communication that purports to be a prescription as defined by

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s. 465.003(14) or s. 893.02 when the pharmacist knows or has reason to believe that the purported prescription is not based upon a valid practitioner-patient relationship that includes a documented patient evaluation, including history and a physical examination adequate to establish the diagnosis for which any drug is prescribed and any other requirement established by board rule under chapter 458, chapter 459, chapter 461, chapter 463, chapter 464, or chapter 466.

For felonies in which the defendant entered a plea of guilty or nolo contendere in an agreement with the court to enter a pretrial intervention or drug diversion program, the department shall deny the application if upon final resolution of the case the licensee has failed to successfully complete the program.

Section 22. For the purpose of incorporating the amendments made by this act to sections 465.003 and 893.02, Florida Statutes, in references thereto, paragraph (h) of subsection (1) of section 465.023, Florida Statutes, is reenacted to read:

465.023 Pharmacy permittee; disciplinary action.-

(1) The department or the board may revoke or suspend the permit of any pharmacy permittee, and may fine, place on probation, or otherwise discipline any pharmacy permittee if the permittee, or any affiliated person, partner, officer, director, or agent of the permittee, including a person fingerprinted under s. 465.022(3), has:

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(h) Dispensed any medicinal drug based upon a communication that purports to be a prescription as defined by s. 465.003(14) or s. 893.02 when the pharmacist knows or has reason to believe that the purported prescription is not based upon a valid practitioner-patient relationship that includes a documented patient evaluation, including history and a physical examination adequate to establish the diagnosis for which any drug is prescribed and any other requirement established by board rule under chapter 458, chapter 459, chapter 461, chapter 463, chapter 464, or chapter 466.

Section 23. For the purpose of incorporating the amendment made by this act to section 893.02, Florida Statutes, in a reference thereto, paragraph (i) of subsection (5) of section 112.0455, Florida Statutes, is reenacted to read:

112.0455 Drug-Free Workplace Act.-

- (5) DEFINITIONS.—Except where the context otherwise requires, as used in this act:
- (i) "Prescription or nonprescription medication" means a drug or medication obtained pursuant to a prescription as defined by s. 893.02 or a medication that is authorized pursuant to federal or state law for general distribution and use without a prescription in the treatment of human diseases, ailments, or injuries.

Section 24. For the purpose of incorporating the amendment made by this act to section 893.02, Florida Statutes, in a reference thereto, paragraph (b) of subsection (7) of section

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381.986, Florida Statutes, is reenacted to read:

381.986 Compassionate use of low-THC cannabis.-

(7) EXCEPTIONS TO OTHER LAWS.-

(b) Notwithstanding s. 893.13, s. 893.135, s. 893.147, or any other provision of law, but subject to the requirements of this section, an approved dispensing organization and its owners, managers, and employees may manufacture, possess, sell, deliver, distribute, dispense, and lawfully dispose of reasonable quantities, as established by department rule, of low-THC cannabis. For purposes of this subsection, the terms "manufacture," "possession," "deliver," "distribute," and "dispense" have the same meanings as provided in s. 893.02.

Section 25. For the purpose of incorporating the amendment made by this act to section 893.02, Florida Statutes, in a reference thereto, paragraph (1) of subsection (1) of section 440.102, Florida Statutes, is reenacted to read:

- 440.102 Drug-free workplace program requirements.—The following provisions apply to a drug-free workplace program implemented pursuant to law or to rules adopted by the Agency for Health Care Administration:
- (1) DEFINITIONS.—Except where the context otherwise requires, as used in this act:
- (1) "Prescription or nonprescription medication" means a drug or medication obtained pursuant to a prescription as defined by s. 893.02 or a medication that is authorized pursuant to federal or state law for general distribution and use without

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a prescription in the treatment of human diseases, ailments, or injuries.

Section 26. For the purpose of incorporating the amendment made by this act to section 893.02, Florida Statutes, in a reference thereto, subsection (14) of section 499.0121, Florida Statutes, is reenacted to read:

499.0121 Storage and handling of prescription drugs; recordkeeping.—The department shall adopt rules to implement this section as necessary to protect the public health, safety, and welfare. Such rules shall include, but not be limited to, requirements for the storage and handling of prescription drugs and for the establishment and maintenance of prescription drug distribution records.

wholesale distributor, out-of-state prescription drug wholesale distributor, retail pharmacy drug wholesale distributor, manufacturer, or repackager that engages in the wholesale distribution of controlled substances as defined in s. 893.02 shall submit a report to the department of its receipts and distributions of controlled substances listed in Schedule II, Schedule III, Schedule IV, or Schedule V as provided in s. 893.03. Wholesale distributor facilities located within this state shall report all transactions involving controlled substances, and wholesale distributor facilities located outside this state shall report all distributions to entities located in this state. If the prescription drug wholesale distributor, out-

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729 of-state prescription drug wholesale distributor, retail 730 pharmacy drug wholesale distributor, manufacturer, or repackager does not have any controlled substance distributions for the 731 732 month, a report shall be sent indicating that no distributions occurred in the period. The report shall be submitted monthly by 733 734 the 20th of the next month, in the electronic format used for 735 controlled substance reporting to the Automation of Reports and 736 Consolidated Orders System division of the federal Drug 737 Enforcement Administration. Submission of electronic data must 738 be made in a secured Internet environment that allows for manual 739 or automated transmission. Upon successful transmission, an acknowledgment page must be displayed to confirm receipt. The 740 741 report must contain the following information:

- (a) The federal Drug Enforcement Administration registration number of the wholesale distributing location.
- (b) The federal Drug Enforcement Administration registration number of the entity to which the drugs are distributed or from which the drugs are received.
- (c) The transaction code that indicates the type of transaction.
- (d) The National Drug Code identifier of the product and the quantity distributed or received.
- (e) The Drug Enforcement Administration Form 222 number or Controlled Substance Ordering System Identifier on all Schedule II transactions.
  - (f) The date of the transaction.

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The department must share the reported data with the Department of Law Enforcement and local law enforcement agencies upon request and must monitor purchasing to identify purchasing levels that are inconsistent with the purchasing entity's clinical needs. The Department of Law Enforcement shall investigate purchases at levels that are inconsistent with the purchasing entity's clinical needs to determine whether violations of chapter 893 have occurred.

Section 27. For the purpose of incorporating the amendment made by this act to section 893.02, Florida Statutes, in a reference thereto, paragraph (b) of subsection (1) of section 768.36, Florida Statutes, is reenacted to read:

768.36 Alcohol or drug defense.-

- (1) As used in this section, the term:
- (b) "Drug" means any chemical substance set forth in s. 877.111 or any substance controlled under chapter 893. The term does not include any drug or medication obtained pursuant to a prescription as defined in s. 893.02 which was taken in accordance with the prescription, or any medication that is authorized under state or federal law for general distribution and use without a prescription in treating human diseases, ailments, or injuries and that was taken in the recommended dosage.

Section 28. For the purpose of incorporating the amendment made by this act to section 893.02, Florida Statutes, in a

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reference thereto, paragraph (f) of subsection (3) of section 810.02, Florida Statutes, is reenacted to read:

810.02 Burglary.-

- (3) Burglary is a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084, if, in the course of committing the offense, the offender does not make an assault or battery and is not and does not become armed with a dangerous weapon or explosive, and the offender enters or remains in a:
- (f) Structure or conveyance when the offense intended to be committed therein is theft of a controlled substance as defined in s. 893.02. Notwithstanding any other law, separate judgments and sentences for burglary with the intent to commit theft of a controlled substance under this paragraph and for any applicable possession of controlled substance offense under s. 893.13 or trafficking in controlled substance offense under s. 893.135 may be imposed when all such offenses involve the same amount or amounts of a controlled substance.

However, if the burglary is committed within a county that is subject to a state of emergency declared by the Governor under chapter 252 after the declaration of emergency is made and the perpetration of the burglary is facilitated by conditions arising from the emergency, the burglary is a felony of the first degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084. As used in this subsection, the term "conditions

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arising from the emergency" means civil unrest, power outages, curfews, voluntary or mandatory evacuations, or a reduction in the presence of or response time for first responders or homeland security personnel. A person arrested for committing a burglary within a county that is subject to such a state of emergency may not be released until the person appears before a committing magistrate at a first appearance hearing. For purposes of sentencing under chapter 921, a felony offense that is reclassified under this subsection is ranked one level above the ranking under s. 921.0022 or s. 921.0023 of the offense committed.

Section 29. For the purpose of incorporating the amendment made by this act to section 893.02, Florida Statutes, in a reference thereto, paragraph (c) of subsection (2) of section 812.014, Florida Statutes, is reenacted to read:

812.014 Theft.-

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(c) It is grand theft of the third degree and a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084, if the property stolen is:

- 1. Valued at \$300 or more, but less than \$5,000.
- 2. Valued at \$5,000 or more, but less than \$10,000.
- 3. Valued at \$10,000 or more, but less than \$20,000.
  - 4. A will, codicil, or other testamentary instrument.
  - 5. A firearm.
  - 6. A motor vehicle, except as provided in paragraph (a).

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7. Any commercially farmed animal, including any animal of the equine, bovine, or swine class or other grazing animal; a bee colony of a registered beekeeper; and aquaculture species raised at a certified aquaculture facility. If the property stolen is aquaculture species raised at a certified aquaculture facility, then a \$10,000 fine shall be imposed.

- 8. Any fire extinguisher.
- 9. Any amount of citrus fruit consisting of 2,000 or more individual pieces of fruit.
- 10. Taken from a designated construction site identified by the posting of a sign as provided for in s. 810.09(2)(d).
  - 11. Any stop sign.

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- 12. Anhydrous ammonia.
- 13. Any amount of a controlled substance as defined in s. 893.02. Notwithstanding any other law, separate judgments and sentences for theft of a controlled substance under this subparagraph and for any applicable possession of controlled substance offense under s. 893.13 or trafficking in controlled substance offense under s. 893.135 may be imposed when all such offenses involve the same amount or amounts of a controlled substance.

However, if the property is stolen within a county that is subject to a state of emergency declared by the Governor under chapter 252, the property is stolen after the declaration of emergency is made, and the perpetration of the theft is

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859 facilitated by conditions arising from the emergency, the 860 offender commits a felony of the second degree, punishable as 861 provided in s. 775.082, s. 775.083, or s. 775.084, if the 862 property is valued at \$5,000 or more, but less than \$10,000, as provided under subparagraph 2., or if the property is valued at 863 864 \$10,000 or more, but less than \$20,000, as provided under 865 subparagraph 3. As used in this paragraph, the term "conditions 866 arising from the emergency" means civil unrest, power outages, 867 curfews, voluntary or mandatory evacuations, or a reduction in 868 the presence of or the response time for first responders or 869 homeland security personnel. For purposes of sentencing under 870 chapter 921, a felony offense that is reclassified under this 871 paragraph is ranked one level above the ranking under s. 872 921.0022 or s. 921.0023 of the offense committed. 873 Section 30. For the purpose of incorporating the amendment 874 made by this act to section 893.02, Florida Statutes, in a 875 reference thereto, paragraph (c) of subsection (1) of section 876 856.015, Florida Statutes, is reenacted to read: 877

856.015 Open house parties.-

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- (1)Definitions.—As used in this section:
- "Drug" means a controlled substance, as that term is defined in ss. 893.02(4) and 893.03.

Section 31. For the purpose of incorporating the amendment made by this act to section 893.02, Florida Statutes, in a reference thereto, paragraph (a) of subsection (1) of section 944.47, Florida Statutes, is reenacted to read:

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944.47 Introduction, removal, or possession of certain articles unlawful; penalty.—

- (1)(a) Except through regular channels as authorized by the officer in charge of the correctional institution, it is unlawful to introduce into or upon the grounds of any state correctional institution, or to take or attempt to take or send or attempt to send therefrom, any of the following articles which are hereby declared to be contraband for the purposes of this section, to wit:
- 1. Any written or recorded communication or any currency or coin given or transmitted, or intended to be given or transmitted, to any inmate of any state correctional institution.
- 2. Any article of food or clothing given or transmitted, or intended to be given or transmitted, to any inmate of any state correctional institution.
- 3. Any intoxicating beverage or beverage which causes or may cause an intoxicating effect.
- 4. Any controlled substance as defined in s. 893.02(4) or any prescription or nonprescription drug having a hypnotic, stimulating, or depressing effect.
- 5. Any firearm or weapon of any kind or any explosive substance.
- 6. Any cellular telephone or other portable communication device intentionally and unlawfully introduced inside the secure perimeter of any state correctional institution without prior

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authorization or consent from the officer in charge of such correctional institution. As used in this subparagraph, the term "portable communication device" means any device carried, worn, or stored which is designed or intended to receive or transmit verbal or written messages, access or store data, or connect electronically to the Internet or any other electronic device and which allows communications in any form. Such devices include, but are not limited to, portable two-way pagers, handheld radios, cellular telephones, Blackberry-type devices, personal digital assistants or PDA's, laptop computers, or any components of these devices which are intended to be used to assemble such devices. The term also includes any new technology that is developed for similar purposes. Excluded from this definition is any device having communication capabilities which has been approved or issued by the department for investigative or institutional security purposes or for conducting other state business.

Section 32. For the purpose of incorporating the amendment made by this act to section 893.02, Florida Statutes, in a reference thereto, subsection (1) of section 951.22, Florida Statutes, is reenacted to read:

951.22 County detention facilities; contraband articles.-

(1) It is unlawful, except through regular channels as duly authorized by the sheriff or officer in charge, to introduce into or possess upon the grounds of any county detention facility as defined in s. 951.23 or to give to or

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receive from any inmate of any such facility wherever said inmate is located at the time or to take or to attempt to take or send therefrom any of the following articles which are hereby declared to be contraband for the purposes of this act, to wit: Any written or recorded communication; any currency or coin; any article of food or clothing; any tobacco products as defined in s. 210.25(11); any cigarette as defined in s. 210.01(1); any cigar; any intoxicating beverage or beverage which causes or may cause an intoxicating effect; any narcotic, hypnotic, or excitative drug or drug of any kind or nature, including nasal inhalators, sleeping pills, barbiturates, and controlled substances as defined in s. 893.02(4); any firearm or any instrumentality customarily used or which is intended to be used as a dangerous weapon; and any instrumentality of any nature that may be or is intended to be used as an aid in effecting or attempting to effect an escape from a county facility.

Section 33. For the purpose of incorporating the amendment made by this act to section 893.02, Florida Statutes, in a reference thereto, paragraph (a) of subsection (1) of section 985.711, Florida Statutes, is reenacted to read:

- 985.711 Introduction, removal, or possession of certain articles unlawful; penalty.—
- (1)(a) Except as authorized through program policy or operating procedure or as authorized by the facility superintendent, program director, or manager, a person may not introduce into or upon the grounds of a juvenile detention

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facility or commitment program, or take or send, or attempt to take or send, from a juvenile detention facility or commitment program, any of the following articles, which are declared to be contraband under this section:

- 1. Any unauthorized article of food or clothing.
- 2. Any intoxicating beverage or any beverage that causes or may cause an intoxicating effect.
- 3. Any controlled substance, as defined in s. 893.02(4), or any prescription or nonprescription drug that has a hypnotic, stimulating, or depressing effect.
- 4. Any firearm or weapon of any kind or any explosive substance.

Section 34. For the purpose of incorporating the amendment made by this act to section 893.02, Florida Statutes, in a reference thereto, paragraph (i) of subsection (1) of section 1003.57, Florida Statutes, is reenacted to read:

1003.57 Exceptional students instruction.-

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- (i) For purposes of paragraph (h), the term:
- 1. "Controlled substance" means a drug or other substance identified under Schedule I, Schedule II, Schedule III, Schedule IV, or Schedule V of the Controlled Substances Act, 21 U.S.C. s. 812(c) and s. 893.02(4).
- 2. "Weapon" means a device, instrument, material, or substance, animate or inanimate, which is used for, or is readily capable of, causing death or serious bodily injury;

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however, this definition does not include a pocketknife having a blade that is less than 2 1/2 inches in length.

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Section 35. For the purpose of incorporating the amendment made by this act to section 893.02, Florida Statutes, in a reference thereto, subsection (8) of section 1006.09, Florida Statutes, is reenacted to read:

1006.09 Duties of school principal relating to student discipline and school safety.—

The school principal shall require all school personnel to report to the principal or principal's designee any suspected unlawful use, possession, or sale by a student of any controlled substance, as defined in s. 893.02; any counterfeit controlled substance, as defined in s. 831.31; any alcoholic beverage, as defined in s. 561.01(4); or model glue. School personnel are exempt from civil liability when reporting in good faith to the proper school authority such suspected unlawful use, possession, or sale by a student. Only a principal or principal's designee is authorized to contact a parent or legal quardian of a student regarding this situation. Reports made and verified under this subsection shall be forwarded to an appropriate agency. The principal or principal's designee shall timely notify the student's parent that a verified report made under this subsection with respect to the student has been made and forwarded.

Section 36. For the purpose of incorporating the amendments made by this act to sections 893.04 and 893.05,

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Florida Statutes, in references thereto, paragraphs (d) and (e) of subsection (3) of section 893.0551, Florida Statutes, are reenacted to read:

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893.0551 Public records exemption for the prescription drug monitoring program.—

- (3) The department shall disclose such confidential and exempt information to the following persons or entities upon request and after using a verification process to ensure the legitimacy of the request as provided in s. 893.055:
- (d) A health care practitioner who certifies that the information is necessary to provide medical treatment to a current patient in accordance with ss. 893.05 and 893.055.
- (e) A pharmacist who certifies that the requested information will be used to dispense controlled substances to a current patient in accordance with ss. 893.04 and 893.055.

Section 37. This act shall take effect July 1, 2016.

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#### HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #:

HB 1245

Medicaid Provider Overpayments

SPONSOR(S): Peters

TIED BILLS:

IDEN./SIM. BILLS: SB 1370

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Innovation Subcommittee		McElroy (M	Poche My
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

#### **SUMMARY ANALYSIS**

In the Florida Medicaid program, the state has one year from the date that the Agency for Health Care Administration (AHCA) or federal Centers for Medicare & Medicaid Services (CMS) discover an overpayment to a Medicaid provider to recover or seek to recover the overpayment. After the one-year period, Florida must refund the federal share of the overpayment, regardless of whether AHCA has actually recovered payment from the Medicaid provider. Federal law provides an exemption from repayment if the Medicaid provider has gone out of business. To use this exemption, AHCA must certify that a Medicaid provider is out of business and that any overpayment cannot be collected. AHCA does not currently have statutory authority to make this certification and, as a result, Florida repays the federal share of the overpayments to out-of-business Medicaid providers. The annual repayment amount has ranged from \$1.5 million to \$7.3 million.

HB 1245 authorizes AHCA to certify that a Medicaid provider is out of business and that any overpayments made to the provider cannot be collected. This allows Florida to use the exemption from any mandatory repayment of the federal share for Medicaid provider overpayments.

The bill appears to have an indeterminate, positive fiscal impact on state government.

The bill provides an effective date of July 1, 2016.

This document does not reflect the intent or official position of the bill sponsor or House of Representatives. STORAGE NAME: h1245.HIS.DOCX

#### **FULL ANALYSIS**

#### I. SUBSTANTIVE ANALYSIS

# A. EFFECT OF PROPOSED CHANGES:

#### **Present Situation**

# Medicaid

Medicaid is a jointly funded partnership of the federal and state governments that provides access to health care for low-income families and individuals. The structure of each state's Medicaid program varies and what states must pay for is largely determined by the federal government<sup>1</sup>, as a condition of receiving federal funds. Federal law sets the amount, scope, and duration of services offered in the program, among other requirements. These federal requirements create an entitlement that comes with constitutional due process protections. The entitlement means that two parts of the Medicaid cost equation – people and utilization – are largely predetermined for the states.

The Centers for Medicare & Medicaid Services (CMS), within the U.S. Department of Health and Human Services, is responsible for the administration of the Medicaid program. CMS, through its Center for Program Integrity, is tasked with identifying, prosecuting and preventing fraud, waste and abuse within the Medicaid program.<sup>2</sup> To accomplish this task, CMS has authority to:

- Hire contractors to review provider activities, audit claims, identify overpayments, and educate providers and others on program integrity issues;
- Provide support and assistance to states in their efforts to combat provider fraud and abuse;
   and
- Eliminate and recover improper payments.

# Medicaid Program in Florida

The Medicaid program in Florida is administered by AHCA. Reimbursement for services provided to Medicaid recipients is established through various methodologies which may include fee schedules, reimbursement methods based on cost reporting, negotiated fees, competitive bidding and other mechanisms that are efficient and effective for purchasing services or goods on behalf of recipients.<sup>3</sup> Reimbursement is limited to claims for services provided for covered injuries or illnesses<sup>4</sup> by a provider who has a valid Medicaid provider agreement.<sup>5</sup> Since its inception in 1970, the program has paid nearly \$300 billion to Medicaid providers of goods and services.<sup>6</sup>

AHCA's Office of Medicaid Program Integrity (MPI) and the Medicaid Fraud Control Unit (MFCU) in the Office of the Attorney General are responsible for ensuring that fraudulent and abusive behavior and

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<sup>&</sup>lt;sup>1</sup> The Federal Medical Assistance Percentages (FMAPs) are used to determine the amount of matching funds for state expenditures for assistance payments for certain social services, and state medical and medical insurance expenditures. The regular average state FMAP is 57%, but ranges from 50% in wealthier states up to 75% in states with lower per capita incomes (the maximum regular FMAP is 82%). *Financing & Reimbursement*, Medicaid.gov <a href="https://www.medicaid.gov/medicaid-chip-program-information/by-topics/eligibility/eligibility.html">https://aspe.hhs.gov/federal-medical-assistance-percentages-or-federal-financial-participation-state-assistance-expenditures</a> (last viewed on January 20, 2016).

<sup>&</sup>lt;sup>2</sup> Program Integrity, Medicaid.gov <a href="https://www.medicaid.gov/medicaid-chip-program-information/by-topics/eligibility/eligibility.html">https://www.medicaid.gov/medicaid-chip-program-information/by-topics/eligibility/eligibility.html</a> (last viewed on January 20, 2016).

<sup>&</sup>lt;sup>3</sup> Section 409.908, F.S.

<sup>&</sup>lt;sup>4</sup> "Covered injury or illness" means any sickness, injury, disease, disability, deformity, abnormality disease, necessary medical care, pregnancy, or death for which a third party is, may be, could be, should be, or has been liable, and for which Medicaid is, or may be, obligated to provide, or has provided, medical assistance. S. 409.901(9), F.S.

<sup>&</sup>lt;sup>5</sup> Section 409.907, F.S. Medicaid provider agreements are voluntary agreements between AHCA and a provider for the provision of services to Medicaid recipients and include background screening requirements, notification requirements for change of ownership, authority for AHCA site visits of provider service locations, and surety bond requirements.

<sup>6</sup> Id.

neglect of recipients occur to the minimum extent possible, and to recover overpayments and impose sanctions as appropriate.7

MPI is statutorily required to develop statistical methodologies to identify providers who exhibit aberrant billing patterns.<sup>8</sup> MPI utilizes these methodologies to perform comprehensive audits and generalized analyses of Medicaid providers. Overpayments identified through these audits are referred to AHCA's Division of Operations, Bureau of Financial Services (Financial Services) for collection. 10 Financial Services collects the overpayments through either direct payment or through withholding payment to the provider. 11

Any suspected criminal violation identified by AHCA is referred to the MFCU. MFCU is responsible for investigating and prosecuting provider fraud within the Medicaid program which commonly involves fraud related to providers' billing practices, including billing for services that were not provided, overcharging for services that were provided and billing for services that were not medically necessary.<sup>12</sup> AHCA and MFCU are required to submit an annual joint report to the Legislature documenting the effectiveness of the state's efforts to control Medicaid fraud and abuse and to recover Medicaid overpayments during the previous fiscal year. 13

# Reimbursement of Medicaid Overpayment

Federal law requires the state to refund the federal share of any overpayment made to a Medicaid provider. An overpayment occurs when a Medicaid provider is paid in an amount in excess of the Medicaid established allowable amount for the service. 14 Overpayments can be discovered in a variety of ways, including audits performed by AHCA or CMS under their program integrity offices. 15 The state has one year from the date that AHCA or CMS discover an overpayment to recover or seek to recover the overpayment. 16 After one year, the state must refund the federal share of the overpayment, regardless of whether AHCA has actually recovered payment from the provider. 17

Federal law also provides an exception to the mandatory federal share repayment provision. Audits are not always performed contemporaneously with payment and may occur several years after the overpayment to the Medicaid provider. Sometimes, the provider has gone out of business prior to the discovery of the overpayment. A state is not required to refund the federal portion of the overpayment if the provider is out of business on the date of discovery of the overpayment or if the provider goes out of business before the end of the one year period following discovery.<sup>18</sup> To prove the provider is out of business, a state must: 19

- Document its efforts to locate the party and its assets;<sup>20</sup> and
- Provide an affidavit or certification from the appropriate state legal authority establishing that the provider is out of business and that the overpayment cannot be collected under state law and procedures, and citing the effective date of that determination.

<sup>&</sup>lt;sup>7</sup> Section 409.913, F.S.

<sup>&</sup>lt;sup>9</sup> Agency for Health Care Administration and the Department of Legal Affairs, The State's Efforts to Control Medicaid Fraud and Abuse, FY 2014-15, December 15, 2015, available at

https://ahca.myflorida.com/Executive/Inspector General/docs/Medicaid Fraud Abuse Annual Reports/2014-15 MedicaidFraudandAbuseAnnualReport.pdf (last viewed January 23, 2016). 10 ld.

<sup>&</sup>lt;sup>11</sup> ld.

<sup>&</sup>lt;sup>12</sup> ld.

<sup>&</sup>lt;sup>13</sup> ld.

<sup>&</sup>lt;sup>14</sup> 42 C.F.R. 433.304

<sup>&</sup>lt;sup>15</sup> Section 409.913, F.S.; Section 1936 of the Social Security Act.

<sup>&</sup>lt;sup>16</sup> 42 C.F.R. 433.312(a)(1).

<sup>&</sup>lt;sup>17</sup> 42 C.F.R. 433.312(a)(2).

<sup>&</sup>lt;sup>18</sup> 42 C.F.R. 433.318(d)(1).

<sup>&</sup>lt;sup>19</sup> 42 C.F.R. 433.318(d)(2)(i) and (ii).

<sup>&</sup>lt;sup>20</sup> These efforts must be consistent with applicable state policies and procedures.

Florida is currently required to repay the federal share of an overpayment when a provider is out business. There are no state law provisions that authorize AHCA to certify that a provider is out of business and that the overpayment cannot be collected, so the exemption from mandatory repayment is not available. As a result, Florida refunded the federal government \$7.3 million in FY 2011-12, \$1.5 million in FY 2012-13 and \$2.8 million in FY 2013-14 for the federal share of Medicaid provider overpayments that it could have otherwise retained.<sup>21</sup>

# **Effect of Proposed Changes**

HB 1245 authorizes AHCA to certify that a Medicaid provider is out of business and that any overpayments made to the provider cannot be collected under state law and procedures. This allows Florida to qualify for the exemption from mandatory federal share repayment for Medicaid provider overpayments, and retain those funds.

# **B. SECTION DIRECTORY:**

**Section 1:** Amends s. 409.908, F.S., relating to reimbursement of Medicaid providers.

Section 2: Reenacts s. 409.8132, F.S., relating to Medikids program component.

Section 3: Provides an effective date of July 1, 2016.

#### II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

# A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

Florida refunded to the federal government \$7.3 million in FY 2011-12, \$1.5 million in FY 2012-13 and \$2.8 million in FY 2013-14 for the federal share of Medicaid provider overpayments. The bill permits AHCA to certify that a provider is out-of-business and that overpayments cannot be collected. As a result, Florida will retain the federal share of future Medicaid overpayments to providers who are certified as out-of-business, which AHCA estimates will total between \$1 and \$3 million per fiscal year.<sup>22</sup>

2. Expenditures:

None.

#### B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

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<sup>&</sup>lt;sup>21</sup> Agency for Health Care Administration, *2016 Agency Legislative Bill Analysis for HB 1245*, January 23, 2016 (on file with the Health Innovation Subcommittee staff).

# III. COMMENTS

# A. CONSTITUTIONAL ISSUES:

- 1. Applicability of Municipality/County Mandates Provision: Not applicable. The bill does not appear to affect county or municipal governments.
- 2. Other:

None.

**B. RULE-MAKING AUTHORITY:** 

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

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

**DATE**: 1/23/2016

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A bill to be entitled

An act relating to Medicaid provider overpayments; amending s. 409.908, F.S.; authorizing the Agency for Health Care Administration to certify that a Medicaid provider is out of business and that overpayments made to a provider cannot be collected under state law; reenacting s. 409.8132(4), F.S., relating to the applicability of certain laws to the Medikids program, to incorporate the amendment made by the act to s. 409.908, F.S., in a reference thereto; providing an effective date.

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

Section 1. Subsection (25) is added to section 409.908, Florida Statutes, to read:

409.908 Reimbursement of Medicaid providers.—Subject to specific appropriations, the agency shall reimburse Medicaid providers, in accordance with state and federal law, according to methodologies set forth in the rules of the agency and in policy manuals and handbooks incorporated by reference therein. These methodologies may include fee schedules, reimbursement methods based on cost reporting, negotiated fees, competitive bidding pursuant to s. 287.057, and other mechanisms the agency considers efficient and effective for purchasing services or goods on behalf of recipients. If a provider is reimbursed based

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27 on cost reporting and submits a cost report late and that cost 28 report would have been used to set a lower reimbursement rate for a rate semester, then the provider's rate for that semester 29 30 shall be retroactively calculated using the new cost report, and 31 full payment at the recalculated rate shall be effected 32 retroactively. Medicare-granted extensions for filing cost 33 reports, if applicable, shall also apply to Medicaid cost reports. Payment for Medicaid compensable services made on 34 behalf of Medicaid eligible persons is subject to the 35 36 availability of moneys and any limitations or directions 37 provided for in the General Appropriations Act or chapter 216. 38 Further, nothing in this section shall be construed to prevent 39 or limit the agency from adjusting fees, reimbursement rates, 40 lengths of stay, number of visits, or number of services, or 41 making any other adjustments necessary to comply with the 42 availability of moneys and any limitations or directions 43 provided for in the General Appropriations Act, provided the 44 adjustment is consistent with legislative intent.

(25) In accordance with 42 C.F.R. s. 433.318(d), the agency may certify that a Medicaid provider is out of business and that any overpayments made to the provider cannot be collected under state law and procedures.

Section 2. For the purpose of incorporating the amendment made by this act to section 409.908, Florida Statutes, in a reference thereto, subsection (4) of section 409.8132, Florida Statutes, is reenacted to read:

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

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409.8132 Medikids program component.—

(4) APPLICABILITY OF LAWS RELATING TO MEDICAID.—The provisions of ss. 409.902, 409.905, 409.906, 409.907, 409.908, 409.912, 409.9121, 409.9122, 409.9123, 409.9124, 409.9127, 409.9128, 409.913, 409.916, 409.919, 409.920, and 409.9205 apply to the administration of the Medikids program component of the Florida Kidcare program, except that s. 409.9122 applies to Medikids as modified by the provisions of subsection (7). Section 3. This act shall take effect July 1, 2016.

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# HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1269 Adult Cardiovascular Services

SPONSOR(S): Pigman

TIED BILLS: IDEN./SIM. BILLS: SB 1518

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Innovation Subcommittee		Langstor(W)	Poche W
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

#### **SUMMARY ANALYSIS**

Hospitals are regulated by the Agency for Health Care Administration (AHCA) under chapter 395, F.S., and the general licensure provisions of part II, of chapter 408, F.S. Adult cardiovascular services (ACS) were previously regulated through AHCA's Certificate-of-Need (CON) program. CON review has been eliminated for adult cardiac catheterization and adult open-heart surgery services. Hospitals are now approved to provide these services by AHCA through the licensure process.

Licensed Level I ACS programs provide diagnostic and therapeutic cardiac catheterization services, including percutaneous coronary intervention (PCI), on a routine and emergency basis, but do not have on-site open heart surgery capability. Level I ACS programs must comply with national guidelines that apply to diagnostic cardiac catheterization services PCI. Additionally, they must comply with national reporting requirements and meet specified staffing requirements. For example, nursing and technical catheterization laboratory staff in a Level I ACS program must have 500 hours of experience in a dedicated cardiac interventional laboratory at a hospital with a Level II ACS program.

Licensed Level II ACS programs provide the same services as a Level I ACS program, but have on-site open heart surgery capability. In addition to Level I requirements, Level II programs must comply with additional guidelines regarding staffing, physician training and experience, operating procedures, equipment, physical plant, patient selection criteria, and reporting requirements.

HB 1269 authorizes hospitals with Level I ACS programs to provide the prerequisite 500 hours of training required for nursing and technical catheterization laboratory staff, if, throughout the training period, the program:

- Meets an annual volume of 200 or more PCIs;
- Achieves a demonstrated success rate of 95 percent or greater for PCIs;
- Experiences a complication rate of less than five percent for PCIs;
- Experiences required emergent coronary artery bypass grafting on less than two percent of the patients undergoing a PCI; and
- Performs diverse cardiac procedures.

The bill requires AHCA to include, at a minimum, specific requirements in the rules for establishing and maintaining Level I and Level II ACS programs. The rules must require hospitals seeking licensure of Level I or Level II ACS programs to meet specified staffing requirements, perform at least 36 PCIs annually, implement a training program, and submit a quarterly report to AHCA that details patient characteristics, treatment, and outcomes for all patients receiving emergency PCIs.

The bill deletes outdated and obsolete language providing an exemption from the CON program for ACS. ACS requirements are addressed in the rules for licensure of Level I and Level II ACS programs.

The bill may have a significant, negative fiscal impact AHCA and no fiscal impact on local governments.

The bill provides an effective date of July 1, 2016.

This document does not reflect the intent or official position of the bill sponsor or House of Representatives. STORAGE NAME: h1269.HIS.DOCX

#### **FULL ANALYSIS**

#### I. SUBSTANTIVE ANALYSIS

#### A. EFFECT OF PROPOSED CHANGES:

#### Hospital Licensure

Hospitals are regulated by the Agency for Health Care Administration (AHCA) under chapter 395, F.S., and the general licensure provisions of part II, of chapter 408, F.S. Hospitals offer a range of health care services with beds for use beyond 24 hours by individuals requiring diagnosis, treatment, or care. Hospitals must make regularly available at least clinical laboratory services, diagnostic X-ray services, and treatment facilities for surgery or obstetrical care, or other definitive medical treatment.<sup>2</sup>

Hospitals must meet initial licensing requirements by submitting a completed application and required documentation, and the satisfactory completion of a facility survey. Section 395.1055, F.S., authorizes AHCA to adopt rules for hospitals; these rules must include minimum standards to ensure:

- A sufficient number of qualified types of personnel and occupational disciplines are on duty and available at all times to provide necessary and adequate patient care;
- Infection control, housekeeping, sanitary conditions, and medical record procedures are established and implemented to adequately protect patients;
- A comprehensive emergency management plan is prepared and updated annually;
- Licensed facilities are established, organized, and operated consistent with established standards and rules; and
- Licensed facility beds conform to minimum space, equipment, and furnishing standards.<sup>3</sup>

The minimum standards for hospital licensure are contained in Chapter 59A-3, F.A.C.

#### Regulation of Adult Cardiovascular Services

Adult cardiovascular services (ACS) were previously regulated through the Certificate-of-Need (CON)<sup>4</sup> program. In 2007, CON review was eliminated for adult cardiac catheterization and adult open-heart surgery services<sup>5</sup> and regulation was accomplished through the licensure process. Hospitals that provided ACS at the time the CON review process was eliminated were grandfathered into the current licensure program;<sup>6</sup> however, those hospitals were required to meet licensure standards applicable to existing programs for every subsequent licensure period.<sup>7</sup>

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<sup>&</sup>lt;sup>1</sup> S. 395.002(12), F.S.

<sup>&</sup>lt;sup>2</sup> ld.

<sup>&</sup>lt;sup>3</sup> S. 395.1055(1), F.S.

<sup>&</sup>lt;sup>4</sup> The CON regulatory process under chapter 408, F.S., requires specified health care services and facilities to be approved by AHCA before they are made available to the public. In addition, the CON program requires a facility to demonstrate a need for a new, converted, expanded, or otherwise significantly modified health care facility or health service. Section 408.036, F.S., specifies which health care projects are subject to review and provides three levels of review: full, expedited and exempt. Unless a hospital project is exempt from the CON program, it must undergo a full comparative review or an expedited review.

<sup>&</sup>lt;sup>5</sup> Ch. 2007-214, Laws of Fla. CON review remains in effect for pediatric cardiac catheterization and pediatric open-heart surgery. Rule 59C-1.002(41), F.A.C.

<sup>&</sup>lt;sup>6</sup> Existing providers and any provider with a notice of intent to grant a CON or a final order of the agency granting a CON for ACS or burn units were considered grandfathered and received a license for their programs effective July 1, 2004. The grandfathered license was effective for three years or until July 1, 2008, whichever was longer. S. 408.0361(2), F.S.; s. 2, ch. 2004-382, Laws of Fla. <sup>7</sup> S. 408.0361(2), F.S.

Section 408.0361, F.S., establishes two levels of hospital program licensure for ACS:

- Level I: The program is authorized to perform adult percutaneous cardiac intervention (PCI) without onsite cardiac surgery.
- Level II: The program is authorized to perform PCI with onsite cardiac surgery.<sup>8</sup>

Adult Diagnostic Cardiac Catheterization Program

Diagnostic cardiac catheterization is a procedure requiring the passage of a catheter into one or more chambers of the heart, with or without coronary arteriograms, for the purpose of diagnosing congenital or acquired cardiovascular diseases, or for determining measurement of blood pressure flow. It also includes the selective catheterization of the coronary ostia with injection of contrast medium into the coronary arteries.

AHCA regulates the operation of adult inpatient diagnostic cardiac catheterization programs through licensure. This license permits the program to perform diagnostic procedures<sup>13</sup> only; the license does not allow for the performance of therapeutic procedures.<sup>14</sup> <sup>15</sup> Providers of diagnostic cardiac catheterization services comply with the most recent guidelines of the American College of Cardiology and American Heart Association for cardiac catheterization and cardiac catheterization laboratories.<sup>16</sup>

As of January 11, 2016, there are 21 general acute care hospitals with an adult diagnostic cardiac catheterization program in Florida. 17

Level I ACS Programs

Licensed Level I ACS programs provide diagnostic and therapeutic cardiac catheterization services, including PCI, on a routine and emergency basis, but do not have on-site open heart surgery capability.<sup>18</sup> For a hospital seeking a Level I ACS program license, it must demonstrate that, for the most recent 12-month period as reported to AHCA, it has:

Provided a minimum of 300 adult inpatient and outpatient diagnostic cardiac catheterizations; or

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<sup>&</sup>lt;sup>8</sup> S. 408.0361(3)(a), F.S.

An arteriogram is an imaging test that uses x-rays and a contrast dye to see inside the arteries of the heart.

<sup>&</sup>lt;sup>10</sup> Rule 59A-3.2085(13)(b)1., F.A.C.

A coronary ostia is either of the two openings in the aortic sinuses – the pouches behind each of the three leaflets of the aortic valve – that mark the origins of the left and right coronary arteries.

<sup>&</sup>lt;sup>12</sup> Rule 59A-3.2085(13)(b)1., F.A.C.

<sup>&</sup>lt;sup>13</sup> Diagnostic procedures include left heart catheterization with coronary angiography and left ventriculography; right heart catheterization; hemodynamic monitoring line insertion; aortogram; emergency temporary pacemaker insertion; myocardial biopsy; diagnostic trans-septal procedures; intra-coronary ultrasound (CVIS); fluoroscopy; and hemodynamic stress testing. Rule 59A-3.2085(13)(b)4., F.A.C.

<sup>&</sup>lt;sup>14</sup> Examples of therapeutic procedures are PCI or stent insertion, intended to treat an identified condition or the administering of intracoronary drugs, such as thrombolytic agents. Rule 59A-3.2085(13)(b)3., F.A.C. <sup>15</sup> S. 408.0361(1)(b), F.S.

<sup>&</sup>lt;sup>16</sup> S. 408.0361(1)(a), F.S.; Rule 59A-3.2085(13)(g), F.A.C., requires compliance with the guidelines found in the American College of Cardiology/Society for Cardiac Angiography and Interventions Clinical Expert Consensus Document on Cardiac Catheterization Laboratory Standards: Bashore, et al., *ACC/SCAI Clinical Expert Consensus Document on Catheterization Laboratory Standards*, Journal of the American College of Cardiology, Vol. 37, No. 8, June 2001: 2170-214 available at

http://www.scai.org/asset.axd?id=d4338c24-9beb-4f5a-8f14-a4edaeff7461&t=633921658057830000 (last visited January 20, 2016). These guidelines address, among other things, clinical proficiency, patient outcomes, equipment maintenance and management, quality improvement program development, and minimum caseload volumes for cardiac catheterization laboratories as well as patient preparations, procedural issues, performance issues, and post procedural issues for the performance of cardiac catheterization.

<sup>&</sup>lt;sup>17</sup> Agency for Health Care Administration, *Hospital & Outpatient Services Unit: Reports*, available at <a href="http://www.fdhc.state.fl.us/MCHQ/Health">http://www.fdhc.state.fl.us/MCHQ/Health</a> Facility Regulation/Hospital Outpatient/reports/Adult Inpatient Diagnostic Cath Labs.pdf (last visited January 20, 2016).

<sup>&</sup>lt;sup>18</sup> Rule 59A-3.2085(16)(a), F.A.C. Level I programs are prohibited from performing any therapeutic procedure requiring trans-septal puncture, any lead extraction for a pacemaker, biventricular pacer or implanted cardioverter defibrillator.

- Discharged or transferred at least 300 inpatients with the principal diagnosis of ischemic heart disease;<sup>19</sup> and
- A formalized, written transfer agreement with a hospital that has a Level II program.<sup>20</sup>

Licensed Level I ACS programs must comply with the guidelines that apply to diagnostic cardiac catheterization services<sup>21</sup> and PCI, including guidelines for staffing, physician training and experience, operating procedures, equipment, physical plant, and patient selection criteria to ensure patient quality and safety.<sup>22</sup> Additionally, they must comply with the reporting requirements of the American College of Cardiology-National Cardiovascular Data Registry.<sup>23</sup>

Level I ACS programs must meet the following staffing requirements:

- Each cardiologist shall be an experienced physician who has performed a minimum of 75 interventional cardiology procedures, exclusive of fellowship training, within the previous 12 months from the date of the Level I ACS application or renewal application.
- Physicians with less than 12 months experience shall fulfill applicable training requirements
  prior to being allowed to perform emergency PCI in a hospital that is not licensed for a Level II
  ACS program.
- Nursing and technical catheterization laboratory staff must:
  - o Be experienced in handling acutely ill patients requiring intervention or balloon pump;
  - Have at least 500 hours of previous experience in dedicated cardiac interventional laboratories at a hospital with a Level II adult cardiovascular services program;
  - Be skilled in all aspects of interventional cardiology equipment; and
  - o Participate in a 24-hour-per-day, 365 day-per-year call schedule.
- A member of the cardiac care nursing staff who is adept in hemodynamic monitoring and Intraaortic Balloon Pump management shall be in the hospital at all times.<sup>24</sup>

As of January 11, 2016, there are 52 general acute care hospitals with a Level I ACS program in Florida.<sup>25</sup>

Level II ACS Programs

Licensed Level II ACS programs provide diagnostic and therapeutic cardiac catheterization services on a routine and emergency basis, but have on-site open heart surgery capability.<sup>26</sup> For a hospital seeking a Level II program license, it must demonstrate that, for the most recent 12-month period as reported to AHCA, it has:

<sup>&</sup>lt;sup>19</sup> Heart condition caused by narrowed heart arteries. This is also called "coronary artery disease" and "coronary heart disease."

<sup>&</sup>lt;sup>20</sup> S. 408.0361(3)(b), F.S.

<sup>&</sup>lt;sup>21</sup> Rule 59A-3.2085(16)(a)5., F.A.C.

<sup>&</sup>lt;sup>22</sup> Rule 59A-3.2085(16)(a)2.., F.A.C., requires compliance with the American College of Cardiology/Society for Cardiac Angiography and Interventions Clinical Expert Consensus Document on Cardiac Catheterization Laboratory Standards: Bashore, et al., *ACC/SCA&I Clinical Expert Consensus Document on Catheterization Laboratory Standards*, Journal of the American College of Cardiology, Vol. 37, No. 8, June 2001: 2170-214. The rule also requires compliance the *ACC/AHA/SCAI 2005 Guideline Update for Percutaneous Coronary Intervention A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (<i>ACC/AHA/SCAI Writing Committee to Update the 2001 Guidelines for Percutaneous Coronary Intervention*) available at <a href="http://circ.ahajournals.org/content/113/1/156.full.pdf+html">http://circ.ahajournals.org/content/113/1/156.full.pdf+html</a> (last visited January 21, 2016), which revises the guidelines for procedural complications, quality assurance, volume of elective procedures, the role of on-site cardiac surgical back-up, treatment of patients with certain diagnoses or medical history, the use of specified procedures and devices, and the use of certain drugs.

<sup>&</sup>lt;sup>23</sup> Rule 59Å-3.2085(16)(a)8., F.A.C. The reporting requirements include patient demographics; provider and facility characteristics; history/risk factors, cardiac status, treated lesions; intracoronary device utilization and adverse event rates; appropriate use criteria for coronary revascularization; and compliance with ACC/AHA clinical guideline recommendations.

<sup>&</sup>lt;sup>24</sup> Rule 59A-3.2085(16)(b), F.A.C.

<sup>&</sup>lt;sup>25</sup> Agency for Health Care Administration, *Hospital & Outpatient Services Unit: Reports*, available at <a href="http://ahca.myflorida.com/MCHQ/Health">http://ahca.myflorida.com/MCHQ/Health</a> Facility Regulation/Hospital Outpatient/reports/Level | ACS Listing.pdf (last visited January 20, 2016).

<sup>&</sup>lt;sup>26</sup> Rule 59A-3.2085(17)(a), F.A.C. **STORAGE NAME**: h1269.HIS.DOCX

- Performed a minimum of 1,100 adult inpatient and outpatient cardiac catheterizations, of which at least 400 must be therapeutic catheterizations; or
- Discharged at least 800 patients with the principal diagnosis of ischemic heart disease.<sup>27</sup>

In addition to the licensure requirements for a Level I ACS program, Level II ACS programs must also comply with the ACC/AHA 2004 Guideline Update for Coronary Artery Bypass Graft Surgery: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee to Update the 1999 Guidelines for Coronary Artery Bypass Graft Surgery) Developed in Collaboration With the American Association for Thoracic Surgery and the Society of Thoracic Surgeons, which includes standards regarding staffing, physician training and experience, operating procedures, equipment, physical plant, and patient selection criteria to ensure patient quality and safety. Level II ACS programs must also document an ongoing quality improvement plan to ensure that their cardiac catheterization, PCI, and cardiac surgical programs meet or exceed national quality and outcome benchmarks reported by the American College of Cardiology-National Cardiovascular Data Registry and the Society of Thoracic Surgeons. In addition to the reporting requirements for Level I ACS Programs, Level II ACS programs must meet the reporting requirements for the Society of Thoracic Surgeons National Database. Data Database.

As of January 11, 2016, there are 77 general acute care hospitals<sup>31</sup> with a Level II ACS program in Florida.<sup>32</sup>

#### Effect of the Bill

# Training for Nursing and Technical Staff

HB 1269 authorizes a hospital with a Level I ACS program to provide the prerequisite 500 hours of training required for nursing and technical staff to work in the cardiac interventional laboratory, if, throughout the training period, the ACS program:

- Meets an annual volume of 200 or more percutaneous coronary intervention procedures (PCI);
- Achieves a demonstrated success rate of 95 percent or greater for PCIs:
- Experiences a complication rate of less than 5 percent for PCIs:
- Experiences required emergent coronary artery bypass grafting on less than 2 percent of the patients undergoing a PCI; and
- Performs diverse cardiac procedures, including, but not limited to, balloon angioplasty and stenting, rotational atherectomy, cutting balloon atheroma remodeling, and procedures relating to left ventricular support capability.

Under current law, nursing and technical catheterization laboratory staff in a Level I ACS program must acquire the necessary training and experience at a dedicated interventional laboratory at a hospital with a Level II ACS program. The bill will enable Level I ACS programs to train their nursing and technical catheterization laboratory staff at their facilities instead of requiring that their staff be trained in a Level II ACS program.

STORAGE NAME: h1269.HIS.DOCX

<sup>&</sup>lt;sup>27</sup> S. 408.0361(3)(c), F.S.

<sup>&</sup>lt;sup>28</sup> Rule 59A-3.2085(16)(a)5., F.A.C.

<sup>&</sup>lt;sup>29</sup> Id. Eligible professionals must satisfactorily report 50 percent performance on at least nine quality measures for the annual reporting period. The measures address topics such as preoperative screenings, length of postoperative intubation, and length of postoperative stay.

stay.

Nule 59A-3.2085(16)(a)5., F.A.C. The data collection form is available at <a href="https://www.ncdr.com/WebNCDR/docs/default-source/tvt-public-page-documents/tvt-registry">https://www.ncdr.com/WebNCDR/docs/default-source/tvt-public-page-documents/tvt-registry</a> 2 0 tavr data-collection-form.pdf?sfvrsn=2 (last visited January 23, 2016).

<sup>&</sup>lt;sup>31</sup> 64 Level II ACS programs were licensed pursuant to the grandfathering provisions of Chapters 2004-382 and 2004-383, Laws of Fla.; Agency for Health Care Administration, *Agency Analysis of 2016 SB 1518*, Jan. 12, 2016 (on file with Health Innovation Subcommittee staff).

<sup>&</sup>lt;sup>32</sup> Agency for Health Care Administration, *Hospital & Outpatient Services Unit: Reports*, available at <a href="http://ahca.myflorida.com/MCHQ/Health\_Facility\_Regulation/Hospital\_Outpatient/reports/Level\_II\_ACS\_Listing.pdf">http://ahca.myflorida.com/MCHQ/Health\_Facility\_Regulation/Hospital\_Outpatient/reports/Level\_II\_ACS\_Listing.pdf</a> (last visited January 20, 2016).

# Licensure Requirements for ACS Programs

The bill requires AHCA to include, at minimum, specific program requirements in the rules for establishing Level I and Level II ACS programs. To obtain a license as a Level I or Level II ACS program, a hospital must:

- Provide a minimum of 36 primary interventions annually:
- Offer sufficient physician, nursing, and laboratory staff to provide the services 24 hours a day, seven days a week;
- Undertake a training program of three to six months, prior to implementing ACS, which includes:
  - Establishing standards and testing logistics
  - o Creating quality assessment and error management practices; and
  - Formalizing patient-selection criteria.
- Certify that they will use at all times the patient-selection criteria for the performance of primary angioplasty at hospitals without adult open-heart-surgery programs issued by the American College of Cardiology and the American Heart Association; and
- Submit a quarterly report to AHCA, within 15 days of after the close of the quarter, which details patient characteristics, treatment, and outcomes for all patients receiving emergency PCI.

AHCA has indicated that it will need to develop a reporting form to allow for uniform reporting, for the quarterly reporting requirement, which may require the expertise of the technical advisory panel.<sup>33</sup>

### Requirements Related to Physicians

The bill requires ACHA, in the minimum requirements for licensure, to require ACS programs to have a physician available to provide such services 24 hours a day, seven days a week, which expands the current minimum criteria. Current rules and guidelines require sufficient nursing and technical staff to be available 24 hours per day, seven days per week, 365 days per year; however, that regulation does not apply to physicians.

Additionally, the bill requires ACHA to require ACS program cardiologists to perform a minimum of 50 interventions annually, averaged over 2 years. This reduces the number of minimum interventions per year for physicians from 75 annually to 50 annually, which is recommended by the most recent update to the guidelines.<sup>34</sup> AHCA is currently in rule development to incorporate the reduction of annual interventions into rule.35

# Requirements for Nursing and Technical Staff

The bill codifies the current minimum standards for ACS program nursing and technical staff in rule. Additionally, the bill requires ACHA to require, in the minimum requirements for licensure, those providing cardiac care nursing to be adept in the operation of temporary pacemakers, management of indwelling arterial and venous sheaths, and identifying potential complications.

# Repeal of CON Exemptions and Rules

The bill deletes language from ss. 408.0361(2) and (4), F.S., regarding CON review requirements that expired July 1, 2008. Additionally, the bill repeals paragraphs (m) and (n) of s. 408.036(3), F.S., which contain obsolete language for exemption from CON review of ACS programs. ACS programs are addressed under an AHCA licensure structure in rules.

Supra, note 31.

<sup>33</sup> Supra, note 31.

<sup>&</sup>lt;sup>34</sup> Dehmer GJ, Blankenship JC, Cilingiroglu M, et al., SCAI/ACC/AHA Expert Consensus Document: 2014 Update on Percutaneous Coronary Intervention Without On-Site Surgical Backup, Journal of the American College of Cardiology, Vol. 63, No. 23, June 2014: 2624-2641, available at http://content.onlinejacc.org/data/Journals/JAC/930319/03002.pdf (last visited January 21, 2016).

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Section 1: Amends s. 408.0361, F.S., relating to cardiovascular services and burn unit licensure.

Section 2: Repeals s. 408.036(3)(m) and (n), F.S., relating to projects subject to review; exemptions.

Section 3 Provides an effective date of July 1, 2016.

# II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

Α	FISCAL	IMPACT	ON STATE	GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

AHCA estimates first year costs of \$165,004, and \$6,300 in recurring costs, to develop a database to collect pertinent PCI data required by the quarterly reporting of the bill.<sup>36</sup>

- 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. The bill does not appear to affect county or municipal governments.

2. Other:

None.

**B. RULE-MAKING AUTHORITY:** 

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

<sup>36</sup> Supra, note 31. STORAGE NAME: h1269.HIS.DOCX DATE: 1/23/2016

# IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

STORAGE NAME: h1269.HIS.DOCX DATE: 1/23/2016

A bill to be entitled

1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 |

An act relating to adult cardiovascular services; amending s. 408.0361, F.S.; expanding rulemaking criteria for the Agency for Health Care Administration for licensure of hospitals performing percutaneous coronary intervention; deleting provisions relating to newly licensed hospitals seeking a specified program status; repealing s. 408.036(3)(m) and (n), F.S., relating to exemptions for certificate of need projects subject to review relating to adult openheart services in a hospital and percutaneous coronary intervention; providing an effective date.

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

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Section 1. Section 408.0361, Florida Statutes, is amended to read:

408.0361 Cardiovascular services and burn unit licensure.

- (1) Each provider of diagnostic cardiac catheterization services shall comply with rules adopted by the agency that establish licensure standards governing the operation of adult inpatient diagnostic cardiac catheterization programs. The rules shall ensure that such programs:
- (a) Comply with the most recent guidelines of the American College of Cardiology and American Heart Association Guidelines for Cardiac Catheterization and Cardiac Catheterization

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27 Laboratories.

- (b) Perform only adult inpatient diagnostic cardiac catheterization services and will not provide therapeutic cardiac catheterization or any other cardiology services.
- (c) Maintain sufficient appropriate equipment and health care personnel to ensure quality and safety.
- (d) Maintain appropriate times of operation and protocols to ensure availability and appropriate referrals in the event of emergencies.
- (e) Demonstrate a plan to provide services to Medicaid and charity care patients.
- operator of a burn unit shall comply with rules adopted by the agency that establish licensure standards that govern the provision of adult cardiovascular services or the operation of a burn unit. Such rules shall consider, at a minimum, staffing, equipment, physical plant, operating protocols, the provision of services to Medicaid and charity care patients, accreditation, licensure period and fees, and enforcement of minimum standards. The certificate-of-need rules for adult cardiovascular services and burn units in effect on June 30, 2004, are authorized pursuant to this subsection and shall remain in effect and shall be enforceable by the agency until the licensure rules are adopted. Existing providers and any provider with a notice of intent to grant a certificate of need or a final order of the agency granting a certificate of need for adult cardiovascular

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services or burn units shall be considered grandfathered and receive a license for their programs effective on the effective date of this act. The grandfathered licensure shall be for at least 3 years or until July 1, 2008, whichever is longer, but shall be required to meet licensure standards applicable to existing programs for every subsequent licensure period.

- (3) In establishing rules for adult cardiovascular services, the agency shall include provisions that allow for:
- (a) Establishment of two hospital program licensure levels: a Level I program authorizing the performance of adult percutaneous cardiac intervention without onsite cardiac surgery and a Level II program authorizing the performance of percutaneous cardiac intervention with onsite cardiac surgery.
- (b) For a hospital seeking a Level I program, demonstration that, for the most recent 12-month period as reported to the agency, it has provided a minimum of 300 adult inpatient and outpatient diagnostic cardiac catheterizations or, for the most recent 12-month period, has discharged or transferred at least 300 inpatients with the principal diagnosis of ischemic heart disease and that it has a formalized, written transfer agreement with a hospital that has a Level II program, including written transport protocols to ensure safe and efficient transfer of a patient within 60 minutes. However, a hospital located more than 100 road miles from the closest Level II adult cardiovascular services program does not need to meet the 60-minute transfer time protocol if the hospital

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demonstrates that it has a formalized, written transfer agreement with a hospital that has a Level II program. The agreement must include written transport protocols to ensure the safe and efficient transfer of a patient, taking into consideration the patient's clinical and physical characteristics, road and weather conditions, and viability of ground and air ambulance service to transfer the patient. At a minimum, the rules must require the following:

- 1. Cardiologists must be experienced interventionalists who have performed a minimum of 50 interventions annually, averaged over 2 years, that were performed in institutions performing more than 200 total intervention procedures annually and more than 36 primary intervention procedures annually.
- 2. The hospital must provide a minimum of 36 primary interventions annually in order to continue to provide the service.
- 3. The hospital must offer sufficient physician, nursing, and laboratory staff to provide the services 24 hours a day, 7 days a week.
- 4. Nursing and technical staff must have demonstrated experience in handling acutely ill patients requiring intervention based on the staff members' previous experience in dedicated interventional laboratories or surgical centers. In order for experience acquired at a dedicated interventional laboratory at a hospital without an approved adult open-heart-surgery program to qualify, the cardiac interventional

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105	laboratory must have, throughout the training period:
106	a. Had an annual volume of 200 or more percutaneous
107	coronary intervention procedures;
108	b. Achieved a demonstrated success rate of 95 percent or
109	greater for percutaneous coronary intervention procedures;
110	c. Experienced a complication rate of less than 5 percent
111	for percutaneous coronary intervention procedures;
112	d. Experienced required emergent coronary artery bypass
113	grafting on less than 2 percent of the patients undergoing a
114	percutaneous coronary intervention procedure; and
115	e. Performed diverse cardiac procedures, including, but
116	not limited to, balloon angioplasty and stenting, rotational
117	atherectomy, cutting balloon atheroma remodeling, and procedures
118	relating to left ventricular support capability.
119	5. Cardiac care nursing staff must be adept in hemodynamic
120	monitoring, operation of temporary pacemakers, intra-aortic
121	balloon pump management, management of indwelling arterial and
122	venous sheaths, and identifying potential complications.
123	6. Hospitals implementing the service must first undertake
124	a training program of 3 to 6 months' duration, which includes
125	establishing standards and testing logistics, creating quality
126	assessment and error management practices, and formalizing
127	patient-selection criteria.
128	7. The applicant must certify that the hospital will use
129	at all times the patient-selection criteria for the performance
130	of primary angioplasty at hospitals without adult open-heart-

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CODING: Words  $\underline{\text{stricken}}$  are deletions; words  $\underline{\text{underlined}}$  are additions.

surgery programs issued by the American College of Cardiology and the American Heart Association.

- 8. The hospital must agree to submit a quarterly report to the agency detailing patient characteristics, treatment, and outcomes for all patients receiving emergency percutaneous coronary interventions pursuant to this paragraph. This report must be submitted within 15 days after the close of each calendar quarter.
- (c) For a hospital seeking a Level II program, demonstration that, for the most recent 12-month period as reported to the agency, it has performed a minimum of 1,100 adult inpatient and outpatient cardiac catheterizations, of which at least 400 must be therapeutic catheterizations, or, for the most recent 12-month period, has discharged at least 800 patients with the principal diagnosis of ischemic heart disease.
- (d) Compliance with the most recent guidelines of the American College of Cardiology and American Heart Association guidelines for staffing, physician training and experience, operating procedures, equipment, physical plant, and patient selection criteria to ensure patient quality and safety.
- (e) Establishment of appropriate hours of operation and protocols to ensure availability and timely referral in the event of emergencies.
- (f) Demonstration of a plan to provide services to Medicaid and charity care patients.
  - (4) In order to ensure continuity of available services,

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157 the holder of a certificate of need for a newly licensed 158 hospital that meets the requirements of this subsection may 159 apply for and shall be granted Level I program status regardless 160 of whether rules relating to Level I programs have been adopted. 161 To qualify for a Level I program under this subsection, a 162 hospital seeking a Level I program must be a newly licensed 163 hospital established pursuant to a certificate of need in a 164 physical location previously licensed and operated as a 165 hospital, the former hospital must have provided a minimum of 166 300 adult inpatient and outpatient diagnostic cardiac 167 catheterizations for the most recent 12-month period as reported 168 to the agency, and the newly licensed hospital must have a 169 formalized, written transfer agreement with a hospital that has 170 a Level II program, including written transport protocols to 171 ensure safe and efficient transfer of a patient within 60 172 minutes. A hospital meeting the requirements of this subsection 173 may apply for certification of Level I program status before 174 taking possession of the physical location of the former 175 hospital, and the effective date of Level I program status shall 176 be concurrent with the effective date of the newly issued 177 hospital license. 178  $(4)\frac{(5)}{(5)}$  (a) The agency shall establish a technical advisory 179 panel to develop procedures and standards for measuring outcomes 180 of adult cardiovascular services. Members of the panel shall 181 include representatives of the Florida Hospital Association, the 182 Florida Society of Thoracic and Cardiovascular Surgeons, the

Page 7 of 9

Florida Chapter of the American College of Cardiology, and the Florida Chapter of the American Heart Association and others with experience in statistics and outcome measurement. Based on recommendations from the panel, the agency shall develop and adopt rules for the adult cardiovascular services that include at least the following:

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- 1. A risk adjustment procedure that accounts for the variations in severity and case mix found in hospitals in this state.
- 2. Outcome standards specifying expected levels of performance in Level I and Level II adult cardiovascular services. Such standards may include, but shall not be limited to, in-hospital mortality, infection rates, nonfatal myocardial infarctions, length of stay, postoperative bleeds, and returns to surgery.
- 3. Specific steps to be taken by the agency and licensed hospitals that do not meet the outcome standards within specified time periods, including time periods for detailed case reviews and development and implementation of corrective action plans.
- (b) Hospitals licensed for Level I or Level II adult cardiovascular services shall participate in clinical outcome reporting systems operated by the American College of Cardiology and the Society for Thoracic Surgeons.
- Section 2. Paragraphs (m) and (n) of subsection (3) of section 408.036, Florida Statutes, are repealed.

Page 8 of 9

209 Section 3. This act shall take effect July 1, 2016.

Page 9 of 9



Amendment No.

	COMMITTEE/SUBCOMMITTEE 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	Committee/Subcommittee hearing bill: Health Innovation
2	Subcommittee
3	Representative Pigman offered the following:
4	
5	Amendment
6	Remove lines 66-138 and insert:
7	At a minimum, the rules must require the following:
8	1. Cardiologists must be experienced interventionists who
9	have performed a minimum of 50 interventions annually, averaged
10	over 2 years, that were performed in institutions performing
11	more than 200 total intervention procedures annually and more
12	than 36 primary intervention procedures annually.
13	2. The hospital must provide a minimum of 36 primary
14	interventions annually in order to continue to provide the
15	service.
16	3. The hospital must offer sufficient physician, nursing,
17	and laboratory staff to provide the services 24 hours a day, 7

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Amendment No.

18	days	a	week.

- 4. Nursing and technical staff must have demonstrated experience in handling acutely ill patients requiring intervention based on the staff members' previous experience in dedicated interventional laboratories or surgical centers. In order for experience acquired at a dedicated interventional laboratory at a hospital without an approved adult open-heart-surgery program to qualify, the cardiac interventional laboratory must have, throughout the training period:
- <u>a. Had an annual volume of 200 or more percutaneous</u> coronary intervention procedures;
- b. Achieved a demonstrated success rate of 95 percent or greater for percutaneous coronary intervention procedures;
- c. Experienced a complication rate of less than 5 percent for percutaneous coronary intervention procedures;
- d. Experienced required emergent coronary artery bypass grafting on less than 2 percent of the patients undergoing a percutaneous coronary intervention procedure; and
- e. Performed diverse cardiac procedures, including, but not limited to, balloon angioplasty and stenting, rotational atherectomy, cutting balloon atheroma remodeling, and procedures relating to left ventricular support capability.
- 5. Cardiac care nursing staff must be adept in hemodynamic monitoring, operation of temporary pacemakers, intra-aortic balloon pump management, management of indwelling arterial and venous sheaths, and identifying potential complications.

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Amendment No.

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- 6. Hospitals implementing the service must first undertake a training program of 3 to 6 months' duration, which includes establishing standards and testing logistics, creating quality assessment and error management practices, and formalizing patient-selection criteria.
- 7. The applicant must certify that the hospital will use at all times the patient-selection criteria for the performance of primary angioplasty at hospitals without adult open-heart-surgery programs issued by the American College of Cardiology and the American Heart Association.
- (b) For a hospital seeking a Level I program, demonstration that, for the most recent 12-month period as reported to the agency, it has provided a minimum of 300 adult inpatient and outpatient diagnostic cardiac catheterizations or, for the most recent 12-month period, has discharged or transferred at least 300 inpatients with the principal diagnosis of ischemic heart disease and that it has a formalized, written transfer agreement with a hospital that has a Level II program, including written transport protocols to ensure safe and efficient transfer of a patient within 60 minutes. However, a hospital located more than 100 road miles from the closest Level II adult cardiovascular services program does not need to meet the 60-minute transfer time protocol if the hospital demonstrates that it has a formalized, written transfer agreement with a hospital that has a Level II program. The agreement must include written transport protocols to ensure the

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Amendment No.

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safe and efficient transfer of a patient, taking into
consideration the patient's clinical and physical
characteristics, road and weather conditions, and viability of
ground and air ambulance service to transfer the patient.

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# HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1335 Long-term Care Prioritization

SPONSOR(S): Magar

TIED BILLS: IDEN./SIM. BILLS:

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Innovation Subcommittee		Guzzo	Poche MW
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

#### **SUMMARY ANALYSIS**

In 2011, the Legislature created the Statewide Medicaid Managed Care Program as an integrated managed care program for all covered services, including long-term care services. The Statewide Medicaid Managed Care Program consists of two programs: the Managed Medical Assistance Program (MMA Program) and the Long-Term Care Managed Care Program (LTC Program). The MMA Program covers primary and acute medical assistance and related services to Medicaid recipients.

The LTC Program provides services to Medicaid recipients in nursing facilities and in community settings, including an individual's home, an assisted living facility, or an adult family care home. To be eligible for the LTC Program, an individual must be:

- Age 65 or older and eligible for Medicaid, or age 18 or older and eligible for Medicaid by reason of a disability; and
- Determined to require nursing home care, or be at imminent risk of requiring nursing home care.

When an individual, or the individual's representative, expresses an interest in receiving services, the Department of Elder Affairs (DOEA) screens and scores the individual based on his or her frailty and need for services. The individual is then placed on the waitlist for services. When funding is available, individuals are released from the waitlist based on their priority score, which indicates their level of frailty. The individual must be determined to be medically eligible for services by DOEA, and financially eligible for Medicaid by the Department of Children and Families (DCF), before they are approved to be enrolled in the LTC Program.

The process for prioritizing individuals to be placed on the waitlist, placing them on the waitlist, and releasing them from the waitlist for enrollment in the LTC Program is not currently provided in statute or administrative rule.

HB 1335 establishes in statute the process DOEA uses to prioritize individuals for enrollment in the LTC Program. The process involves frailty-based screening, which results in a priority score that is used to place individuals on the waitlist. The bill requires DOEA to make the methodology used to calculate an individual's priority score publicly available on its website. The bill requires DOEA to rescreen individuals on the waitlist annually and provides for a rescreening due to a significant change in the individual's condition or circumstances. The bill establishes specific criteria for DOEA to terminate an individual from the waitlist. The bill exempts the following persons from the screening and waitlist process:

- Individuals age 18, 19, or 20, who have a chronic debilitating disease or conditions of one or more physiological or organ systems which make them dependent on 24-hour medical supervision;
- Individuals determined to be at high risk and referred by the adult protective services program within DCF; and
- Nursing facility residents who wish to transition into the community and who have resided in a skilled nursing facility licensed in Florida for at least 60 consecutive days.

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

The bill provides an effective date of July 1, 2016.

This document does not reflect the intent or official position of the bill sponsor or House of Representatives. STORAGE NAME: h1335.HIS.DOCX

# **FULL ANALYSIS**

#### I. SUBSTANTIVE ANALYSIS

# A. EFFECT OF PROPOSED CHANGES:

#### Background

# Statewide Medicaid Managed Care

In 2010, the Florida House of Representatives contracted with a consultant to analyze Florida's Medicaid program and identify problems and possible solutions; the consultant concluded that Florida Medicaid's fragmented, complex system made it difficult to improve value for patients and taxpayers. As a result, in 2011, the Legislature established the Statewide Medicaid Managed Care (SMMC) program as Part IV of Chapter 409, F.S.

The SMMC program is an integrated managed care program for Medicaid enrollees to provide all mandatory and optional Medicaid benefits. A unified, coordinated system of care is a primary characteristic of the SMMC program, in part because it solves the problem of complexity with which Florida's Medicaid program was plagued for decades. In the SMMC program, each Medicaid recipient has one managed care organization to coordinate all health care services, rather than various entities.<sup>2</sup> Within the SMMC program, the Managed Medical Assistance (MMA) program provides primary and acute medical assistance and related services to enrollees. The Long-term Care Managed Care (LTC) program provides services to Medicaid recipients in nursing facilities and in community settings, including an individual's home, an assisted living facility, or an adult family care home.

# Managed Medical Assistance Program

The MMA Program requires AHCA to make payments for primary and acute medical assistance and related services using a managed care model.<sup>3</sup> Managed care plans in the MMA Program are required to cover, at a minimum, the following services:

- Advanced registered nurse practitioner services;
- Ambulatory surgical treatment center services;
- Birthing center services;
- Chiropractic services:
- Dental Services;
- Early periodic screening diagnosis and treatment services for recipients under age 21;
- Emergency services;
- Family planning services and supplies;
- Health start services;
- Hearing services;
- Home health agency services;
- Hospice services;
- Hospital inpatient services;
- Hospital outpatient services;
- Laboratory and imaging services;
- Medical supplies, equipment, prostheses, and orthoses;
- Mental health services;

<sup>3</sup> S. 409.971, F.S.

STORAGE NAME: h1335.HIS.DOCX DATE: 1/23/2016

<sup>&</sup>lt;sup>1</sup> Medicaid Managed Care Study, Pacific Health Policy Group, p. 73, March 2010

<sup>&</sup>lt;sup>2</sup> This comprehensive coordinated system of care was first successfully implemented in the 5-county Medicaid reform pilot program from 2006-2014.

- Nursing care;
- Optical services and supplies;
- Optometrist services;
- Physical, occupational, respiratory, and speech therapy services;
- Physician services, including physician assistant services;
- Podiatric services:
- Prescription drugs;
- Renal dialysis services;
- Respiratory equipment and supplies;
- Rural health clinic services;
- Substance abuse treatment services; and
- Transportation to access covered services.<sup>4</sup>

## Long Term Care Program

The LTC Program provides long term care services, including nursing facility and home and community based services, to eligible Medicaid recipients. Long-term care plans are required to, at a minimum, cover the following:

- Nursing facility care;
- Services provided in assisted living facilities;
- Hospice;
- Adult day care;
- Medical equipment and supplies, including incontinence supplies;
- Personal care;
- Home accessibility adaptation;
- Behavior management;
- Home-delivered meals;
- Case Management;
- Occupation therapy;
- Speech therapy;
- Respiratory therapy;
- Physical therapy;
- Intermittent and skilled nursing;
- Medication administration;
- Medication Management;
- Nutritional assessment and risk reduction;
- Caregiver training;
- Respite care;
- Transportation; and
- Personal emergency response systems.<sup>5</sup>

To be eligible for the LTC Program, an individual must be:

- Age 65 or older and eligible for Medicaid, or age 18 or older and eligible for Medicaid by reason of a disability; and
- Determined by the Comprehensive Assessment Review and Evaluation for Long-Term Care Services (CARES) Program to require nursing facility care as defined in s. 409.985(3), F.S.<sup>6</sup>

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<sup>&</sup>lt;sup>4</sup> S. 409.973(1), F.S.

<sup>&</sup>lt;sup>5</sup> S. 409.98, F.S.

<sup>&</sup>lt;sup>6</sup> S. 409.979(1), F.S.

When determining the need for nursing facility care, the nature of the services prescribed, the level of nursing or other health care personnel necessary to provide such services, and the availability of and access to community or alternative resources are all considered. For purposes of the LTC Program. "nursing facility care" means the individual requires, or is at imminent risk of...

- Nursing home placement as evidenced by the need for medical observation throughout a 24hour period and care required to be performed on a daily basis by, or under the direct supervision of, a registered nurse or other health care professional:
  - Also, the services are sufficiently medically complex to require supervision, assessment, planning, or intervention by a registered nurse because of a mental or physical incapacitation by the individual.
- Nursing home placement as evidenced by the need for observation throughout a 24-hour period and care and the constant availability of medical and nursing treatment;
  - Also, the services needed on a daily or intermittent basis are to be performed under the supervision of licensed nursing or other health professionals because the individual is incapacitated mentally or physically.
- Nursing home placement as evidenced by the need for observation throughout a 24-hour period and care and the constant availability of medical and nursing treatment.
  - Also, the necessary limited services are to be performed under the supervision of licensed nursing or other health professionals because the individual is mildly incapacitated mentally or physically.

The Department of Elder Affairs (DOEA) administers programs and services for elders through 11 Area Agencies on Aging (AAAs), which also operate Aging and Disability Resource Centers (ADRCs). The ADRCs provide information and referral services to individuals seeking long-term care services. The ADRCs also screen individuals for eligibility for long-term care services.

The LTC Program enrollment process is administered by DOEA, the Department of Children and Families (DCF), and AHCA. An individual in need of services or seeking services must contact the appropriate ADRC to request a screening. The screening is intended to provide the ADRC with information describing the individual's level of frailty. During the screening, the ADRC gathers basic information about the individual, including general health information and any assistance the individual needs with activities of daily living. Based on the screening, the individual receives a priority score, which indicates the level of need for services and reflects the level of the individual's frailty. Using the priority score, the individual is then placed on the waitlist.

When funding becomes available, the frailest individuals are taken off the waitlist first, based upon priority score. The individual must then go through a comprehensive face-to-face assessment conducted by the local Comprehensive Assessment and Review for Long-Term Care Services (CARES) staff.8 After CARES determines the medical eligibility of the individual, DCF determines the financial eligibility of the individual. If approved for both medical and financial eligibility, AHCA must notify the individual and provide information on selecting a long-term care plan.

The process for prioritizing individuals to be placed on the waitlist, placing them on the waitlist, and releasing them from the waitlist for enrollment in the LTC Program is not currently provided in statute or administrative rule.

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S. 409.985(3), F.S.

<sup>&</sup>lt;sup>8</sup> Florida Department of Elder Affairs, Comprehensive Assessment and Review for Long-Term Care Services (CARES), available at: www.elderaffairs.state.fl.us/does/cares.php (last viewed January 23, 2016). Comprehensive Assessment and Review for Long-Term Care Services (CARES) is Florida's federally mandated pre-admission screening program for nursing home applicants. A registered nurse or assessor performs client assessments. A physician or registered nurse reviews each application to determine the level of care that is most appropriate for the applicant. The assessment identifies long-term care needs, and establishes the appropriate level of care (medical eligibility for nursing facility care), and recommends the least restrictive, most appropriate placement. Federal law also mandates that the CARES Program perform an assessment or review of each individual who requests Medicaid reimbursement for nursing facility placement, or who seeks to receive home and community-based services through Medicaid waivers. STORAGE NAME: h1335.HIS.DOCX

# **Effect of Proposed Changes**

HB 1335 establishes in statute the process DOEA uses to prioritize individuals for enrollment in the LTC Program. The process involves frailty-based screening that provides a priority score that is used to place individuals on the waitlist. The screening must be conducted by a person certified by DOEA. The bill requires DOEA to make the methodology used to calculate an individual's priority score publicly available on its website. The bill requires DOEA to rescreen individuals on the waitlist annually and provides for a rescreening due to a significant change in the individual's condition or circumstances.

The bill authorizes DOEA to terminate an individual from the waitlist if he or she:

- Does not have a current priority score;
- Wishes to be removed from the waitlist;
- Does not keep an appointment to complete the rescreening without rescheduling beforehand;
- Is no longer eligible to receive services because he or she has not completed or met clinical or financial eligibility requirements;
- · Begins the eligibility process for the LTC Program; or
- Begins receiving home and community-based services through the long-term care managed care program.

The bill provides that certain individuals have priority for enrollment in the LTC Program and are exempt from participating in the screening or waitlist process, including individuals:

- Age 18, 19, or 20, who have a chronic debilitating disease or conditions of one or more physiological or organ systems which make them dependent on 24-hour medical supervision;
- Determined to be at high risk and referred by the adult protective services program within DCF;
   and
- Nursing facility residents who wish to transition into the community and who have resided in a skilled nursing facility licensed in Florida for at least 60 consecutive days.

The bill provides an effective date of July 1, 2016.

#### **B. SECTION DIRECTORY:**

Section 1: Amends s. 409.962, F.S., relating to definitions.

Section 2: Amends s. 409.979, F.S., relating to eligibility.

Section 3: Provides an effective date of July 1, 2016.

## II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

#### A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

None.

## **B. FISCAL IMPACT ON LOCAL GOVERNMENTS:**

1. Revenues:

None.

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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 affect county or municipal governments.

2. Other:

None.

**B. RULE-MAKING AUTHORITY:** 

See Drafting Issues, Section III, c., below.

C. DRAFTING ISSUES OR OTHER COMMENTS:

DOEA requires specific rulemaking authority to promulgate rules associated with the LTC Program enrollment process. The bill does not provide authority for DOEA to engage in the required rulemaking process.

# IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

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1 A bill to be entitled 2 An act relating to long-term care prioritization; 3 amending s. 409.962, F.S.; defining terms; amending s. 4 409.979, F.S.; providing a process for waitlist 5 prioritization and enrollment in the long-term care 6 managed care program; requiring the Agency for Health 7 Care Administration and the Department of Elderly 8 Affairs to implement a screening and prioritization process; requiring the department to send written 9 correspondence under certain circumstances; 10 11 authorizing the department to terminate an individual from the waitlist under certain circumstances; 12 13 requiring individuals to be financially and clinically eligible before enrollment in the program; providing 14 15 exemptions from the screening or waitlist process; 16 providing an effective date. 17 Be It Enacted by the Legislature of the State of Florida: 18 19 20 Section 1. Section 409.962, Florida Statutes, is amended 21 to read: 22 409.962 Definitions.-As used in this part, except as 23 otherwise specifically provided, the term: 24 "Accountable care organization" means an entity 25 qualified as an accountable care organization in accordance with

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federal regulations, and which meets the requirements of a

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27 provider service network as described in s. 409.912(2).

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

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- (3) "Aging network service provider" means a provider that participated in a home and community-based waiver administered by the Department of Elderly Affairs or the community care service system pursuant to s. 430.205 as of October 1, 2013.
- (4) "APPL" means the assessed priority pipeline list, maintained by the Department of Elderly Affairs, which lists individuals who have been released from the waitlist for potential enrollment in the long-term care managed care program.
- (5) "Authorized or designated representative" means an individual who has the legal authority to make decisions on behalf of a Medicaid enrollee or potential Medicaid enrollee in matters related to the screening process, the eligibility process, or the managed care plan.
- (6)(4) "Comprehensive long-term care plan" means a managed care plan, including a Medicare Advantage Special Needs Plan organized as a preferred provider organization, provider-sponsored organization, health maintenance organization, or coordinated care plan, which that provides services described in s. 409.973 and also provides the services described in s. 409.98.
- $\underline{(7)}$  "Department" means the Department of Children and Families.
  - (8) (6) "Eligible plan" means a health insurer authorized

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under chapter 624, an exclusive provider organization authorized under chapter 627, a health maintenance organization authorized under chapter 641, or a provider service network authorized under s. 409.912(2) or an accountable care organization authorized under federal law. For purposes of the managed medical assistance program, the term also includes the Children's Medical Services Network authorized under chapter 391 and entities qualified under 42 C.F.R. part 422 as Medicare Advantage Preferred Provider Organizations, Medicare Advantage Provider-sponsored Organizations, Medicare Advantage Health Maintenance Organizations, Medicare Advantage Coordinated Care Plans, and Medicare Advantage Special Needs Plans, and the Program of All-inclusive Care for the Elderly.

- (9)(7) "Long-term care plan" means a managed care plan that provides the services described in s. 409.98 for the long-term care managed care program.
- (10) (8) "Long-term care provider service network" means a provider service network a controlling interest of which is owned by one or more licensed nursing homes, assisted living facilities with 17 or more beds, home health agencies, community care for the elderly lead agencies, or hospices.
- (11) "Managed care plan" means an eligible plan under contract with the agency to provide services in the Medicaid program.
- $\underline{(12)}$  "Medicaid" means the medical assistance program authorized by Title XIX of the Social Security Act, 42 U.S.C.

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ss. 1396 et seq., and regulations thereunder, as administered in this state by the agency.

- (13) (11) "Medicaid recipient" or "recipient" means an individual who the department or, for Supplemental Security Income, the Social Security Administration determines is eligible pursuant to federal and state law to receive medical assistance and related services for which the agency may make payments under the Medicaid program. For the purposes of determining third-party liability, the term includes an individual formerly determined to be eligible for Medicaid, an individual who has received medical assistance under the Medicaid program, or an individual on whose behalf Medicaid has become obligated.
- (14)(12) "Prepaid plan" means a managed care plan that is licensed or certified as a risk-bearing entity, or qualified pursuant to s. 409.912(2), in the state and is paid a prospective per-member, per-month payment by the agency.
- (15) "Priority score" means a number that indicates an individual's need for services and that is used to prioritize an individual's enrollment in the long-term care managed care program.
- (16) (13) "Provider service network" means an entity qualified pursuant to s. 409.912(2) of which a controlling interest is owned by a health care provider, or group of affiliated providers, or a public agency or entity that delivers health services. Health care providers include Florida-licensed

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health care professionals or licensed health care facilities, federally qualified health care centers, and home health care agencies.

- (17) "Rescreening" means the use of a screening tool by staff of the Department of Elderly Affairs to conduct a recurring annual screening of an individual or a screening due to a significant change in the individual's condition. The Department of Elderly Affairs shall conduct the annual screening within 13 months after the previous screening.
- (18) "Screening" means the use of a screening tool by Department of Elderly Affairs staff for initial screenings, which must occur prior to placement on the waitlist.
- (19) "Significant change in the individual's condition" means, in relation to screening or rescreening for long-term care services, a change in the individual's health status after an accident or illness; a change in his or her living situation; a change in his or her caregiver relationship; the loss, damage, or deterioration of his or her home environment; or the loss of his or her spouse or caregiver.
- (20) (14) "Specialty plan" means a managed care plan that serves Medicaid recipients who meet specified criteria based on age, medical condition, or diagnosis.
- (21) "Waitlist" means the statewide assessed priority consumer list, maintained by the Department of Elderly Affairs, which lists in priority order individuals who have completed the scoring and placement process before enrollment in the home and

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community-based services portion of the long-term care managed care program.

Section 2. Subsection (3) of section 409.979, Florida Statutes, is amended, and subsections (4) through (10) are added to that section, to read:

409.979 Eligibility.-

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- individuals for enrollment in the long-term care managed care program using a frailty-based screening that provides a priority score that is used to place individuals on the waitlist. The Department of Elderly Affairs shall make offers for enrollment to eligible individuals based on the assigned priority score a wait-list prioritization and subject to the availability of funds. Before making enrollment offers, the department must shall determine that sufficient funds exist to support additional enrollment into plans.
- (4) The Department of Elderly Affairs shall maintain the waitlist, which is the only waitlist for the long-term care managed care program and, with the agency, may limit enrollment in the program so as not to exceed:
- (a) The number of Medicaid recipients who may be enrolled, or who are projected to be enrolled, in the long-term care managed care program under the total long-term care managed care program allocation in the General Appropriations Act.
- (b) The available funding to serve the total number of individuals on the APPL.

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(5) A person certified by the Department of Elderly
Affairs shall complete the screening for each individual
requesting enrollment in the long-term care managed care
program. The individual requesting long-term care services, or
the individual's authorized or designated representative, must
participate in an initial screening. The screening must be
completed in its entirety before an individual may be placed on
the waitlist for the program.

(6) The Department of Elderly Affairs shall generate a

- continuous priority score upon completion of the screening, which shall be used to prioritize an individual's order of enrollment into the program. Upon completion of the scoring and waitlist placement process, the Department of Elderly Affairs shall provide the individual, or his or her authorized or designated representative, with notification of waitlist placement and shall make publicly available on its website the specific methodology used to calculate an individual's priority score. The individual, or his or her authorized or designated representative, may request a rescreening due to a significant change in the individual's condition. The Department of Elderly Affairs shall perform a rescreening annually so that an individual may remain on the waitlist.
- (7) If the Department of Elderly Affairs is unable to contact the individual to schedule an initial screening, a significant change rescreening, or an annual rescreening, it shall send written correspondence to the last documented address

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183	of the individual or to the authorized or designated		
184	representative listed for that individual. The written		
185	correspondence shall request that the individual contact the		
186	Department of Elderly Affairs within 10 business days after the		
187	date of the notice and notify the individual that he or she may		
188	be terminated from the screening process or waitlist due to the		
189	Department of Elderly Affairs' inability to successfully make		
190	contact and perform the screening or rescreening.		
191	(8) The Department of Elderly Affairs may terminate an		
192	individual from the waitlist if he or she meets any of the		
193	following criteria:		
194	(a) Does not have a current priority score.		
195	(b) Wishes to be removed from the waitlist.		
196	(c) Does not keep an appointment to complete the		
197	rescreening without rescheduling beforehand.		
198	(d) Is no longer eligible to receive services because he		
199	or she has not completed or met clinical or financial		
200	eligibility requirements.		
201	(e) Begins the eligibility process for the long-term care		
202	managed care program.		
203	(f) Begins receiving home and community-based services		
204	through the long-term care managed care program.		
205	(9) Before enrollment in the program, individuals must be		
206	determined financially and clinically eligible. The Department		

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of Elderly Affairs shall determine clinical eligibility, and the

Department of Children and Families shall determine financial

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209	eligibility, for Medicaid pursuant to s. 409.919.
210	(10) The following individuals have priority for
211	enrollment in the long-term care managed care program and are
212	exempt from participating in the screening or waitlist process
213	if all other program eligibility requirements are met:
214	(a) Individuals who are at least 18 years, but younger
215	than 21 years, of age who have chronic debilitating diseases or
216	conditions of one or more physiological or organ systems which
217	generally make them dependent on 24-hour-a-day medical, nursing,
218	or health supervision or intervention.
219	(b) Individuals determined to be at high risk and referred
220	by the adult protective services program within the Department
221	of Children and Families.
222	(c) Nursing facility residents who wish to transition into
223	the community and who have resided in a skilled nursing facility
224	licensed in this state for at least 60 consecutive days.

Section 3. This act shall take effect July 1, 2016.

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