Health Quality Subcommittee

Wednesday, February 22, 2017
8:00 AM – 10:30 AM
Mashburn Hall (306 HOB)

Richard Corcoran
Speaker

Cary Pigman
Chair

Committee Meeting Notice

HOUSE OF REPRESENTATIVES

Health Quality Subcommittee

Start Date and Time:	Wednesday, February 22, 2017 08:00 am
End Date and Time:	Wednesday, February 22, 2017 10:30 am
Location:	Mashburn Hall (306 HOB)
Duration:	2.50 hrs

Consideration of the following bill(s):

CS/HB 19 Termination of Pregnancies by Civil Justice & Claims Subcommittee, Grall
HB 129 Advanced Registered Nurse Practitioners by Plasencia
HB 557 Prescription Drug Monitoring Program by Duran

Pursuant to rule 7.11, the deadline for amendments to bills on the agenda by non-appointed members shall be 6:00 p.m., Tuesday, February 21, 2017.

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., Tuesday, February 21, 2017.

NOTICE FINALIZED on 02/15/2017 3:56PM by Iseminger.Bobbye

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 19 Liability for Termination of Pregnancies
SPONSOR(S): Civil Justice & Claims Subcommittee; Grall and others
TIED BILLS: None **IDEN./SIM. BILLS:** None

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Civil Justice & Claims Subcommittee	10 Y, 6 N, As CS	Stranburg	Bond
2) Health Quality Subcommittee		Roth	McElroy
3) Judiciary Committee			

SUMMARY ANALYSIS

Chapter 766, F.S. sets out several requirements for petitioners who wish to bring forth an action for medical malpractice in Florida. Medical malpractice is harm that occurs to a patient by a doctor or other medical professional who fails to competently perform his or her medical duties.

CS/HB 19 creates a new cause of action separate from ch. 766, F.S., for women upon whom an abortion is performed for any physical or emotional injuries caused by the physician's negligence or failure to obtain the informed consent required by s. 390.0111, F.S. Damages available under this cause of action include all special and general damages recoverable in intentional tort, negligence, survival, or wrongful death claims.

The bill creates a statute of limitation for this cause of action. A woman must bring a claim within 4 years from the injury or 4 years from the time the woman knew or should have known of the injury but in no case may an action be commenced later than 10 years after the time of the incident giving rise to the injury. The limitations periods are tolled while a woman is a minor.

The bill authorizes the award of attorney's fees to prevailing plaintiffs.

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

The bill provides an effective date of July 1, 2017.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Federal Abortion Law

Right to Abortion

In 1973, the foundation of modern abortion jurisprudence, *Roe v. Wade*[1], was decided by the U.S. Supreme Court. Using strict scrutiny, the Court determined that a woman's right to an abortion is part of a fundamental right to privacy guaranteed under the Due Process Clause of the Fourteenth Amendment of the U.S. Constitution. Further, the Court reasoned that state regulation limiting the exercise of this right must be justified by a compelling state interest, and must be narrowly drawn.[2] In 1992, the fundamental holding of *Roe* was upheld by the U.S. Supreme Court in *Planned Parenthood v. Casey*.[3]

Undue Burden

In *Planned Parenthood v. Casey*, the U.S. Supreme Court established the undue burden standard for determining whether a law places an impermissible obstacle to a woman's right to an abortion. The Court held that health regulations which impose undue burdens on the right to abortion are invalid.[4] State regulation imposes an "undue burden" on a woman's decision to have an abortion if it has the purpose or effect of placing a substantial obstacle in the path of the woman who seeks the abortion of a nonviable fetus.[5] However, the court opined, not every law which makes the right to an abortion more difficult to exercise is an infringement of that right.[6]

Florida Abortion Law

Right to Abortion

The Florida Constitution, as interpreted by Florida courts, affords greater privacy rights than those provided by the U.S. Constitution. While the federal Constitution traditionally shields enumerated and implied individual liberties from state or federal intrusion, the U.S. Supreme Court has noted that state constitutions may provide greater protections.[7] Unlike the U.S. Constitution, Article I, § 23 of the Florida Constitution contains an express right to privacy:

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

The Florida Supreme Court opined in *In re T.W.* that this express privacy clause provides greater privacy rights than those implied by the U.S. Constitution.[8]

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[1] *Roe v. Wade*, 410 U.S. 113 (1973).
[2] *Id.*
[3] *Planned Parenthood v. Casey*, 505 U.S. 833 (1992).
[4] *Id.* at 878.
[5] *Id.* at 877.
[6] *Id.* at 873.
[7] *In re T.W.*, 551 So.2d 1186, 1191 (Fla. 1989), citing *Pruneyard Shopping Center v. Robins*, 100 S.Ct. 2035, 2040 (1980).
[8] *Id.* at 1191-1192.

The Florida Supreme Court has recognized Florida's constitutional right to privacy "is clearly implicated in a woman's decision whether or not to continue her pregnancy."[9] In *In re T.W.*, the Florida Supreme Court ruled that[10]:

> [P]rior to the end of the first trimester, the abortion decision must be left to the woman and may not be significantly restricted by the state. Following this point, the state may impose significant restrictions only in the least intrusive manner designed to safeguard the health of the mother. Insignificant burdens during either period must substantially further important state interests....Under our Florida Constitution, the state's interest becomes compelling upon viability....Viability under Florida law occurs at that point in time when the fetus becomes capable of meaningful life outside the womb through standard medical procedures.

The court recognized that after viability, the state can regulate abortion in the interest of the unborn child if the mother's health is not in jeopardy.[11]

Informed Consent for Abortion

The Agency for Health Care Administration (AHCA) licenses and regulates abortion clinics in the state, pursuant to ch. 390, F.S., and part II of ch. 408, F.S.[12] There are 61 licensed abortion clinics in Florida.[13] An abortion must be performed by a physician[14] licensed under ch. 458, F.S., or ch. 459, F.S., or a physician practicing allopathic or osteopathic medicine in the employment of the United States.[15] Physicians are regulated by the Board of Medicine or Board of Osteopathic Medicine (Boards), within the Department of Health (DOH), under those chapters. In 2016, there were 225,255 live births in Florida,[16] and 69,765 abortion procedures.[17]

In 1997, the Florida Legislature enacted the "Woman's Right to Know Act," now codified in s. 390.0111(3), F.S., which prohibits a termination of pregnancy unless and until the woman has given voluntary and written informed consent (except when there is a medical emergency). The physician must inform the woman of the nature of the procedure, and risks of undergoing and not undergoing the procedure, the medical risks of carrying the pregnancy to term and the probable gestational age of the fetus. The physicians must also provide printed materials with a description of the fetus, a list of agencies that offer alternatives to terminating the pregnancy, and information on the availability of medical assistance benefits for pre-natal and neo-natal care and childbirth.[18] Later amendments to the statute require an ultrasound to verify gestational age and an opportunity to view and receive an explanation of the ultrasound, and require the informed consent to be obtained in-person and at least 24 hours prior to the procedure.[19]

A 1998 constitutional challenge was resolved by the Florida Supreme Court in 2006, which found that the Act is not unconstitutional in that it "constitutes a neutral informed consent statute that is

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[9] *Id.* at 1192.
[10] *Id.* at 1193.
[11] *Id.* at 1194.
[12] Section 408.802(3) provides for the applicability of the Health Care Licensing Procedures Act to abortion clinics.
[13] Agency for Health Care Administration, *Abortion Clinic Results*, available at http://www.floridahealthfinder.gov/facilitylocator/ListFacilities.aspx (last viewed February 16, 2017).
[14] Section 390.0111(2), F.S.
[15] Section 390.011(9), F.S.
[16] Florida Department of Health, Bureau of Vital Statistics, *FLHealthCHARTS query, live births 2016 (provisional)*, available at http://www.flhealthcharts.com.
[17] AHCA, *Reported Induced Terminations of Pregnancy Calendar Year 2016*, on file with the Health Quality Subcommittee Staff.
[18] Section 390.0111(5), F.S. (2006).
[19] Section 390.0111(5), F.S. (2016). The 24-hour waiting period is currently being challenged in state court, and on February 16, 2017, the Florida Supreme Court upheld the circuit court's temporary injunction on the 24-hour waiting period. *Gainesville Woman Care, LLC v. State of Florida*, Case No. SC16-381.

comparable to the common law and to informed consent statutes implementing the common law that exist for other types of medical procedures."[20]

Florida Tort Actions Related to Abortion

There is no statutory or common law cause of action specific to abortion. There are, however, statutory and common law causes of action whereby an injured person may sue for damages resulting from an abortion. These include claims for medical malpractice[21], wrongful death,[22] negligence,[23] assault,[24] battery,[25] and intentional infliction of emotional distress.[26]

A tort is a civil wrong, other than a breach of contract, for which a remedy may be obtained, usually in the form of damages; and/or a breach of a duty that the law imposes on persons who stand in a particular relation to one another.[27] Negligence is the failure to use such care as a reasonably prudent and careful person would use under similar circumstances.[28] Common tort actions include claims for negligence and medical malpractice.

For an individual to prevail on a claim for negligence or medical malpractice, the plaintiff must establish four elements: 1) the health care provider owed the patient a duty to conform to a certain standard of conduct (duty); 2) the health care provider failed to conform to the standard of conduct (breach); 3) the failure was both the factual and legal cause of the patient's injuries (causation); and 4) the injuries were of the type and extent that the law requires compensation (economic and non-economic damages).[29]

Florida Medical Malpractice

In general, a person has a common law cause of action against another for personal injury caused by the other's negligence. The term "medical malpractice" refers to any personal injury or wrongful death tort action, regardless of legal theory, arising from negligence committed by medical professionals.[30] In Florida, medical malpractice cases are governed by ch. 766, F.S. and carry strict pre-suit procedural rules that negligence cases (governed by ch. 768, F.S.) do not require.

Medical malpractice lawsuits have a number of differences from other negligence lawsuits. A claimant (prospective medical malpractice plaintiff) must investigate whether there are any reasonable grounds to believe that a health care provider was negligent in the care and treatment of the claimant and whether such treatment resulted in injury to the claimant.[31] After completion of the presuit investigation, a claimant must send a presuit notice to each prospective defendant.[32] This notice includes lists of healthcare providers seen before and after the alleged act of negligence and the medical records relied

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[20] *State v. Presidential Women's Ctr.*, 937 So. 2d 114 (Fla. 2006).
[21] Chapter 766, F.S.
[22] The Florida Wrongful Death Act is at ss. 768.16-.26, F.S.
[23] *Mascheck, Inc. v. Mausner*, 264 So. 2d 859, 861 (Fla. 3d DCA 1972) ("Negligence is the failure to use that degree of care, diligence and skill that is one's legal duty to use in order to protect another person from injury.")
[24] *Lay v. Kremer*, 411 So. 2d 1347, 1349 (Fla. 1st DCA 1982) ("Assault is defined as an intentional, unlawful offer of corporal injury to another by force, or force unlawfully directed toward another under such circumstances as to create a fear of imminent peril, coupled with the apparent present ability to effectuate the attempt.")
[25] *Paul v. Holbrook*, 696 So. 2d 1311, 1312 (Fla. 5th DCA 1997) ("A battery consists of the infliction of a harmful or offensive contact upon another with the intent to cause such contact or the apprehension that such contact is imminent.").
[26] *Gallogly v. Rodriguez*, 970 So. 2d 470 (Fla. 2d DCA 2007); *see Johnson v. Thigpen*, 788 So. 2d 410, 412 (Fla. 1st DCA 2001) (In order to state a cause of action for intentional infliction of emotional distress, the plaintiff must demonstrate that: 1) the wrongdoer acted recklessly or intentionally; 2) the conduct was extreme and outrageous; 3) the conduct caused the plaintiff's emotional distress; and 4) plaintiff's emotional distress was severe.).
[27] *Black's Law Dictionary* (3rd Pocket ed. 2006).
[28] *Black's Law Dictionary* (6th ed. 1990).
[29] *Limones v. Sch. Dist.*, 161 So. 3d 384 (Fla. 2015).
[30] Section 766.104(1), F.S.
[31] Section 766.203(2), F.S.
[32] Section 766.106(2)(a), F.S.

upon by the corroborating expert in the presuit investigation.[33] Once the presuit notice is received, all parties must make discoverable information available for a period of informal discovery.[34]

At any time in an action for recovery of damages for medical malpractice, the court may require, upon motion by either party, that the claim be submitted to nonbinding arbitration.[35] Upon selection of the arbitrators, the hearing must be scheduled within 60 days after the date of selection, provided there has been at least 20 days notice to the parties.[36] The decision of the panel is nonbinding.[37] If the parties accept the decision, the decision is deemed to be a settlement of the case and the case is dismissed with prejudice.[38] After the arbitration award is rendered, any party may demand a trial de novo in circuit court.[39]

Ch. 766.118, F.S., limits noneconomic damages (pain and suffering damages) for negligence of health care providers in medical malpractice cases. There is a $500,000 cap on noneconomic damages against practitioners[40] and a $750,000 cap against non-practitioners[41]. If the negligence results in a permanent vegetative state or death there is a cap of $1 million dollars for practitioners[42] and $1.5 million for non-practitioners[43]. There is no cap for economic damages (past and future medical care necessitated by the malpractice).

Prohibition Against Double Recovery

Double recovery is a judgment that erroneously awards damages twice for the same loss, based on two different theories of recovery.[44] The prohibition against double recovery is aimed at preventing enrichment of one party at the expense of another in circumstances which the law treats as unjust. In Florida, once a party obtains satisfaction of its claim under one theory, it may not use a different theory of recovery to obtain a second recovery for the same injuries.[45] However, when the remedies in question redress different injuries or enforce different and distinct rights, a party is not required to elect among them.[46]

Statutes of Limitations

Statutes of limitations bars claims after a specified period of time, to require diligent prosecution of known claims, thereby providing finality and predictability in legal affairs and ensuring that claims will be resolved while evidence is reasonably available and fresh.[47]

Section 95.11, F.S., sets out Florida's statute of limitations for all civil actions other than the recovery of real property. An action founded on negligence must be brought within four years of the negligent act.[48] An act for medical malpractice must be commenced within two years from the time the incident giving rise to the action occurred or within two years from the time the incident is discovered, but not later than four years from the incident.[49] If it can be showed that fraud, concealment, or intentional misrepresentation of fact prevented the discovery of the injury, the medical malpractice claim must be

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[33] *Id.*
[34] Section 766.106(6), F.S.
[35] Section 766.107(1), F.S.
[36] Section 766.107(3), F.S.
[37] Section 766.107(4), F.S.
[38] *Id.*
[39] *Id.*
[40] Section 766.118(2)(a), F.S.
[41] Section 766.118(3)(a), F.S.
[42] Section 766.118(2)(b), F.S.
[43] Section 766.118(3)(b), F.S.
[44] Double Recovery, Black's Law Dictionary (3rd Pocket ed. 2006).
[45] *Lutheran Brotherhood v. Hooten*, 237 So. 2d 23 (Fla. 2d DCA 1970).
[46] *Security & Investment Corp. of the Palm Beaches v. Droege*, 529 So. 2d 799 (Fla. 4th DCA 1988).
[47] Statute of Limitations, *Black's Law Dictionary* (3rd Pocket ed. 2006).
[48] Section 95.11(3)(a), F.S.
[49] Section 95.11(4)(b), F.S.

commenced within seven years.[50] When the claimant in a medical malpractice case is age eight or younger the statute of limitations do not apply to such claimant.[51]

Abortion-Related Cause of Action in Other States

In 1993, South Dakota amended its abortion laws to create a strict liability cause of action against an abortion provider for failing to provide informed consent. The law required a plaintiff be awarded punitive damages of $10,000 and triple of her actual damages if the abortion provider failed to obtain informed consent.[52] The 8th Circuit Court of Appeal held that the award of punitive damages without a finding of willful, wanton or malicious conduct by the abortion provider and the mandatory $10,000 award was improper and struck down the law.[53]

In 1997, Louisiana passed Act 825, now Louisiana Revised Statutes Section 9:2800.12, Liability for termination of a pregnancy.[54] The Act provides a cause of action for women who have suffered injuries as a result of a termination of pregnancy, imposing strict liability on providers. The Act was challenged by providers three times. In two cases, federal courts dismissed the actions for lack of case or controversy.[55]

In the third case,[56] the 5th Circuit Court of Appeal found health care providers lacked standing to claim compensation fund coverage under the state's medical malpractice law. The Court also upheld the Act, finding it was rationally related to the promotion of informed consent and that, though the exemption of the entitlement to the benefits of the state's malpractice law may make it difficult for those providers to obtain relevant insurance, that limitation "is merely a 'means of unequal subsidization of abortion and other medical services.'"[57] The court further held that, "while 'government may not place obstacles in the path of a woman's exercise of her freedom of choice, it need not remove those' obstacles, like Louisiana's dearth of affordable insurance, that are 'not of the government's own creation.'"[58]

Effect of Proposed Changes

The bill creates s. 390.035, F.S., relating to the termination of pregnancies. The bill creates a cause of action for a woman who suffers injury or death as a result of an abortion or emotional distress based on the physician's failure to obtain the woman's informed consent before the abortion. The bill provides that the signing of an informed consent form does not bar the woman from bringing a claim pursuant to this section.

The bill provides that this claim is not a claim for medical malpractice and ch. 766, F.S., does not apply. The presuit investigation and notice, informal discovery, and court ordered arbitration required by ch. 766, F.S., therefore, do not apply to these claims.

The cause of action created by the bill does not bar any other statutory or common law cause of action otherwise available regarding an injury from abortion procedures or diminish the nature or extent of those causes of action, including medical malpractice. Therefore, the cause of action created in the bill is in addition to any other statutory or common law cause of action.

The bill provides a 4 year statute of limitations from the time of the injury or from the time the woman discovered or should have discovered the injury, whichever is longer. In no case will the limitations

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[50] *Id.*
[51] *Id.*
[52] *Planned Parenthood v. Miller*, 63 F.3d 1452 (8th Cir. SD 1995).
[53] *Id.*
[54] *K.P. v. Leblanc*, 729 F.3d 427 (5th Cir. La. 2013)
[55] *Okpalobi v. Foster*, 244 F.3d 405 (5th Cir. La. 2001); *Women's Health Clinic v. State*, 825 So. 2d 1208 (La. App. 1 Cir 2002).
[56] Plaintiffs argued unconstitutional vagueness, equal protection violations without rational basis, and undue burden privacy violations caused by an anticipated reduction in service availability due to the inapplicability of the state's medical malpractice act.
[57] *K.P. v. Leblanc* (5th Circuit La. 2013), at 442, quoting *Harris v. McRae*, 448 U.S. 297 at 315 (1980).
[58] *Id.*, quoting *McRae*, 448 U.S. at 316.

period extend beyond 10 years from the time of the incident. The limitations periods in the bill are tolled while the woman is a minor.

A prevailing plaintiff in an action pursuant to this bill is entitled to reasonable attorney's fees and costs.

The cause of action created by the bill provides that damages includes all special and general damages recoverable in an intentional tort, negligence, survival, or wrongful death claim, including actual and punitive damages.

B. SECTION DIRECTORY:

Section 1 creates s. 390.035, F.S., relating to liability for acts related to a termination of pregnancy.

Section 2 provides an effective date of July 1, 2017.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   The bill does not appear to have any impact on state revenues.

2. Expenditures:

   The bill does not appear to have any impact on state expenditures.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   The bill does not appear to have any impact on local revenues.

2. Expenditures:

   The bill does not appear to have any impact on local expenditures.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The bill creates a cause of action that may financially benefit women who have been harmed by an abortion, and correspondingly cause providers to pay the judgment.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

The bill does not appear to create rulemaking authority or a need for rulemaking.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On February 9, 2017, the Civil Justice & Claims Subcommittee adopted a proposed committee substitute and reported the bill favorably as a committee substitute. The committee substitute differs from the bill as filed by removing comparative negligence language, matching statutes of limitations of minors and adults, and adding tolling of the statute of limitations while a woman is a minor. This analysis is drafted to the committee substitute as passed by the Civil Justice & Claims Subcommittee.

A bill to be entitled

An act relating to termination of pregnancies; creating s. 390.035, F.S.; creating a cause of action for physical and emotional injury resulting from a termination of pregnancy; providing that this cause of action is not an exclusive remedy; providing that laws on medical malpractice actions do not apply to this cause of action; providing a statute of limitations and statute of repose; providing for tolling of the limitations periods; authorizing an award of attorney fees and costs to a prevailing plaintiff; defining the term "damages"; providing an effective date.

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

Section 1. Section 390.035, Florida Statutes, is created to read:

390.035 Liability for acts related to a termination of pregnancy; remedies; limitations.—

(1) A woman who suffers injury or death as a result of an abortion, or who suffers emotional distress as a result of a physician's failure to obtain the informed consent as required by s. 390.0111, has a cause of action for damages against the physician who performed the abortion or failed to provide the statutorily required informed consent.

(2) The signing of an informed consent form by the woman prior to the abortion does not bar a cause of action brought under this section.

(3) An action brought pursuant to this section is not a claim for medical malpractice, and chapter 766 does not apply. This section may not be construed as barring any other statutory or common law cause of action for medical malpractice otherwise available resulting from an abortion procedure or diminish the nature or the extent of those causes of action. The cause of action created in this section is in addition to any other statutory or common law cause of action available to an injured person.

(4) Notwithstanding s. 95.11 or any other provision of law, any action for damages brought under this section shall be commenced within the latter of 4 years from the time the incident giving rise to the action occurred or 4 years from the time the injury is discovered or should have been discovered with the exercise of due diligence; however, in no event shall the action be commenced later than 10 years from the time the incident giving rise to the action occurred. The limitations periods created by this subsection shall be tolled while the woman is a minor.

(5) A prevailing plaintiff in any action brought under this section is entitled to reasonable attorney fees and costs.

(6) For the purposes of this section, the term "damages"

means all special and general damages which are recoverable in an intentional tort, negligence, survival, or wrongful death action, including, but not limited to, actual and punitive damages.

Section 2. This act shall take effect July 1, 2017.

Amendment No. 1

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	_____

Committee/Subcommittee hearing bill: Health Quality Subcommittee

Representative Grall offered the following:

Amendment

Remove line 37 and insert:

person. A woman who elects to pursue an action under this section is precluded from seeking redress under ch. 766.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 129 Advanced Registered Nurse Practitioners
SPONSOR(S): Plasencia
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee		Siples	McElroy
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

The Health Care Clinic Act (Act) was enacted in 2003 to reduce fraud and abuse in the personal injury protection insurance system. Pursuant to the Act, the Agency for Health Care Administration (AHCA) licenses health care clinics, ensures that such clinics meet basic standards, and provide administrative oversight.

Health clinics are entities that provide health care to individuals and tenders charges for reimbursement for such services. Health care clinics must appoint a medical director that agrees in writing to accept legal responsibility for performing certain activities on behalf of the clinic which include:

- Displaying signs that identify the medical or clinical director posted in a conspicuous location within the clinic readily visible to all patients;
- Ensuring that all practitioners providing health care services or supplies to patients maintain a current active and unencumbered Florida license;
- Reviewing any patient referral contracts or agreements executed by the clinic;
- Ensuring that all health care practitioners at the clinic have active appropriate certification or licensure for the level of care being provided;
- Serving as the clinic records owner;
- Ensuring compliance with the recordkeeping, office surgery, and adverse incident reporting requirements;
- Conducting systematic reviews of clinic billings to ensure that the billings are not fraudulent or unlawful; and
- Ensuring that the clinic publishes a schedule of charges for the medical services offered to patients.

A medical director must be a licensed allopathic, osteopathic, chiropractic, or podiatric physician, except for limited circumstances. HB 129 authorizes an advanced registered nurse practitioner (ARNP) to serve as the medical director of a health care clinic.

ARNPs are licensed registered nurses with post-graduate education in nursing that prepares them to perform advanced or specialized nursing. ARNPs may perform nursing or medical acts that are authorized pursuant to a written protocol with a physician. ARNPs may only sign those documents that are directly related to the performance of the nursing or medical acts authorized pursuant to a protocol, unless otherwise prohibited by law. The bill authorizes an ARNP to provide a signature, certification, stamp, verification, or other endorsement required by law to be signed by a physician.

The bill has no fiscal impact on state or local government.

The bill provides an effective date of July 1, 2017.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Health Care Clinics

Regulation of Health Care Clinics

The Health Care Clinic Act (Act) was enacted in 2003 to reduce fraud and abuse in the personal injury protection (PIP) insurance system.[1] Pursuant to the Act, the Agency for Health Care Administration (AHCA) licenses health care clinics, ensures that such clinics meet basic standards, and provide administrative oversight.

Any entity that meets the definition of a health care clinic must be licensed as a health care clinic. To be licensed, an entity must submit a completed application form to AHCA[2] and must:

- Submit to a Level 2 background screening of the applicant, including owners and certain employees and officers of the entity;
- Provide a description or explanation of any exclusions, suspensions, or terminations of the applicant from the Medicare, Medicaid, or federal Clinical Laboratory Improvement Amendment (CLIA) programs;
- Demonstrate financial ability to operate by showing that the applicant's assets, credits, and projected revenues will meet or exceed projected liabilities and expense[3] or provide a surety bond of at least $500,000 payable to AHCA;[4]
- Provide proof of the applicant's legal right to occupy the property in which the clinic is located; and
- Provide proof of any required insurance.[5]

AHCA has 60 days after the receipt of the completed application for licensure to approve or deny the application. Licenses must be renewed biennially.

Although all clinics must be licensed by AHCA, the Act creates a number of exceptions from the health care clinic licensure requirements, including:

- Entities licensed or registered by the state under one or more specified practice acts and that only provide services within the scope of their license, and entities that own such entities, and entities under common ownership with such entities;
- Entities that are wholly owned and controlled by one or more licensed health care practitioners or wholly owned and controlled by one or more licensed health care practitioner and certain family members.
- Entities that are exempt from federal taxation under 26 U.S.C. sec. 501(c)(3) or sec. 501(c)(4);
- Clinical facilities affiliated with an accredited medical school which provides certain training;

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[1] Chapter 2003-411, Laws of Fla. PIP insurance is no fault auto insurance that provides certain benefits for individuals injured as a result of a motor vehicle accident. All motor vehicles registered in this state must have PIP insurance.
[2] Section 408.806, F.S.
[3] Section 408.8069, F.S. This also includes providing AHCA with financial statements, including balance sheet, income and expense statement, a statement of cash flow for the first 2 years of operation that provides evidence that the applicant has sufficient assets, credits, and projected revenues to cover liabilities and expenses, and a statement of the applicant's startup costs and sources of funds through the breakeven point.
[4] Section 408.8069, F.S.
[5] Section 408.810, F.S.

- Entities that provide only oncology or radiation therapy services by physicians and are owned by publicly-traded corporations;
- Clinical facilities affiliated with certain educational institutions;
- Entities that provide a certain amount of practitioner staffing or anesthesia services to certain health care facilities;
- Orthotic, prosthetic, pediatric cardiology, or perinatology clinical facilities or anesthesia clinical facilities wholly owned by publicly-traded corporations;
- Entities that are owned by a corporation that has $250 million or more in total annual sales of health care services and the person(s) responsible for the operations of the entity is a Florida-licensed health care practitioner;
- Entities that employ 50 or more health care providers licensed under ch. 458, F.S., or ch. 459, F.S., that bill for medical services under a single tax identification number.[6]

There are currently 2,016 health care clinics licensed by AHCA and 10,238 Certificates of Exemption.[7]

Each clinic must appoint a medical or clinical director[8] who must agree in writing to accept the legal responsibility for the following activities on behalf of the clinic:

- Display signs that identify the medical or clinical director posted in a conspicuous location within the clinic readily visible to all patients;
- Ensure that all practitioners providing health care services or supplies to patients maintain a current active and unencumbered Florida license;
- Review any patient referral contracts or agreements executed by the clinic;
- Ensure that all health care practitioners at the clinic have active appropriate certification or licensure for the level of care being provided;
- Serve as the clinic records owner;
- Ensure compliance with the recordkeeping, office surgery, and adverse incident reporting requirements;
- Conduct systematic reviews of clinic billings to ensure that the billings are not fraudulent or unlawful;
- Not refer a patient to the clinic if the clinic performs magnetic resonance imaging, static radiographs, computed tomography, or positron emission tomography; and
- Ensure that the clinic publishes a schedule of charges for the medical services offered to patients.[9]

If the health care clinic's medical director is a physician, it may provide any health care service or treatment that a physician is authorized to provide. However, if the health care clinic employs another health care practitioner as its clinic director, the health care services it may offer is limited to those services within the scope of practice of that health care practitioner's license.[10] For example, if the clinic director is a licensed under ch. 463, F.S., as an optometrist, the health care clinic services would be limited to optometric services.

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[6] *Id.*
[7] E-mail correspondence with AHCA staff dated February 16, 2017, (on file with the Health Quality Subcommittee).
[8] A medical director is a physician employed or under contract with a clinic and who maintains and unencumbered licensed in accordance with ch. 458, F.S., ch. 459, F.S., ch. 460, F.S., or ch. 461, F.S. In 2013, the Legislature amended the definition of medical director to allow for the appointment of a clinical director for a clinic that does not provide services that are regulated by the practice act of one of the physician types, such as acupuncture or counseling services. In those situations, a duly licensed health care practitioner may serve as clinic director as long as the services provided are not beyond the scope of the practitioner's license.
[9] Section 400.9935, F.S.
[10] Section 400.9905 (5), F.S.

Advanced Registered Nurse Practitioners

Advanced registered nurse practitioners (ARNPs) are regulated under part I of ch. 464, F.S., the Nurse Practice Act. The Board of Nursing (BON), established under s. 464.004, F.S., provides by rule the eligibility criteria for applicants to be certified as ARNPs and the applicable regulatory standards for ARNP nursing practices. Additionally, the BON is responsible for administratively disciplining an ARNP who commits an act prohibited under ss. 464.018 or 456.072, F.S.

To be eligible to be certified as an ARNP, the applicant must be licensed as a registered nurse, have a master's degree in a nursing clinical specialty area with preparation in specialized practitioner skills, and submit proof that the applicant holds a current national advanced practice certification from a board-approved nursing specialty board.[11] 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 for examination;
- Maintain program accreditation or review mechanism that adheres to criteria which are substantially equivalent to requirements in Florida; and
- Identify standards or scope of practice statements appropriate for each nursing specialty.[12]

ARNPs are authorized to perform advanced or specialized nursing to include, in addition to practices of professional nursing that registered nurses are authorized to perform, advanced-level nursing acts approved by the BON as appropriate for ARNPs to perform by virtue of their post-basic specialized education, training, and experience. Advanced or specialized nursing acts may only be performed if authorized under a supervising physician's protocol.[13]

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

- Prescribe, dispense, administer, or order any drug;[14]
- Initiate appropriate therapies for certain conditions;
- Perform additional functions as may be determined by Board rule;
- Order diagnostic tests and physical and occupational therapy;
- Perform certain acts within his or her specialty; and
- Perform medical acts authorized as authorized within the framework of an established supervisory physician's protocol.[15]

An ARNP may sign only those documents that are directly related to the performance of authorized nursing or medical acts performed pursuant to a physician's protocol and do not, by law, require a physician's signature.

Effect of Proposed Changes

HB 129 authorizes an ARNP to serve as a medical director of a health care clinic. The ARNP must be employed or be under contract with the clinic and must have an active and unencumbered license under ch. 464, F.S., and be certified under s. 464.012, F.S.

The bill also authorizes an ARNP to sign, certify, stamp, verify, or endorse a document that requires the signature, certification, stamp, verification, or endorsement of a physician. This includes, among other

[11] Section 464.012(1), F.S., and Rule 64B9-4.002, F.A.C.
[12] Rule 64B9-4.002(3), F.A.C.
[13] Section 464.003(2), F.S.
[14] Controlled substances may only be prescribed or dispensed if the ARNP has graduated from a program leading to a master's or doctoral degree in a clinical specialty area with training in specialized practitioner skills.
[15] Sections 464.012(3),(4), and 464.003, F.S.

things, signing a certificate to initiate an involuntary examination of a person under the Baker act, signing for the release of persons in receiving facilities under the Baker Act, or signing death certificates.

The bill provides an effective date of July 1, 2017.

B. SECTION DIRECTORY:

Section 1: Amends s. 400.9905, F.S., relating to definitions.
Section 2: Amends s. 464.012, F.S., relating to certification of advanced nurse practitioners; fees; controlled substance prescribing.
Section 3: Provides an effective date of July 1, 2017.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

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.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to advanced registered nurse practitioners; amending s. 400.9905, F.S.; revising the definition of the term "medical director" to include certain advanced registered nurse practitioners; amending s. 464.012, F.S.; authorizing an advanced registered nurse practitioner to sign, certify, stamp, verify, or endorse a document that requires the signature, certification, stamp, verification, or endorsement of a physician; providing an effective date.

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

Section 1. Subsection (5) of section 400.9905, Florida Statutes, is amended to read:

400.9905 Definitions.—

(5) "Medical director" means:

(a) A physician who is employed or under contract with a clinic and who maintains a full and unencumbered physician license in accordance with chapter 458, chapter 459, chapter 460, or chapter 461; or

(b) An advanced registered nurse practitioner who is employed or under contract with a clinic, maintains a full and unencumbered license to practice professional nursing in

accordance with chapter 464, and who is certified in advanced or specialized nursing practice under chapter 464.

If a ~~However, if the~~ clinic does not provide services pursuant to any of the ~~respective~~ physician or nurse practices acts specified ~~listed~~ in this subsection, it may appoint a Florida-licensed health care practitioner who does not provide services pursuant to those ~~the respective physician practices~~ acts ~~listed in this subsection~~ to serve as a clinic director who is responsible for the clinic's activities. A health care practitioner may not serve as the clinic director if the services provided at the clinic are beyond the scope of that practitioner's license; however, ~~except that~~ a licensee specified in s. 456.053(3)(b) who provides only services authorized under that paragraph ~~pursuant to s. 456.053(3)(b)~~ may serve as clinic director of an entity providing such services ~~as specified in s. 456.053(3)(b)~~.

Section 2. Paragraph (f) is added to subsection (3) of section 464.012, Florida Statutes, to read:

464.012 Certification of advanced registered nurse practitioners; fees; controlled substance prescribing.—

(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 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:

(f) Sign, certify, stamp, verify, or endorse a document that requires the signature, certification, stamp, verification, or endorsement of a physician.

Section 3. This act shall take effect July 1, 2017.

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	_____

Committee/Subcommittee hearing bill: Health Quality Subcommittee

Representative Plasencia offered the following:

Amendment (with title amendment)

Remove everything after the enacting clause and insert:

Section 1. Subsection (5) of section 400.9905, Florida Statutes, is amended to read:

400.9905 Definitions.—

(5) "Medical director" means:

(a) A physician or physician assistant who is employed or under contract with a clinic and who maintains a full and unencumbered physician license in accordance with chapter 458, chapter 459, chapter 460, or chapter 461 or a full and unencumbered physician assistant license in accordance with chapter 458 or 459; or

(b) An advanced registered nurse practitioner who is employed or under contract with a clinic, maintains a full and unencumbered license to practice professional nursing in accordance with chapter 464, and who is certified under s. 464.012.

If a ~~However, if the~~ clinic does not provide services pursuant to any of the ~~respective~~ physician or nurse practices acts specified ~~listed~~ in this subsection, it may appoint a Florida-licensed health care practitioner who does not provide services pursuant to those ~~the respective physician practices~~ acts ~~listed in this subsection~~ to serve as a clinic director who is responsible for the clinic's activities. A health care practitioner may not serve as the clinic director if the services provided at the clinic are beyond the scope of that practitioner's license; however, ~~except that~~ a licensee specified in s. 456.053(3)(b) who provides only services authorized under that paragraph ~~pursuant to s. 456.053(3)(b)~~ may serve as clinic director of an entity providing such services ~~as specified in s. 456.053(3)(b)~~.

Section 2. Paragraph (i) is added to subsection (4) of section 458.347, Florida Statutes, to read:

458.347 Physician assistants.—

(4) PERFORMANCE OF PHYSICIAN ASSISTANTS.—

(i) A supervisory physician may delegate to a licensed physician assistant the authority to sign, certify, stamp, verify, or endorse a document that requires the signature, certification, stamp, verification, or endorsement of a physician.

Section 3. Paragraph (h) is added to subsection (4) of section 459.022, Florida Statutes, to read:

(h) A supervisory physician may delegate to a licensed physician assistant the authority to sign, certify, stamp, verify, or endorse a document that requires the signature, certification, stamp, verification, or endorsement of a physician.

Section 4. Paragraph (f) is added to subsection (3) of section 464.012, Florida Statutes, to read:

464.012 Certification of advanced registered nurse practitioners; fees; controlled substance prescribing.—

(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 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:

(f) Sign, certify, stamp, verify, or endorse a document that requires the signature, certification, stamp, verification, or endorsement of a physician.

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 health care practitioner regulation; amending s. 400.9905, F.S.; revising the definition of the term "medical director" to include certain physician assistants and advanced registered nurse practitioners; amending s. 458.347, F.S.; authorizing a physician assistant to sign, certify, stamp, verify, or endorse a document that requires the signature, certification, stamp, verification, or endorsement of a physician; amending s. 459.022, F.S.; authorizing a physician assistant to sign, certify, stamp, verify, or endorse a document that requires the signature, certification, stamp, verification, or endorsement of a physician; amending s. 464.012, F.S.; authorizing an advanced registered nurse practitioner to sign, certify, stamp, verify, or endorse a document that requires the

signature, certification, stamp, verification, or endorsement of a physician; providing an effective date.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 557 Prescription Drug Monitoring Program
SPONSOR(S): Duran
TIED BILLS: **IDEN./SIM. BILLS:** SB 840

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee		Siples	McElroy
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

Prescription Drug Monitoring Programs (PDMPs) are state-run electronic databases used to track the prescribing and dispensing of certain controlled prescription drugs to patients. PDMPs are designed to monitor this information for suspected abuse or diversion and provide prescribers and pharmacists with critical information regarding a patient's controlled substance prescription history. As of December 19, 2014, 49 states either had an operational PDMP database or had adopted legislation authorizing the creation of one.

In 2009, the Legislature created the Prescription Drug Monitoring Program (PDMP) within the Department of Health (DOH). The PDMP employs a database to monitor the prescribing and dispensing of certain controlled substances. Dispensers of controlled substances listed in Schedule II, III, or IV must report certain information to the PDMP database, including the name of the prescriber, the date the prescription is filled and dispensed, and the name, address, and date of birth of the person to whom the controlled substance is dispensed. Currently, dispensers must report dispensing controlled substances to the database within seven days of dispensing the controlled substances.

Dispensing and administering controlled substances are exempt in certain health care settings where the risk of controlled substances being overprescribed or diverted is low. These health care settings include a licensed hospital, nursing home, ambulatory surgical center, hospice, intermediate care facility for the developmentally disabled, rehabilitative hospital, and assisted living facility.

Beginning January 1, 2018, HB 557 reduces the amount of time a dispenser has to report the dispensing of a controlled substance to the PDMP database from 7 days after the controlled substance is dispensed to 24 hours after the controlled substance is dispensed. The bill requires the controlled substance reporting by dispensers to be completed via the internet, and eliminates the authority of the department to approve other options, such as submission by disc or by regular mail.

The bill also requires the patient to be present and receiving care for the exemption to the reporting of dispensing of controlled substances provided to a rehabilitation hospital, assisted living facility, or nursing home to apply.

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

The bill provides an effective date of July 1, 2017.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Prescription Drug Monitoring Program

Prescription Drug Monitoring Programs (PDMPs) are state-run electronic databases used to track the prescribing and dispensing of certain controlled prescription drugs to patients.[1] PDMPs are designed to monitor this information for suspected abuse or diversion and provide prescribers and pharmacists with critical information regarding a patient's controlled substance prescription history.[2] As of December 19, 2014, 49 states either had an operational PDMP database or had adopted legislation authorizing the creation of one.[3]

Chapter 2009-197, Laws of Fla., established Florida's PDMP within the Department of Health (DOH), and is codified in s. 893.055, F.S. The PDMP uses an electronic database system to monitor the prescribing and dispensing of certain controlled substances.[4] The PDMP database became operational on September 2011, when it began receiving prescription data from pharmacies and dispensing practitioners.[5] As of December 19, 2014, 49 states either had an operational PDMP database or had adopted legislation authorizing the creation of one.[6]

PDMP Reporting Requirements

Dispensers of controlled substances listed in Schedule II, III, or IV of the Florida Comprehensive Drug Abuse Prevention and Control Act must report specified information to the PDMP database.[7] The following information is submitted for inclusion in the PDMP database:

- The name of the prescribing practitioner, the practitioners federal Drug Enforcement Administration (DEA) registration number, the practitioner's National Provider Identification (NPI) or other appropriate identifier, and the date of the prescription;
- The date the prescription was filled and the method of payment, such as cash by an individual or third-party payment;
- The full name, address, and date of birth of the person for whom the prescription was written;
- The name, national drug code, quantity, and strength of the controlled substance dispensed;
- The full name, federal DEA registration number, and address of the pharmacy, other location, or other practitioner from which the controlled substance was dispensed;
- The name of the pharmacy or practitioner, other than a pharmacist, dispensing the controlled substance and the practitioner's NPI; and

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[1] Centers for Disease Control and Prevention, *Prescription Drug Monitoring Programs, available at* http://www.cdc.gov/drugoverdose/pdmp/ (last visited February 16, 2017).
[2] *Id.*
[3] Brandeis University, Institute of Behavioral Health, and the U.S. Department of Justice, Bureau for Justice Assistance, PDMP Center of Excellence, *Status of Prescription Drug Monitoring Programs (PDMPs), available at* http://www.pdmpassist.org/pdf/PDMPProgramStatus2014.pdf (last visited February 16, 2017). Missouri is the only state without a PDMP. Legislation was filed in December 2016 to establish a program. *See* *http://www.senate.mo.gov/17info/BTS_Web/Bill.aspx?SessionType=R&BillID=57095432* (last visited February 18, 2017).
[4] Section 893.055(2)(a), F.S.
[5] Florida Department of Health, Electronic-Florida Online Reporting of Controlled Substances Evaluation (E-FORCSE), 2015-2016 Prescription Drug Monitoring Program Annual Report, (December 1, 2016), *available at* http://www.floridahealth.gov/statistics-and-data/e-forcse/_documents/2016PDMPAnnualReport.pdf (last visited February 16, 2017).
[6] Brandeis University, Institute of Behavioral Health, and the U.S. Department of Justice, Bureau for Justice Assistance, PDMP Center of Excellence, *Status of Prescription Drug Monitoring Programs (PDMPs), available at* http://www.pdmpassist.org/pdf/PDMPProgramStatus2014.pdf (last visited February 16, 2017).
[7] Section 893.055(3), F.S.; controlled substances listed in Schedule II, III, or IV can be found in s. 893.03(2)-(4), F.S.

- Other appropriate identifying information as determined by DOH rule.[8]

Dispensers must report dispensing a specified controlled substance to the PDMP database within seven days.[9] As of June 30, 2016, approximately 96 percent of pharmacies required to report data to the PDMP had uploaded information into the system within the seven-day statutory limit.[10] Of those, 66 percent reported the information within 24 hours.[11] More than 6,500 dispensers have reported to the PDMP creating the more than 198 million dispensing records that are maintained in the PDMP system.[12]

Exemptions from PDMP Reporting Requirements

The purpose of the PDMP is to track the dispensing of prescribed controlled substances to provide information to subsequent prescribing physicians and prevent the overprescribing of such substances, and also to prevent the diversion of such substances. However, there are some circumstances in which there is inherently a low risk of controlled substances being overprescribed or diverted, and in those circumstances, the law exempts practitioners from having to report the dispensing of controlled substances. Specifically, the following acts are not required to be reported:

- A health care practitioner administering a controlled substance directly to a patient if the amount of the controlled substance is adequate to treat the patient during that particular treatment session;
- A pharmacist or health care practitioner administering a controlled substance to a patient or resident receiving care as a patient at a hospital, nursing home, ambulatory surgical center, hospice, or intermediate care facility for the developmentally disabled which is licensed in this state;
- A practitioner administering or dispensing a controlled substance in the health care system of the Department of Corrections;
- A practitioner administering a controlled substance in the emergency room of a licensed hospital;
- A health care practitioner administering or dispensing a controlled substance to a person under the age of 16;
- A pharmacist or a dispensing practitioner dispensing a one-time, 72-hour emergency resupply of a controlled substance to a patient; and
- A rehabilitative hospital, assisted living facility, or nursing home dispensing a certain dosage of a controlled substance, as needed, to a patient as ordered by the patient's treating physician.[13]

Access to PDMP Database

Direct access to the PDMP database is presently limited by law to a pharmacy, prescriber, or dispenser.[14] A pharmacy, prescriber, or dispenser has access to information in the PDMP database that relates to a patient of that pharmacy, prescriber, or dispenser, as needed, for reviewing the patient's controlled substance prescription history.[15]

Health care practitioners[16] began accessing the PDMP database on October 17, 2011.[17] As of June 30 2016, 36,718 health care practitioners, or 23.7 percent of all licensed health care practitioners, were

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[8] *Id.*
[9] Section 893.055(4), F.S.
[10] *Supra* note 5.
[11] *Id.*
[12] *Id.*
[13] Section 893.055(5). F.S.
[14] Section 893.055(7)(b), F.S.
[15] *Id.*
[16] Section 893.055(1)(d), F.S., defines health care practitioner for the purpose of the PDMP program as those practitioners who are subject to licensure or regulation by DOH under ch. 458, F.S., (Medicine), ch. 459, F.S., (Osteopathic Medicine), ch. 461, F.S., (Podiatric Medicine), ch. 462, F.S., (Naturopath), ch. 463, F.S., (Optometry), ch. 464, F.S., (Nursing), ch. 465, F.S., (Pharmacy), or ch. 466, F.S., (Dentistry).

registered to use the PDMP Database. [18] Pharmacists have had the highest utilization rate of the PDMP; from July 1, 2015 to June 30, 2016, 54.5 percent of pharmacists were registered to use the PDMP and 90.1 percent of pharmacists registered to use the PDMP had queried it.[19] From July 1, 2015 to June 30, 2016, in-state prescribers issued 37,048,030 controlled substance prescriptions to 7,387,884 Florida residents.[20] During that same timeframe, 28,984 registered health care practitioners queried the PDMP database 27,501,266 times.[21]

In Florida, indirect access to the PDMP database is provided to:

- DOH and its relevant health care regulatory boards;
- The Attorney General for Medicaid fraud cases involving prescribed controlled substances;
- A law enforcement agency during active investigations regarding potential criminal activity, fraud, or theft regarding prescribed controlled substances; and
- A patient or the legal guardian or designated health care surrogate of an incapacitated patient, for verifying the accuracy of database information.[22]

Entities with indirect access to the PDMP database may request information from the PDMP program manager that is otherwise confidential and exempt from public disclosure under s. 893.0551, F.S.[23] Prior to release, the PDMP program manager must verify that the request is authentic and authorized with the requesting organization.[24]

Public Records Exemption for Information in the PDMP Database

Section 893.0551, F.S.,[25] provides that personal information of a patient and certain information concerning health care practitioners contained in the PDMP database are confidential and exempt from s. 119.07(1), F.S., and article I, section 24 of the Florida Constitution.[26] The statute makes confidential and exempt identifying information, including, but not limited to, the name, address, telephone number, insurance plan number, government-issued identification number, provider number, Drug Enforcement Administration number, or any other unique identifying number of a patient, patient's agent, health care practitioner or practitioner as defined in s. 893.055, F.S., or an employee of the practitioner who is acting on behalf of and at the direction of the practitioner, a pharmacist, or a pharmacy, which is contained in the PDMP database.

Any agency or person that obtains information pursuant to s. 893.0551, F.S., must maintain the confidential and exempt status of that information.[27]

Effect of Proposed Changes

Beginning January 18, 2018, HB 557 reduces the amount of time a pharmacy or dispenser has to report the dispensing of a controlled substance to the PDMP database from 7 days after the controlled substance is dispensed to 24 hours after the controlled substance is dispensed.

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[17] Florida Department of Health, Electronic-Florida Online Reporting of Controlled Substances Evaluation (E-FORCSE), 2012-2013 Prescription Drug Monitoring Program Annual Report, Dec. 1, 2013, available at www.floridahealth.gov/reports-and-data/e-forcse/news-reports/_documents/2012-2013pdmp-annual-report.pdf (last visited February 17, 2017).
[18] *Supra* note 5 at p. 10.
[19] *Id.* at p. 10, 18.
[20] *Id.* at p. 14.
[21] *Id.* at p. 18.
[22] Section 893.055(7)(c), F.S.
[23] *Id.*
[24] *Id.*
[25] The public records exemption was established in 2009 in conjunction with the PDMP. See s. 1, ch. 2009-197, Laws of Fla. Additionally, the public records exemption was reauthorized in 2014. See .s 1 ch. 2014-156, Laws of Fla.
[26] Section 893.0551(2), F.S.
[27] Section 893.0551(6), F.S. However, a law enforcement agency with lawful access to such information is permitted to disclose confidential and exempt information received from DOH to a criminal justice agency as part of an active investigation of a specific violation of law. Section 893.0551(4).

The bill requires the controlled substance reporting by pharmacies or dispensers to be done via the internet, and eliminates the authority of the department to approve other options, such as submission by disc or by regular mail.

The bill clarifies that the exemption to the reporting required under this section provided to a rehabilitation hospital, assisted living facility, or nursing homes, applies only while the patient is present and receiving care as ordered by the patient's treating physician.

The provides an effective date of July 1, 2017.

B. SECTION DIRECTORY:

Section 1: Amends s. 893.055, F.S., relating to prescription drug monitoring program.
Section 2: Provides an effective date for a specific requirement of the bill.
Section 3: Provides an effective date of July 1, 2017.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   DOH may incur insignificant costs associated with rulemaking to amend current rules to align with the statutory changes proposed by the bill. Current budget authority is adequate to absorb such costs.[28]

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

A pharmacy or dispenser may incur additional costs associated with meeting the new requirement to report the dispensing of a controlled substance within 24 hours.

D. FISCAL COMMENTS:

None.

[28] Department of Health, *2017 Agency Legislative Bill Analysis: House Bill 557*, January 27, 2017, (on file with the Health Quality Subcommittee).

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:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to the prescription drug monitoring program; amending s. 893.055, F.S.; revising requirements for reporting the dispensing of controlled substances; limiting an exception to reporting requirements for certain facilities dispensing controlled substances; specifying when a revised reporting requirement takes effect; providing an effective date.

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

Section 1. Subsection (4) and paragraph (g) of subsection (5) of section 893.055, Florida Statutes, are amended to read:

893.055 Prescription drug monitoring program.—

(4) Each time a controlled substance is dispensed to an individual, the controlled substance shall be reported to the department through the system as soon thereafter as possible, but not more than 24 hours ~~7 days~~ after ~~the date~~ the controlled substance is dispensed unless an extension is approved by the department for cause as determined by rule. A dispenser must meet the reporting requirements of this section by submitting via the Internet ~~providing~~ the required information concerning each controlled substance that it dispensed ~~in a department-approved, secure methodology and format~~. ~~Such approved formats~~

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

~~may include, but are not limited to, submission via the Internet, on a disc, or by use of regular mail.~~

(5) When the following acts of dispensing or administering occur, the following are exempt from reporting under this section for that specific act of dispensing or administration:

(g) A rehabilitative hospital, assisted living facility, or nursing home dispensing a certain dosage of a controlled substance, as needed, to a patient while the patient is present and receiving care as ordered by the patient's treating physician.

Section 2. The requirement that the dispensing of a controlled substance be reported to the Department of Health within 24 hours in s. 893.055(4), Florida Statutes, as amended by this act, shall take effect January 1, 2018.

Section 3. This act shall take effect July 1, 2017.

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	_____

Committee/Subcommittee hearing bill: Health Quality Subcommittee

Representative Duran offered the following:

Amendment (with title amendment)

Remove everything after the enacting clause and insert:

Section 1. Subsection (4) and paragraph (g) of subsection (5), and paragraphs (a) and (b) of subsection (7) of section 893.055, Florida Statutes, are amended to read:

893.055 Prescription drug monitoring program.—

(4) Each time a controlled substance is dispensed to an individual, the controlled substance shall be reported to the department through the system as soon thereafter as possible, but no later than the close of the next business day ~~not more than 7 days~~ after the day ~~date~~ the controlled substance is dispensed unless an extension is approved by the department for

cause as determined by rule. A dispenser must meet the reporting requirements of this section by submitting via the department-approved electronic system ~~providing~~ the required information concerning each controlled substance that it dispensed ~~in a department-approved, secure methodology and format~~. ~~Such approved formats may include, but are not limited to, submission via the Internet, on a disc, or by use of regular mail~~.

(5) When the following acts of dispensing or administering occur, the following are exempt from reporting under this section for that specific act of dispensing or administration:

(g) A rehabilitative hospital, assisted living facility, or nursing home dispensing a certain dosage of a controlled substance, as needed, to a patient while the patient is present and receiving care as ordered by the patient's treating physician.

(7)(a) A practitioner or pharmacist who dispenses a controlled substance must submit the information required by this section in an electronic ~~or other~~ method in an ASAP format approved by rule of the department unless otherwise provided in this section. The cost to the dispenser in submitting the information required by this section may not be material or extraordinary. Costs not considered to be material or extraordinary include, but are not limited to, regular postage, electronic media, regular electronic mail, and facsimile charges.

(b) A pharmacy, prescriber, or dispenser, or the designee of a pharmacy, prescriber, or dispenser, shall have access to information in the prescription drug monitoring program's database which relates to a patient of that pharmacy, prescriber, or dispenser in a manner established by the department as needed for the purpose of reviewing the patient's controlled substance prescription history. An employee of the United States Department of Veterans' Affairs who provides health care services pursuant to such employment and has the authority to prescribe controlled substances shall have access to the information in the prescription drug monitoring program's database in a manner established by the department. Such access is limited to the information that relates to a patient of such employee and may only be accessed for the purpose of reviewing the patient's controlled substance prescription history. Other access to the program's database shall be limited to the program's manager and to the designated program and support staff, who may act only at the direction of the program manager or, in the absence of the program manager, as authorized. Access by the program manager or such designated staff is for prescription drug program management only or for management of the program's database and its system in support of the requirements of this section and in furtherance of the prescription drug monitoring program. Confidential and exempt information in the database shall be released only as provided

in paragraph (c) and s. 893.0551. The program manager, designated program and support staff who act at the direction of or in the absence of the program manager, and any individual who has similar access regarding the management of the database from the prescription drug monitoring program shall submit fingerprints to the department for background screening. The department shall follow the procedure established by the Department of Law Enforcement to request a statewide criminal history record check and to request that the Department of Law Enforcement forward the fingerprints to the Federal Bureau of Investigation for a national criminal history record check.

Section 2. The requirement that the dispensing of a controlled substance be reported to the Department of Health no later than the next business day in s. 893.055(4), Florida Statutes, as amended by this act, shall take effect January 1, 2018.

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

Remove line 7 and insert:

dispensing controlled substances; authorizing certain employees of the United States Department of Veterans' Affairs access to certain information in the prescription drug monitoring program's database; specifying when a