The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Committee on Health Policy

BILL:	CS/SB 1192
INTRODUCER:	Health Policy Committee and Senator Bean
SUBJECT:	Electronic Prescribing
DATE:	April 9, 2019
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Rossitto-Van Winkle	Brown	HP	**Fav/CS**
2.			AHS	
3.			AP	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 1192 requires certain health care practitioners to, under specified conditions, electronically generate and transmit prescriptions for medicinal drugs upon license renewal or by July 20, 2021, whichever is earlier, and provides exceptions. The bill also:

- Authorizes the Department of Health (DOH), in consultation with the Board of Medicine and the Board of Osteopathic Medicine, to adopt rules;
- Revises the definitions of the terms "prescribing decision" and "point of care"; and
- Revises the requirements for electronic prescribing software.

The bill has an effective date of January 1, 2020.

II. Present Situation:

In 2007, the Legislature created s. 408.0611, F.S., to promote the implementation of e-prescribing by health care practitioners, health care facilities, and pharmacies in order to prevent prescription drug abuse, improve patient safety, and reduce unnecessary prescriptions. To that end, the Legislature created a clearinghouse in the Agency for Health Care Administration (ACHA) to provide information on e-prescribing to:

- Convey the process and advantages of e-prescribing;
- Provide information regarding the availability of e-prescribing products, including no-cost or low-cost products; and

- Regularly convene stakeholders to assess and accelerate the implementation of e-prescribing.[1]

Section 408.0611 (2)(a), F.S., defines "electronic prescribing" as, at a minimum, the electronic review of the patient's medication history, the electronic generation of the patient's prescription, and the electronic transmission of the patient's prescription to a pharmacy.

The AHCA is required to work in collaboration with private sector e-prescribing initiatives and relevant stakeholders to create and maintain the clearinghouse. These stakeholders must include organizations that:

- Represent health care practitioners;
- Represent health care facilities;
- Represent pharmacies;
- Operate e-prescribing networks;
- Create e-prescribing products; and
- Represent regional health information organization.[2]

Specifically, the AHCA was tasked to provide on its website:

- Information regarding the advantages of e-prescribing, including using medication history data to prevent drug interactions, prevent allergic reactions, and deter doctor-shopping and pharmacy-shopping for controlled substances;
- Links to federal and private sector websites that provide guidance on selecting an appropriate e-prescribing product; and
- Links to state, federal, and private sector incentive programs for the implementation of e-prescribing.[3]

The AHCA annually reports to the Governor and Legislature on the implementation of e-prescribing by health care practitioners, facilities, and pharmacies.[4] The AHCA reports that as of the end of September 2018, the average number of e-prescribers is 50,200 and that almost 10 million e-prescriptions are transmitted each month.[5] Florida's e-prescribing rate has steadily increased since 2007 with an estimated 75.7 percent of all prescriptions being e-prescribed.[6] However, Florida prescribers have been slower to adopt e-prescribing for controlled substances.[7] In 2017, only 7.8 percent of controlled substance prescriptions were e-prescribed.[8]

Section 456.42, F.S., requires that prescriptions that are electronically generated and transmitted contain the following:

- The name of the prescriber;

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[1] Section 408.0611, F.S.
[2] Section 408.0611(3), F.S.
[3] Section 408.0611, (3)(a), F.S.
[4] Agency for Health Care Administration, Florida Center for Health Information and Transparency, *Florida's Annual Electronic Prescribing Report for 2018* (January 2019), *available at* http://www.fhin.net/eprescribing/fleprescribingRpts.shtml (last visited April 3, 2019).
[5] *Supra* note 4.
[6] Id. E-prescribing rate is defined as the amount of e-prescribing relative to all prescriptions that could have been e-prescribed.
[7] Agency for Health Care Administration, Florida Center for Health Information and Transparency, *2018 Florida Electronic Prescribing Quarterly Summary*, available at http://www.fhin.net/eprescribing/dashboard/docs/2018eprescribemetrics.pdf (last visited April 3, 2019).
[8] Id.

- The name and strength of the drug prescribed;
- The quantity of the drug prescribed in numerical format;
- Directions for use; and
- The date of the prescription and electronic signature of the prescriber.

E-prescribing software may not interfere with a patient's choice of pharmacy or use any means, such as pop-up ads, advertising, or instant messaging to influence or attempt to influence the prescribing decision of the prescriber at the point of care. E-prescribing software may provide formulary information, as long as nothing makes it more difficult or precludes a prescriber from selecting a specific pharmacy or drug.

E-prescribing is done by health care practitioners through the use of electronic devices such as a computer, tablets, or phones that are equipped with software to securely enter and transmit prescriptions to pharmacies also using special software and connectivity to a transmission network.[9]

Federal Regulation on E-Prescribing

The federal Drug Enforcement Administration (DEA) implements the Comprehensive Drug Abuse Prevention and Control Act of 1970, often referred to as the Controlled Substances Act (CSA) and the Controlled Substances Import and Export Act, as amended.[10] The DEA publishes the implementing regulations for these statutes in Title 21 of the Code of Federal Regulations, Parts 1300 to 1399. These regulations are designed to ensure an adequate supply of controlled substances for legitimate medical, scientific, research, and industrial purposes, and to deter the diversion of controlled substances to illegal purposes. The CSA mandates that the DEA establish a closed system of control for manufacturing, distributing, and dispensing controlled substances. Any person who manufactures, distributes, dispenses, imports, exports, or conducts research or chemical analysis with controlled substances must register with the DEA, unless exempt, and must comply with the applicable requirements for the activity.[11]

The Controlled Substances Act (CSA) and Current Regulations

The CSA and DEA's regulations were originally adopted at a time when most transactions and particularly prescriptions were done on paper. The CSA provides that a controlled substance in Schedule II may only be dispensed by a pharmacy pursuant to a "written prescription," except in emergency situations.[12] By contrast, for controlled substances in Schedules III and IV, the CSA provides that a pharmacy may dispense pursuant to a "written or oral prescription."[13]

[9] The Office of the National Coordinator for Health Information Technology, *What is Electronic Prescribing?* (September 22, 2017) *available at* https://www.healthit.gov/faq/what-electronic-prescribing (last visited April 3, 2019).
[10] 21 U.S.C. 801–971.
[11] Federal Register, Part II, Department of Justice, Drug Enforcement Administration, 21 C.F.R. Parts 1300, 1304, 1306 and 1311, *Electronic Prescribing of Controlled Substances;* Final Rule (March 31, 2010) *available at* https://www.govinfo.gov/content/pkg/FR-2010-03-31/pdf/2010-6687.pdf p. 16237 (last visited April 8, 2019).
[12] 21 U.S.C. 829(a).
[13] 21 U.S.C. 829(b).

Where an oral prescription is permitted by the CSA, the DEA regulations further provide that a practitioner may transmit to the pharmacy a facsimile of a written, manually signed prescription in lieu of an oral prescription.[14]

Under longstanding federal law, for a prescription for a controlled substance to be valid, it must be issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice[15] The DEA regulations state, "[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription."[16] The prescription provides a record of the actual dispensing of the controlled substance to the patient and, therefore, is critical to documenting that controlled substances held by a pharmacy have been dispensed legally. The maintenance by pharmacies of complete and accurate prescription records is an essential part of the overall CSA regulatory scheme established by Congress.[17]

The CSA is unique among criminal laws in that it stipulates acts pertaining to controlled substances that are permissible. So, if the CSA does not explicitly permit an action pertaining to a controlled substance, then, by its lack of explicit permissibility, the act is prohibited. Violations of the CSA can be civil or criminal, which may result in administrative, civil, or criminal proceedings. Remedies under the CSA can range from modification to revocation of DEA registration, monetary penalties, or imprisonment, depending on the nature, scope, and extent of the violation.[18]

Over the last few years, 15 states have enacted mandatory e-prescribing laws.[19]

State	Effective Date	Applicable Prescriptions
Arizona	January 1, 2019 in large counties; July 1, 2019 in small counties	Schedule II opioids
California	January 1, 2022	All
Connecticut	Currently required	Controlled substances
Iowa	January 1, 2020	All
Maine	Currently required	All controlled substances containing opiates
Massachusetts	January 1, 2020	Schedules II-VI controlled substances
Minnesota	Currently required	All
New Jersey	May 1, 2020	Schedule II controlled substances
New York	Currently required	All
North Carolina	January 1, 2020	Schedule II and III opioids
Oklahoma	January 1, 2020	Controlled substances
Pennsylvania	October 24, 2019	Controlled substances

[14] 21 C.F.R. 1306.21(a).
[15] United States v. Moore, 423 U.S. 122 (1975); 21 C.F.R. 1306.04(a).
[16] 21 C.F.R. 1306.04(a).
[17] Supra note 12, p. 16238.
[18] 21 U.S.C. 841 - 844.
[19] DrFirst, *E-Prescribing Mandate Map*, available at https://www.drfirst.com/resources/e-prescribing-mandate-map/ (last visited April 8, 2019), and SureScripts, *Electronic Prescribing for Controlled Substances*, available at https://surescripts.com/enhance-prescribing/e-prescribing/e-prescribing-for-controlled-substances/ (last visited April 8, 2019).

State	Effective Date	Applicable Prescriptions
Rhode Island	January 1, 2020	Controlled substances
Tennessee	July 1, 2020	Schedule II controlled substances
Virginia	July 1, 2020	All prescriptions containing opiates

Medicare E-Prescribing

Prior to 2010, a major obstacle to e-prescribing was a prohibition by the U.S. Drug Enforcement Administration (DEA) on e-prescribing of controlled substances. However, in 2010, the DEA adopted a rule that allowed providers to write electronic prescriptions for controlled substances and permitted pharmacies to receive, dispense, and archive these electronic prescriptions.[20] To e-prescribe controlled substances, a health care practitioner must:

- Purchase or use DEA-compliant software that supports e-prescribing;
- Complete the identity-proofing process to acquire a two-factor authentication credential or digital certificate;
- Attach the authentication credential to his or her identity;
- Set access controls so that only individuals who may legally prescribe a controlled substance are allowed to do so; and
- Access the e-prescribing or electronic health record platform.[21]

The FDA requires that an individual practitioner to sign and transmit electronic prescriptions for controlled substances provided the practitioner meets all of the following requirements:

- The practitioner must comply with all FDA requirements for issuing controlled substance prescriptions;
- The practitioner must use an application that meets FDA requirements; and
- The practitioner must comply with FDA practitioner requirements.[22]

In 2018, Congress mandated e-prescribing for controlled substances under the Medicare Part D program by January 1, 2021, as a part of a comprehensive bill to address the opioid crisis.[23] The Secretary of the federal Department of Health and Human Services may waive this requirements for a Medicare Part D covered schedule II, III, IV, and V controlled substance required to be electronically transmitted in the following cases:

- A prescription issued when the practitioner and dispensing pharmacy are the same entity;
- A prescription issued that cannot be transmitted electronically under the most recently implemented version of the National Council for Prescription Drug Programs SCRIPT Standard;

[20] U.S. Department of Justice, Drug Enforcement Administration, Diversion Control Division, *Electronic Prescriptions for Controlled Substance (EPCS)*, available at https://www.deadiversion.usdoj.gov/ecomm/e_rx/ (last visited April 3, 2019).
[21] *Id*. See also, DrFirst, *EPCS: Getting Started with Electronic Prescribing of Controlled Substances*, available at http://www.drfirst.com/wp-content/uploads/EPCS_Infographic_from_DrFirst-1.png (last visited April 3, 2019).
[22] 21 C.F.R. 1306.08, 42 U.S.C. s. 1395W-104, (e)(7)(A), p. 24, *available at* https://www.law.cornell.edu/uscode/text/42/1395w-104 (last visited April 8, 2019).
[23] Substance Use-Disorder Prevention that Promotes Opioid Recovery Treatment (SUPPORT) for Patients and Communities Act, Pub. Law No. 115-271 s. 2003 (2018). *See also* U.S. House of Representatives, Energy and Commerce Committee, *HR 6: SUPPORT for Patients and Communities Act*, available at https://www.congress.gov/bill/115th-congress/house-bill/6/text#toc-H7820B15EE005461C9DA95E7E747412DD (last visited April 3, 2019).

- A prescription issued by a practitioner who received a waiver or a renewal for a period of time, not to exceed one year, from the requirement to use electronic prescribing due to economic hardship, technological limitations outside the control of the practitioner, or other exceptional circumstances
- A prescription issued by a practitioner under circumstances in which, notwithstanding the practitioner's ability to submit a prescription electronically, the practitioner reasonably determines that it would be impractical for the individual to obtain the substances prescribed by electronic prescription in a timely manner, and such delay would adversely impact the individual's medical condition;
- A prescription prescribing a drug under a research protocol;
- A prescription or a drug for which the FDA requires a prescription to contain elements that are not able to be included in e-prescribing, such as a drug with risk evaluation and mitigation strategies that include elements to assure safe use;
- A prescription issued by a practitioner:
  - For an individual who receives hospice care; and
  - That is not covered under the hospice benefit; and
- A prescription for an individual who is:
  - A resident of a nursing facility; and
  - Eligible for Medicare benefits.[24]

E-Prescribing Software and Systems

National Council for Prescription Drug Programs (NCPDP)

The National Council for Prescription Drug Programs (NCPDP) is a not-for-profit membership organization that uses a consensus-based process for standards development. The NCPDP creates national standards for electronic health care transactions used in prescribing, dispensing, monitoring, managing and paying for medications and pharmacy services. The organization also develops standardized business systems and best practices that safeguard patients. Members collaborate to achieve solutions they all can support. NCPDP members are pharmacies, pharmacists, physicians, health plans, long-term care providers, claims processors, e-prescribing system vendors, pharmaceutical manufacturers, and government agencies such as the federal Centers for Medicare & Medicaid Services and the Food and Drug Administration.[25]

Stanford Computerized Researcher Information Profile Technique (SCRIPT)

SCRIPT is a standard developed for transmitting prescription information electronically between prescribers, pharmacies, payers, and other entities for new prescriptions, changes of prescriptions, prescription refill requests, prescription fill status notifications, cancellation notifications, relaying of medication history, transactions for long-term care, electronic prior authorization, and other transactions.[26]

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[24] 42 U.S.C. s. 1395W-104, (e)(7)(B), Beneficiary Protections for Qualified Prescription Drug Coverage, *available at* https://www.law.cornell.edu/uscode/text/42/1395w-104, p. 24 (last visited April 8, 2019).
[25] National Council for Prescription Drug Programs, *Frequently Asked Questions*, available at https://www.ncpdp.org/About-Us/FAQ (last visited April 8, 2019).
[26] National Council for Prescription Drug Programs, *Standards Information*, available at https://www.ncpdp.org/Standards-Development/Standards-Information (last visited April 8, 2019).

The current SCRIPT standard is version 10.6, which is anticipated to sunset on December 31, 2019, and be replaced by version 2017071 on January 1, 2020.[27]

The Cost of E-Prescribing

The cost of an e-prescribing system used by prescribers is based on the number of prescribers using the system and the options included in the system. It is estimated that the cost of an electronic health record system for an office with 10 full-time prescribers is approximately $42,332 for implementation and $14,725 for annual maintenance.[28]

III. Effect of Proposed Changes:

The bill amends s. 456.42, F.S., to require that prescribing a health care practitioners who maintains a system of EHR,[29] or who prescribes drugs as an owner, employee, or contractor of a licensed health care facility or practice that maintains such a system, and who is prescribing in that capacity, may only electronically transmit prescriptions for such drugs. This requirement takes effect upon renewal of the health care practitioner's license or by July 1, 2021, whichever is earlier, but does not apply if:

- The practitioner and the dispenser are the same entity;
- The prescription cannot be transmitted electronically under the most recently implemented version of the NCPDP SCRIPT program;
- The practitioner has been issued a waiver by the DOH, not to exceed one year, due to demonstrated economic hardship or technological limitations, not reasonably within the practitioner's control, or other exceptional circumstances;
- The practitioner determines that it is impractical for a patient to obtain in a timely manner a drug electronically prescribed and that the delay would adversely impact the patient's medical condition;
- The practitioner is prescribing a drug under a research protocol;
- The prescription is for a drug for which the federal Food and Drug Administration requires the prescription to contain elements that may not be included in electronic prescribing; or
- The prescription is issued to an individual receiving hospice care or who is a resident of a nursing home facility.

Prescribing practitioners who do not have access, in their practice or employment, to an EHR system may still provide written prescriptions to their patients for medicinal drugs. The DOH, in consultation with the Board of Medicine and the Board of Osteopathic Medicine, may adopt rules to implement these provisions.

The bill amends s. 456.43, F.S., to require that electronic prescribing software may not include any means, or permit any person, to influence through economic incentives the prescribing decision of a prescribing practitioner at the point of care, including, but not limited to:

- Advertising;

[27]National Council for Prescription Drug Programs, *NCPDP SCRIPT Standard Implementation Timeline*, p. 7, (October 2018) *available at* https://www.ncpdp.org/NCPDP/media/pdf/NCPDP_SCRIPT_Version_2017071_Timline__Implementation.pdf (last visited April 8, 2019).
[28] *Supra* note **Error! Bookmark not defined.**.
[29] Section 408.051, F.S., defines an electronic health records a record of a person's medical treatment which is created by a licensed health care provider and stored in an interoperable and accessible digital format.

- Instant messaging;
- Pop-up ads; or
- Similar means triggered by the input, selection, or act of a prescribing practitioner in the act of prescribing a drug for patient.

The bill authorizes electronic prescribing software to display information regarding a payer's formulary if nothing is designed to preclude, or make more difficult, the selection of any particular pharmacy by a patient or the selection of a certain medicinal drug by a prescribing practitioner.

The bill revises the definitions of "prescribing decision" and "point of care" as follows:
- "Prescribing decision" means a prescribing practitioner's or his or her agent's decision to prescribe any medicinal drug.
- "Point of care" means the time at which that a prescribing practitioner or his or her agent prescribes any medicinal drug.

The bill makes conforming changes to other areas of the Florida Statutes.

The bill provides an effective date of January 1, 2020.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 456.42, 456.43, 409.912, 456.0392, 458.3265, 458.331, 458.347, 459.0137, and 459.015.

IX. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS by Health Policy on April 8, 2019:
The CS:

- Requires certain health care practitioners to begin issuing all prescriptions through e-prescribing no later than July 1, 2021, if such prescribers have access to an electronic health records (EHR) system;
- Provides an exception to mandatory e-prescribing for those prescribers who do not have access to an EHR system;
- Creates seven exceptions to the requirement that prescribers with access to an EHR system must issue all prescriptions through e-prescribing, which are all consistent with federal-law exceptions to the e-prescribing requirement for the Medicare program;
- Authorizes the DOH to adopt rules in consultation with the Board of Medicine and the Board of Osteopathic Medicine; and
- Makes numerous conforming changes throughout other areas of the Florida Statutes.

B. Amendments:

None.