

## HOUSE OF REPRESENTATIVES STAFF ANALYSIS

**BILL #:** HB 831 Electronic Prescribing  
**SPONSOR(S):** Mariano  
**TIED BILLS:** IDEN./SIM. **BILLS:** SB 1192

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	12 Y, 1 N	Siples	McElroy
2) Health Care Appropriations Subcommittee	9 Y, 0 N	Mielke	Clark
3) Health & Human Services Committee			

### SUMMARY ANALYSIS

Electronic prescribing (e-prescribing) is a method by which an authorized health care practitioner electronically transmits a prescription to a pharmacy using a secure software system. Efforts have been made by states, as well as the federal government, to increase the use of e-prescribing software. For example, Congress passed legislation mandating e-prescribing for certain medicinal drugs under the Medicare Part D program and 15 states enacted mandatory e-prescribing laws.

Beginning January 1, 2020, HB 831 requires prescribers to generate and transmit all prescriptions electronically.

The bill relocates language regarding electronic prescribing from existing s. 456.43, F.S., to s. 456.42, F.S., and repeals current s. 456.43, F.S, as of January 1, 2020, to improve readability by combining several provisions related to e-prescribing in a single section of law.

The bill makes conforming changes throughout Florida statutes.

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

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

# FULL ANALYSIS

## I. SUBSTANTIVE ANALYSIS

### A. EFFECT OF PROPOSED CHANGES:

#### Present Situation

##### Electronic Prescribing

Electronic prescribing (e-prescribing) is a method by which health care practitioners use an electronic device such as a computer or tablet to enter and securely transmit prescriptions to pharmacies using special software and connectivity to a transmission network.<sup>1</sup> Numerous benefits have been attributed to e-prescribing including, improved prescription accuracy, increased patient safety, reduction of opportunities for fraud and abuse, and cost reduction.<sup>2</sup>

##### *Patient Safety*

An adverse drug event (ADE) is harm experienced by the patient as a result of exposure to medicine.<sup>3</sup> Each year, ADEs account for nearly 700,000 emergency room visits and 100,000 hospitalizations.<sup>4</sup> Some ADEs occur without accessing hospital care, such as overdoses to opioid medications.<sup>5</sup> It is estimated that 50 percent of ADEs are preventable.<sup>6</sup> Causes of errors include illegible handwriting, wrong dosage or dosage form, omission of information, and failure to identify drug allergies or drug-drug interactions.<sup>7</sup>

E-prescribing helps reduce such prescription errors.<sup>8</sup> E-prescribing software often includes decision support that notifies the prescriber of potential prescription errors before transmission.<sup>9</sup> The e-prescribing software also prompts the prescriber to verify allergies, confirm dosage accuracy, and identify drug-drug interaction before transmitting the prescription.<sup>10</sup>

##### *Fraud*

Individuals may illegally obtain prescription medication by using fraudulent, forged, or altered written prescriptions. In an effort to reduce fraud related to the use or misuse of controlled substances, Florida law requires prescriptions for controlled substances be written on counterfeit-proof prescription pads purchased from an authorized supplier.<sup>11</sup> A counterfeit-proof prescription pad must include the following features:<sup>12</sup>

- A background color that is blue or green and resists reproduction;
- Printed on artificial watermarked paper;

<sup>1</sup> The Office of the National Coordinator for Health Information Technology, *What is Electronic Prescribing?*, available at <https://www.healthit.gov/faq/what-electronic-prescribing> (last visited Dec. 7, 2018).

<sup>2</sup> Agency for Health Care Administration, *Florida's Annual Electronic Prescribing Reports*, available at <http://www.fhin.net/eprescribing/fleprescribingRpts.shtml> (last visited Dec. 7, 2018).

<sup>3</sup> U.S Department of Health and Human Services, Agency for Healthcare Research and Quality, *Medication Errors and Adverse Drug Events*, (Aug. 2018), available at <https://psnet.ahrq.gov/primers/primer/23/Medication-Errors-and-Adverse-Drug-Events> (last visited January 3, 2019).

<sup>4</sup> Id.

<sup>5</sup> Id.

<sup>6</sup> Id.

<sup>7</sup> Megan Ducker, et. al., *Pros and Cons of E-Prescribing in Community Pharmacies*, US Pharm. 2013 8(38):4-7, available at <https://www.uspharmacist.com/article/pros-and-cons-of-e-prescribing-in-community-pharmacies-42392> (last visited January 3, 2019).

<sup>8</sup> Giampaolo P. Velo and Pietro Minuz, *Medication Errors: Prescribing Faults and Prescription Errors*, 67 British J of Clin Pharmacology, 624-628 (2009), available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2723200/> (last visited January 3, 2019).

<sup>9</sup> *Supra* note 7.

<sup>10</sup> Id.

<sup>11</sup> Section 456.42, F.S.

<sup>12</sup> Rule 64B-3.005, F.A.C.

- Resists erasures and alterations; and
- The word “void” or “illegal” must appear on any photocopy or reproduction;

Unused counterfeit-proof prescription pads must be destroyed by the health care practitioner or health care facility that purchased them and returned to the vendor.<sup>13</sup> Even with these precautions, there is still the danger of a legitimate prescription pad being stolen from a health care practitioner’s office or a health care facility and fraudulent prescriptions written.<sup>14</sup>

E-prescribing eliminates the risk of stolen prescription pads and, with the two-factor authentication required by the U.S. Drug Enforcement Administration (DEA), may further reduce unauthorized or altered prescriptions.<sup>15</sup>

### *Efficiency*

E-prescribing creates efficiencies for prescribers, patients, and pharmacies. For prescribers, e-prescribing can be integrated into electronic health records, which includes patient information such as clinical notes, laboratory results, and clinical decision support functions.<sup>16</sup> E-prescribing also improves the accuracy of prescriptions and helps guide clinical decision-making by checking the appropriateness of a prescription and connecting to a patient’s health insurance for its formulary.<sup>17</sup> Prescribers have also indicated that less time is spent resolving issues with pharmacies, including prior authorizations and refill requests, allowing more time to be spent on patient care.<sup>18</sup> The software also automates certain tasks which allows staff to perform other functions. Such efficiencies may ultimately lower overall operating costs.

Patients may also benefit from e-prescribing efficiencies due to the ability of the prescriber to check for drug interactions, drug allergies, and whether a particular drug is covered by their insurance. This may enable patients to reduce copayment expenses or inconvenience associated with requesting an alternate medication from the prescriber if the drug prescribed is not covered or too expensive.<sup>19</sup>

Finally, pharmacies will likely benefit from e-prescribing efficiencies because it reduces the time spent on interpreting a prescription. Pharmacists must contact prescribers if a prescription is illegible or inconsistent, which affords the pharmacist more time to counsel patients.<sup>20</sup>

### *Cost Savings*

As noted above, ADEs result in many emergency room visits and hospitalizations, as well as additional visits to the prescriber’s office. Although e-prescribing will not prevent all ADEs,<sup>21</sup> they may reduce the number of ADEs due to improved prescribing and the assistance of decision support systems.<sup>22</sup> The efficiencies noted above may also lead to a reduction to overall operating costs. For example, one

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<sup>13</sup> Id.

<sup>14</sup> U.S. Department of Justice, Drug Enforcement Administration, Diversion Control Division, *A Pharmacist’s Guide to Prescription Fraud*, (Feb. 2000), available at <https://www.deadiversion.usdoj.gov/pubs/brochures/pharmguide.htm> (last visited January 3, 2019).

<sup>15</sup> National Association of Chain Drug Stores, *Opioid Abuse Epidemic: Solutions from the Front Lines of Care*, (last rev. Oct. 19, 2018), available at <https://www.nacds.org/pdfs/government/2017/Opioid-Policy-Oct-2017.pdf> (last visited December 13, 2018).

<sup>16</sup> Amber Porterfield, et. al., *Electronic Prescribing: Improving the Efficiency and Accuracy of Prescribing in the Ambulatory Care Setting*, *Perspect. Health Inf. Manage.* 2014 Spring: 11 (Apr. 2014), available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3995494/> (last visited December 14, 2018).

<sup>17</sup> Academy of Managed Care Pharmacy, *Concept Series Paper on Electronic Prescribing*, available at <http://amcp.org/WorkArea/DownloadAsset.aspx?id=9297> (last visited December 14, 2018).

<sup>18</sup> *Supra* note 16.

<sup>19</sup> Id.

<sup>20</sup> *Supra* note 7.

<sup>21</sup> Some ADEs are unavoidable even if the medication is properly prescribed and administered. These are often known side effects of a medication. See *supra* note 3.

<sup>22</sup> *Supra* note 3.

health system in Michigan estimated that it saved \$3 million after mandatory e-prescribing was implemented in that state.<sup>23</sup>

### *Cost of Implementation*

The cost of an e-prescribing system is based on the number of prescribers using the system and the options included in the system. It is estimated that the cost for 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.<sup>24</sup> The Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009, authorized incentive payments through Medicare and Medicaid to health care practitioners and hospitals when they meaningfully used electronic health care records to help offset some of the costs related to the adoption of electronic health record systems.<sup>25</sup> The incentive program consists of two stages. Stage one required the electronic capture of clinical data, including transmitting at least 40 percent of eligible prescriptions electronically.<sup>26</sup> In stage two, health care providers must demonstrate meaningful use for a full year; stage two retains the objective that eligible prescriptions be transmitted electronically.<sup>27</sup>

### *E-Prescribing System Design Errors*

Practitioners and researchers identify several issues related to the design of an e-prescribing system. Some systems may lack appropriate alerts and other systems may not have alerts configured in a meaningful way so that a prescriber receives an overload of alerts.<sup>28</sup> Other issues are related to the interface or screen design of the software. In such cases, errors may occur in the use of drop-down boxes and automatic fill functions which may lead to more manual entry and editing or prescriptions.<sup>29</sup> Additionally, these systems may be configured to bundle prescriptions or to transmit at a time other than the time of entry.<sup>30</sup> For example, the system may allow users to input prescriptions over the course of a specified duration and then send all entered prescriptions at a designated time or interval.<sup>31</sup>

### Florida Law on Electronic Prescriptions in Florida

Current law requires that prescriptions that are electronically generated and transmitted contain the following:<sup>32</sup>

- The name of the prescriber;
- The name and strength of the drug prescribed;
- The quantity of the drug prescribed in numerical format;
- Directions for use;
- Date 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

<sup>23</sup> Annie Hahn and Annesha Lovett, *Electronic Prescribing: An Examination of Cost Effectiveness, Clinician Adoption, and Limitations*, Universal J of Clin Med (2)(1):1-24 (2014), available at <http://www.hrpub.org/download/20131215/UJCM1-16900871.pdf> (last visited December 15, 2018).

<sup>24</sup> *Supra* note 16.

<sup>25</sup> Medscape, *EHR Incentive Programs: Achieving Meaningful Use*, available at [https://www.medscape.org/viewarticle/770841#content=0\\_0](https://www.medscape.org/viewarticle/770841#content=0_0) (last visited December 15, 2018).

<sup>26</sup> *Id.*

<sup>27</sup> Centers for Medicare and Medicaid Services, *Stage 2 Overview Tipsheet*, (Aug. 2012), available at [https://www.cms.gov/regulations-and-guidance/legislation/ehrincentiveprograms/downloads/stage2overview\\_tipsheet.pdf](https://www.cms.gov/regulations-and-guidance/legislation/ehrincentiveprograms/downloads/stage2overview_tipsheet.pdf) (last visited December 15, 2018). For the initial year of stage 2, CMS required providers to demonstrate meaningful use for 90 days, but in subsequent year the requirement is for a full year.

<sup>28</sup> *Supra* note 16.

<sup>29</sup> *Supra* note 7.

<sup>30</sup> *Id.*

<sup>31</sup> *Id.*

<sup>32</sup> Section 456.42, F.S.

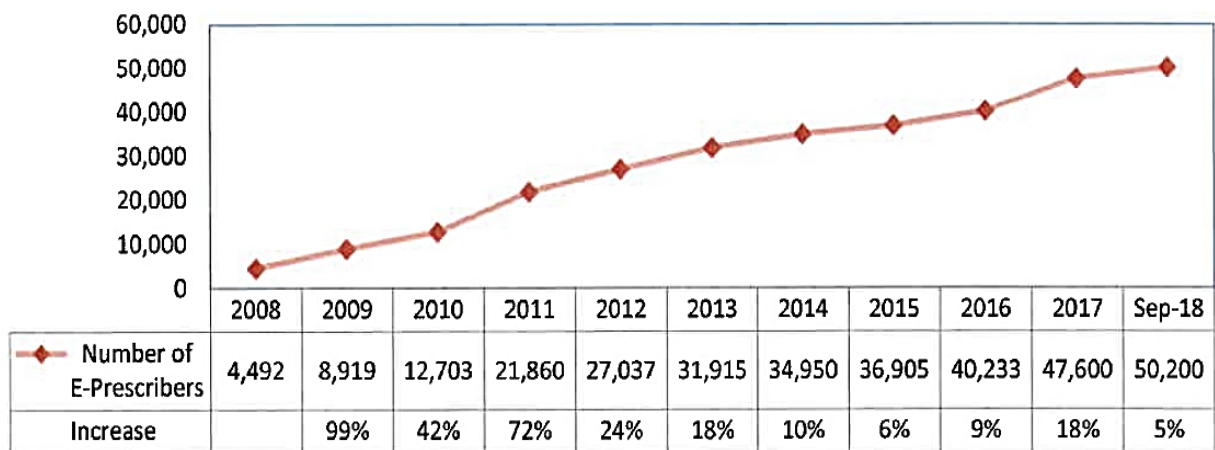
decision of the prescriber at the point of care.<sup>33</sup> E-prescribing software may provide formulary information, as long as nothing makes it more difficult or precludes a prescriber from selecting a specific pharmacy or drug.<sup>34</sup>

### Florida Prescribers

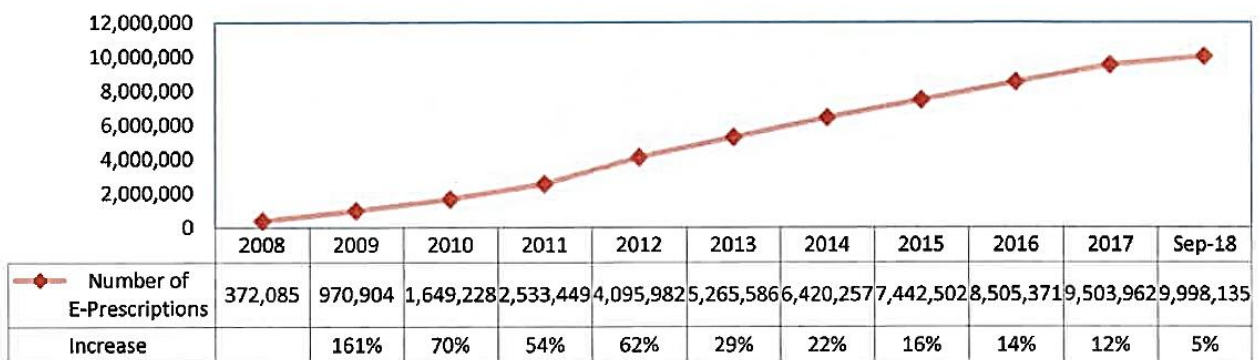
The Agency for Health Care Administration (AHCA) houses a clearinghouse of information on electronic prescribing, including information on trends in e-prescribing in the state and electronic health records systems.<sup>35</sup> AHCA annually reports to the Governor and Legislature on the implementation of electronic prescribing by health care practitioners, facilities, and pharmacies.<sup>36</sup>

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.<sup>37</sup>

**Figure 2. Average Number of Electronic Prescribers per Month in 2008 - 2018 and Annual Increase**



**Figure 1. Average Number of Electronic Prescriptions Per Month in 2008 - 2018 and Annual Increase**



<sup>33</sup> Section 456.43, F.S.

<sup>34</sup> Id.

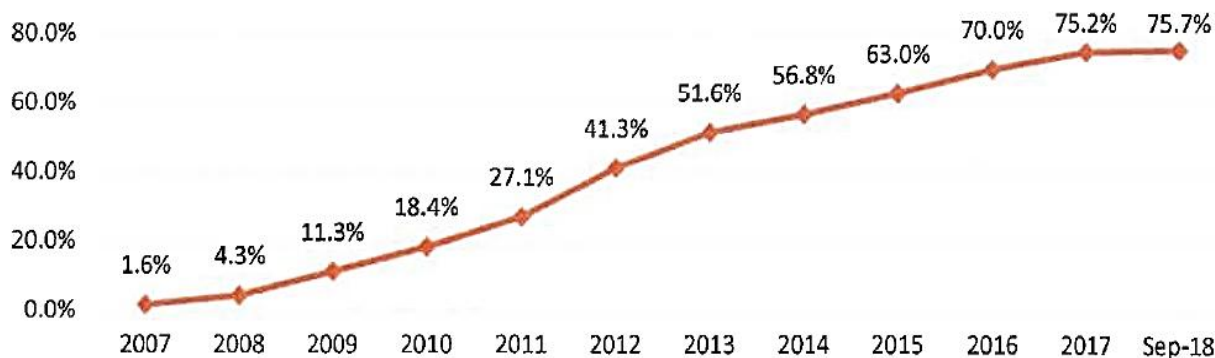
<sup>35</sup> Section 408.0611, F.S.

<sup>36</sup> Agency for Health Care Administration, Florida Center for Health Information and Transparency, "Florida Electronic Prescribing Annual Report for 2018," (Jan. 2019), available at <http://www.fhin.net/eprescribing/docs/reports/Florida2018ePrescribeReport.pdf> (last visited March 3, 2019).

<sup>37</sup> *Supra* note 36.

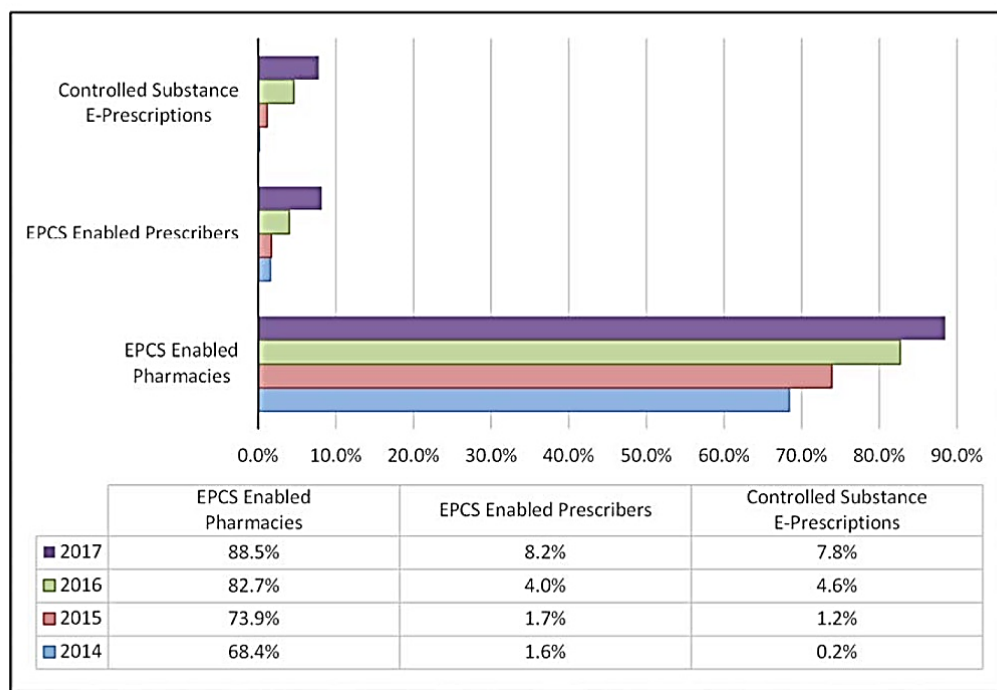
Florida's e-prescribing rate has steadily increased since 2007 with an estimated 75.7 percent of all prescriptions being e-prescribed.<sup>38</sup>

**Figure 3. Estimated Average Annual Electronic Prescribing Rate, 2007 - 2018**



However, Florida prescribers have been slower to adopt e-prescribing for controlled substances.<sup>39</sup> In 2017, only 7.8 percent of controlled substance prescriptions were e-prescribed.

**Percent of Electronic Prescribing of Controlled Substances (EPCS), EPCS Enabled Pharmacies and EPCS Enabled Providers in Florida<sup>1</sup>, 2014 to 2017**



<sup>38</sup> Id. Electronic prescribing rate is defined as the amount of e-prescribing relative to all prescriptions that could have been e-prescribed.

<sup>39</sup> 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/2018eprescribmetrics.pdf> (last visited March 3, 2019).



## Mandatory E-Prescribing

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.<sup>40</sup> Under the HITECH Act of 2009, the federal government provides incentive payments to those who adopt and meaningfully use electronic health record technology, including the use of e-prescribing.<sup>41</sup>

Over the last few years, 15 states have enacted mandatory e-prescribing laws.<sup>42</sup>

State	Date E-Prescribing Mandate is Effective	Prescriptions that must be Transmitted Electronically
Arizona	January 1, 2019 in large counties; July 1, 2019 in smaller 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
Rhode Island	January 1, 2020	Controlled substances
Tennessee	July 1, 2020	Schedule II controlled substances
Virginia	July 1, 2020	All prescriptions containing opiates

The industry anticipates that additional states will introduce and pass legislation mandating e-prescribing in some fashion, whether it includes all prescriptions or is limited to controlled substances.<sup>43</sup>

Previously, a major obstacle to e-prescribing was a prohibition by the U.S. Drug Enforcement Administration (DEA) on electronic 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.<sup>44</sup> To e-prescribe controlled substances, a health care practitioner must:<sup>45</sup>

- 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;

<sup>40</sup> Substance Use-Disorder Prevention that Promotes Opioid Recovery Treatment (SUPPORT) for Patients and Communities Act, Pub. L. 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://energycommerce.house.gov/wp-content/uploads/2018/06/HR6\\_Summary-of-Provisions\\_06192018\\_FINAL.pdf](https://energycommerce.house.gov/wp-content/uploads/2018/06/HR6_Summary-of-Provisions_06192018_FINAL.pdf) (last visited January 3, 2019).

<sup>41</sup> *Supra* note 25.

<sup>42</sup> DrFirst, *E-Prescribing Mandate Map*, available at <https://www.drfirst.com/resources/e-prescribing-mandate-map/> (last visited January 3, 2019), and SureScripts, *Electronic Prescribing for Controlled Substances*, available at <https://surescripts.com/enhance-prescribing/e-prescribing/e-prescribing-for-controlled-substances/> (last visited January 3, 2019).

<sup>43</sup> SureScripts, *EPCS Legislation Shows Power and Promise*, (May 3, 2018), available at <https://surescripts.com/news-center/intelligence-in-action/opioids/epcs-legislation-shows-power-and-promise/> (last visited January 3, 2019).

<sup>44</sup> Department of Justice, Drug Enforcement Administration, *Electronic Prescriptions for Controlled Substance (EPCS)*, available at [https://www.deadiversion.usdoj.gov/e-comm/e\\_rx/](https://www.deadiversion.usdoj.gov/e-comm/e_rx/) (last visited December 13, 2018).

<sup>45</sup> *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](http://www.drfirst.com/wp-content/uploads/EPCS_Infographic_from_DrFirst-1.png) (last visited December 13, 2018).

- 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.

### **Effect of Proposed Changes**

The bill requires all prescribers to generate and transmit all prescriptions electronically, and effectively prohibits any written prescriptions.

The bill relocates language regarding electronic prescribing from existing s. 456.43, F.S., to s. 456.42, F.S., and repeals current s. 456.43, F.S. These provisions regulates the use of e-prescribing software. The bill does not amend these provisions but simply relocates them.

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

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

- Section 1:** Amends s. 456.42, F.S., relating to written prescriptions for medicinal drugs.  
**Section 2:** Amends s. 409.91196, F.S., relating to supplemental rebate agreements; public records, and public meetings exemption.  
**Section 3:** Amends s. 409.912, F.S., relating to cost-effective purchasing of health care.  
**Section 4:** Amends s. 456.0392, F.S., relating to prescription labeling.  
**Section 5:** Amends s. 458.3265, F.S., relating to pain management clinics.  
**Section 6:** Amends s. 458.331, F.S., relating to grounds for disciplinary action; action by the board and department.  
**Section 7:** Amends s. 458.347, F.S., relating to physician assistants.  
**Section 8:** Amends s. 459.0137, F.S., relating to pain management clinics.  
**Section 9:** Amends s. 459.015, F.S., relating to grounds for disciplinary action; action by the board and department.  
**Section 10:** Amends s. 459.022, F.S., relating to physician assistants.  
**Section 11:** Repeals: s. 456.43, F.S., relating to electronic prescribing for medicinal drugs; s. 831.311, F.S., relating to unlawful sale, manufacture, alteration, delivery, uttering, or possession of counterfeit-resistant prescription blanks for controlled substances; and s. 893.065, F.S., relating to counterfeit-resistant prescription blanks for controlled substances.  
**Section 3:** Provides an effective date of January 1, 2020.

## **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:

Prescribers may achieve savings in operating costs based on the efficiencies offered by using e-prescribing software. However, prescribers who do not have such software will incur costs associated with the initial installation and ongoing maintenance. Pharmacies may also achieve cost savings related to the efficiencies provided by e-prescribing.

Vendors currently authorized to sell the counterfeit-proof prescription pads will experience a decrease in demand, which may result in a financial loss.

Vendors of e-prescribing software will experience an increase in demand.

D. FISCAL COMMENTS:

None.

### III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

Rulemaking authority is not necessary to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

### IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES