By the Committees on Appropriations; and Health Policy; and Senators Bean, Baxley, and Rouson

576-04635-19 20191192c2

A bill to be entitled

An act relating to electronic prescribing; amending s. 456.42, F.S.; requiring certain health care practitioners to electronically generate and transmit prescriptions for medicinal drugs upon license renewal or by a specified date; providing exceptions; authorizing the Department of Health, in consultation with the Board of Medicine, the Board of Osteopathic Medicine, the Board of Podiatric Medicine, the Board of Dentistry, the Board of Nursing, and the Board of Optometry, to adopt rules; amending s. 456.43, F.S.; revising the definitions of the terms "prescribing decision" and "point of care"; revising the authority for electronic prescribing software to display information regarding a payor's formulary under certain circumstances; amending ss. 409.912, 456.0392, 458.3265, 458.331, 459.0137, and 459.015, F.S.; conforming provisions to changes made by the act; providing an effective date.

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

Section 1. Section 456.42, Florida Statutes, is amended to read:

456.42 Written prescriptions for medicinal drugs.—

(1) A written prescription for a medicinal drug issued by a health care practitioner licensed by law to prescribe such drug must be legibly printed or typed so as to be capable of being understood by the pharmacist filling the prescription; must

contain the name of the prescribing practitioner, the name and strength of the drug prescribed, the quantity of the drug prescribed, and the directions for use of the drug; must be dated; and must be signed by the prescribing practitioner on the day when issued. However, a prescription that is electronically generated and transmitted must contain the name of the prescribing practitioner, the name and strength of the drug prescribed, the quantity of the drug prescribed in numerical format, and the directions for use of the drug and must contain the date and an electronic signature, as defined in s. 668.003(4), ~~be dated and signed~~ by the prescribing practitioner only on the day issued~~, which signature may be in an electronic format as defined in s. 668.003(4)~~.

(2) A written prescription for a controlled substance listed in chapter 893 must have the quantity of the drug prescribed in both textual and numerical formats, must be dated in numerical, month/day/year format, or with the abbreviated month written out, or the month written out in whole, and must be either written on a standardized counterfeit-proof prescription pad produced by a vendor approved by the department or electronically prescribed as that term is used in s. 408.0611. As a condition of being an approved vendor, a prescription pad vendor must submit a monthly report to the department that, at a minimum, documents the number of prescription pads sold and identifies the purchasers. The department may, by rule, require the reporting of additional information.

(3) A health care practitioner licensed by law to prescribe a medicinal drug who maintains a system of electronic health

records as defined in s. 408.051(2)(a), or who prescribes medicinal drugs as an owner, an employee, or a contractor of a licensed health care facility or practice that maintains such a system and who is prescribing in his or her capacity as such an owner, an employee, or a contractor, may only electronically transmit prescriptions for such drugs. This requirement applies to such a health care practitioner upon renewal of the health care practitioner's license or by July 1, 2021, whichever is earlier, but does not apply if:

(a) The practitioner and the dispenser are the same entity;

(b) The prescription cannot be transmitted electronically under the most recently implemented version of the National Council for Prescription Drug Programs SCRIPT Standard;

(c) The practitioner has been issued a waiver by the department, not to exceed 1 year in duration, from the requirement to use electronic prescribing due to demonstrated economic hardship, technological limitations that are not reasonably within the control of the practitioner, or another exceptional circumstance demonstrated by the practitioner;

(d) The practitioner reasonably determines that it would be impractical for the patient in question to obtain a medicinal drug prescribed by electronic prescription in a timely manner and such delay would adversely impact the patient's medical condition;

(e) The practitioner is prescribing a drug under a research protocol;

(f) 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

(g) The prescription is issued to an individual receiving hospice care or who is a resident of a nursing home facility.

(h) The practitioner determines that it is in the best interest of the patient, or the patient determines that it is in his or her own best interest, to compare prescription drug prices among area pharmacies. The practitioner must document such determination in the patient's medical record.

The department, in consultation with the Board of Medicine, the Board of Osteopathic Medicine, the Board of Podiatric Medicine, the Board of Dentistry, the Board of Nursing, and the Board of Optometry, may adopt rules to implement this subsection.

Section 2. Section 456.43, Florida Statutes, is amended to read:

456.43 Electronic prescribing for medicinal drugs.—

(1) Electronic prescribing may ~~shall~~ not interfere with a patient's freedom to choose a pharmacy.

(2) Electronic prescribing software may ~~shall~~ not use any means or permit any other person to use any means to influence or attempt to influence, through economic incentives or otherwise, the prescribing decision of a prescribing practitioner or his or her agent at the point of care, including, but not limited to, means such as advertising, instant messaging, ~~and~~ pop-up ads, and similar means ~~to influence or attempt to influence, through economic incentives or otherwise, the prescribing decision of a prescribing practitioner at the point of care. Such means shall not be~~ triggered by or in specific response to the input, selection, or

act of a prescribing practitioner or his or her agent in prescribing a certain medicinal drug ~~pharmaceutical~~ or directing a patient to a certain pharmacy. For purposes of this subsection, the term:

(a) ~~The term~~ "Prescribing decision" means a prescribing practitioner's or his or her agent's decision to prescribe any medicinal drug ~~a certain pharmaceutical~~.

(b) ~~The term~~ "Point of care" means the time at which ~~that~~ a prescribing practitioner or his or her agent prescribes any medicinal drug ~~is in the act of prescribing a certain pharmaceutical~~.

(3) Electronic prescribing software may display ~~show~~ information regarding a payor's formulary if ~~as long as~~ nothing is designed to preclude or make more difficult the selection of ~~the act of a prescribing practitioner or patient selecting~~ any particular pharmacy by a patient or the selection of a certain medicinal drug by a prescribing practitioner or his or her agent ~~pharmaceutical~~.

Section 3. Paragraph (a) of subsection (5) of section 409.912, Florida Statutes, is amended to read:

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

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

Medicaid providers by developing a provider network through provider credentialing. The agency may competitively bid single-source-provider contracts if procurement of goods or services results in demonstrated cost savings to the state without limiting access to care. The agency may limit its network based on the assessment of beneficiary access to care, provider availability, provider quality standards, time and distance standards for access to care, the cultural competence of the provider network, demographic characteristics of Medicaid beneficiaries, practice and provider-to-beneficiary standards, appointment wait times, beneficiary use of services, provider turnover, provider profiling, provider licensure history, previous program integrity investigations and findings, peer review, provider Medicaid policy and billing compliance records, clinical and medical record audits, and other factors. Providers are not entitled to enrollment in the Medicaid provider network. The agency shall determine instances in which allowing Medicaid beneficiaries to purchase durable medical equipment and other goods is less expensive to the Medicaid program than long-term rental of the equipment or goods. The agency may establish rules to facilitate purchases in lieu of long-term rentals in order to protect against fraud and abuse in the Medicaid program as defined in s. 409.913. The agency may seek federal waivers necessary to administer these policies.

(5)(a) The agency shall implement a Medicaid prescribed-drug spending-control program that includes the following components:

1. A Medicaid preferred drug list, which shall be a listing of cost-effective therapeutic options recommended by the

Medicaid Pharmacy and Therapeutics Committee established pursuant to s. 409.91195 and adopted by the agency for each therapeutic class on the preferred drug list. At the discretion of the committee, and when feasible, the preferred drug list should include at least two products in a therapeutic class. The agency may post the preferred drug list and updates to the list on an Internet website without following the rulemaking procedures of chapter 120. Antiretroviral agents are excluded from the preferred drug list. The agency shall also limit the amount of a prescribed drug dispensed to no more than a 34-day supply unless the drug products' smallest marketed package is greater than a 34-day supply, or the drug is determined by the agency to be a maintenance drug in which case a 100-day maximum supply may be authorized. The agency may seek any federal waivers necessary to implement these cost-control programs and to continue participation in the federal Medicaid rebate program, or alternatively to negotiate state-only manufacturer rebates. The agency may adopt rules to administer this subparagraph. The agency shall continue to provide unlimited contraceptive drugs and items. The agency must establish procedures to ensure that:

a. There is a response to a request for prior consultation by telephone or other telecommunication device within 24 hours after receipt of a request for prior consultation; and

b. A 72-hour supply of the drug prescribed is provided in an emergency or when the agency does not provide a response within 24 hours as required by sub-subparagraph a.

2. Reimbursement to pharmacies for Medicaid prescribed drugs shall be set at the lowest of: the average wholesale price

(AWP) minus 16.4 percent, the wholesaler acquisition cost (WAC) plus 1.5 percent, the federal upper limit (FUL), the state maximum allowable cost (SMAC), or the usual and customary (UAC) charge billed by the provider.

3. The agency shall develop and implement a process for managing the drug therapies of Medicaid recipients who are using significant numbers of prescribed drugs each month. The management process may include, but is not limited to, comprehensive, physician-directed medical-record reviews, claims analyses, and case evaluations to determine the medical necessity and appropriateness of a patient's treatment plan and drug therapies. The agency may contract with a private organization to provide drug-program-management services. The Medicaid drug benefit management program shall include initiatives to manage drug therapies for HIV/AIDS patients, patients using 20 or more unique prescriptions in a 180-day period, and the top 1,000 patients in annual spending. The agency shall enroll any Medicaid recipient in the drug benefit management program if he or she meets the specifications of this provision and is not enrolled in a Medicaid health maintenance organization.

4. The agency may limit the size of its pharmacy network based on need, competitive bidding, price negotiations, credentialing, or similar criteria. The agency shall give special consideration to rural areas in determining the size and location of pharmacies included in the Medicaid pharmacy network. A pharmacy credentialing process may include criteria such as a pharmacy's full-service status, location, size, patient educational programs, patient consultation, disease

management services, and other characteristics. The agency may impose a moratorium on Medicaid pharmacy enrollment if it is determined that it has a sufficient number of Medicaid-participating providers. The agency must allow dispensing practitioners to participate as a part of the Medicaid pharmacy network regardless of the practitioner's proximity to any other entity that is dispensing prescription drugs under the Medicaid program. A dispensing practitioner must meet all credentialing requirements applicable to his or her practice, as determined by the agency.

5. The agency shall develop and implement a program that requires Medicaid practitioners who issue written prescriptions for medicinal ~~prescribe~~ drugs to use a counterfeit-proof prescription pad for Medicaid prescriptions. The agency shall require the use of standardized counterfeit-proof prescription pads by ~~Medicaid-participating prescribers or~~ prescribers who issue written ~~write~~ prescriptions for Medicaid recipients. The agency may implement the program in targeted geographic areas or statewide.

6. The agency may enter into arrangements that require manufacturers of generic drugs prescribed to Medicaid recipients to provide rebates of at least 15.1 percent of the average manufacturer price for the manufacturer's generic products. These arrangements shall require that if a generic-drug manufacturer pays federal rebates for Medicaid-reimbursed drugs at a level below 15.1 percent, the manufacturer must provide a supplemental rebate to the state in an amount necessary to achieve a 15.1-percent rebate level.

7. The agency may establish a preferred drug list as

described in this subsection, and, pursuant to the establishment of such preferred drug list, negotiate supplemental rebates from manufacturers that are in addition to those required by Title XIX of the Social Security Act and at no less than 14 percent of the average manufacturer price as defined in 42 U.S.C. s. 1936 on the last day of a quarter unless the federal or supplemental rebate, or both, equals or exceeds 29 percent. There is no upper limit on the supplemental rebates the agency may negotiate. The agency may determine that specific products, brand-name or generic, are competitive at lower rebate percentages. Agreement to pay the minimum supplemental rebate percentage guarantees a manufacturer that the Medicaid Pharmaceutical and Therapeutics Committee will consider a product for inclusion on the preferred drug list. However, a pharmaceutical manufacturer is not guaranteed placement on the preferred drug list by simply paying the minimum supplemental rebate. Agency decisions will be made on the clinical efficacy of a drug and recommendations of the Medicaid Pharmaceutical and Therapeutics Committee, as well as the price of competing products minus federal and state rebates. The agency may contract with an outside agency or contractor to conduct negotiations for supplemental rebates. For the purposes of this section, the term "supplemental rebates" means cash rebates. Value-added programs as a substitution for supplemental rebates are prohibited. The agency may seek any federal waivers to implement this initiative.

8. The agency shall expand home delivery of pharmacy products. The agency may amend the state plan and issue a procurement, as necessary, in order to implement this program. The procurements must include agreements with a pharmacy or

pharmacies located in the state to provide mail order delivery services at no cost to the recipients who elect to receive home delivery of pharmacy products. The procurement must focus on serving recipients with chronic diseases for which pharmacy expenditures represent a significant portion of Medicaid pharmacy expenditures or which impact a significant portion of the Medicaid population. The agency may seek and implement any federal waivers necessary to implement this subparagraph.

9. The agency shall limit to one dose per month any drug prescribed to treat erectile dysfunction.

10.a. The agency may implement a Medicaid behavioral drug management system. The agency may contract with a vendor that has experience in operating behavioral drug management systems to implement this program. The agency may seek federal waivers to implement this program.

b. The agency, in conjunction with the Department of Children and Families, may implement the Medicaid behavioral drug management system that is designed to improve the quality of care and behavioral health prescribing practices based on best practice guidelines, improve patient adherence to medication plans, reduce clinical risk, and lower prescribed drug costs and the rate of inappropriate spending on Medicaid behavioral drugs. The program may include the following elements:

(I) Provide for the development and adoption of best practice guidelines for behavioral health-related drugs such as antipsychotics, antidepressants, and medications for treating bipolar disorders and other behavioral conditions; translate them into practice; review behavioral health prescribers and

compare their prescribing patterns to a number of indicators that are based on national standards; and determine deviations from best practice guidelines.

(II) Implement processes for providing feedback to and educating prescribers using best practice educational materials and peer-to-peer consultation.

(III) Assess Medicaid beneficiaries who are outliers in their use of behavioral health drugs with regard to the numbers and types of drugs taken, drug dosages, combination drug therapies, and other indicators of improper use of behavioral health drugs.

(IV) Alert prescribers to patients who fail to refill prescriptions in a timely fashion, are prescribed multiple same-class behavioral health drugs, and may have other potential medication problems.

(V) Track spending trends for behavioral health drugs and deviation from best practice guidelines.

(VI) Use educational and technological approaches to promote best practices, educate consumers, and train prescribers in the use of practice guidelines.

(VII) Disseminate electronic and published materials.

(VIII) Hold statewide and regional conferences.

(IX) Implement a disease management program with a model quality-based medication component for severely mentally ill individuals and emotionally disturbed children who are high users of care.

11. The agency shall implement a Medicaid prescription drug management system.

a. The agency may contract with a vendor that has

experience in operating prescription drug management systems in order to implement this system. Any management system that is implemented in accordance with this subparagraph must rely on cooperation between physicians and pharmacists to determine appropriate practice patterns and clinical guidelines to improve the prescribing, dispensing, and use of drugs in the Medicaid program. The agency may seek federal waivers to implement this program.

b. The drug management system must be designed to improve the quality of care and prescribing practices based on best practice guidelines, improve patient adherence to medication plans, reduce clinical risk, and lower prescribed drug costs and the rate of inappropriate spending on Medicaid prescription drugs. The program must:

(I) Provide for the adoption of best practice guidelines for the prescribing and use of drugs in the Medicaid program, including translating best practice guidelines into practice; reviewing prescriber patterns and comparing them to indicators that are based on national standards and practice patterns of clinical peers in their community, statewide, and nationally; and determine deviations from best practice guidelines.

(II) Implement processes for providing feedback to and educating prescribers using best practice educational materials and peer-to-peer consultation.

(III) Assess Medicaid recipients who are outliers in their use of a single or multiple prescription drugs with regard to the numbers and types of drugs taken, drug dosages, combination drug therapies, and other indicators of improper use of prescription drugs.

(IV) Alert prescribers to recipients who fail to refill prescriptions in a timely fashion, are prescribed multiple drugs that may be redundant or contraindicated, or may have other potential medication problems.

12. The agency may contract for drug rebate administration, including, but not limited to, calculating rebate amounts, invoicing manufacturers, negotiating disputes with manufacturers, and maintaining a database of rebate collections.

13. The agency may specify the preferred daily dosing form or strength for the purpose of promoting best practices with regard to the prescribing of certain drugs as specified in the General Appropriations Act and ensuring cost-effective prescribing practices.

14. The agency may require prior authorization for Medicaid-covered prescribed drugs. The agency may prior-authorize the use of a product:

a. For an indication not approved in labeling;

b. To comply with certain clinical guidelines; or

c. If the product has the potential for overuse, misuse, or abuse.

The agency may require the prescribing professional to provide information about the rationale and supporting medical evidence for the use of a drug. The agency shall post prior authorization, step-edit criteria and protocol, and updates to the list of drugs that are subject to prior authorization on the agency's Internet website within 21 days after the prior authorization and step-edit criteria and protocol and updates are approved by the agency. For purposes of this subparagraph,

the term "step-edit" means an automatic electronic review of certain medications subject to prior authorization.

15. The agency, in conjunction with the Pharmaceutical and Therapeutics Committee, may require age-related prior authorizations for certain prescribed drugs. The agency may preauthorize the use of a drug for a recipient who may not meet the age requirement or may exceed the length of therapy for use of this product as recommended by the manufacturer and approved by the Food and Drug Administration. Prior authorization may require the prescribing professional to provide information about the rationale and supporting medical evidence for the use of a drug.

16. The agency shall implement a step-therapy prior authorization approval process for medications excluded from the preferred drug list. Medications listed on the preferred drug list must be used within the previous 12 months before the alternative medications that are not listed. The step-therapy prior authorization may require the prescriber to use the medications of a similar drug class or for a similar medical indication unless contraindicated in the Food and Drug Administration labeling. The trial period between the specified steps may vary according to the medical indication. The step-therapy approval process shall be developed in accordance with the committee as stated in s. 409.91195(7) and (8). A drug product may be approved without meeting the step-therapy prior authorization criteria if the prescribing physician provides the agency with additional written medical or clinical documentation that the product is medically necessary because:

a. There is not a drug on the preferred drug list to treat

the disease or medical condition which is an acceptable clinical alternative;

b. The alternatives have been ineffective in the treatment of the beneficiary's disease; or

c. Based on historic evidence and known characteristics of the patient and the drug, the drug is likely to be ineffective, or the number of doses have been ineffective.

The agency shall work with the physician to determine the best alternative for the patient. The agency may adopt rules waiving the requirements for written clinical documentation for specific drugs in limited clinical situations.

17. The agency shall implement a return and reuse program for drugs dispensed by pharmacies to institutional recipients, which includes payment of a $5 restocking fee for the implementation and operation of the program. The return and reuse program shall be implemented electronically and in a manner that promotes efficiency. The program must permit a pharmacy to exclude drugs from the program if it is not practical or cost-effective for the drug to be included and must provide for the return to inventory of drugs that cannot be credited or returned in a cost-effective manner. The agency shall determine if the program has reduced the amount of Medicaid prescription drugs which are destroyed on an annual basis and if there are additional ways to ensure more prescription drugs are not destroyed which could safely be reused.

Section 4. Section 456.0392, Florida Statutes, is amended to read:

456.0392 Prescription labeling.—

(1) A prescription issued ~~written~~ by a practitioner who is authorized under the laws of this state to prescribe ~~write prescriptions for~~ drugs that are not listed as controlled substances in chapter 893 but who is not eligible for a federal Drug Enforcement Administration number shall include that practitioner's name and professional license number. The pharmacist or dispensing practitioner must include the practitioner's name on the container of the drug that is dispensed. A pharmacist shall be permitted, upon verification by the prescriber, to document any information required by this section.

(2) A prescription for a drug that is not listed as a controlled substance in chapter 893 which is issued ~~written~~ by an advanced practice registered nurse licensed under s. 464.012 is presumed, subject to rebuttal, to be valid and within the parameters of the prescriptive authority delegated by a practitioner licensed under chapter 458, chapter 459, or chapter 466.

(3) A prescription for a drug that is not listed as a controlled substance in chapter 893 which is issued ~~written~~ by a physician assistant licensed under chapter 458 or chapter 459 is presumed, subject to rebuttal, to be valid and within the parameters of the prescriptive authority delegated by the physician assistant's supervising physician.

Section 5. Paragraph (d) of subsection (3) of section 458.3265, Florida Statutes, is amended to read:

458.3265 Pain-management clinics.—

(3) PHYSICIAN RESPONSIBILITIES.—These responsibilities

apply to any physician who provides professional services in a pain-management clinic that is required to be registered in subsection (1).

(d) A physician authorized to prescribe controlled substances who practices at a pain-management clinic is responsible for maintaining the control and security of his or her prescription blanks or electronic prescribing software ~~and any other method~~ used for prescribing controlled substance pain medication. A ~~The~~ physician who issues written prescriptions shall comply with the requirements for counterfeit-resistant prescription blanks in s. 893.065 and the rules adopted pursuant to that section. A ~~The~~ physician shall notify, in writing, the department within 24 hours after ~~following~~ any theft or loss of a prescription blank or breach of his or her electronic prescribing software used ~~any other method~~ for prescribing pain medication.

Section 6. Paragraph (qq) of subsection (1) of section 458.331, Florida Statutes, is amended to read:

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

(1) The following acts constitute grounds for denial of a license or disciplinary action, as specified in s. 456.072(2):

(qq) Failing to timely notify the department of the theft of prescription blanks from a pain-management clinic or a breach of a physician's electronic prescribing software ~~other methods for prescribing~~ within 24 hours as required by s. 458.3265(3).

Section 7. Paragraph (d) of subsection (3) of section 459.0137, Florida Statutes, is amended to read:

459.0137 Pain-management clinics.—

(3) PHYSICIAN RESPONSIBILITIES.—These responsibilities apply to any osteopathic physician who provides professional services in a pain-management clinic that is required to be registered in subsection (1).

(d) An osteopathic physician authorized to prescribe controlled substances who practices at a pain-management clinic is responsible for maintaining the control and security of his or her prescription blanks or electronic prescribing software ~~and any other method~~ used for prescribing controlled substance pain medication. An ~~The~~ osteopathic physician who issues written prescriptions shall comply with the requirements for counterfeit-resistant prescription blanks in s. 893.065 and the rules adopted pursuant to that section. An ~~The~~ osteopathic physician shall notify, in writing, the department within 24 hours after ~~following~~ any theft or loss of a prescription blank or breach of his or her electronic prescribing software used ~~any other method~~ for prescribing pain medication.

Section 8. Paragraph (ss) of subsection (1) of section 459.015, Florida Statutes, is amended to read:

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

(1) The following acts constitute grounds for denial of a license or disciplinary action, as specified in s. 456.072(2):

(ss) Failing to timely notify the department of the theft of prescription blanks from a pain-management clinic or a breach of an osteopathic physician's electronic prescribing software ~~other methods for prescribing~~ within 24 hours as required by s. 459.0137(3).

Section 9. This act shall take effect January 1, 2020.