PRESCRIPTION DRUG MONITORING PROGRAM
4052 BALD CYPRESS WAY, BIN #C-16
TALLAHASSEE, FLORIDA 32399-3254
(850) 245-4797

RULE HEARING

Public Agenda Materials

October 7, 2019

4042 Bald Cypress Way, Room 301
Tallahassee, FL 32399
1:00 PM

Rebecca R. Poston, BPharm, MHL, Program Manager
Linda McMullen, Esq., Assistant General Counsel

Section 120.525(2), *Florida Statutes*, requires this agenda, along with any meeting materials available in electronic form excluding confidential and exempt information, shall be published on our web site.

Ron DeSantis
Governor

Scott A. Rivkees, MD
State Surgeon General

Notice of Meeting/Workshop Hearing

DEPARTMENT OF HEALTH
Prescription Drug Monitoring Program
RULE NO.: RULE TITLE:
64K-1.001: Patient Advisory Alerts and Reports
64K-1.003: Accessing Database
64K-1.004: Management and Operation of Database
64K-1.005: Privacy of Controlled Substance Prescription Dispensing Information
64K-1.007: Indicators of Controlled Substance Abuse
64K-1.008: Electronic Health Recordkeeping System Integration
The Prescription Drug Monitoring Program announces a hearing to which all persons are invited.
DATE AND TIME: Monday, October 7, 2019; at 1:00 p.m.
PLACE: Department of Health, 4042 Bald Cypress Way, Tallahassee, FL 32311
GENERAL SUBJECT MATTER TO BE CONSIDERED: Portions of the proposed rules, including but not limited to the definition of these rules and the effect of the rules on Collective Medical's ability to operate its business.
A copy of the agenda may be obtained by contacting: Rebecca Poston, Program Manager, Prescription Drug Monitoring program, 4052 Bald Cypress Way, Bin #C-16, Tallahassee, Florida 32399 or Rebecca.Poston@FlHealth.gov.
Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least 5 days before the workshop/meeting by contacting: Rebecca Poston, Program Manager, at the contact information shown above. If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice).

AGENDA
DEPARTMENT OF HEALTH
PRESCRIPTION DRUG MONITORING PROGRAM
RULE HEARING
OCTOBER 7, 2019
1:00PM
4042 BALD CYPRESS WAY
Room 301
Tallahassee, FL 32399
(850) 245-4797
e-forcse@flhealth.gov

Program Representatives:
Rebecca R. Poston, BPharm, MHL Program Manager
Kelli Ferrell, PharmD, PhD, Senior Pharmacist
Linda McMullen, Assistant General Counsel

Call to Order and Introductions: Rebecca R. Poston, BPharm, MHL

TAB 1: Rule Hearing

Instructions- Linda McMullen, Assistant General Counsel

1. Rule 64K-1.001 Patient Advisory Alerts and Reports- Repealed
2. Rule 64K-1.003 Accessing Database
3. Rule 64K-1.004 Management and Operation of Database
4. Rule 64K-1.005 Privacy of Controlled Substance Prescription Dispensing Information
5. Rule 64K-1.007 Indicators of Controlled Substance Abuse
6. Rule 64K-1.008 Electronic Health Record System Integration

TAB 2: Written Comments

Adjourn

Note: Items shown on the agenda may be taken out of order.

Notice of Proposed Rule

DEPARTMENT OF HEALTH
Prescription Drug Monitoring Program
RULE NO.: RULE TITLE:
64K-1.001: Patient Advisory Alerts and Reports
64K-1.003: Accessing Database
64K-1.004: Management and Operation of Database
64K-1.005: Privacy of Controlled Substance Prescription Dispensing Information
64K-1.007: Indicators of Controlled Substance Abuse
64K-1.008: Electronic Health Recordkeeping System Integration
PURPOSE AND EFFECT: For rule 64K-1.001, F.A.C., to repeal references to obsolete alerts and reports; for rule 64K-1.003, F.A.C., to update forms and review procedures; for rule 64K-1.004, F.A.C., to update the required reporting time period as required by recently enacted legislation; for rule 64K-1.005, F.A.C., to repeal obsolete quarterly report requirement; for rule 64K-1.007, F.A.C., to update the schedule of controlled substances required to be reported pursuant to recently enacted legislation; and for rule 64K-1.008, F.A.C., to provide the process for approved entities to connect electronic health recordkeeping systems to the Prescription Drug Monitoring Program system as required by recently enacted legislation.
SUMMARY: Deletes references to obsolete alerts and reports; revises the time periods for reporting dispensed controlled substances; updates the controlled substance schedules subject to the reporting requirements and provides the process for electronic health recordkeeping systems to connect with the Prescription Drug Monitoring Program system as required by recently enacted legislation.
SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS AND LEGISLATIVE RATIFICATION:
The Agency has determined that this will not have an adverse impact on small business or likely increase directly or indirectly regulatory costs in excess of $200,000 in the aggregate within one year after the implementation of the rule. A SERC has not been prepared by the Agency.
The Agency has determined that the proposed rule is not expected to require legislative ratification based on the statement of estimated regulatory costs or if no SERC is required, the information expressly relied upon and described herein: Based on the SERC checklist, this rulemaking will not have an adverse impact on regulatory costs in excess of $1 million within five years as established in s.120.541(2)(a), F.S.
Any person who wishes to provide information regarding a statement of estimated regulatory costs, or provide a proposal for a lower cost regulatory alternative must do so in writing within 21 days of this notice.
RULEMAKING AUTHORITY: 893.055, F.S.
LAW IMPLEMENTED: 893.055, 893.0551 F.S.
IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE SCHEDULED AND ANNOUNCED IN THE FAR.
THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Rebecca Poston, Program Manager, Prescription Drug Monitoring program, 4052 Bald Cypress Way, Bin #C-16, Tallahassee, Florida 32399 or Rebecca.Poston@FlHealth.gov.

THE FULL TEXT OF THE PROPOSED RULE IS:

64K-1.001 Patient Advisory Alerts and Reports.

Rulemaking Authority 893.055 FS. Law Implemented 893.055 FS. History—New 11-24-11, Repealed.

64K-1.003 Accessing Database.

(1) through (2) No change.

(3)(a) Pharmacists, prescribers and dispensers licensed in Florida may directly access the information in E-FORCSE® by registering at https://florida.pmpaware.net/login. A pharmacist, prescriber or dispenser must review the "PMP AWARxE Requestor User Support Manual, Florida Prescription Drug Monitoring Program, Version 2.0" DH8009-PDMP, effective 12/2018~~7/2018~~, which is incorporated by reference and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-~~10134~~_____, prior to registering. Certification of this review is required before registration can be completed. ~~A permanent user name and password will be emailed to the successful registrant.~~ Registration denials, stating the reason for denial, will be emailed to the unsuccessful registrant.

(b) No change.

(4)(a) A designee of a prescriber or dispenser may directly access the information in E-FORCSE® by registering at https://florida.pmpaware.net/login. A designee must review the "PMP AWARxE Requestor User Support Manual" and the "Information Security and Privacy Training Course for Designees," DH8019-PDMP, effective 7/2016, incorporated by reference and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-07629 or http://www.floridahealth.gov/statistics-and-data/e-forcse/health_care_practitioners/index.html, prior to registering and complete the "Designee Certification Form" DH8026-PDMP, effective 5/2019, incorporated by reference and available at http://www.flrules.org/Gateway/reference.asp?No=Ref-XXXX. The designee must provide a printed copy of the "Designee Certification Form" to the designating prescriber or dispenser. ~~A permanent user name and password will be emailed to the successful registrant.~~ Registration denials, stating the reason for the denial, will be emailed to the unsuccessful registrant.

(b) A registered designee will not have access to E-FORCSE® until the designating prescriber or dispenser affirmatively accepts responsibility for the designee and links the designee to a pharmacy, prescriber or dispenser E-FORCSE® account as described in the "PMP AWARxE Requestor User Support Manual." The linking process will require the prescriber or dispenser to certify that the designee has reviewed the "PMP AWARxE Requestor User Support Manual" and the "Information Security and Privacy Training Course for Designees." The designating prescriber or dispenser shall maintain ~~printed~~ copies of the certification of these reviews and make them available to the program manager upon request.

(c) No change.

(5) Prescribers and dispensers and their designees employed by the United States Department of Veterans Affairs (DVA), United States Department of Defense (DOD), and the Indian Health Service (IHS) who are authorized to prescribe or dispense controlled substance and are not licensed in Florida but provide health care services to patients in this state pursuant to such employment, may directly access E-FORCSE® by registering at https://florida.pmpaware.net/login. An employee of the DVA, DOD and IHS must review the "PMP AWARxE Requestor User Support Manual" prior to registering. ~~A permanent user name will be emailed to the successful registrant.~~ Registration denials, stating the reason for the denial, will be emailed to the unsuccessful registrant.

(a) through (c) No change.

(6)(a) Law enforcement and other agencies ~~Entities~~ that do not have direct access to E-FORSCE® may request information from the program manager by having the agency head or a person appointed by the agency head for this purpose execute an "Agency User Agreement," DH8017-PDMP, effective 7/2019~~7/2015~~, incorporated by reference and available at http://www.flrules.org/Gateway/reference.asp?No=Ref-~~06462~~_____. If approved, the program manager will execute and return the agreement to the agency.

(b) After approval of the "Agency User Agreement," each agency head or person appointed by the agency head for this purpose shall appoint an agency administrator with an "Agency Administrator Appointment Form," DH8010-PDMP~~DH 8010 PDMP~~, effective 5/2019~~1/2015~~, incorporated by reference and available at

http://www.flrules.org/Gateway/reference.asp?No=Ref-~~06457~~ . ~~Approved administrators will be notified and provided instructions for appointing authorized users.~~ The agency administrator may register at https://florida.pmpaware.net/login. Prior to registration, each agency administrator must review the "PMP AWARxE Law Enforcement and Regulatory User Support Manual," DH8012-PDMP, effective 6/2019, incorporated by reference and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXX and the "Information Security and Privacy Training Course," and complete the "Authorized User Certification Form", DH8025-PDMP, effective 7/2019, incorporated by reference and available at http://www.flrules.org/Gateway/reference.asp?No=Ref-XXXX. The agency administrator shall maintain the "Authorized User Certification Form" for the duration of the appointment and make it available for examination upon request of the program manager. Upon registration, the agency administrator will upload the "Agency User Agreement" and the "Agency Administrator Appointment Form." Registration denials, stating the reason for the denial, will be emailed to the unsuccessful registrant.

(c) No change.

(d) ~~Each agency administrator may appoint authorized users to request and receive information on behalf of the agency using an "Agency Authorized User Appointment Form," DH 8015-PDMP, effective 1/2015, incorporated by reference and available at http://www.flrules.org/Gateway/reference.asp?No=Ref-06460. Prior to appointment each authorized user must review the "Training Guide for Enforcement and Investigative Agencies," DH 8012-PDMP, effective 7/2018, incorporated by reference and available at http://www.flrules.org/Gateway/reference.asp?No=Ref-10121, and the "E-FORCSE® Information Security and Privacy Training Course, effective 7/2016, incorporated by reference and available at http://www.flrules.org/Gateway/reference.asp?No=Ref-07631. Certification of these reviews is required before registration can be completed. The authorized user must provide printed copies of the certifications from both courses to the agency administrator who shall maintain them for the duration of the appointment and make them available for examination upon request of the program manager. Approved authorized users will be notified by email and provided with instructions for requesting and receiving information from E-FORCSE®.~~ A designee of an agency administrator may register at https://florida.pmpaware.net/login. A registered designee will not have access to E-FORCSE® until the agency administrator affirmatively accepts responsibility for the designee and links the designee to the agency administrator's account as described in the "PMP AWARxE Law Enforcement and Regulatory User Support Manual." The linking process will require the agency administrator to certify that the designee has reviewed the "PMP AWARxE Law Enforcement and Regulatory User Support Manual" and the "E-FORCSE® Information Security and Privacy Training Course." The designee must provide a printed copy of the "Authorized User Certification Form" to the agency administrator who shall maintain it for the duration of the appointment and make it available for examination upon request of the program manager. Registration denials, stating the reason for the denial, will be emailed to the unsuccessful registrant.

(e) An authorized law enforcement user must have actual knowledge of an active investigation as defined by section 893.055(1)(a), F.S., prior to submitting a request and is prohibited from requesting information on behalf of another law enforcement agency or entity.

(f) Each agency administrator shall immediately update user access permissions upon separation or reassignment of users and immediately update user access permissions upon discovery of negligence, improper or unauthorized use or dissemination of information and promptly notify the program manager or support staff by email ~~of authorized user changes and verify the list of authorized users on or immediately prior to June 30 of each year~~.

(g) Prior to the release of information in active investigations or pending civil or criminal litigation involving prescribed controlled substances, the Attorney General or his or her designee must upload evidence of the trial court granting the petition or motion which specifically identifies the active or pending matter leading to the discovery of admissible evidence.

(7) through (8) No change.

Rulemaking Authority, 893.055 FS. Law Implemented 893.055, 893.0551 FS. History–New 11-24-11, Amended 2-17-16, 2-14-17, 12-19-18, _____.

64K-1.004 Management and Operation of Database.

(1) All non-exempt entities that dispense controlled substances as defined in section 893.055(1)(c), F.S. ~~Schedules II – IV~~, are required to register and report to the program database. Orders for administration are exempt from reporting.

(2) Dispensers must register electronically at https://pmpclearinghouse.net/registrations/new. ~~https://flpdmp-reporting.hidinc/ using the temporary user name "newacct" and temporary password "welcome." A permanent user name and password will be provided electronically to successful registrants.~~ Prior to registration, a dispenser must review the "Data Submission Dispenser Guide, ~~Certification that the dispenser has reviewed the "Dispenser's Implementation Guide,"~~ DH8013-PDMP, effective 7/2018~~7/2015~~, incorporated by reference and available at http://www.flrules.org/Gateway/reference.asp?No=Ref-~~06459~~, ~~is required~~ before registration can be completed.

(3) All dispensers shall electronically report dispensing information to E-FORCSE® ~~the program's database~~ as soon as possible, but no later than the close of the next business day ~~not more than 7 days~~ after the day the controlled substance is dispensed. Extensions of time to report the dispensing of a controlled substance may be granted for no more than 30 days upon request to the program by any dispenser unable to submit data by electronic means if the dispenser provides evidence of having suffered a mechanical or electronic failure or cannot report for reasons beyond the control of the dispenser or if E-FORCSE® ~~the database~~ is unable to receive submissions. A dispenser that has no dispensing transactions to report for the preceding business ~~seven~~ day ~~period~~ must submit a zero activity report as described in the "Data Submission Dispenser Guide ~~"Dispenser's Implementation Guide~~."

(4) Dispensing information with errors or omissions shall be corrected and resubmitted to E-FORCSE® ~~the database~~ by the reporting dispenser within one ~~seven~~ business day ~~days~~ of receiving electronic or written notice from the program manager or support staff of the error or omission.

(5) The program will file a complaint with the Department and refer to law enforcement any failure to report the dispensing of ~~Schedules II – IV~~ controlled substances as defined in section 893.055(1)(c), F.S.

(6) Pharmacies and registered dispensing practitioners that do not dispense controlled substances in or into this state must submit a "Notification of Exemption From Reporting," DH8016-PDMP, effective 7/2018~~(effective 7/2015)~~, incorporated by reference and available at http://www.flrules.org/Gateway/reference.asp?No=Ref-~~06461~~ or https://forms.office.com/Pages/ResponsePage.aspx?id=gI_NKEQ8J0uBoM0rA6MbjTnNU-2qGcdHpmNOMX7FE7hUNloxQ01PWEkwWUFESEZBNFRWU1FXV1lPNyQlQCN0PWcu. Exemptions must be renewed on or before February 28 in odd years by making the appropriate election on the biennial pharmacy permit renewal form or on "Renewal of Notification of Exemption from Reporting Form," DH8018-PDMP, effective 7/2018~~(effective 7/2015)~~, incorporated by reference and available at http://www.flrules.org/Gateway/reference.asp?No=Ref-~~06463~~ or https://forms.office.com/Pages/ResponsePage.aspx?id=gI_NKEQ8J0uBoM0rA6MbjTnNU-2qGcdHpmNOMX7FE7hURUg0TVBWRkFUWEEyUUlXRkpGUDZWRzhaTyQlQCN0PWcu . Pharmacies and registered dispensing practitioners seeking to begin dispensing controlled substances must notify the program electronically and be removed from the exempt list ~~prior to registering to report to the program database~~.

(7)(a) A patient, health care provider, prescriber, or dispenser may submit an electronic request to the program manager for the correction of erroneous information in E-FORCSE® ~~the database~~. The request shall include:

1. A statement explaining in detail the error and the basis for the requested correction,
2. The precise change requested,
3. Documentation establishing the correct information,
4. The requester's name, address, telephone number, and license number if licensed as a health care provider in Florida.

(b) The program manager or support staff will review all requests to correct information and will request the reporting dispenser ~~reporting the incorrect information~~ to correct identified errors. No correction will be made if no error is found. The program will notify the entity or person requesting the correction of the results of the review.

(8) Information reported to E-FORCSE® will be available for access ~~maintained in the database~~ for a period of 2 years from the date the prescription was dispensed.

~~(9) Information submitted to the database by dispensers directly dispensing a controlled substance shall include~~

~~the telephone number of the person for whom the prescription was written.~~

Rulemaking Authority 893.055 FS. Law Implemented 893.055 FS. History–New 11-24-11, Amended 2-17-16, 1-12-17, _____.

64K-1.005 Privacy of Controlled Substance Prescription Dispensing Information.

(1) through (7) No change.

~~(8) Agency administrators shall provide a quarterly report to the program manager with the status of each active investigation case which has required program database access. The report shall include, at a minimum, whether the case is active or inactive and the disposition, if applicable.~~

Rulemaking Authority 893.055 FS. Law Implemented 893.055, 893.0551 FS. History–New 11-24-11, Amended 2-17-16, _____.

64K-1.007 Indicators of Controlled Substance Abuse.

(1) The following behavior indicates controlled substance abuse:

A patient who within a 90-day time period: (1) obtains a prescription for a controlled substance ~~in Schedules II, III, or IV,~~ as defined in section 893.055(1)(c) ~~893.03~~, F.S., from more than one prescriber; and (2) is dispensed a controlled substance ~~in Schedules II, III, or IV,~~ as defined in section 893.055(1)(c)~~893.03~~, F.S., from five or more pharmacies.

(2) No change.

Rulemaking Authority 893.055 FS. Law Implemented 893.055(2) FS. History–New 5-21-12, Amended _____.

64K-1.008 Electronic Health Recordkeeping System Integration

(1) Definitions.

(a) "Approved entity" means an eligible entity that has been approved by the department to connect an electronic health recordkeeping system directly to E-FORCSE®, the prescription drug monitoring data system.

(b) "Authorized user" means a health care practitioner as defined in section 893.055(f), F.S., or his or her designee.

(c) "Electronic health record" is an electronic or digital version of a patient's medical history, maintained over time and may include all of the key administrative clinical data relevant to that person's medical care under a particular provider, including demographics, progress notes, problems, medications, vital signs, past medical history, immunizations, laboratory data and radiology reports. The electronic health record uses computer hardware and software for the storage, retrieval, sharing and use of health care information and data. The electronic health record must provide audit trail information at the time of the request, including but not limited to facility name; facility identification type; facility identification; facility state; requester first name; requester last name; requester role; requester identification type; requester identification; request date and time; request type; PDMP disclosure identification; patient last name; patient first name; and patient date of birth.

(d) "Eligible entity" means an organization or entity that operates, provides, or makes available an electronic health recordkeeping system to a health care practitioner or a designee of the practitioner.

(2) An eligible entity may apply to the department to request and receive information directly from E-FORCSE® through an electronic health recordkeeping system by completing an "Integration Request Form," DH8024-PDMP, effective 7/2018, incorporated by reference and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXX or http://www.floridahealth.gov/statistics-and-data/e-forcse/EHR_Integration/index.html, and submitting the form to the department.

(3) Eligible entities and authorized users may retain patient prescription monitoring information in the electronic health recordkeeping system and must ensure that the confidential and exemption information is not inadvertently released or accessed by unauthorized persons or entities.

(4) Only individuals authorized by sections 893.055 and 893.0551, F.S., who are active registered E-FORCSE® users are authorized to request and receive information directly from E-FORCSE® through an electronic health record.

(5) Pursuant to Section 893.055(8), F.S., prescribers and dispensers are required to consult the E-FORCSE® database to review a patient's controlled substance dispensing history prior to prescribing or dispensing a controlled

substance to that patient. Review of summary information provided through an electronic health recordkeeping system integration does not meet this requirement.

(6) The department may suspend or revoke integration approval if an eligible entity or authorized user does not adhere to the department's terms and conditions, including security and privacy requirements. The department will immediately notify the approved entity or authorized user upon suspension or revocation of approval.

Rulemaking Authority, 893.055 FS. Law Implemented 893.055(7) FS. History–New .

NAME OF PERSON ORIGINATING PROPOSED RULE: Rebecca Poston, Program Manager, Prescription Drug Monitoring Program

NAME OF AGENCY HEAD WHO APPROVED THE PROPOSED RULE: Scott A. Rivkees, MD, Surgeon General and Secretary

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: August 20, 2019

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAR: June 20, 2019

FOLEY
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CLIENT/MATTER NUMBER
111586-0103

September 17, 2019

VIA EMAIL
Ms. Linda McMullen
Florida Department of Health
4052 Bald Cypress Way
Tallahassee, FL 32399
Linda.Mcmullen@flhealth.gov

Re: Request for Public Hearing on Notice of Proposed Rule
Prescription Drug Monitoring Program

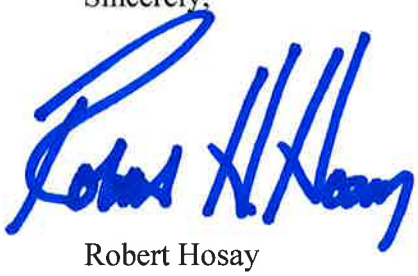
Dear Ms. McMullen,

Foley & Lardner LLP represents Collective Medical in connection with the Department of Health's Notice of Proposed Rule for the Prescription Drug Monitoring Program. Collective Medical operates a real-time care collaboration network that collects data about patients to seamlessly connect each member of the patient's care team together for effective collaboration. Collective Medical has concerns with portions of the proposed rules, including but not limited to the definitions, and their effect on Collective Medical's ability to operate its business. Pursuant to section 120.54(3)(c)1, Florida Statutes, and the Notice of Proposed Rule, Collective Medical submits this letter as a request for a public hearing.

Section 120.54(3)(c)1, Florida Statutes, provides that an affected person may request a public hearing on a proposed rule within 21 days after the date of publication of the notice of intended agency action. Upon receipt of the request, the agency shall schedule a public hearing on the rule. § 120.54(3)(c)1, Fla. Stat. To operate Collective Medical's collaboration network it must be able to connect electronic health recordkeeping systems to the Prescription Drug Monitoring Program system. Accordingly, the proposed rules will impact Collective Medical's ability to operate its network. Collective Medical is an "affected person" for the purposes of requesting a hearing.

Thank you for your help in this regard. We look forward to working with the Department on the proposed rules for the Prescription Drug Monitoring Program.

Sincerely,



Robert Hosay

Cc: Ms. Rebecca Poston
Program Manager
4052 Bald Cypress Way, Bin C-16
Tallahassee, FL 32399
Rebecca.Poston@FlHealth.gov