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

## RULE HEARING

## Public Agenda Materials

## August 23, 2018

## 4042 Bald Cypress Way
## Room 301
## Tallahassee, FL 32399
## 1:00 PM to 5:00 PM

## Rebecca R. Poston, BPharm, MHL, Program Manager

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.

**Rick Scott**
**Governor**

**Celeste Philip, MD, MPH**
**Surgeon General and Secretary**

**AGENDA**
**DEPARTMENT OF HEALTH**
**PRESCRIPTION DRUG MONITORING PROGRAM**
**RULE HEARING**
**AUGUST 23, 2018**
**1:00PM to 5:00PM**

**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
Linda McMullen, Assistant General Counsel

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**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 Rule 64K-1.001 Patient Advisory Alerts and Reports- Repealed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-1.002 American Society for Automation in Pharmacy Standards and Formats
3. Rule 64K-1.003 Accessing Database
4. Rule 64K-1.004 Management and Operation of Database
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 Development of Rulemaking

**DEPARTMENT OF HEALTH**
**Prescription Drug Monitoring Program**
RULE NO.: RULE TITLE:
64K-1.001: Patient Advisory Alerts and Reports
64K-1.002: American Society of Automation in Pharmacy Standards and Formats
64K-1.003: Accessing Database
64K-1.004: Management and Operation of Database
64K-1.007: Indicators of Controlled Substance Abuse
64K-1.008: Electronic Health Recordkeeping System Integration
PURPOSE AND EFFECT: For rules 64K-1.001, .002, .003, .004 and .007, F.A.C., to provide for revising the requirements for reporting dispensing of controlled substances, to allow employees of the U.S. Department of Veterans Affairs, U.S. Department of Defense, and Indian Health Services to access certain information pursuant to recently enacted legislation. 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.
SUBJECT AREA TO BE ADDRESSED: For rules 64K-1.001, .002, .003, .004 and .007, F.A.C., reporting and query requirements for dispensers and prescribers of controlled substances and access to certain information by employees of the U.S. Department of Veterans Affairs, U.S. Department of Defense, and Indian Health Services pursuant to recently enacted legislation. For rule 64K-1.008, F.A.C., electronic health recordkeeping system connections.
RULEMAKING AUTHORITY: 893.055, F.S.
LAW IMPLEMENTED: 893.055, F.S., 893.0551, F.S.
IF REQUESTED IN WRITING AND NOT DEEMED UNNECESSARY BY THE AGENCY HEAD, A RULE DEVELOPMENT WORKSHOP WILL BE NOTICED IN THE NEXT AVAILABLE FLORIDA ADMINISTRATIVE REGISTER.
THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE DEVELOPMENT AND A COPY OF THE PRELIMINARY DRAFT, IF AVAILABLE, 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 PRELIMINARY TEXT OF THE PROPOSED RULE DEVELOPMENT IS NOT AVAILABLE.

Notice of Proposed Rule

**DEPARTMENT OF HEALTH**
**Prescription Drug Monitoring Program**

| RULE NO.: | RULE TITLE: |
|---|---|
| 64K-1.001 | Patient Advisory Alerts and Reports |
| 64K-1.002 | American Society of Automation in Pharmacy Standards and Formats |
| 64K-1.003 | Accessing Database |
| 64K-1.004 | Management and Operation of Database |
| 64K-1.007 | Indicators of Controlled Substance Abuse |
| 64K-1.008 | Electronic Health Recordkeeping System Integration |

PURPOSE AND EFFECT: For rules 64K-1.001, .002, .003, .004 and .007, F.A.C., to provide for revising the requirements for reporting dispensing of controlled substances, to allow employees of the U.S. Department of Veterans Affairs, U. S. Department of Defense, and Indian Health Services to access certain information pursuant to recently enacted legislation. For rules 64K-1.007 and .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: For rules 64K-1.001, .002, .003, .004 and .007, F.A.C., reporting and query requirements for dispensers and prescribers of controlled substances and access to certain information by employees of the U.S. Department of Veterans Affairs, U.S. Department of Defense, and Indian Health Services pursuant to recently enacted legislation. For rule 64K-1.007 and .008, F.A.C., electronic health recordkeeping system connections 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, FS.

LAW IMPLEMENTED: 893.055, 893.0551, FS.

A HEARING WILL BE HELD AT THE DATE, TIME AND PLACE SHOWN BELOW:

DATE AND TIME: Thursday, August 23, 2018, 1:00 p.m. to 5:00 p.m.

PLACE: Florida Department of Health, 4042 Bald Cypress Way, Room 301, Tallahassee, FL 32311

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-1.002 American Society for Automation in Pharmacy Standards and Formats.

The format for submission to the E-FORCSE® database shall be in accordance with the electronic reporting standards of the American Society for Automation in Pharmacy (ASAP) contained in the "Implementation Guide ASAP Standard for Prescription Monitoring Programs Version 4, Release 2A ~~2,~~" (10/2016) ~~(9/2011)~~, incorporated by reference. E-FORCSE® ~~The PDMP~~ will continue to accept reports in the ASAP 2011 ~~2009~~ version 4.2 ~~4.1~~

standard for one year from the effective date of this rule (to be determined ~~October 21, 2015~~), after which all reports must be made using the ASAP 2016 version 4.2A ~~2011 version 4.2~~ standard. The format for submission to the E-FORCSE® database if no controlled substances are dispensed shall be in accordance with the incorporated by reference ASAP Error and Zero Report Standard (10/2016 ~~9/2011~~). The agency has determined that posting the incorporated materials would be a violation of federal copyright law. The materials are available for public inspection at the Department of Health, 4052 Bald Cypress Way, Tallahassee, FL 32399, and the Department of State, R.A. Gray Building, 500 South Bronough Street, Tallahassee, FL 32399. A copy of the e~~E~~lectronic r~~R~~eporting Standard for Prescription Drug Monitoring Programs may be obtained from the American Society for Automation in Pharmacy, 492 Norristown Road, Suite 160, Blue Bell, Pennsylvania 19422, Telephone: (610)825-7783, Website: www.asapnet.org.

Rulemaking Authority 893.055 FS. Law Implemented 893.055 FS. History–New 2-20-12, Amended 10-21-15, _____.

64K-1.003 Accessing Database.

(1) Definitions:

(a) "Designee" means a person, preferably a licensed or certified health care professional, appointed to act as an agent of a prescriber or dispenser for the purposes of requesting or receiving information from the Prescription Drug Monitoring Program database, E-FORCSE®.

(b) "E-FORCSE®" is the comprehensive electronic database system established by the Department of Health that has controlled substance prescribing and dispensing information reported to it and that provides the information to persons and entities allowed by law to access, request and receive this information.

(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.

(d)~~(b)~~ "Impaired practitioner consultant" means an ~~approved~~ impaired practitioner program designated by the department through contract with a consultant to evaluate, refer and monitor impaired practitioners. The department has designated the Intervention Project for Nurses (IPN) and Professionals Resource Network (PRN) as the Approved Impaired Practitioner Programs.

(e) "Order" means a written, transmitted or oral direction from a prescriber for a controlled substance to be administered to a patient in an inpatient setting.

(f) "Prescribe" means the act of a prescriber issuing, writing or transmitting a direction to a pharmacist to dispense a specified controlled substance to a specified patient.

(2) Pharmacists, prescribers and dispensers, or their designees, are required to access and consult E-FORCSE® to review a patient's controlled substance dispensing history each time a controlled substance, other than a nonopioid drug listed on Schedule V, is prescribed or dispensed, but not ordered, for a patient age 16 or older unless a statutory exception applies.

(3)~~(2)~~(a) Pharmacists, prescribers and dispensers licensed in Florida may directly access the information in E-FORCSE® ~~the program database~~ by registering ~~on the E-FORCSE® secure web portal~~ at https://florida.pmpaware.net/login ~~https://flpdmp-phreg.hidinc.com using the temporary user name "newacct" and temporary password "welcome." A written request may be submitted to the program manager if information must be received by alternate means~~. A pharmacist, prescriber or dispenser must review the "PMP AWARxE User Support Manual ~~Training Guide for Florida Practitioners and Pharmacists~~," DH8009-PDMP, effective 7/2018 ~~7/2016~~, which is incorporated by reference and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-_____~~07628~~, 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) A prescriber or dispenser may request and receive information from E-FORCSE® ~~the database~~ using a secure recordkeeping system integration ~~web service~~ associated with his or her electronic health record ~~The web service shall transmit the authorized user's login credentials and query parameters to E-FORCSE® for authentication~~. If the user is authenticated, E-FORCSE® will return query results to the ~~authorized user through the~~

~~web service~~ ~~for display only viewing within the~~ authorized user's electronic health record.

(4)~~(3)~~(a) A designee of a prescriber or dispenser may directly access the information in E-FORCSE® ~~the program database~~ by registering ~~on the E-FORCSE® secure web portal~~ at https://florida.pmpaware.net/login ~~https://flpdmp-phreg.hidinc.com using the temporary user name "newacct" and temporary password "welcome."~~ ~~A written request may be submitted to the program manager if information must be received by alternate means~~. A designee must review the "PMP AWARxE User Support Manual ~~Training Guide for Florida Practitioners and Pharmacists~~" 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, prior to registering. 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® ~~the database~~ 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 User Support Manual ~~Training Guide for Florida Practitioners and Pharmacists~~." The linking process will require the prescriber or dispenser to certify that the designee has reviewed the "PMP AWARxE User Support Manual ~~Training Guide for Florida Practitioners and Pharmacists~~" 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) Registered designees who do not access ~~the~~ E-FORCSE® ~~database~~ for a period in excess of six months will be deactivated. Deactivated designees may reapply for access.

(5)~~(4)~~ 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 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) A registered employee of the DVA, DOD, and IHS will not have access to E-FORCSE® until his or her employment is verified.

(b) Direct access to the information in E-FORCSE® is limited to the information that relates to a patient of such employee and may be accessed only for the purpose of reviewing that patient's controlled substance prescription history.

(c) A prescriber or dispenser or designee employed by the DVA, DOD or IHS that is an authorized E-FORCSE user must notify E-FORSCE within 30 days of termination of employment.

(6)(a) Entities that do not have direct access to E-FORCSE® ~~the database~~ 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 7/2015, incorporated ~~herein~~ by reference and available at https://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," DH 8010-PDMP, effective 1/2015, incorporated by reference and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-06457. Approved administrators will be notified and provided instructions for appointing authorized users.

(c) Each agency head or person appointed by the agency head for this purpose shall immediately notify the program manager or support staff of a change in the agency administrator. Authority to request and receive information from ~~the~~ E-FORCSE® ~~database~~ shall be suspended during an agency administrator vacancy.

(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 https://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 ~~6/2016~~, incorporated by reference and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-_____~~07630~~, and the "E-FORCSE® Information Security and Privacy Training Course," effective 7/2016, incorporated by reference and available at https://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 ~~through the secure~~ E-FORCSE® ~~web portal~~.

(e) An authorized user must have actual knowledge of an active investigation as defined by section 893.055(1)(a ~~h~~), 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 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.

(7)~~(5)~~(a) Impaired practitioner consultants do not have direct access to E-FORCSE® ~~the information in the database~~ but may request and review information relating to persons referred to or participating in the approved impaired practitioner programs ~~from the program manager~~ by having the Medical Director or Executive Director of the ~~approved~~ impaired practitioner program execute an "Impaired Practitioner Consultant User Agreement," DH8020-PDMP, effective 7/2016, incorporated by reference and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-07632. If approved, the program manager will execute and return the agreement to the Medical Director or Executive Director of the ~~approved~~ impaired practitioner program.

(b) The impaired practitioner consultant shall immediately notify the program manager or support staff of a change of Medical Director or Executive Director. Authority to request and receive information from ~~the~~ E-FORCSE® ~~database~~ shall be suspended while the position of Medical Director or Executive Director is vacant.

(c) Upon approval of the impaired practitioner consultant user agreement, the Medical Director or Executive Director of the approved practitioner program may appoint up to three (3) authorized users who are employees of the ~~approved~~ impaired practitioner consultant to request and receive information on behalf of the ~~approved~~ impaired practitioner program using an "Impaired Practitioner Program Authorized User Appointment Form," DH8022-PDMP, effective 7/2016, incorporated by reference and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-07633. Prior to appointment, each authorized user must review the "Training Guide for Impaired Practitioner Consultants," DH8021-PDMP, effective 7/2018 ~~7/2016~~, incorporated by reference and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-_____~~07634~~. Certification of this review is required before registration can be completed. The authorized user must provide a printed copy of this certification to the Medical Director or Executive Director of the ~~approved~~ impaired practitioner program 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 ~~through the secure~~ E-FORCSE® ~~web portal~~. Registration denials, stating the reason for the denial, will be emailed to the Medical Director or Executive Director.

(d) The Medical Director or Executive Director of the ~~approved~~ impaired practitioner consultant shall immediately 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.

(e) The person referred to or participating in the ~~approved~~ impaired practitioner program must provide written authorization for the ~~approved~~ impaired practitioner consultant to request and review ~~any~~ information from E-FORCSE® relating to that person. The referred or participating person shall use the "Authorization for Impaired Practitioner Consultant Access," Form DH8023-PDMP, effective 7/2016, incorporated by reference and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-07635, to provide this authorization. The impaired practitioner consultant or authorized user must upload the executed authorization form with the request for information from ~~the~~ E-FORCSE® ~~database~~ relating to the referred or participating person. Each access for a referred person requires a new authorization form. Authorizations for impaired practitioner program participants can be in effect no longer than the duration of the monitoring contract with the impaired practitioner program. If approved, the program manager will return the information on the referred or participating person from E-FORCSE®

to the impaired practitioner consultant or authorized user ~~through the secure E-FORCSE® web portal~~. If denied, the program manager will notify the impaired practitioner consultant or authorized user with the reason for the denial.

(f) Impaired practitioner program consultants and authorized users may only query information relating to the referred or participating person who has given authorization to access the information, and not any prescriber or dispenser. An impaired practitioner program consultant may make a notation of the query in the impaired practitioner program file.

(g) Information in ~~the~~ E-FORCSE® ~~database~~ relating to referred and participating persons accessed by impaired practitioner consultants and authorized users is confidential and exempt and shall not be disclosed or transmitted to any other person, program or entity, including the Department. To prevent inadvertent disclosure, the information should not be included in the referred or participating person's impaired practitioner program file, downloaded or printed.

(8)~~(6)~~ A patient or the legal guardian or designated health care surrogate of an incapacitated patient may request information from E-FORCSE® ~~the program database~~ to verify the accuracy of the ~~database~~ information by contacting the Prescription Drug Monitoring Program by mail at 4052 Bald Cypress Way, Bin #C-16, Tallahassee, FL 32399-3254, or by telephone at (850)245-4797 and submitting~~. Requesters must complete~~ form DH 2143, "Patient Information Request," effective 7/2018 ~~6/2016~~, incorporated by reference and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-_____07636. ~~The patient or other authorized person must make an appointment, appear in person at the program or department field office, and produce a valid government-issued identification, which includes a photograph, to review the requested information.~~

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

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 https://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 after the day the controlled substance ~~not more than 7 days after 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 day ~~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 ~~7/2015~~), incorporated by reference and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-_____06461. 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 ~~7/2015~~), incorporated by reference and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-_____ ~~06463~~. 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 ~~maintained in the database~~ available for access 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-1.007 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) Upon identifying a patient who exhibits or for whom the behavior outlined in subsection (1), has been exhibited, the Program Manager may provide relevant information to the identified health care practitioners who have prescribed or dispensed controlled substances to the identified patient within the 90-day period.

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

64K-1.008 Electronic Health Record System Integration

(1) Definitions.

(a) "Approved entity" means an eligible entity that has been approved by the department to connect an electronic health record 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.

(d) "Eligible entity" means an organization or entity that operates or provides or makes available an electronic health record 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 record system by completing the following steps:

(a) Complete an Integration Request Form, DH8024-PDMP, effective 7/2018, incorporated by reference and available at http://www.flrules.org/Gateway/reference.asp?No=Ref-####.

(b) Submit the Integration Request Form to the department.

(3) The department will review the submitted form and notify each applicant by email if the request to integrate

is approved or denied.

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

(5) 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.

(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: Celeste Philip, MD, MPH, Surgeon General and Secretary

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: July 31, 2018

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAR: June 21, 2018

Written Comments

Tab 1:

Rule 64K-1.002 American Society of Automation in Pharmacy Standards and Formats

- Publix- Jillanne Smith
- Publix- Adam Maingot

Rule 64K-1.003, Accessing Database

- Joseph Shega
  Vitas Healthcare
- Allen Grossman, JD
  Grossman Furlow and Bayó, LLC
- Joshua Lenchus, DO, RPh, FACP, SFHM
  President, Florida Osteopathic Medical Association

## Poston, Rebecca

**From:** zzzz Feedback, MQA_E-Forcse
**Sent:** Monday, July 2, 2018 3:46 PM
**To:** 'Jillanne Smith'; zzzz Feedback, MQA_E-Forcse
**Subject:** RE: Publix - confirmation/affirmation of interpretation

**Tracking:**

| Recipient | Read |
|---|---|
| 'Jillanne Smith' | |
| zzzz Feedback, MQA_E-Forcse | Read: 7/3/2018 8:14 AM |

Thank you for your email. Effective July 1, 2018, there are four new reporting elements: telephone number, number of refills authorized, identification of the person picking up the prescription, and the permit/license number of the pharmacy/dispenser.
The first two reporting elements may be reported using the current reporting standard. The remaining elements cannot be reported in the current standard. We are in the process of rulemaking to adopt the ASAP 4.2a standard to allow this reporting to occur and anticipate that the rule will take effect sometime in August. Dispensers will have 1 year from the effective date to begin reporting these new elements in the new standard.

Section 893.055(3)(a)7. Florida Statutes requires the pharmacy to report the name of the individual picking up the controlled substance prescription and type and issuer of the identification provided.

The PMP Clearinghouse Data Submitter Guide is available at http://www.floridahealth.gov/statistics-and-data/e-forcse/dispenser/index.html and the ASAP 4.2A requirements are available at wal@computertalk.com or www.ASAPnet.org.

Thanks,
Becki

Rebecca R. Poston, BPharm, MHL | Program Manager | E-FORCSE Florida's Prescription Drug Monitoring Program | 4052 Bald Cypress Way, Bin C-16 Tallahassee, FL 32399 | Office: 850-245-4797 | Fax: 850-617-6430 | website: www.e-forcse.com
Mission: To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.
Vision: To be the Healthiest State in the Nation

Values: I CARE
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Collaboration: We use teamwork to achieve common goals and solve problems.
Accountability: We perform with integrity and respect.
Responsiveness: We achieve our mission by serving our customers and engaging our partners.
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Please note:
Florida has a very broad public records law. Most written communications to or from state officials regarding state business are public records available to the public and media upon request. Your e-mail communications may therefore be subject to public disclosure.

**From:** Jillanne Smith [mailto:Jillanne.Smith@publix.com]
**Sent:** Monday, July 2, 2018 12:32 PM
**To:** zzzz Feedback, MQA_E-Forcse <MQA.E-Forcse@flhealth.gov>
**Subject:** Publix - confirmation/affirmation of interpretation

Becki,

Good morning! I know you are very busy with the new opioid law going into effect over the weekend. I just wanted to take a minute to thank you for all the information you have made available to us via the Take Control website – it was very helpful in our design of processes and procedures to ensure compliance at Publix. I also wanted to take a minute to share with you one topic that we continue to discuss internally regarding interpretation of this law, especially as you work toward publishing PDMP rules in the future.

Certain provisions governing pharmacists' duty to verify the identity of pick-up persons were relocated and now reside in the Pharmacy Practice Act, Florida Statutes Chapter 465, while others remain in Chapter 893 alongside amended PDMP reporting obligations. The latter reporting obligations now include, for the first time, reporting of information identifying pick-up persons. We understand that the relocation of the duty to verify identity at pick-up was not intended to change the scope of that obligation as the language didn't change. We also understand the same for mail delivered prescriptions under Chapter 893, as there was no change to this section. We are further assuming the PDMP rules under development will retain the flexibility/scope of the transferred section (from 863 to 465) which allows a pharmacist to rely on an alternative to photographic identification for verification purposes, or otherwise not to verify or collect verification information when the statute allows.

With this in mind, we are assuming the PDMP system (and related rules) accommodate situations where identity verification is permissibly accomplished via an alternative to the pick-up person's photographic identification, or permissibly not performed. By way of example, the PDMP could include among the menu of options for reporting pick-up person identity: "pick-up person known to pharmacist", "verification by health plan via real-time patient eligibility confirmation" and/or "prescription dispensed for patient in an institutional setting".

I'm unsure if you have received any feedback on these particular sections of the law. We do want to ensure proper interpretation and compliance and are hopeful that you'd take a look at this and comment, or we could discuss further at your convenience. Again, I know you are busy at this time, but I did think it was important to share with you this piece of information regarding our interpretation.

Thank you!!
*Jillanne Smith*
Publix Super Markets, Inc.
Pharmacy, Manager of Recruiting, Training, & Compliance
Phone: (863) 688-1188 Ext. 58004
Fax: (863) 284-3322
Email: <Jillanne.Smith@publix.com>

**From:** Poston, Rebecca
**Sent:** Thursday, July 5, 2018 8:23 AM
**To:** McMullen, Linda N
**Subject:** Fwd: HB21 follow up.

Please see comments below.

Get Outlook for iOS

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**From:** Gee, Lucy
**Sent:** Thursday, July 5, 2018 7:18:34 AM
**To:** Poston, Rebecca
**Subject:** FW: HB21 follow up.

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**From:** Whitten, Mark
**Sent:** Tuesday, July 3, 2018 7:12 PM
**To:** Gee, Lucy <Lucy.Gee@flhealth.gov>
**Subject:** Fwd: HB21 follow up.

See you Thursday. Message from Publix below.

Sent from my iPhone

Begin forwarded message:

> **From:** Adam Maingot <Adam.Maingot@publix.com>
> **Date:** July 3, 2018 at 6:09:50 PM EDT
> **To:** "'Mark.Whitten@flhealth.gov'" <Mark.Whitten@flhealth.gov>
> **Cc:** William Hammond <William.Hammond@publix.com>, Melynda Heidle <Melynda.Heidle@publix.com>
> **Subject: HB21 follow up.**
>
> Mark,
>
> Great to speak with you this morning. The Department's updated FAQ has been distributed to all Publix pharmacies throughout Florida. The FAQ provided needed clarity to ensure patient access to medications. Thank you!
>
> On a separate but related note, please let me know how Publix may work with the Department (e.g., comments to proposed rules, etc.) to ensure that the upcoming EFORCSE rules do not inadvertently prevent patients from receiving medications when the patient (or patient's agent) does not possess identification when picking up the prescription.
>
> I believe that EFORCSE leadership may be reading a new unintended requirement into Section 893.055(3)(a)(7) compelling every pharmacy to obtain and report the type and issuer of the identification of any

individual that picks up a controlled substance prescription from the pharmacy (regardless of whether the pharmacy is permitted to rely on the pharmacist's knowledge of the patient/agent picking up the medication or the prescriber or health plan validation as referenced in Section 10 of the FAQ). Note that fields AIR03 (Issuing Jurisdiction) and AIR04 (ID Qualifier of Person Dropping Off or Picking Up Rx) contained within page 53 of the EFORCSE Data Submission Dispenser Guide v1.1 (Eff. April 18, 2018) are marked "S" situational, but are not structured to capture *known to pharmacist*, *verified with prescriber*, or *verified with health plan*. It is possible that these validation options fit within AIR04 field as "99 Other (agreed upon ID)", but the industry needs clarity on this point.

Additional analysis / support follows:

Prior to enactment of Florida CS/CS/HB 21, Florida Statutes Chapter 893 governed pharmacists' duties both to: (a) verify the identity of pick-up persons, and (b) report controlled substance dispensing to the PDMP. As a result of Florida CS/CS/HB 21, effective July 1, 2018, certain provisions governing pharmacists' duty to verify the identity of pick-up persons were relocated and now reside in the Pharmacy Practice Act, Florida Statutes Chapter 465, while others remain in Chapter 893 alongside amended PDMP reporting obligations. The latter reporting obligations now include, for the first time, reporting of information identifying "pick-up" persons.

## I. **Pick-up Person Verification Requirements are Unchanged by CS/CS/HB 21**

Both before and after CS/CS/HB 21 takes effect, only when the pick-up person is not known to the pharmacist is the pharmacist obligated to verify the identity of the pick-up person via photographic identification or other appropriate verification. Other appropriate verification includes verification by health plan eligibility confirmation via a health plan's real-time inquiry or adjudication system. Importantly, if the pick-up person does not have identification, the pharmacist may validate the prescription and identity of the patient with the prescriber/prescriber's agent in lieu of verifying the identity of the pick-up person.[[1] Compare Florida Statutes, Section 893.055(14) (2017) with Florida Statutes, Section 465.0155(2)(a) (effective July 1, 2018).1] The verification obligation does not apply when pharmacists dispense for a patient in an institutional setting (including a hospital patient).[[2] Compare Florida Statutes, Section 893.055(14) (2017) with Florida Statutes, Section 465.0155(2)(b) (effective July 1, 2018).2] Lastly, both before and after CS/CS/HB 21 takes effect, pharmacists are not required to verify identity through proper identification when mailing a controlled substance listed in Schedule II, Schedule III, or Schedule IV if the pharmacist verified the patient's identification through the patient's prescription benefit plan via health plan eligibility confirmation.[[3] See Florida Statutes, Section 893.04(2)(b).3]

## II. PDMP Reporting Requirements Relating to Pick-up Person

### A. Prior to Effective Date of CS/CS/HB 21.

Prior to enactment of CS/CS/HB 21, PDMP reporting requirements did not impose an obligation on pharmacists to report to the PDMP any information relating to the pick-up person.[[4] See Florida Statutes, Section 893.055(3) (2017).4] Then, as we believe remains true after July 1, 2018, the legislature's intent was (and is) to limit reporting to information pharmacists necessarily collected as part of the dispensing process, including:

(a) The name of the prescribing practitioner, the practitioner's federal Drug Enforcement Administration registration number, the practitioner's National Provider Identification (NPI) or other appropriate identifier, and the date of the prescription.
(b) The date the prescription was filled and the method of payment, such as cash by an individual, insurance coverage through a third party, or Medicaid payment. This paragraph does not authorize the department to include individual credit card numbers or other account numbers in the database.
(c) The full name, address, and date of birth of the person for whom the prescription was written.
(d) The name, national drug code, quantity, and strength of the controlled substance dispensed.
(e) The full name, federal Drug Enforcement Administration registration number, and address of the pharmacy or other location from which the controlled substance was dispensed. If the controlled substance was dispensed by a practitioner other than a pharmacist, the practitioner's full name, federal Drug Enforcement Administration registration number, and address.
(f) The name of the pharmacy or practitioner, other than a pharmacist, dispensing the controlled substance and the practitioner's National Provider Identification (NPI).
(g) Other appropriate identifying information as determined by department rule.[[5] *Id.*5]

Importantly, each of the above required data elements is obtained as part of ordinary prescription intake, dispensing, and billing processes, and reporting these to the PDMP does not conflict with any other statutory obligation governing the scope of a pharmacist's responsibilities.

### B. After the Effective Date of CS/CS/HB 21

As a result of changes implemented by CS/CS/HB 21, effective July 1, 2018 pharmacists must begin reporting to the PDMP certain additional information relating to the pick-up person, including "the name of the individual picking up the controlled substance prescription and type

and issuer of the identification provided".[[6] See Florida Statutes, Section 893.055(3)(a)(7) (effective July 1, 2018).6] Significantly, Section 893.055(3)(a) is a reporting obligation and does not include any explicit obligation to verify/collect information relating to the pick-up person. The scope of the obligation to verify/collect information relating to the pick-up person remains governed by the language transferred from Chapter 893 to Section 465.0155, and, with respect to mail delivered prescriptions, in Section 893.04(2)(b).

## III. Rules Implementing PDMP Reporting Requirement Established by CS/CS/HB 21 Must Be Harmonized with, and not Negate, the Scope of Pharmacists' Identification Verification Requirements

When making the rules implementing CS/CS/HB 21's PDMP reporting requirements relating to the identity of pick-up persons, the Department must harmonize the reporting requirements with other related statutory provisions, including the provisions governing the scope of pharmacists' obligation to verify the identity of pick-up persons. This outcome is dictated by the legislature's expressed intent, basic rules governing statutory construction, and historical operation of the PDMP.

### A. The Legislature Was Clear it did NOT Intend CS/CS/HB 21 to Change the Scope of Pharmacists' Obligations with Respect to Verifying Pick-up Person Identity

In CS/CS/HB 21, the Legislature (a) relocated from Chapter 893 to Chapter 465 certain provisions governing the scope of pharmacists' obligation to verify pick-up person identity when dispensing prescriptions at the counter or in an institutional setting (including for hospital patients), and (b) left untouched within Chapter 893 provisions governing pharmacists' obligation to verify identity in the context of mail delivered prescriptions. In consciously preserving these provisions, it is obvious the Legislature intended they continue to be given meaning and effect. In fact, the Legislature confirmed this intent in the Florida House of Representatives Final Bill Analysis, which explicitly states: "[CS/CS/HB 21] relocates from [Section 893.055(14), Florida Statutes], to the pharmacy practice act ([Section 465.0155(2)(a)-(b), Florida Statutes]) an existing requirement that a pharmacist verifies the identity of an individual prior to dispensing a controlled substance. The bill does not make any substantive changes to this requirement."[[7] Fla. H.R. Health Quality Subcomm., CS/CS/HB 21 (2018) Staff Analysis 24 (Mar. 20, 2018)(emphasis added).7] Because it is clear the Legislature intended to preserve the scope of pharmacists' verification obligation "as is", any interpretation of CS/CS/HB 21 and any rules implementing CS/CS/HB 21, including those relating to PDMP reporting, cannot alter that scope.[[8] See School Board of Palm Beach County v. Survivors Charters Schools, Inc., 3 So.3d 1220, 1232 (Fl. Sup. Ct. 2009) (making clear that legislative intent "is the polestar" in matters of statutory construction).8]

B. **Basic Rules of Statutory Construction Require that Changes to PDMP Reporting Requirements Implemented by CS/CS/HB 21 be Interpreted to Give Meaning and Effect to Related Provisions Governing the Scope of Pharmacists' Obligation to Verify Pick-up Person Identity**

When interpreting statutory language for purposes of rulemaking, agencies must adhere to basic rules of statutory construction, which include first looking to the actual language used in the statute and giving effect to its plain meaning within the context of the entire Act (i.e., bill). [[9] See Estate of Cowart v. Nicklos Drilling Co., 112 S. Ct. 2589, 2594 (1992) (in statutory construction case, the beginning point must be the language of the statute); John Hancock Mut. Life Ins. Co. v. Harris Trust & Sav. Bank, 114 S. Ct. 517, 523 (1993) (holding courts should examine first the language of the governing statute, guided not by a single sentence or member of a sentence, but looking to the provisions of the whole law, and to its object and policy).

9] As it relates to the scope of pharmacists' obligation to verify/collect information pertaining to pick-up persons, the statute's plain language, as contemplated and otherwise unaffected by CS/CS/HB 21, requires pharmacists' to verify/collect pick-up person photographic identification information when dispensing controlled substances unless:

- the pick-up person is known to the pharmacist; or
- the pharmacist relies on other appropriate verification, including verification by health plan eligibility via a health plan's real-time inquiry or adjudication system; or
- the pick-up person does not have appropriate identification and the pharmacist validates the prescription and identity of the patient with the prescriber/prescriber's agent; or
- the pharmacist is dispensing for a patient in an institutional setting, including for a hospital patient; or
- the pharmacist is mailing a controlled substance listed in Schedule II, Schedule III, or Schedule IV and the pharmacist verified the patient's identification via the patient's prescription benefit plan via health plan eligibility confirmation.

Consistent with the first, most basic rule of statutory construction, when making the rules implementing new PDMP reporting requirements, the Department must ensure those rules retain the statutory flexibility afforded pharmacists to rely on an alternative to photographic identification for verification purposes, or otherwise not to verify or collect verification information when the statute allows.

If, instead, rules implementing PDMP reporting requirements were to dictate pharmacists must verify the pick-up person through photographic identification in every case when dispensing, the rules

would negate the meaning and effect of statutory provisions setting forth the circumstances when pharmacists may rely on alternatives to photographic verification or otherwise are not required to perform identity verification. That outcome would irreconcilably conflict with basic principles of statutory construction requiring that interpretations harmonizing provisions of a statute are favored over interpretations which render meaningless other related statutory provisions.[[10] See School Board of Palm Beach County, 3 So.3d at 1234 ("Basic to our examination of statutes, and an important aspect of our analysis here, is the 'elementary principle of statutory construction that significance and effect must be given to every word, phrase, sentence, and part of the statute if possible, ….'"; "we '**give** full **effect** to all statutory provisions and construe related statutory provisions in harmony with one another.'")[10]]

C. **Historically, the PDMP Reporting Requirement have not Been Interpreted to Impose Obligations on Pharmacists with Respect to Information Collection**

As discussed in Section II.A. above, prior to July 1, 2018, the legislature limited reporting to information pharmacists necessarily collected as part of the dispensing process. Pharmacists collected the required data elements as part of the ordinary processes of prescription intake, dispensing, and billing, and reporting the required data fields did not conflict with any other statutory provisions governing the scope of a pharmacist's responsibilities. Accordingly, we believe the Legislature intended PDMP reporting obligations to align with pharmacy information collection practices and did not intend to impose new or different information collection obligations on pharmacists by way of the PDMP reporting obligations.

Any rules made to implement PDMP reporting of pick-up person identification information must respect and reflect the flexibility pharmacists are afforded – by statute – to use alternatives to photographic identification verification when appropriate, and not to verify pick-up person identification in certain circumstances. As explained above, this is dictated by the Legislature's explicit statement it did not intend CS/CS/HB 21 to change the scope of pharmacists' pick-up person identity verification responsibilities, basic principles of statutory construction and the fact PDMP reporting historically has not been applied in a manner conflicting with related provisions governing information collection obligations on pharmacists.

I hope the analysis is helpful.

Wishing you and your family a great Fourth of July!

Kindest regards,

Adam R. Maingot
Senior Healthcare Attorney

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[1] Compare Florida Statutes, Section 893.055(14) (2017) with Florida Statutes, Section 465.0155(2)(a) (effective July 1, 2018).

[2] Compare Florida Statutes, Section 893.055(14) (2017) with Florida Statutes, Section 465.0155(2)(b) (effective July 1, 2018).

[3] See Florida Statutes, Section 893.04(2)(b).

[4] See Florida Statutes, Section 893.055(3) (2017).

[5] Id.

[6] See Florida Statutes, Section 893.055(3)(a)(7) (effective July 1, 2018).

[7] Fla. H.R. Health Quality Subcomm., CS/CS/HB 21 (2018) Staff Analysis 24 (Mar. 20, 2018)(emphasis added).

[8] See School Board of Palm Beach County v. Survivors Charters Schools, Inc., 3 So.3d 1220, 1232 (Fl. Sup. Ct. 2009) (making clear that legislative intent "is the polestar" in matters of statutory construction).

[9] See Estate of Cowart v. Nicklos Drilling Co., 112 S. Ct. 2589, 2594 (1992) (in statutory construction case, the beginning point must be the language of the statute); John Hancock Mut. Life Ins. Co. v. Harris Trust & Sav. Bank, 114 S. Ct. 517, 523 (1993) (holding courts should examine first the language of the governing statute, guided not by a single sentence or member of a sentence, but looking to the provisions of the whole law, and to its object and policy).

[1]0 See School Board of Palm Beach County, 3 So.3d at 1234 ("Basic to our examination of statutes, and an important aspect of our analysis here, is the 'elementary principle of statutory construction that significance and effect must be given to every word, phrase, sentence, and part of the statute if possible, ….'"; "we '**give** full **effect** to all statutory provisions and construe related statutory provisions in harmony with one another.'")

**From:** McMullen, Linda N
**Sent:** Monday, August 13, 2018 2:32 PM
**To:** Poston, Rebecca
**Subject:** FW: HB-21 EFORCE/Hospice Considerations

Do you have this one in the materials?

Linda

Linda McMullen
Assistant General Counsel | Office of General Counsel
Phone: (850) 245-4025 | Fax: (850) 245-4790

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**From:** zzzz Feedback, MQA_TakeControl
**Sent:** Friday, June 1, 2018 12:01 PM
**To:** McMullen, Linda N <Linda.McMullen@flhealth.gov>
**Cc:** Poston, Rebecca <Rebecca.Poston@flhealth.gov>
**Subject:** FW: HB-21 EFORCE/Hospice Considerations

Hi Linda,

Please see the email below regarding our rulemaking efforts to address the institutional issues.

Thanks,
Erika
Erika L. Marshall | **E-FORCSE Florida Prescription Drug Monitoring Program** | Program Outreach Director | Phone: 850-901-6870

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**From:** Joseph Shega [mailto:Joseph.Shega@vitas.com]
**Sent:** Friday, June 1, 2018 8:07 AM
**To:** zzzz Feedback, MQA_TakeControl <TakeControl@flhealth.gov>
**Subject:** HB-21 EFORCE/Hospice Considerations

EFORCE Team,

My name is Joseph Shega and I am the National Medical Director/Chief Medical Officer for VITAS Healthcare and a Florida physician that does direct patient care for hospice patients.

My purpose in reaching out is to advocate for special considerations for hospice as part of the rulemaking process. The work of the EFORCE group to protect, promote, and improve the health of Florida residents is admirable and necessary in the current landscape of the opioid epidemic. However, I believe the current law is particularly burdensome for hospices and will delay timely access of opioid medications for vulnerable patients who are suffering with intractable pain and shortness of breath.

The hospice population including VITAS is distinct in that we care for 7,000 plus patients every day in Florida with an average life expectancy of someone on hospice being 14 to 18 days (similar to other hospices within Florida). Hospices admit and care for patients 24 hours a day/ 7 days a week in the patients home. Regular work hours incorporate 8 of 24 hours within a day and much of our care happens after hours.

Taken together, the current requirements of HB-21 create a unique and substantial burden on hospices placing the most vulnerable patients at risk of delays in the standard of care-opioid therapy.

My hope is to encourage the EFORCE team to adopt a pragmatic solution as part of the rulemaking process that weighs the needs of vulnerable dying patients with those of the general population when it comes to opioids and a database check.

One approach taken by Connecticut provides a waiver for hospice patients. Another implemented most recently by California strikes a balance of patient needs at the end of life and public safety, so that hospice patients do not require a check of the database for the initial opioid dispense (note a majority of our patients die before a second dispense occurs). The database is required to be checked prior to a second dispense and specifies rechecking the database at a "regular interval" thereafter. An ideal regular interval for hospice would mirror the current hospice recertification process. Hospice physicians or their designee would then check the EFORCE database at the time of the second opioid dispense, at 90 and 180 days, and every 60 days thereafter, so that checking the database becomes incorporated as part of an existing administrative process. The benefits of the approach decreases burden on hospices as patients can get their initial medications without the barrier and burden of an EFORCE database check which is often after hours and for those that live longer would have a database check with the second dispense and at the time of re-certifications.

I would be happy to discuss the challenges hospice face and viable solutions that balance the needs of dying patients and those of the community via phone or face to face in Tallahassee.

Thank you for your consideration and the great work you do for the benefit of Florida residents.

All the best,

Joseph Shega, MD
Chief Medical Officer, VITAS Helathcare.

## Marshall, Erika

**From:** Poston, Rebecca
**Sent:** Monday, July 30, 2018 8:01 AM
**To:** Marshall, Erika
**Subject:** FW: Draft Rule 64K-1.003(1)(e), F.A.C.

Please save for the record and include a copy in the agenda materials.

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**From:** Allen Grossman [mailto:a.grossman@gfblawfirm.com]
**Sent:** Friday, July 27, 2018 3:09 PM
**To:** McMullen, Linda N <Linda.McMullen@flhealth.gov>
**Cc:** Diane L. Godfrey <Diane.Godfrey@flhosp.org>; Garza, Cassandra <Cassandra.Garza@flhosp.org>; Kishbaugh, Troy <Troy.Kishbaugh@Flhosp.org>; Poston, Rebecca <Rebecca.Poston@flhealth.gov>
**Subject:** RE: Draft Rule 64K-1.003(1)(e), F.A.C.

Linda,

Thank you for the acknowledgement of receipt and the consideration

Allen R. Grossman
Grossman Furlow and Bayó, L.L.C.
2022-2 Raymond Diehl Road
Tallahassee, Florida 32308
(850) 385-1314
(850) 385-4240 (fax)
www.gfblawfirm.com



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**From:** McMullen, Linda N [mailto:Linda.McMullen@flhealth.gov]
**Sent:** Friday, July 27, 2018 3:06 PM
**To:** Allen Grossman <a.grossman@gfblawfirm.com>

**Cc:** Diane L. Godfrey <Diane.Godfrey@flhosp.org>; Garza, Cassandra <Cassandra.Garza@flhosp.org>; Kishbaugh, Troy <Troy.Kishbaugh@Flhosp.org>; Poston, Rebecca <Rebecca.Poston@flhealth.gov>
**Subject:** RE: Draft Rule 64K-1.003(1)(e), F.A.C.

Allen,

Thank you for these written comments which will be incorporated into the rulemaking record and given every consideration.

Best regards,

Linda McMullen
Assistant General Counsel
Office of the General Counsel
Florida Department of Health
4052 Bald Cypress Way, Bin A02
Tallahassee, FL 32399-1703
Telephone: (850) 245-4005
Facsimile: (850) 245-4790

**Mission:** To protect, promote, & improve the health of all people in Florida through integrated state, county & community efforts.
**Vision:** To be the healthiest state in the nation.

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**From:** Allen Grossman <a.grossman@gfblawfirm.com>
**Sent:** Friday, July 27, 2018 2:31 PM
**To:** McMullen, Linda N <Linda.McMullen@flhealth.gov>
**Cc:** Diane L. Godfrey <Diane.Godfrey@flhosp.org>; Garza, Cassandra <Cassandra.Garza@flhosp.org>; Kishbaugh, Troy <Troy.Kishbaugh@Flhosp.org>
**Subject:** Draft Rule 64K-1.003(1)(e), F.A.C.

Linda,

Thank you for providing the preliminary draft of DOH's rules regarding implementation of HB21. As I believe you already know, my client, Adventist Health System/Florida Hospital, has already requested a workshop as provided in the June 21, 2018 Notice of Rule Development. In looking over the draft, my client has a suggestion in regard to the draft language for 64K-1.003(1)(e). This is the definition of "Order". My client definitely appreciates the effort to clarify that HB21 does not intend that the administration of controlled substances triggers PDMP queries or reports. The language in various portions of HB21 clearly distinguishes between administration, dispensing and prescribing and requires only that queries be made prior to writing a prescription for a controlled substance or dispensing a controlled substance for a patient over the age of 16 and reporting to the PDMP when a controlled substance is dispensed.

By defining the word "order" the draft rules clearly and succinctly acknowledge the steps usually taken to facilitate the administration of medications, including controlled substances, in various settings and situations. However, my client believes that the inclusion of the words "in an inpatient setting" at the end of the definition could be read to confusingly and inappropriately limit the settings and situations in which the administration of controlled substances does routinely and is likely to continue to occur. My client believes that a period should be placed after the word "patient."

*(e) "Order" means a written, transmitted or oral direction from a prescriber for a controlled substance to be administered to a patient.*

In this manner, the rule could not reasonably be read to leave out the administration of controlled substances in settings including, as examples, an Emergency Department of a hospital where the patient has not yet been admitted as an inpatient; or by a paramedic or EMT at the site of an accident or other emergency or during the transportation of a patient; or in an ASC, in conjunction with a procedure being performed; or by hospice as part of palliative care provided to a patient; or in a dental office or office surgical facility in conjunction with a dental or surgical procedure being performed on a patient. The intent and purpose of HB21 is to limit the provision of controlled substances in situations where they may end up on the street or otherwise pose a danger to the health, safety and welfare of individual patients or the community in general. In any case where the patient is not being provided with controlled substances to take with them or being provided with a script giving the patient the ability to obtain the controlled substance for their own use, there is no issue regarding over use, abuse, illegal distribution or misappropriation of the controlled substance, and therefore these situations do not fall within the protection intended by HB21 or the querying and reporting requirements of HB21.

My client hopes that the Department of Health will consider this small but both necessary and appropriate modification of the draft language.

Please let me know if you have any questions or concerns about this suggestion or wish to discuss it further.

Thanks again.

Allen R. Grossman
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## Marshall, Erika

**From:** Poston, Rebecca
**Sent:** Monday, July 30, 2018 7:58 AM
**To:** Marshall, Erika
**Cc:** McMullen, Linda N
**Subject:** FW: Questions

Please add to the record and agenda materials for the Rule Workshop..

---

**From:** Joshua Lenchus [mailto:jlenchus@yahoo.com]
**Sent:** Saturday, July 28, 2018 10:21 AM
**To:** Poston, Rebecca <Rebecca.Poston@flhealth.gov>
**Cc:** Joshua Lenchus <jlenchus@yahoo.com>
**Subject:** Fw: Questions

Becki, thanks for thslide. I have incorporated it into my presentation for this afternoon, and will include it in the future. I did notice that the FOMA course was not listed under the medicine tab. As our course was approved by the Board of Medicine, could you see to it that it is listed as an option there also please?

Additionally, please see some questions listed below. I have forwarded them to folks on the Boards, but wanted you to be aware of them as these are unresolved issues in my mind.

Finally, with respect to the inpatient conversation we had yesterday, consider the following. I am not a lawyer so this may require revision, but it's a start.

Ordering is defined as a written, electronic, or verbal instruction to a licensed healthcare professional, within an inpatient setting, emergency room, ambulatory surgical center, or any other facility or location in which the medication will be provided as a single dose directly to a patient for timely administration.

Prescribing is defined as a written, electronic, or verbal instruction to a healthcare professional licensed to dispense, generally within an outpatient setting, other than those encompassed in ordering, in which the medication will be provided in whole or in part to the patient or his/her representative for self-administration.

Administering is defined as the provision of a medication by a licensed healthcare professional in the usual course of his/her duties for the purposes of carrying out a prescriber's order. Medications administered are single doses given to patients in inpatient settings, emergency rooms, ambulatory surgical centers, or any other facility or location in which the patient does not maintain personal control over the medication.

Dispensing is defined as the provision of a medication by a healthcare professional iicensed to dispense, generally within an outpatient setting, other than those encompassed in ordering. Medications dispensed are provided in whole or in part to the patient or his/her representative, who maintains personal control over the medication, for self-administration.

The PDMP must be consulted for all controlled substances, except C-V nonopioids, prescribed or dispensed to patients age 16 years or older. Those that are ordered or administered are exempt from this requirement.

Would appreciate hearing your thoughts on this. Below, please find my contact information. Thank you for all that you do for us and the State of Florida.

Joshua

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Recently, we completed our first live sessions of the opioid course. I compiled a list of questions with answers that are still, I believe, lacking in clarity. Please see below and opine if there is additional information of which I am unaware. Otherwise, I suggest that these questions be discussed with the Boards/DOH/E-FORCSE, as relevant. If done, please feed back responses so we can incorporate them. Thanks.

1. Long term care facilities (DOH?): controlled substances there are actually prescribed, dispensed, and administered. Need the prescriber check the PDMP before prescribing for a patient who is admitted to one of these facilities? Is the prescriber limited to a 3-7 day supply of a C-II opioid when treating acute pain? [*I would suspect that it would be unnecessary for prescribers to consult the PDMP for patients who reside in facilities, whether a hospital, long-term care, or rehab facility. Further, I would argue that any controlled substances administered need not require PDMP consultation beforehand. Presently, reporting administration is exempt from PDMP, but not the administration*.]

2. Certificate of exemption for pain management clinics (DOH): when will the form adopted in rule be released and distributed? [*Don't know*]

3. PDMP: who can be assigned as a designee? Is there a list of staff categories that are acceptable, within the confines of HIPAA, or do we simply use that as a guide? A prescriber would not assign the mailman, but what about his medical assistant, the secretary? [*I would imagine that the application of HIPAA laws help guide who can be assigned, but it seems pretty open right now*.]

4. PDMP: is there a limit on the number of designees under a prescriber/dispenser? Physicians and pharmacists typically supervise several people. Can they only designate a single person, or are multiple designees allowed? [*I realize that the prescriber/dispenser is ultimately responsible for the actions of their designees, but I am unaware of any guidance here*.]

5. PDMP: we need clarification on whether or not the PDMP information contained in the query can be printed out and/or incorporated into the patient's EMR. If, in fact, it can, need it be redacted if the patient's medical records are requested from the patient, a lawyer, law enforcement, etc.? [*Addressed by E-FORCSE personnel, Florida Administrative Code]*

6. PDMP: to document that the PDMP was properly consulted, will boilerplate language be suggested to guide prescribers and dispensers, or is that to be left up to each person individually? [*Likely, no specific language will be promulgated, but had to ask*]

7. PDMP: how far in advance of prescribing a controlled substance can the PDMP be consulted? Hours, days, weeks? Is there a specific time frame? [*I have been telling folks that the information contained in the PDMP is there as a resource to potentially help guide prescribing. To that end, prescribers should want the most updated information so there should be temporal proximity between consulting the database and prescribing*.]

8. Represcribing (BOARD?): if a patient being treated for acute pain with a C-II opioid still has pain that warrants continuation of such after the initial prescription's duration, need the patient return to the office for a face-to-face visit, or can another prescription be written absent such evaluation? [*Don't know*]

9. Acute pain (BOARD?): do patients need informed consent before being prescribed a C-II opioid? [*I imagine that the Boards will get around to employing some element of informed decision making, even to limited prescribing of opioids for treating acute pain]*

Josh

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