

### **COMMONWEALTH OF VIRGINIA**

# Department of Health Professions

Perimeter Center, 9960 Mayland Drive, Second Floor Henrico, Virginia 23233

(804) 367-4456 (Tel) (804) 527-4472(Fax)

### Tentative Agenda of E-prescribing Workgroup

August 29, 2017 9AM – 12PM

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#### HHR/DHP E-Prescribing Workgroup

# Wednesday, August 2, 2017 Perimeter Center, 2<sup>nd</sup> Floor Conference Center, Board Room 2 Henrico, Virginia

#### \*\*\*DRAFT\*\*\*MEETING MINUTES

#### **Workgroup Members Present**

David Brown, DC Department of Health Professions, Director

Caroline Juran Board of Pharmacy, Executive Director

Omar Abubaker, DMD, Ph.D. Virginia Dental Association

Ruth A. Carter
Drug Enforcement Administration

Tyler Cox HCA Hospitals

Carol Forster, MD Kaiser Permanente

Kelly Gottschalk, DVM Virginia Veterinary Medical Association

Richard Grossman Virginia Council of Nurse Practitioners

Stephanie Lynch Virginia Association of Health Plans Rusty Maney Virginia Association of Chain Drug Stores

Jodi Manz, MSW
Policy Advisor, Office of the Secretary of Health & Human Resources

Johnny Moore Virginia Pharmacists Association

Ken Whittemore, Jr., R.Ph., MBA Surescripts, LLC

#### Alternate Members Present

Lauren Bates-Rowe Medical Society of Virginia

#### **Workgroup Members Absent**

Barbara Brown, Ph.D. Virginia Hospital & Healthcare Association

Ralston King Medical Society of Virginia

#### Staff Present

Laura Z. Rothrock, Virginia Department of Health Professions, Executive Assistant to Director David E. Brown, DC

#### Opening Remarks and Approval of Agenda:

David E. Brown, DC, Director, Department of Health Professions

The meeting was called to order at 9:10am. Dr. Brown informed the members that the Secretary of Health and Human Resources, Dr. Hazel, was unable to attend the meeting. Dr. Brown asked that the members introduce themselves. Following the introductions, Dr. Brown provided emergency egress information and then asked if there were any comments on or changes to the agenda; there were none.

#### Call for Public Comment:

Dr. Brown asked if anyone in the audience wished to make any comments; there were none.

#### **Overview of E-Prescribing Requirements:**

#### Federal Regulations

Dr. Brown requested that Ms. Juran provide an overview. Ms. Juran provided a brief recap of the federal regulations (in the agenda packet on pages 1-20) and asked that Ms. Carter elaborate if needed.

Ms. Juran indicated that the goal of the meeting is to accomplish as much of the agenda as possible. A second meeting will be held on August 29, 2017, if necessary.

There appears to be some confusion as to whether prescriptions for drugs in Schedules II-V may be transmitted electronically. Ms. Juran clarified that federal regulations have authorized electronic transmission of prescriptions for drugs in Schedules II-V since 2010. Shortly thereafter, the Board of Pharmacy adopted State regulation authorizing the electronic transmission of prescriptions for drugs in Schedules II-VI. Schedule II through V must be transmitted in compliance with federal regulations.

#### HB2165

Ms. Juran discussed HB 2165 (in the agenda packet on pages 21-26), in particular:

- Line 126 Amends the definition section by deleting the term "electronic transmission
  prescription" and simply defining the term "electronic prescription" which more closely
  mirrors the federal definition and the definition written into board regulations
- Line 289 requires a prescription for a controlled substance that contains an opiate to be issued as an electronic prescription
- Line 332 states no pharmacist shall dispense such a prescription unless issued as an electronic prescription
- HB2165 contains two enactment clauses:
  - Line 334 First enactment Mandate for prescriptions for a controlled substance that contains an opiate to be issued as an electronic prescription to become effective 7/1/2020;
  - Line 335 Second enactment Workgroup to be convened with an interim report due to legislators by November 1, 2017 and a final report by November 1, 2018;
     Workgroup to evaluate the hardships on prescribers, inability of prescribers to

comply with deadline and make recommendations to the General Assembly for any extension or exemption processes relative to compliance or disruptions due to natural or manmade disasters or technology gaps, failures or interruptions of services.

#### Virginia Statistics

Mr. Whittemore provided an overview of the Virginia Statistics found on page 27 of the agenda packet using Surescripts network data. The statistics are representative of the current state of eprescribing in the Commonwealth. There are two types of prescribers shown: Active E-Prescribers (prescribers who have sent e-prescriptions to pharmacies using Surescripts network in the last 30 days using their EHR software applications) and Active E-Prescribers EPCS Enabled (prescribers who use an EHR software that is Electronic Prescriptions for Controlled Substances certified and audit approved). As of June 2017, Mr. Whittemore reported that 56.8% of Virginia prescribers are active E-prescribers with 6.3% EPCS enabled. Nationally, 17.1% of prescribers are EPCS enabled. Of the Active E-Prescribers, 95% use software that is currently certified, but this does not mean that the software has been downloaded. Over 300 electronic medical records are certified. Mr. Whittemore further reported that 97.5% of Virginia pharmacies are active eRx pharmacies (pharmacies that are ready and processing e-prescriptions from prescribers' applications) and that 90.3% are EPCS enabled pharmacies (pharmacies with certified and audit approved software ready to receive EPCS transactions from prescribers). The percentage of EPCS enabled pharmacies for Virginia reflects favorably with the national number of 90.5%.

## ACTION ITEM: Mr. Whittemore has asked his colleagues to generate an analysis by county for the workgroup.

Mr. Whittemore indicated that some pharmacies have not embraced the technology and some vendors have chosen not to provide e-prescribing for controlled substances (approximately 50 vendors serve the national market).

Dr. Gottschalk inquired of Mr. Whittemore if veterinarians are eligible to transmit; he was unsure. Dr. Gottschalk further indicated that some electronic prescription formats do not allow for the name of species or client's name and therefore, are not veterinarian specific, so there is some concern for mandating veterinarian use of e-prescribing.

Dr. Forster inquired of Mr. Whittemore as to whether Kaiser Permanente was included in the numbers. Mr. Whittemore indicated that it was not included as it is a closed network, so there are approximately 700 providers not included in the numbers.

Ms. Juran inquired of Ms. Carter as to whether the electronic transmission of a prescription to an in-house hospital pharmacy must comply with federal rules for electronically transmitting prescriptions. Ms. Carter indicated later in the meeting that the rules for electronically transmitting a prescription do not apply in an inpatient hospital setting as the prescribing is treated as an "order" and not a "prescription". If the electronic prescribing of a medication is being transmitted to a pharmacy other than the inpatient hospital pharmacy, then it does have to comply.

#### New York Mandate

Dr. Brown indicated that the state of New York has already mandated electronic prescribing and referred everyone to the FAQs in the agenda packet at pages 28-32. Ms. Juran provided that New York's mandate applies to all controlled and non-controlled substances and was part of the 2013 I-STOP law designed to curb prescription drug abuse. Exceptions to New York's mandate can be found on page 32, and Ms. Juran indicated that the workgroup may want to use the list as a starting point if it felt similar exemptions were necessary.

The workgroup discussed the first exception: "Approved waiver from electronic prescribing." The waiver is for one year, and the practitioner must reapply as to why a continued waiver is needed. It can be for economic hardship (e.g., single provider) or technological challenges. Mr. Whittemore indicated that in the first year there were 6,200 waivers related to approximately 19,000 practitioners (New York has approximately 103,000); in the second year there were 3,128 waivers related to approximately 8,620 practitioners.

Dr. Brown inquired as to whether there were any questions as to what New York has done. The following concerns were expressed:

- Cost for individual practitioners and hospitals (each physician would need a license)
- Hospitals sending to the correct pharmacy
- Rural dentists is there an exception?
- Community volunteer clinics is there an exception?

### ACTION ITEM: There is a lot of variability of cost in the physician market, and Ms. Bates-Rowe will reach out to the New York medical society to identify a range of costs.

Dr. Brown inquired of the difficulty in obtaining the two-factor credential. Dr. Forster explained Kaiser Permanente's process. There is a password to access the system. If the prescription is for a controlled substance, a popup will appear requesting the authentication. The code can be obtained through use of a key fob or app on iPhone. It takes approximately two seconds to do. The identity proofing process takes some time, but once it is done, the process is easy.

#### **Challenges for Prescribers:**

The challenges identified include:

- Veterinarians generally do not have Electronic Medical Records (EMR) and should be exempted from the mandate.
  - o Seven states have adopted e-prescribing and exempt veterinarians.
  - Veterinarian prescriptions go through the Prescription Monitoring Program (PMP).
     The PMP is working on species codes.
- No access to Internet in some areas of the Commonwealth.
- Cost of obtaining a system or activating a system that already has the capability for eprescribing.
- Exemptions for cancer or hospice patients should be considered.
- Majority of prescribers have EMR in place but not the component to e-prescribing in accordance with federal rules.
- Licensing fees for EMR are already being paid. There may be an additional cost; how
  much depends on the vendor. Mr. Whittemore indicated there is a table on Surescripts'
  website that specifies vendor functionalities.

### ACTION ITEM: Ms. Lynch may be able to provide additional information regarding additional costs for EMRs.

- Will there be penalties (e.g., reduced Medicaid/Medicare payments) if EMR and eprescribing are not done?
- HB2165 relates to opiates only. Providers may not always know the item prescribed is an
  opiate.

It was noted that any exemptions should possibly be captured in regulations.

#### **Challenges for Dispensers:**

It was noted that pharmacies are ahead of the curve. Challenges identified include:

- With prescribers possibly obtaining waivers exempting them from an e-prescribing mandate, determining if a prescription has been issued in a compliant manner should not be up to the pharmacist.
  - New York states that the pharmacist is not required to verify the reason for a written or oral prescription.
- If prescription is sent electronically to the wrong pharmacy, this may cause patient harm. Patient may have to go back to the provider and get a handwritten prescription.
  - o Would pharmacist have to contact provider to determine if valid?

O Could manner of transmission be challenged on third-party insurance audit of the pharmacy? Are there financial protections for the pharmacy that could be implemented?

The workgroup took a 15-minute break.

#### **Exceptions to E-Prescribing Identified in New York:**

Dr. Brown announced that the workgroup would go through the New York exceptions line by line.

- 1. Approved waiver from electronic prescribing+
  - o Previously discussed
- Nursing home or RHCF (Residential Health Care Facility) defined in Article 2801 of the Public Health Law

### ACTION ITEM: Ms. Juran will look into how New York defines RHCF and how it relates to the Virginia's licensing standards,

- 3. Complicated directions
  - o No comment
- 4. Directions longer than 140 characters
  - o No comment
- 5. Compounded prescriptions containing two (2) or more products
  - o No comment
- 6. Compounded infusion prescriptions containing two (2) or more products
  - o Per Mr. Whittemore, the next NCPDP version will fix exemptions #4, 5, and 6, but it will be into 2018 before ready. There will be a change from 140 to 1,000 characters, and there will be additional fields for compounding prescriptions to be inputted accurately and completely.
- 7. A prescription containing certain elements required by the federal Food and Drug Administration (FDA), such as an attachment
  - o Mr. Maney indicated this exemption has to do with specialty medications regarding risk mitigation strategies that are currently in place. Mr. Whittemore stated that the electronic prescribing standard does not provide for attachments.
- 8. Approved protocols under expedited partner therapy (EPT)
  - o Ms. Juran questioned if this exemption was necessary for Virginia since EPT is not currently authorized in Virginia. Mr. Whittemore indicated that there is guidance on how to handle this in states which authorize it.
- 9. Approved protocols under collaborative drug management
  - o No comment

- 10. Response to a public health emergency that would allow a non-patient specific prescription
  - No comment
- 11. Approved research protocol
  - No comment
- 12. A non-patient specific prescription for an opioid antagonist (e.g., naloxone)
  - o Do we need an exception since we have a standing order?

## ACTION ITEM: Ms. Juran will work with board counsel regarding New York's exemption #12 since Virginia's language for dispensing an opioid antagonist is different.

- 13. Veterinarian
  - o There is an obvious need for an exception.
- 14. Temporary technical failure
  - o Straightforward, no comment
- 15. Temporary electronic failure
  - o Straightforward, no comment
- 16. The prescription will be dispensed out-of-state, including federal installations such as Veteran Administration Facilities, Fort Drum & West Point
  - If going out of state and electronic prescription is printed and given to the patient, it must be signed.
  - Consideration for people who live near the border may be necessary.
- 17. Patient harm if the practitioner determines that an electronic prescription cannot be issued in a timely manner and that the patient's condition is at risk
  - o This may be an emergency situation in which the patient would not know which pharmacy is open.
  - o In the case of a house call/hospice/palliative, e-prescribing would be dependent on access to the Internet.
    - Need to balance taking care of the patient against diversion issue (e.g., person filing prescription for person who already died).
    - Do e-prescribing systems have mobile capability? Yes.
    - How many areas of the state do not have Internet capability?
  - o Mobile clinics (e.g., volunteer dental activities) may need to have an exception.

#### **Public Comment:**

Dr. Brown again asked if anyone wished to offer public comment.

Chuck Duvall, Virginia Dental Association, stated that during the Southwest Virginia dental clinic most prescribing was Extra Strength Tylenol, not opiates. Dentists may prescribe opiates two times a month and yet they have to pay for these systems; the workgroup may want to look at an exception for this. He thought it was a great discussion and learned a lot.

### ACTION ITEM: Mr. Duvall will get figures on potential costs for dentists to provide to the workgroup.

Lauren Schmitt, Virginia Association of Health System Pharmacists requested confirmation of requirements for transmitting inpatient orders in the hospital setting.

Brent Rawlings, Virginia Hospital & Healthcare Association (VHHA), was grateful for the work being done by the committee. In the future, he will represent VHHA as an alternate.

#### **Next Steps:**

Dr. Brown inquired of the workgroup what the Commonwealth needs to do to implement the Act and what are next steps.

ACTION ITEM: Mr. Whittemore will look into what categories New York's first year waivers were. He distributed a handout which included e-prescribing statistics for New York prescribers and pharmacies.

Should there be an exemption for prescribers who write less than 25 prescriptions per year?

Since funding will be a challenge, look at 90/10 Hi Tech matching funds. Strong arguments from CMS (U.S. Centers for Medicare & Medicaid Services) that it would be complimentary to funding received to implement EMR into PMP.

#### ACTION ITEM: Ms. Lynch will look into the possibility of 90/10 Hi Tech matching funds.

Electronic prescribing could support efforts toward electronic prior authorizations.

There was a brief discussion about possibly expanding e-prescribing to all Schedule II-V drugs with Dr. Forster noting her support. In terms of technology, opiates would not be segregated. ADHD drugs and benzodiazepines are also being abused.

ACTION ITEM: Mr. Moore indicated that VPhA will poll it members regarding impact of expanding mandate to all drug Schedules.

The appropriateness of a 2020 deadline was discussed. Some members felt it could be implemented earlier (possibly 2019). Some felt 2020 allows time for possibly addressing state budgetary needs and/or applying for funding.

Regulation seems more appropriate versus a guidance document for DHP.

ACTION ITEM: Ms. Juran will follow-up to see if New York placed exemptions in regulation or some form of guidance.

Impact on telemedicine also needs to be considered.

Dr. Brown indicated that the next meeting will be August 29, 2017. If a member is unable to attend, they should designate someone else to attend in their place.

ACTION ITEM: Dr. Brown requested that the members talk to stakeholders to determine if e-prescribing should be limited to opiates.

#### Adjourn:

With no further business to discuss, Dr. Brown adjourned the meeting at 11:40am.

David E. Brown, DC Director	Date

#### Juran, Caroline (DHP)

From:

Rawlings, Brent <br/> <br/>brawlings@vhha.com>

Sent: To:

Wednesday, August 2, 2017 12:43 PM Brown, Gary (VDH); Juran, Caroline (DHP)

Cc:

Brown, Barbara

Subject:

E-Prescribing Work Group Follow-Up

Dear Dr. Brown and Ms. Juran,

Thank you for a good meeting today. Dr. Brown, as I mentioned to you, I wanted to pass along this "blanket waiver" adopted by the State of New York in case you had not also seen this. It provides a more detailed description of various exemptions:

https://www.health.ny.gov/professionals/narcotic/electronic\_prescribing/docs/2017-03-02\_commissioners\_letter.pdf

Also wanted to direct you to materials in Maine:

http://www.maine.gov/dhhs/samhs/osa/data/pmp/e-prescribing.htm http://www.maine.gov/dhhs/samhs/osa/data/pmp/E-Prescribing-Waiver-and-Policy\_Individual.pdf

For our part, we will try to get additional information from our members on cost of implementation and timelines for completion as this may be informative for the group. We will also carefully review the list of exemptions from New York and other states to see if there are any additions or clarifications that might be helpful. Please let us know if you need anything specific from us.

Thanks,

#### **Brent**

#### R. Brent Rawlings

Vice President and General Counsel Virginia Hospital & Healthcare Association 4200 Innslake Drive, Suite 203 P.O. Box 31394, Richmond, VA 23294 Phone: (804) 965-1228 Mobile: (804) 307-0366











ANDREW M. CUOMO Governor

HOWARD A. ZUCKER, M.D., J.D. Commissioner

**SALLY DRESLIN, M.S., R.N.**Executive Deputy Commissioner

March 2, 2017

Dear Practitioners and Pharmacists:

This letter is to inform you of a blanket waiver of the electronic prescribing requirements of Public Health Law (PHL) § 281 and Education Law § 6810, for certain exceptional circumstances in which electronic prescribing cannot be performed due to limitations in software functionality. As of March 26, 2017, this blanket waiver replaces and supersedes my prior blanket waiver, issued by letter dated March 16, 2016.

The Department recognizes that the standards developed by the National Council for Prescription Drug Programs (NCPDP), as adopted by the Centers for Medicare and Medicaid Services, have been continuously revised since they were first published in 2005 but still do not address every prescribing scenario. The current standards allow only a limited number of characters in the prescription directions to the patient, including, but not limited to, taper doses, insulin sliding scales, and alternating drug doses.

Similarly, for compound drugs, no unique identifier is available for the entire formulation. Typing the entire compound on one text line may lead to prescribing or dispensing errors, potentially compromising patient safety.

Further, the Department is mindful that practitioners must issue non-patient specific prescriptions in certain instances, and that such prescriptions cannot be properly entered into the electronic prescription software.

For these reasons, pursuant to my authority in PHL § 281(3), I hereby continue to waive the following exceptional circumstances from the requirements of electronic prescribing:

- any practitioner prescribing a controlled or non-controlled substance, containing two (2) or more products, which is compounded by a pharmacist;
- any practitioner prescribing a controlled or non-controlled substance to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion;
- any practitioner prescribing a controlled or non-controlled substance that contains long or complicated directions;
- any practitioner prescribing a controlled or non-controlled substance that requires a prescription to contain certain elements required by the federal Food and Drug Administration (FDA) that are not able to be accomplished with electronic prescribing;
- any practitioner prescribing a controlled or non-controlled substance under approved protocols for expedited partner therapy, collaborative drug

management or comprehensive medication management, or in response to a public health emergency that would allow a non-patient specific prescription;

- any practitioner prescribing an opioid antagonist that would allow a nonpatient specific prescription;
- any practitioner prescribing a controlled or non-controlled substance under a research protocol;
- a pharmacist dispensing controlled and non-controlled substance compounded prescriptions, prescriptions containing long or complicated directions, and prescriptions containing certain elements required by the FDA or any other governmental agency that are not able to be accomplished with electronic prescribing;
- a pharmacist dispensing prescriptions issued under a research protocol, or under approved protocols for expedited partner therapy, or for collaborative drug management or comprehensive medication management; and
- a pharmacist dispensing non-patient specific prescriptions, including opioid antagonists, or prescriptions issued in response to a declared public health emergency.

This waiver is hereby issued for the ten above-listed exceptional circumstances and shall be effective from March 26, 2017, until March 25, 2018. Before March 25, 2018, I will determine whether the software available for electronic prescribing has sufficient functionality to accommodate each of these exceptional circumstances.

The Department further acknowledges that, while many nursing home/residential health care facilities have adopted electronic prescribing, there remain some facilities in which electronic prescribing may not be currently possible due to technological or economic issues or other exceptional circumstances, including a heavy reliance upon oral communications with the prescriber and pharmacy.

For these reasons, pursuant to my authority in PHL § 281(3), and as directed by Governor Cuomo in Veto Message #218 of 2016, I hereby continue to waive from the requirements of electronic prescribing:

- a practitioner prescribing a controlled or non-controlled substance either through an Official New York State Prescription form or an oral prescription communicated to a pharmacist serving as a vendor of pharmaceutical services, by an agent who is a health care practitioner, for patients in nursing homes and residential health care facilities as defined by PHL § 2801; and
- a pharmacist serving as a vendor of pharmaceutical services dispensing a controlled or non-controlled substance through an Official New York State Prescription form or an oral prescription communicated by an agent who is a health care practitioner, for patients in nursing homes and residential health care facilities as defined by PHL § 2801.

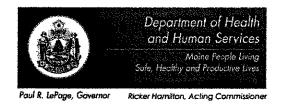
This waiver is hereby issued for the above two exceptional circumstances involving nursing homes and residential health care facilities, as defined by PHL § 2801, and shall be effective from March 26 through October 31, 2017.

Practitioners issuing prescriptions in all of the above-listed exceptional circumstances may use either the Official New York State Prescription Form or issue an oral prescription, provided, however, that oral prescriptions remain subject to PHL §§ 3334 and 3337, which provide for oral prescriptions of controlled substances in emergencies and for other limited purposes, and subject to § 6810 of the Education Law. Pharmacists may continue to dispense prescriptions issued on the Official New York State Prescription Form or oral prescriptions in all of the above-listed exceptional circumstances.

The above blanket waivers shall not affect other general waivers the Department issues to practitioners pursuant to PHL § 281.

Sincerely,

Howard A. Zucker, M.D., J.D. Commissioner of Health



Department of Health and Human Services
Commissioner's Office
221 State Street
11 State House Station
Augusta, Maine 04333-0011
Tel.: (207) 287-3707; Fax: (207) 287-3005
TTY Users: Dial 711 (Maine Relay)

### **Electronic Prescribing Clarifications**

#### **Electronic Prescribing Mandate**

Pursuant to Public Law, Chapter 488, An Act to Prevent Opiate Abuse by Strengthening the Controlled Substances Prescription Monitoring Program, practitioners are mandated to electronically prescribe opioid medications. However, there are limited exceptions in which a practitioner may issue a written, oral or faxed prescription.

A pharmacist is **NOT** required to verify that a practitioner has a waiver of the requirement to electronically prescribe or properly falls under one of the other exceptions from the requirement to electronically prescribe. Pharmacists may continue to dispense medications from otherwise **valid** written, oral or fax prescriptions that are consistent with current laws and regulations.

The Department will be conducting periodic audits. If a prescriber is identified as repeatedly submitting written prescriptions to a pharmacy, that provider may be at risk for professional discipline.

#### **Exceptional Circumstances** (Written prescription may be most appropriate option)

- · Temporary technological failure
- Temporary electrical failure
- A SAMHS PMP approved e-prescribing waiver
- The practitioner reasonably determines that it would be impractical for the patient to obtain the medication in a timely manner, and such delay would adversely impact the patient's medical condition.
- To be dispensed by a pharmacy located outside the state.
- To be dispensed by a VA or IHS pharmacy.

#### **Frequently Asked Questions**

# What should I do if the system goes down and I am unable to transmit an electronic prescription?

In circumstances when your EMR is down, a written prescription should be issued. It is recommended that, if possible, you print the prescription from your EMR and sign. However, if the system is down completely, a written prescription should be issued and documentation on the patient's chart that a prescription was written and why.

#### What if I am prescribing for a patient with a foreign address?

In most cases it is not possible to issue an electronic prescription for patients with a foreign address. In these circumstances, the prescription should be prepared in your EMR and printed.

#### What should I do if transmission fails?

If the transmission fails you should print the prescription and sign it. Most systems will generate verbiage indicating a failed transmission on the printed script.

Revised August 8, 2017 Johanna Buzzell, PMP Coordinator

# Are any specific fields or specialties excluded from the requirement to electronically prescribe?

No. All practitioners are required to issue electronic prescriptions for opioid medications unless granted a waiver or meet the criteria for any of the listed exceptional circumstances.

(The Veteran's Administration and IHS' prescribers and pharmacies are exempt as they are federally regulated.)

Out-of-state pharmacies and prescribers are also exempt as they are not State regulated.)

# I work at a long-term care facility/nursing home/hospice care facility. Am I exempt from the requirement to electronically prescribe?

No. There is no long-term care facility exception to the e-prescribing mandate. However, per DEA guidelines, schedule II prescriptions may continue to be transmitted via facsimile to the dispensing pharmacy by the above-mentioned facilities.

#### What if my patient is homeless and does not have an address?

It is recommended that you enter any possible address for homeless individuals (shelter, street name, etc.), but if no address is available and you are unable to issue an electronic prescription, a written prescription may be issued.

#### What if my patient's prescription will be dispensed out-of-state?

You may or may not be able to electronically prescribe to an out-of-state pharmacy depending on the laws of that state. It is recommended that you check with the out-of-state pharmacy regarding their electronic prescription capabilities.

# I am not licensed or practicing in Maine, but have a patient who uses a pharmacy in Maine. Do I have to electronically prescribe opioid prescriptions?

Practitioners who are not practicing in Maine are not required to electronically prescribe opioid medications. You must follow your state's laws and regulations.

# Is a pharmacist who is presented with a written prescription after August 1, 2017 required to verify that the practitioner properly falls under one of the exceptions from the requirement to electronically prescribe?

No, pharmacists are not required to verify that a practitioner falls under one of the exceptions.

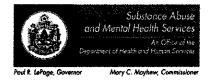
# I am already exempt from the requirement to check the PMP. Am I exempt from electronic prescribing as well?

No. Pursuant to Public Law, Chapter 488, all practitioners must electronically prescribe opioid medications. You may apply for a waiver from the requirement to electronically prescribe. More information can be found on the PMP website: <a href="http://www.maine.gov/dhhs/samhs/osa/data/pmp/e-prescribing.htm">http://www.maine.gov/dhhs/samhs/osa/data/pmp/e-prescribing.htm</a>

#### How do I check the status of my e-prescribing waiver?

The PMP team will respond to your request for waiver within 60 days of receipt. You will not be penalized for non-compliance to the e-prescribing mandate while your application is being reviewed.

Due to the volume of applications received and to process and respond to application requests as quickly as possible, we ask that you please do not contact the PMP team regarding waiver status inquiries. The PMP team will not respond to waiver status inquiries. You will be contacted directly if additional information is needed to process your application. You will be notified, in writing, within 60 days of receipt of the office's determination.



Department of Health and Human Services Substance Abuse and Mental Health Services 41 Anthony Avenue 11 State House Station Augusta, Maine (4333-0011 Tel.: (207) 287-2595; Fax: (207) 287-4334 TTY Users: Dial 711 (Maine Relay)

### **Electronic Prescribing in Maine**

A Guide to Understanding E-Prescribing and its Benefits

Created by: Johanna Buzzell Maine Prescription Monitoring Program Coordinator March 2017

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#### What is Electronic Prescribing

An electronic prescription is a prescription issued with an electronic signature and transmitted by electronic means in accordance with federal requirements. A prescription generated on an electronic system that is printed out on prescription paper and manually signed or transmitted via facsimile is <u>not</u> an electronic prescription.

Electronic prescribing provides practitioners and pharmacies with the ability to use modern technology to issue and dispense controlled substance prescriptions while maintaining a secure, closed system of controls on controlled substance dispensing. Electronic prescribing reduces paperwork and streamlines workflow for practitioners and pharmacies who prescribe and dispense controlled substances and has the potential to reduce prescription forgery. It also has the potential to reduce the number of prescription errors caused by illegible handwriting and misunderstood oral prescriptions.

The computer software application utilized by prescribers and pharmacies in Maine for electronic prescribing, dispensing and archiving of opioid prescriptions must meet the federal security requirements set forth by the Drug Enforcement Agency (DEA). DEA requirements can be found here.

#### **Electronic Prescribing Requirement**

Effective July 1, 2017 all opioid prescriptions issued in Maine will be electronic prescriptions with certain limited exceptions. Please see <u>Public Law Chapter 488</u> for the electronic prescribing requirement.

#### **Definitions**

#### **Electronic Prescription**

A prescription issued with an electronic signature and transmitted by electronic means in accordance with regulations of the department and federal requirements. A prescription generated on an electronic system that is printed out and manually signed or transmitted via facsimile is <u>not</u> considered an electronic prescription.

#### Electronic

Relating to technology having electrical, digital, magnetic, wireless, optical, electromagnetic or similar capabilities. "Electronic" shall not include facsimile according to the DEA for this purpose.

#### **Electronic Record**

A paperless record that is created, generated, transmitted, communicated, received or stored by means of electronic equipment and includes the preservation, retrieval, use and disposition in

accordance with regulations of the department and in compliance with federal law and regulations.

#### **Electronic Signature**

An electronic sound, symbol, or process, attached to or logically associated with an electronic record and executed or adopted by a person with the intent to sign the record, in accordance with regulations of the department.

#### **Certified Software**

A software application that has been audited by a third party auditor or a DEA certifying body to certify that each electronic prescription and pharmacy application used to sign, transmit, or process controlled substances prescriptions is in compliance with DEA regulations pertaining to electronic prescriptions for controlled substances.

#### **Identity Proofing**

The process by which a credential service provider or certification authority validates sufficient information to uniquely identify a person.

#### **Two-Factor Authentication Credentials**

The security credentials that allow the practitioner to sign an electronic prescription. The DEA is allowing the use of two of the following – something you know (a knowledge factor); something you have (a hard token stored separately from the computer being accessed); and something you are (biometric information).

#### Intermediary

Any technology system that receives and transmits an electronic prescription between the practitioner and pharmacy

#### Computer Systems for Electronic Prescribing of Opioid Medications

Maine PMP does not endorse a specific electronic prescribing software application for practitioners to use. Practitioners should research different options and choose a system most appropriate for their practice. Systems may include: standalone applications that can be accessed on a hand-held device; an extensive EHR system that has a built-in e-prescribing module; or speak to professional colleagues or professional associations to determine what options are available. Practitioners may also wish to contact their current Electronic Health Record (EHR) software application provider if they are currently using EHR. The software application company should be able to provide compatibility estimates. In all cases, it is important to verify that the e-prescribing software application meets all federal security requirements for electronically prescribing controlled substances. E-Prescribing vendors often tout their compliance with DEA requirements.

#### **Frequently Asked Questions**

#### Is Electronic Prescribing mandatory for Maine practitioners?

Yes. As of July 1, 2017 it will be mandatory for licensed practitioners whose scope of practice includes prescribing opioid medications to issue electronic prescriptions for opioid medications.

#### Why is electronic prescribing mandatory effective July 1, 2017?

Utilizing modern prescription technology has the potential to minimize medication errors for patients in Maine. Electronic prescribing also allows for the integration of prescription records directly into the patient's EHR. Electronic prescribing has the potential to reduce prescription theft and forgery.

## What steps do I need to complete in order to electronically prescribe opioid prescriptions?

Electronic prescribing software must be obtained. Practitioners may research different options on the internet, speak with professional colleagues or associations to determine what options are available or your contact current Electronic Health Record provider.

Software must meet all of the federal security requirements which can be found on the DEA's web page: <a href="https://www.deadiversion.usdoj.gov/ecomm/e\_rx/">https://www.deadiversion.usdoj.gov/ecomm/e\_rx/</a>

Please note that federal security requirements include a third party audit or DEA certification of the software. Software vendors will often include prominent attestations of compliance with federal regulations.

# If an opioid medication is prescribed for 7 days or less of, does the prescription need to be transmitted electronically?

Yes. Any amount of opioid medication being prescribed requires the prescription to be transmitted electronically.

#### Can a prescriber fax a prescription to a pharmacy after July 1, 2017?

No. A prescription generated on an electronic system that is printed out on prescription paper and manually signed or transmitted via facsimile is **not** an electronic prescription.

#### Why is electronic prescribing important?

Electronic prescribing enables you to maintain compliance with regulatory requirements and supports evidence based practices to improve the standard of care. It has the potential to reduce errors, misuse, abuse and diversion of prescription medications.

#### **Additional Resources for E-Prescribing**

- National Council for Prescription Drug Programs (NCPDP) https://www.ncpdp.org/Resources/ePrescribing
- Drug Enforcement Agency <a href="https://www.deadiversion.usdoj.gov/ecomm/e\_rx/">https://www.deadiversion.usdoj.gov/ecomm/e\_rx/</a>
- Centers for Medicare & Medicaid Services <a href="https://www.cms.gov/Medicare/E-Health/Eprescribing/index.html">https://www.cms.gov/Medicare/E-Health/Eprescribing/index.html</a>

State of Maine

### Substance Abuse and Mental Health Services

An Office of Department of Health and Human Services

DHHS → SAMHS → Substance Abuse → Data & Research + A | -A | Fri 18 Aug 2017 → E-Prescribing

### **E-Prescribing Waivers**

#### For Prescribers

State of Maine licensed practitioners may apply for a waiver from electronically prescribing opioid medications under the following circumstances:

- 1. Technological limitations not reasonably within the control of the practitioner
- Other exceptional circumstances not reasonably within the control of the practitioner

#### **Process for Submitting a Waiver**

- 1. Waivers must be requested from the Office of Substance Abuse and Mental Health Services (SAMHS) Prescription Monitoring Program (PMP).
- 2. Waiver applications must include <u>all</u>of the following. (Please note: Incomplete applications will not be processed. Incomplete applications will be sent back to the applicant with a letter indicating the reason for deferral.)
  - a. Reason for request
  - b. Current electronic prescribing capabilities
  - c. Steps that are being taken to meet the e-prescribing mandate
  - d. Date when electronic prescribing capabilities are expected to be fully functional
  - e. Practitioner's signature
- 3. Responses to waiver requests will be made no later than sixty (60) days from the date a completed application is received by SAMHS PMP. You will not be penalized for non-compliance to the e-prescribing requirement of PL 488 if your completed application has been received by SAMHS PMP and remains under review after July 1, 2017.
- 4. Applicants will receive a verification certificate upon receipt and approval of waiver applications that should be included with all written opioid prescriptions sent to pharmacies.

- 5. Waivers may be granted depending on the circumstances for a period determined appropriate by the office not to exceed twelve (12) months.
- A practitioner may resubmit a waiver application if e-prescribing capabilities are not achieved within the given timeframe.
- Complaint will be filed with the Maine Board of Licensure in Medicine for practitioners not in compliance with the PMP e-prescribing requirements.

Please email the completed form and supporting documentation to SAMHS.PMP@maine.gov with "Prescriber Electronic Prescribing Waiver Request" in the subject line.

Or, mail to:

Department of Health and Human Scrvices
Office of Substance Abuse and Mental Health Services
Prescription Monitoring Program
11 State House Station, 41 Anthony Avenue
Augusta, ME 04330-0011

#### For Pharmacies

State of Maine licensed pharmacies may apply for a waiver from electronically processing opioid medication prescriptions under the following circumstances:

- 1. Technological limitations not reasonably within the control of the pharmacy
- Other exceptional circumstances not reasonably within the control of the pharmacy

#### **Process for Submitting a Waiver**

- 1. Waivers must be requested from the Office of Substance Abuse and Mental Health Services (SAMHS) Prescription Monitoring Program (PMP).
- Waiver applications must include all of the following. Incomplete applications
  will not be processed. (Incomplete applications will be sent back to the
  applicant with a letter indicating the reason for deferral.)
  - 1. Reason for request
  - 2. Current electronic prescribing capabilities
  - 3. Steps that are being taken to meet the e-prescribing mandate
  - Date when electronic prescribing capabilities are expected to be fully functional
  - 5. Authorized signature
- 3. Responses to waiver requests will be made no later than sixty (60) days from the date a completed application is received by SAMHS PMP.

A /4 A /A A 4

- 4. Applicants will receive a verification certificate upon receipt and approval of waiver applications that should be included with all written opioid prescriptions sent to pharmacies.
- 5. Waivers may be granted depending on the circumstances for a period determined appropriate by the office not to exceed twelve (12) months.
- 6. A pharmacy may resubmit a waiver application if e-prescribing capabilities are not achieved within the given timeframe.
- Complaint will be filed with the Maine Board of Pharmacy for pharmacies not in compliance with the PMP e-prescribing requirements.

Please email the completed form and supporting documentation to SAMHS.PMP@maine.gov with "Pharmacy Electronic Prescribing Waiver Request" in the subject line.

#### Or, mail to:

Department of Health and Human Services Office of Substance Abuse and Mental Health Services Prescription Monitoring Program 11 State House Station, 41 Anthony Avenue Augusta, ME 04330-0011

#### Credits

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### Substance Abuse and Mental Health Services

An Office of Department of Health and Human Services

DHHS → SAMHS → Substance Abuse → Data & + A | - A | Wed 23 Aug 2017 Research → E-Prescribing

### **E-Prescribing Waivers**

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Department of Health and Human Services Office of Substance Abuse and Mental Health Services Prescription Monitoring Program 11 State House Station, 41 Anthony Avenue Augusta, ME 04330-0011

#### For Pharmacies

State of Maine licensed pharmacies may apply for a waiver from electronically processing opioid medication prescriptions under the following circumstances:

- 1. Technological limitations not reasonably within the control of the pharmacy
- 2. Other exceptional circumstances not reasonably within the control of the pharmacy

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Please email the completed form and supporting documentation to SAMHS.PMP@maine.gov with "Pharmacy Electronic Prescribing Waiver Request" in the subject line.

#### Or, mail to:

Department of Health and Human Services Office of Substance Abuse and Mental Health Services Prescription Monitoring Program 11 State House Station, 41 Anthony Avenue Augusta, ME 04330-0011

#### **Credits**

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ADA:

3460 Mayland Court, Unit 110
Henrico, Virginia 23233
804.288.5750 F 804.288.1880 www.vadental.org

August 10, 2017

Dr. David Brown, DC Director Department of Health Professions Premier Center 9960 Mayland Drive Henrico, VA 23233

Dear Dr. Brown:

The Virginia Dental Association (VDA) appreciates you affording us an opportunity to participate in the e-prescribing workgroup. The opioid epidemic is real and the VDA wants to be a part of the answer to try and solve that problem.

At the August 2, 2017 meeting of the workgroup you had asked for input from participants. We would suggest the following items for consideration.

#### Duration/Number of Pills

A lot of our members report that they write few prescriptions for opioid based pharmaceuticals. This may vary from month to month but, in most months, they may only prescribe 3-6 prescriptions for opioids. Under that scenario we were wondering if there could be an exception to those providers that write opioid prescriptions for a very limited number of days- say a maximum of 3 days' worth.

#### Cost

Most of our members are solo practitioners. They don't have a large corporate structure over which to spread costs. We asked for a rundown of costs and received the following:

- o PMP Usage \$50 a month
- o Software service \$40-50 a month (this does not cover startup costs)
- o Time it takes 10 minutes for the provider to get on the PMP network put in the password etc., this is time away from the patient and time is money.
- o Also cost & time of the setup of this system
- Our solo practitioners would appreciate an exemption for those practices where there is a single practitioner at that practice site.

#### Out of State

o How do you handle a patient from another state that the system doesn't connect with?

#### Out of Office Contacts

In rural areas, particularly, patients may have pain on the weekend and call the dentist. Today a dentist would ask the patient to stop by their house and write a prescription – how will that be handled?

#### • Free Dental Coverage

As you may be aware, VDA does the free Mission of Mercy (MOM) dental projects all across the Commonwealth. Most of the time we prescribe ibuprofen and double strength Tylenol but in some cases we may need to prescribe an opioid RX. How is that structure to be addressed? There is little or no connectivity in some locations. We would ask for an exemption for those sites.

One interesting comment we received was that particularly with some Medicaid patients they will almost demand an opioid Rx for pain. The patient is told that ibuprofen or Tylenol will handle the problem. What we have found is that a number of these prescriptions for opioid prescriptions are never filled. This could present a problem at the pharmacy where the prescription is filed electronically and is waiting for the patient to show up and the patient never bothers to pick up the prescription. Obviously, there is also the issue of patients not taking all the opioids and sticking them in a cabinet somewhere

Again, Dr. Brown, we appreciate you including the VDA in the workgroup and look forward to continuing to work with you. We hope the above listed issues can be addressed in a fashion that is beneficial to the objective of what you are attempting to accomplish and done in a fashion that won't provide undue labor and expense to those in the provider community.

Again, thank you for the opportunity to provide you input.

Sincerely,

Terry D. Dickinson, DDS

**Executive Director** 

Virginia Dental Association

#### Juran, Caroline (DHP)

From:

Whittemore, Ken <Ken.Whittemore@surescripts.com>

Sent:

Thursday, August 3, 2017 2:23 PM

To:

Rothrock, Laura (DHP); cduvall@lindlcorp.com; rgrossman@vectrecorp.com; tcox@hdjn.com; Ralston King; jmoorerxdm@gmail.com; bbrown@vhha.com; 'abubaker@vcu.edu'; rusty.maney@walgreens.com; gotmarkel@gmail.com; shelley.craft@stores.kroger.com; 'carol.a.forster@kp.org'; Ruth.A.Carter@usdoj.gov; Brown, David (DHP); Juran, Caroline (DHP); Tamayo-Suijk, Sylvia (DHP); Hazel, Bill (GOV);

Manz, Jodi (GOV)

Subject:

Additional Input RE: e-Prescribing Workgroup (HB2165)

Good Afternoon, All:

As a follow-up to yesterday's e-prescribing work group meeting, I would like to share the following:

- Web page listing EHRs connected to the Surescripts network, including the capabilities such as
  electronic prescribing of controlled substances (EPCS) that they are certified for (EPCS is the third
  capability column from the left): http://surescripts.com/network-connections/mns/prescriber-software
- A list of pharmacies and pharmacy software vendors certified for EPCS is pasted underneath my signature block below.
- Web page that discuss many aspects of EPCS as general background: http://surescripts.com/products-and-services/e-prescribing-of-controlled-substances
- Separate web site designed to help providers become enabled for EPCS (which I meant to share
  yesterday but didn't get to it): <a href="http://www.getepcs.com">http://www.getepcs.com</a>. There are two five-minute videos at this site
  designed to quickly walk providers and/or their staffs through the process of becoming enabled for
  EPCS as well as other useful resources.

Take care, and let me know if you have any questions.

Ken

Ken Whittemore, Jr., R.Ph., MBA | VP, Professional & Regulatory Affairs | Surescripts LLC O: 703.921.2114 | C: 540.623.4285 | <a href="www.surescripts.com">www.surescripts.com</a> | <a href="www.surescripts.com">ken.whittemore@surescripts.com</a> | Connect with us: Twitter | LinkedIn | Facebook | YouTube

**Certified Pharmacies and Pharmacy Software Systems** 

The following pharmacies and/or pharmacy software vendors have completed Surescripts certification and third-party audits for e-prescribing of controlled substances:

- Accredo
- AdvanceNet Health Solutions
- Best Computer Systems
- CarePoint
- Cerner Etreby
- Computer-Rx
- Cost Effective Computers
- Creehan & Company
- CVS/caremark mail
- CVS/pharmacy
- CVS/specialty
- DAA Enterprises
- Digital Business Solutions
- Enclara Pharmacia
- Epic Willow Ambulatory
- Express Scripts Home Delivery
- FrameworkLTC by SoftWriters
- Foundation Systems
- Haney's Drug Corner
- HEB Pharmacy
- Health Business Systems
- Humana Pharmacy
- Injured Workers Pharmacy
- KeyCentrix
- Kroger
- Lagniappe Pharmacy Services (Alpha, InteRx, OpusRx, PPC, Rx-1, Synercom, Visual)
- Liberty Software
- McKesson Pharmacy Systems (Condor, EnterpriseRx, PharmacyRx, Pharmasery, Zadall)
- MDScripts
- Micro Merchant Systems
- Omnicare
- OptumRx
- PD-Rx Pharmaceuticals
- PDX
- Pharmacy Systems, Inc
- PharMerica

- PioneerRx
- Prodigy Data Systems
- QS/1 Data Systems
- Rite Aid
- RNA Helix
- ScriptPro USA
- SRS Pharmacy
- SuiteRx
- SuperValu
- · Thrifty White Pharmacy
- Transaction Data Systems
- VIP Computer Systems
- · Walgreens
- Walmart

----Original Appointment----

From: Rothrock, Laura (DHP) [mailto:Laura.Rothrock@dhp.virginia.gov]

Sent: Thursday, July 20, 2017 6:11 PM

To: Rothrock, Laura (DHP); cduvall@lindlcorp.com; rgrossman@vectrecorp.com; tcox@hdjn.com; Ralston King; jmoorerxdm@gmail.com; Whittemore, Ken; bbrown@vhha.com; 'abubaker@vcu.edu'; rusty.maney@walgreens.com; gotmarkel@gmail.com; shelley.craft@stores.kroger.com; 'carol.a.forster@kp.org'; Ruth.A.Carter@usdoj.gov; Brown, David (DHP); Juran, Caroline (DHP); Tamayo-Suijk, Sylvia (DHP); Hazel, Bill (GOV); Manz, Jodi (GOV)

Subject: e-Prescribing Workgroup (HB2165)

When: Wednesday, August 2, 2017 9:00 AM-3:00 PM (UTC-05:00) Eastern Time (US & Canada). Where: DHP, Perimeter Center, 2nd Floor, Board Room 2, 9960 Mayland Drive, Henrico, VA 23233

Good evening,

Pursuant to <u>HB2165</u> and <u>SB1230</u>, the Secretary of Health and Human Resources will convene a workgroup of interested stakeholders to review actions necessary for the implementation of the provisions requiring prescriptions containing opiates to be issued as electronic prescriptions by July 1, 2020, and to evaluate hardships on prescribers, the inability of prescribers to comply with the deadline for electronic prescribing and make recommendations to the General Assembly for any extension or exemption processes relative to compliance or disruptions due to natural or manmade disasters or technology gaps, failures or interruptions of services.

This is the first meeting of the workgroup. The agenda package will be sent in a separate email and will also be available on Town Hall.

As noted in "Location," the meeting will be held in **Board Room 2** on the **Second Floor** of our building. Parking is free and is available in the front and on the side of the building (you may enter through front of building only). <u>Directions can be found here</u>

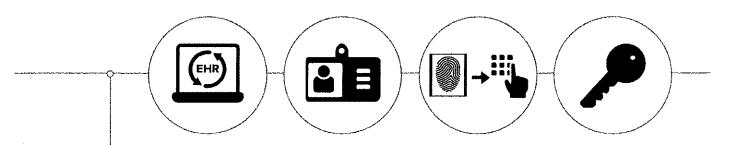
Should the workgroup require an additional meeting, a second meeting will be held from 9am-Noon on August 29, 2017.

If you should have any questions, please let me know.

Thanks,

### Getting Started with

# **Electronic Prescribing**of Controlled Substances



The videos and digital tools on www.getEPCS.com make it easy for you to learn what to do to get your practice up and running with electronic prescribing of controlled substances (EPCS).

Since the Drug Enforcement Administration (DEA) provides two pathways to regulatory compliance for medical practices, the pathway you take depends on how your EHR system is set up.

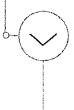


Practitioners using an EHR system registered to an individual DEA number usually fit into the **Solo & Small Group Practices** pathway.



Practitioners registered to an institutional (shared) DEA number are usually part of a **Health System Affiliated Practice** pathway.

Check with your EHR vendor to determine which pathway best fits your practice if you are not sure.





### **Solo & Small Practices**

Practitioners registered to an individual DEA number



#### **EHR Software Update**

- Find out if the EHR software version that your practice uses has already been certified and approved for EPCS
- Use the button labeled "Find your EHR status" at www.getEPCS.com, or you can ask your EHR account manager



#### **ID Proofing**

- ID proofing can be done in-person or online, through companies that work with your EHR
- For online ID proofing, you may need to answer a security question and email scanned copies of government-issued documents along with your photo and your medical license
- · Sometimes an electric bill or bank statement is also needed to confirm your address



#### **Two-Factor Authentication**

- This double-level process ensures that only you can sign and send the controlled substance prescription to the pharmacy
- There are various options: mobile phones, smart cards, fob tokens, USB thumb drives, and biometrics like fingerprint scanners
- . Once you're set up, two-factor authentication requires hardly any extra effort



#### **Setting Software Access**

- For this final step, you'll need two separate people to set secure access controls for your EHR e-prescribing software
- One person needs to be a DEA registrant who has been ID-proofed and has their two-factor authentication method in place—this could be you
- The other is a person who can confirm your identity, such as an office manager or another member of your practice—but they do not need to be an employee of your practice

After completing the four required action steps, you will be able to legally transmit electronic prescriptions for controlled substances. You can trust that your EHR application has been certified to digitally sign a prescription for a controlled substance and send it to a pharmacy of the patient's choice. You, your patients and pharmacists can now enjoy the added convenience and security of EPCS!

For information specific to your EHR software application, always consult with your EHR vendor.



# Health System Affiliated Practices

Practitioners registered to a shared DEA number



## **EHR Software Update**

- Find out if the EHR software version that your practice uses has already been certified and approved for EPCS
- Use the button labeled "Find your EHR status" at www.getEPCS.com or ask your EHR account manager



#### **ID Proofing**

- Your health system's credentialing office may take on this responsibility, but sometimes ID Proofing is conducted online through companies working with your EHR
- · Check with your health system's credentialing office for their exact requirements



#### **Two-Factor Authentication**

- This double-level process ensures that only you can sign and send the controlled substance prescription to the pharmacy
- There are various options: mobile phones, smart cards, fob tokens, USB thumb drives, and biometrics like fingerprint scanners
- Once you're set up, two-factor authentication requires hardly any extra effort
- Ask your health system's credentialing office, IT department, or medical leadership for guidance on credentials and the type of two-factor authentication method they approve



## **Setting Software Access**

- After completing the first three required action steps, your health system is now ready to set secure access controls for your EHR e-prescribing software
- Your health system's credentialing office will send a list of prescribers who have completed their identity proofing and have received two-factor authentication credentials to the IT department
- The IT department will then assign EPCS access and permissions to the prescribers

After completing the four required action steps, you will be able to legally transmit electronic prescriptions for controlled substances. You, your patients and pharmacists can now enjoy the added convenience and security of EPCS!

For information specific to your EHR software application, always consult with your EHR vendor.

US State Pharmacy EPCS Enablement - July 2017 Current as of July 2017

Current as of July 2017			****			
State County	Total Pharmacies	Active eRx E Pharmacies	PSC Enabled Pharmacies	% eRx Active Pharmacies	% EPCA Enabled Pharmacies	Total NexRx Total EPCS Messages
ACCOMACK ALBEMARLE	7	5	5	71.4%	71.4% 94.1%	7,676 82 22,895 243
ALEXANDRIA CITY	917 30	47 28	16 26	190,0% 93.3%	86.7%	37 045 967
alleghany Amelia	<b>?</b>	2 2	<b>2</b>	190:0% 100.0%	\$00.5% 100.0%	5 561 14 1,292 50
AMHERST	i	•	•	400.0%	100.0%	6,543 164
APPCMATYOX ARUNGTON	t 49	5 <b>4</b> 1	5 41	100.0% 95.8%	100.0% 95.3%	6,286 166 46,336 3,219
AUGUSTA	5	5	4	100.0%	80.0%	25,63B 927
BATH BEDFORD	1 9	9		180.0% 100.0%	100.5% 100.0%	2 190 14 520 539
BLAND	4	î	* 1	189.0%	100.0%	4.402
BOTETOURT BRISTOL CITY	3	3	2	100.0% 100.0%	66,7% 85.7%	9,501 32 5,911
BRUNSWICK	1	1	1	100.0% <b>\$90.5%</b>	100.0%	1,113 22
Buchanan Buckingham	9 2	<b>9</b> 2	<b>4</b> 2	100.0%	<b>-61.6%</b> 100.0%	9,901 2,632 189
BUENA VISTA CITY CAMPBELL	<b>1</b>	<b>7</b>		100.0% 100.0%	160.0% 100.0%	#27 4,335 276
CAROLINE	3	3	2	100.0%	66.734	1,892
CARROLL CHARLES CITY	3	3	3	100.0%	100.0%	5 863 163 1 925 27
CHARLOTTE	2	2	2	100.0%	100.0%	2.681 208
CHARLOTTESVILLE CITY CHESAPEAKE CITY	13 45	12 44	42	92.8% 97.8%	<b>53.6%</b> 93.3%	48 846 502 72,362 1,224
CHESTERFIELD CLARKE	55 2	6Ē 2	54 2	100.0% 100.0%	<b>38.7%</b> 100.0%	170 518 2196 1,999
COLONIAL HEIGHTS CITY	•		<b>6</b>	88.5%	86 P%	28,149 933
COVINGTON CITY CRAIG	2	2 4.	2	190 0% 100.0%	100.0% <b>400.0%</b>	1,140 :55\$
CULPÉPER	ŧ	8	8 3	100,0%	100,0%	10,014 10
CUMBERLAND DANVILLE CITY	1 16	16	15	400.0% 100.0%	900.0% 93.8%	<b>1985</b> 33,223 299
DICKENSON DINWIDDIE	ý 2	2	1	100.0% 100.0%	57 3% 50.0%	6,846 1,035 46
EMPORIA CITY		3	(100 g 3	100.0%	1003%	5.161 227
ESSEX FAIRFAX	3 167	3 165	3 167	100.0% 89.4%	100.0% \$4.0%	4,360 45 256,770 6,616
FAIRFAX CITY FALLS CHURCH CITY	16 6	15 6	15 8	93.8% <b>200.0%</b>	93.6% <b>300.0%</b>	16,835 596 8,623 177
FAUQUIER	12	12	12	100.6%	100.0%	18.183 16
FŁOYD FLUVANNA	3	3	3	100.0%	400,0% 100,0%	2,919 16 1,915
FRANKLIN		9 4		100.0%	9).9%	12.810 49 5.614 550
FRANKLIN CITY FREDERICK	4	14	4	100.0% 180.0%	100.0% 100.0%	5,614 550 2,853
FREDERICKSBURG CITY GALAX CITY	11 \$	10 <u>\$</u>	8 E	90.8% 400.0%	72.7% 700.0%	31,371 473 12,379 12
GILES	4	4	4	100.0%	100.0%	6,922
GLOUCESTER GOOCHLAND	6 3	<b>6</b> 2	6 C	190.0% 66.7%	380.0% 0.0%	11.094 (98- 1,017
GRAYSON GREENE	9 9	3	<u>.</u> 2	940.0% 100.0%	100.0% 100.0%	2.146 1,442
GREENSVILLE						
HALIFAX HAMPTON CITY	5 24	5 22	5 22	100.0% 91.7%	100.0% 91.7%	9 782 48,736 2 913
HANOVER HARRISONBURG CITY	25	25	23	190.0%	92.0%	46 177 671
HENRICO	71	68	65	300.0% 95.8%	88254 91.5%	30 643 316 124 741 3 234
HENRY HIGHLAND		<b>5</b> 1		83.3% 100.0%	83.3% 0.0%	7.262 391
HOPEWELL CITY		. 4 5		900.0% 100.0%	194,0% 100,0%	6,700 74 10.453 530
ISLE OF WIGHT JAMES CITY	£ 22	22	21	400.0%	95.5%	43.888 1,237
KING AND QUEEN KING GEORGE	ż	± 100 m	2000 (10 <b>2</b> 2 2000)	160.0%	\$60,0%	384 48 2/307
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LEXINGTON CITY LOUDDUN	5 58	-\$ 58	35 58	100.0% 100.0%	100,0% 100,0%	7,553 23 72,069 1,654
LOUISA			3 6 6	100.0%	75.0%	3574
LUNENBURG LYNCHBURG CITY	2 20	2 26	2 19	100.0% 900.0%	100.0% 96.0%	2,671 51 57,674 2,068
MADISON MANASSAS CITY	1	1 42	1 12	100.0% 100.0%	100.0% 300.0%	1,512 22,854 553
MANASSAS PARK CITY	- A service of the se					
MARTINSVILLE CITY			7.00	100.0%	87.5%	22,912 33

US State Pharmacy EPCS Enablement - July 2017

Curren	ıt as	of	July	2017

State County	Total Pharmacies	Active cRx Pharmacies	EPSC Enabled Pharmacies	% eRx Active Pharmacies	% EPCA Enabled Pharmacies	Total NexRx Total E	PCS Messages
MATHEWS	2	2	0	100.0%	0.0%	1,143	5
MECKLENBURG			ă.	88,9%	55,6%	15,010	526
MIDDLESEX	2	2	<b>†</b>	100.5%	60.0%	2,717	67
MONTGOMERY	_14	14		190,0%	un (%	32,809	325
NELSON NEW KENT	3 ************************************	3 2000000000000000000000000000000000000	3 ::::::::::::::::::::::::::::::::::::	100.0%	100.0%	3.617	26
NEWPORT NEWS C	.8° iTY 30	3 30	3 28	100.0% 100.0%	4 <b>0</b> 0 0% 93.3%	2.60g 79.127	54 3,679
NORFOLK CITY		40	#5	95.5%	90.0%	79,127	1,349
NORTHAMPTON	4	a	**************************************	100.0%	100.0%	6,633	60
NORTHUMBERLANE	) Ž	ž.	3	100.0%	50.0%	2,095	
NORTON CITY	4	4	4	100 0%	100.0%	16.232	Colorecte used utrester
YAWOTTOM		3		100.0%	300.0%	4,595	
GRANGE	a	7	6	87,5%	75.0%	10,161	103
PAGE PATRICK	3 4	<b>8</b> 3	9 3	100.0%	100.0%	6,506	
PETERSBURG CITY	¥2	9D	10	75.0% 83.3%	75.0% \$3.3%	2 981 1 <b>1 469</b>	1.963
PITTSYLVANIA	4	60 000 000 000 000 <b>1</b> 60 000 000 <b>4</b>	4	100.0%	100.0%	5 607	
POQUOSON CITY	3.	3	4	100.6%	100.0%	136	534000-00000
PORTSMOUTH CITY		16	13	100.0%	81,3%	22.299	ine terminal contribution.
POWHATAN	3			100.0%	\$00.0%	5.195	80 Sec. 100 Sec.
PRINCE EDWARD	5	4	4	80.0%	80.0%	8,151	54
PRINCE GEORGE PRINCE WILLIAM	•	•	•			12 544	765
PULASKI	60 \$	60 National Control (1980)	60 7	100.0% 700.0%	100.0% 400.0%	78.786 7.862	1.307
RADFORD	4	1	•	100.0%	100.0%	4,383	
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ROANOKE	16	15	15	93.8%	93.8%	37.741	747
ROANOKE CITY	25	24	21	96.0%	94.0%	61,360	300
ROCKBRIDGE ROCKINGHAM	1		1 ntechoses assentiates tecetor	100.0% 500.0%	100,0%	1.677	9 2000000000000000000000000000000000000
RUSSELL	**************************************	8 5	7	100.0%	87.5% 87.5%	40,983 11 155	8000 B. 1857
SALEM	12	2	44	100.0%	91.7%	20.242	652
SCOTT	6	6	5	700.0%	83.3%	7,570	on the second second
SHENANDOAM	Ť	7	7	100.0%	\$00.0%	6,232	346
\$MYTH	12	12	11	100.0%	81.7%	9,722	
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STAUNTON CITY	9	20	118 9	100.0% 100.0%	95.0% 100.0%	88 850 9 270	379
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SUSSEX	<b>.</b>		2	100,0%	86.7%	4.617	
TAZEWELL	18	18	17	100.0%	94.4%	25.445	57
VIRGINIA BEACH CIT	Y 82	81	76	38.8%	95.1%	116,697	1.852
WARREN WASHINGTON	7 1 <b>e</b>	7	7	100.0% 100.0%	100.0%	10,107	213
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US State Prescriber EPCS Enablement - July 2017

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	STAFFORD	380						46
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	WESTMORELAND	10			30%		1,345	S0
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	WINCHESTER CITY	708	408		_			2.380
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	YORK	157	32			and comment and an experience of the second	7,534	531

# GENERAL ASSEMBLY OF NORTH CAROLINA SESSION 2017

#### SESSION LAW 2017-74 HOUSE BILL 243

AN ACT STRENGTHENING OPIOID MISUSE PREVENTION BY EXTENDING STANDING ORDERS FOR OPIOID ANTAGONIST TO COMMUNITY HEALTH GROUPS; REQUIRING SUPERVISING PHYSICIANS TO PERSONALLY CONSULT WITH PHYSICIAN ASSISTANTS AND NURSE PRACTITIONERS WHO PRESCRIBE CERTAIN SCHEDULE II OR III CONTROLLED SUBSTANCES FOR LONG-TERM USE: REOUIRING ELECTRONIC PRESCRIBING OF CERTAIN SCHEDULE II AND III CONTROLLED SUBSTANCES; ESTABLISHING MAXIMUM LIMITS FOR INITIAL PRESCRIPTIONS OF CERTAIN SCHEDULE II AND III CONTROLLED SUBSTANCES; REQUIRING HOSPICE AND PALLIATIVE CARE PROVIDERS TO PROVIDE EDUCATION REGARDING PROPER DISPOSAL OF CERTAIN UNUSED CONTROLLED SUBSTANCES; CLARIFYING ALLOWABLE FUNDS FOR SYRINGE EXCHANGE PROGRAMS; REQUIRING VETERINARIAN PARTICIPATION IN THE CONTROLLED SUBSTANCES REPORTING SYSTEM; ESTABLISHING CIVIL PENALTIES FOR PHARMACIES THAT EMPLOY DISPENSERS WHO IMPROPERLY REPORT INFORMATION TO THE CONTROLLED SUBSTANCES REPORTING SYSTEM (CSRS); EXPANDING THE ROLE OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (DHHS) IN USING CSRS DATA TO DETECT AND PREVENT FRAUD AND MISUSE; MANDATING DISPENSER REGISTRATION FOR ACCESS TO THE CSRS; MANDATING DISPENSER AND PRACTITIONER USE OF THE CSRS; REQUIRING DHHS TO REPORT PRACTITIONERS WHO FAIL TO PROPERLY USE THE CSRS; CREATING A SPECIAL REVENUE FUND TO SUPPORT THE CSRS; AND REQUIRING AN ANNUAL REPORT FROM DHHS ON THE CSRS.

Whereas, the General Assembly recognizes the substantial impact the nationwide opioid epidemic continues to have on the State of North Carolina; and

Whereas, North Carolina has seen a 442% increase in overdose deaths caused by commonly prescribed opioids between 1999 and 2015; and

Whereas, the General Assembly fully recognizes the appropriate use of opioids in the treatment of acute and chronic pain; Now, therefore,

The General Assembly of North Carolina enacts:

#### PART I. TITLE OF ACT

**SECTION 1.** This act shall be known and may be cited as the "Strengthen Opioid Misuse Prevention Act of 2017" or the "STOP Act."

# PART II. EXTEND STANDING ORDERS FOR OPIOID ANTAGONIST TO COMMUNITY HEALTH GROUPS

**SECTION 2.** G.S. 90-12.7 reads as rewritten:

"§ 90-12.7. Treatment of overdose with opioid antagonist; immunity.



- (a) As used in this section, "opioid antagonist" means naloxone hydrochloride that is approved by the federal Food and Drug Administration for the treatment of a drug overdose.
- (b) The following individuals may prescribe an opioid antagonist in the manner prescribed by this subsection:
  - (1) A practitioner acting in good faith and exercising reasonable care may directly or by standing order prescribe an opioid antagonist to (i) a person at risk of experiencing an opiate-related overdose or (ii) a family member, friend, or other person in a position to assist a person at risk of experiencing an opiate-related overdose. As an indicator of good faith, the practitioner, prior to prescribing an opioid under this subsection, may require receipt of a written communication that provides a factual basis for a reasonable conclusion as to either of the following:
    - a. The person seeking the opioid antagonist is at risk of experiencing an opiate-related overdose.
    - b. The person other than the person who is at risk of experiencing an opiate-related overdose, and who is seeking the opioid antagonist, is in relation to the person at risk of experiencing an opiate-related overdose:
      - 1. A family member, friend, or other person.
      - 2. In the position to assist a person at risk of experiencing an opiate-related overdose.
  - (2) The State Health Director or a designee may prescribe an opioid antagonist pursuant to subdivision (1) of this subsection by means of a statewide standing order.
  - (3) A practitioner acting in good faith and exercising reasonable care may directly or by standing order prescribe an opioid antagonist to any governmental or nongovernmental organization, including a local health department, a law enforcement agency, or an organization that promotes scientifically proven ways of mitigating health risks associated with substance use disorders and other high-risk behaviors, for the purpose of distributing, through its agents, the opioid antagonist to (i) a person at risk of experiencing an opiate-related overdose or (ii) a family member, friend, or other person in a position to assist a person at risk of experiencing an opiate-related overdose.
- (c) A pharmacist may dispense an opioid antagonist to a person described in subdivision (b)(1) of this section or organization pursuant to a prescription issued pursuant to in accordance with subsection (b) of this section. For purposes of this section, the term "pharmacist" is as defined in G.S. 90-85.3.
- (c1) A governmental or nongovernmental organization, including a local health department, a law enforcement agency, or an organization that promotes scientifically proven ways of mitigating health risks associated with substance use disorders and other high-risk behaviors may, through its agents, distribute an opioid antagonist obtained pursuant to a prescription issued in accordance with subdivision (3) of subsection (b) of this section to (i) a person at risk of experiencing an opiate-related overdose or (ii) a family member, friend, or other person in a position to assist a person at risk of experiencing an opiate-related overdose. An organization, through its agents, shall include with any distribution of an opioid antagonist pursuant to this subsection basic instruction and information on how to administer the opioid antagonist.
- (d) A person who receives an opioid antagonist that was prescribed pursuant to subsection (b) of this section or distributed pursuant to subsection (c1) of this section may administer an opioid antagonist to another person if (i) the person has a good faith belief that

the other person is experiencing a drug-related overdose and (ii) the person exercises reasonable care in administering the drug to the other person. Evidence of the use of reasonable care in administering the drug shall include the receipt of basic instruction and information on how to administer the opioid antagonist.

- (e) All of the following individuals are immune from any civil or criminal liability for actions authorized by this section:
  - Any practitioner who prescribes an opioid antagonist pursuant to subsection
     (b) of this section.
  - (2) Any pharmacist who dispenses an opioid antagonist pursuant to subsection (c) of this section.
  - (3) Any person who administers an opioid antagonist pursuant to subsection (d) of this section.
  - (4) The State Health Director acting pursuant to subsection (b) of this section.
  - (5) Any organization, or agent of the organization, that distributes an opioid antagonist pursuant to subsection (c1) of this section."

#### PART III. IMPROVE OPIOID PRESCRIBING PRACTICES

**SECTION 3.** G.S. 90-87 reads as rewritten:

#### "§ 90-87. Definitions.

As used in this Article:

- (26a) "Targeted controlled substance" means any controlled substance included in G.S. 90-90(1) or (2) or G.S. 90-91(d).
- SECTION 4. G.S. 90-18.1(b) is amended by adding a new subdivision to read:
- "(5) A physician assistant shall personally consult with the supervising physician prior to prescribing a targeted controlled substance as defined in Article 5 of this Chapter when all of the following conditions apply:
  - a. The patient is being treated by a facility that primarily engages in the treatment of pain by prescribing narcotic medications or advertises in any medium for any type of pain management services.
  - b. The therapeutic use of the targeted controlled substance will or is expected to exceed a period of 30 days.

When a targeted controlled substance prescribed in accordance with this subdivision is continuously prescribed to the same patient, the physician assistant shall consult with the supervising physician at least once every 90 days to verify that the prescription remains medically appropriate for the patient."

SECTION 5. G.S. 90-18.2(b) is amended by adding a new subdivision to read:

- "(5) A nurse practitioner shall personally consult with the supervising physician prior to prescribing a targeted controlled substance as defined in Article 5 of this Chapter when all of the following conditions apply:
  - a. The patient is being treated by a facility that primarily engages in the treatment of pain by prescribing narcotic medications or advertises in any medium for any type of pain management services.
  - b. The therapeutic use of the targeted controlled substance will or is expected to exceed a period of 30 days.

When a targeted controlled substance prescribed in accordance with this subdivision is continuously prescribed to the same patient, the nurse practitioner shall consult with the supervising physician at least once every

90 days to verify that the prescription remains medically appropriate for the patient."

**SECTION 6.** G.S. 90-106 reads as rewritten:



## "§ 90-106. Prescriptions and labeling.

- (a) Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance included in Schedule II of this Article may be dispensed without the written prescription of a practitioner. No Schedule II substance shall be dispensed pursuant to a written or electronic prescription more than six months after the date it was prescribed.
- (a1) Electronic Prescription Required; Exceptions. Unless otherwise exempted by this subsection, a practitioner shall electronically prescribe all targeted controlled substances. This subsection does not apply to prescriptions for targeted controlled substances issued by any of the following:
  - (1) A practitioner, other than a pharmacist, who dispenses directly to an ultimate user.
  - (2) A practitioner who orders a controlled substance to be administered in a hospital, nursing home, hospice facility, outpatient dialysis facility, or residential care facility, as defined in G.S. 14-32.2.
  - (3) A practitioner who experiences temporary technological or electrical failure or other extenuating circumstance that prevents the prescription from being transmitted electronically; provided, however, that the practitioner documents the reason for this exception in the patient's medical record.
  - (4) A practitioner who writes a prescription to be dispensed by a pharmacy located on federal property; provided, however, that the practitioner documents the reason for this exception in the patient's medical record.
  - (5) A person licensed to practice veterinary medicine pursuant to Article 11 of Chapter 90 of the General Statutes.
- (a2) Verification by Dispenser Not Required. A dispenser is not required to verify that a practitioner properly falls under one of the exceptions specified in subsection (a1) of this section prior to dispensing a targeted controlled substance. A dispenser may continue to dispense targeted controlled substances from valid written, oral, or facsimile prescriptions that are otherwise consistent with applicable laws.
- (a3) Limitation on Prescriptions Upon Initial Consultation for Acute Pain. A practitioner may not prescribe more than a five-day supply of any targeted controlled substance upon the initial consultation and treatment of a patient for acute pain, unless the prescription is for post-operative acute pain relief for use immediately following a surgical procedure. A practitioner shall not prescribe more than a seven-day supply of any targeted controlled substance for post-operative acute pain relief immediately following a surgical procedure. Upon any subsequent consultation for the same pain, the practitioner may issue any appropriate renewal, refill, or new prescription for a targeted controlled substance. This subsection does not apply to prescriptions for controlled substances issued by a practitioner who orders a controlled substance to be wholly administered in a hospital, nursing home licensed under Chapter 131E of the General Statutes, hospice facility, or residential care facility, as defined in G.S. 14-32.2(c1). A practitioner who acts in accordance with the limitation on prescriptions as set forth in this subsection shall be immune from any civil liability or disciplinary action from the practitioner's occupational licensing agency for acting in accordance with this subsection.
- (a4) Definitions. As used in this subsection, the following terms have the following meanings:
  - (1) Acute pain. Pain, whether resulting from disease, accident, intentional trauma, or other cause, that the practitioner reasonably expects to last for three months or less. The term does not include chronic pain or pain being

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- treated as part of cancer care, hospice care, palliative care, or medication-assisted treatment for substance use disorder.
- (2) Chronic pain. Pain that typically lasts for longer than three months or that lasts beyond the time of normal tissue healing.
- Surgical procedure. A procedure that is performed for the purpose of structurally altering the human body by incision or destruction of tissues as part of the practice of medicine. This term includes the diagnostic or therapeutic treatment of conditions or disease processes by use of instruments such as lasers, ultrasound, ionizing, radiation, scalpels, probes, or needles that cause localized alteration or transportation of live human tissue by cutting, burning, vaporizing, freezing, suturing, probing, or manipulating by closed reduction for major dislocations and fractures, or otherwise altering by any mechanical, thermal, light-based, electromagnetic, or chemical means.
- (a5) Dispenser Immunity. A dispenser shall be immune from any civil or criminal liability or disciplinary action from the Board of Pharmacy for dispensing a prescription written by a prescriber in violation of this section.
- (b) In emergency situations, as defined by rule of the Commission, Schedule II drugs may be dispensed upon oral prescription of a practitioner, reduced promptly to writing and filed by the dispensing agent. Prescriptions shall be retained in conformity with the requirements of G.S. 90-104. No prescription for a Schedule II substance may be refilled.
- (c) Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance included in Schedules III or IV, except paregoric, U.S.P., as provided in G.S. 90-91(e)1, may be dispensed without a prescription, and oral prescriptions shall be promptly reduced to writing and filed with the dispensing agent. Such prescription may not be filled more than six months after the date thereof or be refilled more than five times after the date of the prescription.
- (d) No controlled substance included in Schedule V of this Article or paregoric, U.S.P., may be distributed or dispensed other than for a medical purpose.
- (e) No controlled substance included in Schedule VI of this Article may be distributed or dispensed other than for scientific or research purposes by persons registered under, or permitted by, this Article to engage in scientific or research projects.
- (f) No controlled substance shall be dispensed or distributed in this State unless such substance shall be in a container clearly labeled in accord with regulations lawfully adopted and published by the federal government or the Commission.
- (g) When a copy of a prescription for a controlled substance under this Article is given as required by G.S. 90-70, such copy shall be plainly marked: "Copy for information only." Copies of prescriptions for controlled substances shall not be filled or refilled.
- (h) A pharmacist dispensing a controlled substance under this Article shall enter the date of dispensing on the prescription order pursuant to which such controlled substance was dispensed.
- (i) A manufacturer's sales representative may distribute a controlled substance as a complimentary sample only upon the written request of a practitioner. Such request must be made on each distribution and must contain the names and addresses of the supplier and the requester and the name and quantity of the specific controlled substance requested. The manufacturer shall maintain a record of each such request for a period of two years."

**SECTION 7.** Article 5 of Chapter 90 of the General Statutes is amended by adding a new section to read:

# "§ 90-106.3. Disposal of residual pain prescriptions following death of hospice or palliative care patient.

Any hospice or palliative care provider who prescribes a targeted controlled substance to be administered to a patient in his or her home for the treatment of pain as part of in-home hospice or palliative care shall, at the commencement of treatment, provide oral and written information to the patient and his or her family regarding the proper disposal of such targeted controlled substances. This information shall include the availability of permanent drop boxes or periodic "drug take-back" events that allow for the safe disposal of controlled substances such as those permanent drop boxes and events that may be identified through North Carolina Operation Medicine Drop."

# PART IV. CLARIFY ALLOWABLE FUNDS FOR SYRINGE EXCHANGE PROGRAMS

SECTION 8. G.S. 90-113.27(b)(2) reads as rewritten:

"(2) Needles, hypodermic syringes, and other injection supplies at no cost and in quantities sufficient to ensure that needles, hypodermic syringes, and other injection supplies are not shared or reused. No public-State funds may be used to purchase needles, hypodermic syringes, or other injection supplies."

# PART V. STRENGTHEN CONTROLLED SUBSTANCES REPORTING SYSTEM SECTION 9. G.S. 90-113.72 reads as rewritten:

## "§ 90-113.72. Definitions.

The following definitions apply in this Article:

- (1) "Commission" means the Commission. The Commission for Mental Health, Developmental Disabilities, and Substance Abuse Services established under Part 4 of Article 3 of Chapter 143B of the General Statutes.
- (2) "Controlled substance" means a Controlled substance. A controlled substance as defined in G.S. 90-87(5).
- (3) "Department" means the Department. The Department of Health and Human Services.
- (4) "Dispenser" means a Dispenser. A person who delivers a Schedule II through V controlled substance to an ultimate user in North Carolina, but does not include any of the following:
  - a. A licensed hospital or long-term care pharmacy that dispenses such substances for the purpose of inpatient administration.
  - b. Repealed by Session Laws 2013-152, s. 1, effective January 1, 2014, and applicable to prescriptions delivered on or after that date.
  - c. A wholesale distributor of a Schedule II through V controlled substance.
  - d. A person licensed to practice veterinary medicine pursuant to Article 11 of Chapter 90 of the General Statutes.
- (4a) Pharmacy. A person or entity holding a valid pharmacy permit pursuant to G.S. 90-85.21 or G.S. 90-85.21A.
- (5) "Ultimate user" means a Ultimate user. A person who has lawfully obtained, and who possesses, a Schedule II through V controlled substance for the person's own use, for the use of a member of the person's household, or for the use of an animal owned or controlled by the person or by a member of the person's household."

SECTION 10. G.S. 90-113.73 reads as rewritten:

"§ 90-113.73. Requirements for controlled substances reporting system-system; civil penalties for failure to properly report.

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- (a) The Department shall establish and maintain a reporting system of prescriptions for all Schedule II through V controlled substances. Each dispenser shall submit the information in accordance with transmission methods and frequency established by rule by the Commission. The Department may issue a waiver to a dispenser who is unable to submit prescription information by electronic means. The waiver may permit the dispenser to submit prescription information by paper form or other means, provided all information required of electronically submitted data is submitted. The dispenser shall report the information required under this section no later than the close of business three business days after the day when the prescription was delivered, beginning the next day after the delivery date; however, dispensers are encouraged to report the information no later than 24 hoursthe close of the next business day after the prescription is delivered; however, dispensers are encouraged to report the information no later than 24 hours after the prescription was delivered. The information shall be submitted in a format as determined annually by the Department based on the format used in the majority of the states operating a controlled substances reporting system. In the event the dispenser is unable to report the information within the time frame required by this section because the system is not operational or there is some other temporary electrical or technological failure, this inability shall be documented in the dispenser's records. Once the electrical or technological failure has been resolved, the dispenser shall promptly report the information.
- (b) The Commission shall adopt rules requiring dispensers to report the following information. The Commission may modify these requirements as necessary to carry out the purposes of this Article. The dispenser shall report:
  - (1) The dispenser's DEA number.
  - (2) The name of the patient for whom the controlled substance is being dispensed, and the patient's:
    - a. Full address, including city, state, and zip code,
    - b. Telephone number, and
    - c. Date of birth.
  - (3) The date the prescription was written.
  - (4) The date the prescription was filled.
  - (5) The prescription number.
  - (6) Whether the prescription is new or a refill.
  - (7) Metric quantity of the dispensed drug.
  - (8) Estimated days of supply of dispensed drug, if provided to the dispenser.
  - (9) National Drug Code of dispensed drug.
  - (10) Prescriber's DEA number.
  - (11) Method of payment for the prescription.
- (c) A dispenser shall not be required to report instances in which a controlled substance is provided directly to the ultimate user and the quantity provided does not exceed a 48-hour supply.
- (d) A dispenser shall not be required to report instances in which a Schedule V non-narcotic, non-anorectic Schedule V controlled substance is provided directly to the ultimate user for the purpose of assessing a therapeutic response when prescribed according to indications approved by the United States Food and Drug Administration.
- (e) The Department shall assess, against any pharmacy that employs dispensers found to have failed to report information in the manner required by this section within a reasonable period of time after being informed by the Department that the required information is missing or incomplete, a civil penalty of not more than one hundred dollars (\$100.00) for a first violation, two hundred fifty dollars (\$250.00) for a second violation, and five hundred dollars (\$500.00) for each subsequent violation if the pharmacy fails to report as required under this section, up to a maximum of five thousand dollars (\$5,000) per pharmacy per calendar year.

Each day of a continuing violation shall constitute a separate violation. A pharmacy acting in good faith that attempts to report the information required by this section shall not be assessed any civil penalty. The clear proceeds of penalties assessed under this section shall be deposited to the Civil Penalty and Forfeiture Fund in accordance with Article 31A of Chapter 115C of the General Statutes. The Commission shall adopt rules to implement this subsection that include factors to be considered in determining the amount of the penalty to be assessed."

**SECTION 11.** G.S. 90-113.74 reads as rewritten:

## "§ 90-113.74. Confidentiality.

- (b1) The Department may review the prescription information data in the controlled substances reporting system and upon review may:
  - (1a) Notify practitioners and their respective licensing boards of prescribing behavior that (i) increases risk of diversion of controlled substances, (ii) increases risk of harm to the patient, or (iii) is an outlier among other practitioner behavior.
- (c) The Department shall release data in the controlled substances reporting system to the following persons only:
  - (1) Persons authorized to prescribe or dispense controlled substances for the purpose of providing medical or pharmaceutical care for their patients. A person authorized to receive data pursuant to this paragraph may delegate the authority to receive the data to other persons working under his or her direction and supervision, provided the Department approves this delegation.
    - The administrator of a hospital emergency department or hospital a, acute care facility shall provide the Department with a list of prescribers who are authorized to prescribe controlled substances for the purpose of providing medical care for patients of the hospital emergency department or hospital acute care facility and a list of delegates who are authorized to receive data on behalf of the providers listed. The administrator acting under this paragraph shall submit the lists to the Department no later than December 1 of the calendar year preceding the year during which the delegates are to receive data and may provide updated lists at any time during the course of the year. Within one week of receiving the initial or updated lists described in this paragraph, the Department shall establish all of the delegate accounts necessary to enable each delegate listed by the administrator of the hospital emergency department or hospital acute care facility to receive data on behalf of the listed prescribers. Delegations made pursuant to this paragraph are valid during the calendar year for which submitted by the administrator.

SECTION 12. Article 5E of Chapter 90 of the General Statutes is amended by adding new sections to read:

# "§ 90-113.74B. Mandatory dispenser registration for access to controlled substances reporting system; exception.

(a) Within 30 days after obtaining an initial or renewal license to practice pharmacy, the licensee shall demonstrate to the satisfaction of the North Carolina Board of Pharmacy that he or she is registered for access to the controlled substances reporting system. A violation of this section may constitute cause for the Board of Pharmacy to suspend or revoke the license.

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(b) This section does not apply to a licensee employed in a pharmacy practice setting where a Schedule II, III, or IV controlled substance will not be dispensed.

# "§ 90-113.74C. Practitioner use of controlled substances reporting system; mandatory reporting of violations.

- Prior to initially prescribing a targeted controlled substance to a patient, a (a) practitioner shall review the information in the controlled substances reporting system pertaining to the patient for the 12-month period preceding the initial prescription. For every subsequent three-month period that the targeted controlled substance remains a part of the patient's medical care, the practitioner shall review the information in the controlled substances reporting system pertaining to the patient for the 12-month period preceding the determination that the targeted controlled substance should remain a part of the patient's medical care. Each instance in which the practitioner reviews the information in the controlled substances reporting system pertaining to the patient shall be documented in the patient's medical record. In the event the practitioner is unable to review the information in the controlled substances reporting system pertaining to the patient because the system is not operational or there is some other temporary electrical or technological failure, this inability shall be documented in the patient's medical record. Once the electrical or technological failure has been resolved, the practitioner shall review the information in the controlled substances reporting system pertaining to the patient and the review shall be documented in the patient's medical record.
- (b) A practitioner may, but is not required to, review the information in the controlled substances reporting system pertaining to a patient prior to prescribing a targeted controlled substance to the patient in any of the following circumstances:
  - (1) The controlled substance is to be administered to a patient in a health care setting, hospital, nursing home, outpatient dialysis facility, or residential care facility, as defined in G.S. 14-32.2.
  - (2) The controlled substance is prescribed for the treatment of cancer or another condition associated with cancer.
  - (3) The controlled substance is prescribed to a patient in hospice care or palliative care.
- (c) The Department shall conduct periodic audits of the review of the controlled substances reporting system by prescribers. The Department shall determine a system for selecting a subset of prescriptions to examine during each auditing period. The Department shall report to the appropriate licensing board any prescriber found to be in violation of this section. A violation of this section may constitute cause for the licensing board to suspend or revoke a prescriber's license.

#### "§ 90-113.74D. Dispenser use of controlled substances reporting system.

- (a) Prior to dispensing a targeted controlled substance, a dispenser shall review the information in the controlled substances reporting system pertaining to the patient for the preceding 12-month period and document this review under any of the following circumstances:
  - (1) The dispenser has a reasonable belief that the ultimate user may be seeking a targeted controlled substance for any reason other than the treatment of the ultimate user's existing medical condition.
  - (2) The prescriber is located outside of the usual geographic area served by the dispenser.
  - (3) The ultimate user resides outside of the usual geographic area served by the dispenser.
  - (4) The ultimate user pays for the prescription with cash when the patient has prescription insurance on file with the dispenser.
  - (5) The ultimate user demonstrates potential misuse of a controlled substance by any one or more of the following:

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- a. Over-utilization of the controlled substance.
- b. Requests for early refills.
- c. Utilization of multiple prescribers.
- d. An appearance of being overly sedated or intoxicated upon presenting a prescription.
- e. A request by an unfamiliar ultimate user for an opioid drug by a specific name, street name, color, or identifying marks.
- (b) If a dispenser has reason to believe a prescription for a targeted controlled substance is fraudulent or duplicative, the dispenser shall withhold delivery of the prescription until the dispenser is able to contact the prescriber and verify that the prescription is medically appropriate.
- (c) A dispenser shall be immune from any civil or criminal liability for actions authorized by this section. Failure to review the system in accordance with subsection (a) of this section shall not constitute medical negligence.

## "§ 90-113.75A. Creation of Controlled Substances Reporting System Fund.

- (a) The Controlled Substances Reporting System Fund is created within the Department as a special revenue fund. The Department shall administer the Fund. The Department shall use the Fund only for operation of the controlled substances reporting system and to carry out the provisions of this Article.
  - (b) The Fund shall consist of the following:
    - (1) Any moneys appropriated to the Fund by the General Assembly.
    - (2) Any moneys received from State, federal, private, or other sources for deposit into the Fund.
- (c) All interest that accrues to the Fund shall be credited to the Fund. Any balance remaining in the Fund at the end of any fiscal year shall remain in the Fund and shall not revert to the General Fund.

#### "§ 90-113.75B. Annual report to General Assembly and licensing boards.

Annually on February 1, beginning February 1, 2019, the Department shall report to the Joint Legislative Oversight Committee on Health and Human Services, the North Carolina Medical Board, the North Carolina Board of Podiatry Examiners, the North Carolina Board of Nursing, the North Carolina Dental Board, the North Carolina Veterinary Medical Board, and the North Carolina Board of Pharmacy on data reported to the controlled substances reporting system. The report shall include at least all of the following information about targeted controlled substances reported to the system during the preceding calendar year:

- (1) The total number of prescriptions dispensed, broken down by Schedule.
- (2) Demographics about the ultimate users to whom prescriptions were dispensed.
- (3) Statistics regarding the number of pills dispensed per prescription.
- (4) The number of ultimate users who were prescribed a controlled substance by two or more practitioners.
- (5) The number of ultimate users to whom a prescription was dispensed in more than one county.
- (6) The categories of practitioners prescribing controlled substances and the number of prescriptions authorized by each category of practitioner. For the purpose of this subdivision, medical doctors, surgeons, palliative care practitioners, oncologists and other practitioners specializing in oncology, pain management practitioners, practitioners who specialize in hematology, including the treatment of sickle cell disease, and practitioners who specialize in treating substance use disorder shall be treated as distinct categories of practitioners.

(7) Any other data deemed appropriate and requested by the Joint Legislative Oversight Committee on Health and Human Services, the North Carolina Medical Board, the North Carolina Board of Podiatry Examiners, the North Carolina Board of Nursing, the North Carolina Dental Board, the North Carolina Veterinary Medical Board, or the North Carolina Board of Pharmacy."

SECTION 13.(a) Section 12F.16(h) of S.L. 2015-241 reads as rewritten:

"SECTION 12F.16.(h) DHHS shall apply for grant funding from the National Association of Boards of Pharmacy to establish the connection to PMP InterConnect. The Department shall request forty thousand thirty five dollars (\$40,035) to establish the initial interface for PMP InterConnect and thirty thousand dollars (\$30,000) for two years of ongoing service, maintenance, and support for PMP InterConnect in order to create interstate connectivity for the drug monitoring program as required by subdivision (2) of subsection (f) of this section. The Department of Health and Human Services, Division of Mental Health, Developmental Disabilities, and Substance Abuse Services, shall continue to work toward establishing interstate connectivity for the Controlled Substances Reporting System established under G.S. 90-113.73."

**SECTION 13.(b)** Section 12F.16(i)(3) of S.L. 2015-241 reads as rewritten:

"(3) For the 2015 2016 fiscal year, the sum of forty thousand thirty five dollars (\$40,035) shall be used to establish the initial interface for PMP InterConnect, as required by subdivision (2) of subsection (f) of this section. This amount shall be adjusted or eliminated if DHHS is successful in obtaining grant awards or identifying other allowable receipts for this purpose. If receipts are used for this purpose, this nonrecurring appropriation shall revert to the General Fund. The Department of Health and Human Services, Division of Mental Health, Developmental Disabilities, and Substance Abuse Services, shall continue to work toward establishing interstate connectivity for the Controlled Substances Reporting System established under G.S. 90-113.73."

SECTION 14. The Department of Health and Human Services shall conduct a study, in consultation with the Office of the Attorney General and the North Carolina Veterinary Medical Board, on how to implement the provisions of this act pertaining to electronic prescriptions and the submission of data to the Controlled Substances Reporting System as they relate to the practice of veterinary medicine. The Department shall submit a report to the Joint Legislative Oversight Committee on Health and Human Services no later than February 1, 2018.

#### PART VI. EFFECTIVE DATE

**SECTION 15.(a)** Sections 1, 2, 3, 4, 5, 7, 8, 11, and 13 of this act become effective July 1, 2017.



SECTION 15.(b) Subsections (a), (a1), and (a2) of G.S. 90-106, as amended by Section 6 of this act, become effective January 1, 2020.

SECTION 15.(c) Subsections (a3) and (a4) of G.S. 90-106, as amended by Section 6 of this act, become effective January 1, 2018.

SECTION 15.(d) Section 10 of this act and G.S. 90-113.75A and G.S. 90-113.75B, as enacted by Section 12 of this act, become effective September 1, 2017.

SECTION 15.(e) The remainder of this act is effective when it becomes law and applies to acts committed 30 days after the date the State Chief Information Officer notifies the Revisor of Statutes that (i) the upgrades to the Controlled Substances Reporting System (CSRS) database described in subdivisions (1) and (2) of subsection (a) of Section 12F.7 of S.L. 2016-94 have been completed and (ii) the upgraded CSRS database is fully operational within the Department of Information Technology and connected to the statewide health information exchange.

In the General Assembly read three times and ratified this the 28<sup>th</sup> day of June, 2017.

- s/ Daniel J. Forest President of the Senate
- s/ Tim Moore Speaker of the House of Representatives
- s/ Roy Cooper Governor

Approved 10:15 a.m. this 29th day of June, 2017

# N.Y. Public Health Law 281 – Official New York State Prescription Forms

Current as of: 2016 | Check for updates | Other versions

1. In addition to the requirements of section sixty-eight hundred ten of the education law or article thirty-three of this chapter, all prescriptions written in this state by a person authorized by this state to issue such prescriptions shall be on serialized official New York state prescription forms provided by the department. Such forms shall be furnished to practitioners authorized to write prescriptions and to institutional

dispensers, and shall be non-reproducible and non-transferable. The commissioner, in consultation with the commissioner of education, may promulgate emergency regulations for the electronic transmission of prescriptions from prescribers to pharmacists or for ordering and filling requirements of prescription drugs for prescriptions written for recipients eligible for medical assistance pursuant to title eleven of article five of the social services law, for participants in the program for elderly pharmaceutical insurance coverage pursuant to title three of article two of the elder law and for prescriptions written pursuant to article thirty-three of this chapter. Nothing in this section shall prohibit the commissioner in consultation with the commissioner of education from promulgating any additional emergency regulations in furtherance of this subdivision.

2. The commissioner, in consultation with the commissioner of education, shall promulgate regulations requiring that prescription forms and electronic prescriptions include: (a) a section wherein prescribers may indicate whether an individual is limited English proficient, as defined in section sixty-eight hundred twenty-nine of the education law; and (b) if the patient is limited English proficient, a line where the prescriber may specify the preferred language indicated by

the patient. Failure to include such indication on the part of the prescriber shall not invalidate the prescription.

3. On or before December thirty-first, two thousand twelve, the commissioner shall promulgate regulations, in consultation with the commissioner of education, establishing standards for electronic prescriptions. Notwithstanding any other provision of this section or any other law to the contrary, effective three years subsequent to the date on which such regulations are promulgated, no person shall issue any prescription in this state unless such prescription is made by electronic prescription from the person issuing the prescription to a pharmacy in accordance with such regulatory standards, except for prescriptions: (a) issued by veterinarians; (b) issued in circumstances where electronic prescribing is not available due to temporary technological or electrical failure, as set forth in regulation; (c) issued by practitioners who have received a waiver or a renewal thereof for a specified period determined by the commissioner, not to exceed one year, from the requirement to use electronic prescribing, pursuant to a process established in regulation by the commissioner, in consultation with the commissioner of education, due to economic hardship, technological limitations that are not reasonably within the control of the practitioner, or other exceptional circumstance demonstrated by the practitioner; (d) issued by a practitioner under circumstances where, notwithstanding the practitioner's present ability to make an electronic prescription as required by this subdivision, such practitioner reasonably determines that it would be impractical for the patient to obtain substances prescribed by electronic prescription in a timely manner, and such delay would adversely impact the patient's medical condition, provided that if such prescription is for a controlled substance, the quantity of controlled substances does not exceed a five day supply if the controlled substance were used in accordance with the

directions for use; or (e) issued by a practitioner to be dispensed by a pharmacy located outside the state, as set forth in regulation.

\* 3-a. A pharmacy that receives an electronic prescription from the person issuing the prescription may, if the prescription has not been dispensed and at the request of the patient or a

person authorized to make the request on behalf of the patient, immediately transfer or forward such prescription to an alternative pharmacy designated by the requesting party.

- \* NB Effective February 26, 2017
- 4. In the case of a prescription for a controlled substance issued by a practitioner under paragraph (b) of subdivision three of this section, the practitioner shall indicate in the patient's health record that the prescription was issued other than electronically due to temporary technological or electrical failure.
- 5. In the case of a prescription for a controlled substance issued by a practitioner under paragraph (d) or (e) of subdivision three of this section, the practitioner shall, upon issuing such prescription, indicate in the patient's health record either that the prescription was issued other than electronically because it (a) was impractical to issue an electronic prescription in a timely manner and such delay would have adversely impacted the patient's medical condition, or (b) was to be dispensed by a pharmacy located outside the state.
- 6. The waiver process established in regulation pursuant to paragraph (c) of subdivision three of this section shall provide that a practitioner prescribing under a waiver must notify the department in writing promptly upon gaining the capability to use electronic prescribing, and that a waiver shall terminate within a specified period of time after the practitioner gains such capability.
- \* 7. Notwithstanding any other provision of this section or any other law to the contrary, a practitioner shall not be required to issue prescriptions electronically if he or she certifies to the department, in a manner specified by the department, that he or she will not issue more than twenty-five prescriptions during a twelve month period. Prescriptions in both oral and written form for both controlled substances and non-controlled substances shall be included in determining whether the practitioner will reach the limit of twenty-five prescriptions.

(a) A certification shall be submitted in advance of the twelve-month certification period, except that a twelve-month certification submitted on or before July first, two thousand sixteen, may begin March twenty-seven, two thousand sixteen.

(b) A practitioner who has made a certification under this subdivision may submit an additional certification on or before the expiration of the current twelve-month certification period, for a maximum of three twelve-month certifications.

(c) A practitioner may make a certification under this subdivision regardless of whether he or she has previously received a waiver under paragraph (c) of subdivision three of this section.

\* NB Repealed June 1, 2020

# 2017 - S 0546 AS AMENDED

LC001740

## STATE OF RHODE ISLAND

# IN GENERAL ASSEMBLY JANUARY SESSION, A.D. 2017

## AN ACT

# RELATING TO FOOD AND DRUGS – UNIFORM CONTROLLED SUBSTANCES ACT – ELECTRONIC PRESCRIPTION OF CONTROLLED SUBSTANCES

Introduced By: Senators Crowley, Metts, Nesselbush, and Miller

Date Introduced: March 09, 2017

Referred To: Senate Health & Human Services

(Dept. of Health)

It is enacted by the General Assembly as follows:

- 1 SECTION 1. Section 21-28-3.18 of the General Laws in Chapter 21-28 entitled "Uniform
- 2 Controlled Substances Act" is hereby amended to read as follows:
- 3 <u>21-28-3.18. Prescriptions.</u>
- 4 (a) An apothecary in good faith may sell and dispense controlled substances in schedule
- 5 II, III, IV, and V to any person upon a valid prescription by a practitioner licensed by law to
- 6 prescribe or administer those substances, dated and signed by the person prescribing on the day
- 7 when issued and bearing the full name and address of the patient to whom, or of the owner of the
- 8 animal for which, the substance is dispensed and the full name, address, and registration number
- 9 under the federal law of the person prescribing, if he or she is required by that law to be
- registered. If the prescription is for an animal, it shall state the species of the animal for which the
- 11 substance is prescribed.
- 12 (b) When filling a hard-copy prescription for a schedule II controlled substance, the
- apothecary filling the prescription shall sign his or her full name and shall write the date of filling

14	on the	face of the	prescription

- 15 (c) The prescription shall be retained on file by the proprietor of the pharmacy in which it
  16 was filled for a period of two (2) years so as to be readily accessible for inspection by any public
  17 officer or employee engaged in the enforcement of this chapter.
- 18 (d) (1) Hard-copy prescriptions for controlled substances in schedule II shall be filed

separately and shall not be refilled.

(2) The director of health shall, after appropriate notice and hearing pursuant to § 42-35-3, promulgate rules and regulations for the purpose of adopting a system for electronic data transmission, including by facsimile, of prescriptions for controlled substances in schedule II, III, IV, and V. Opioid antagonists, including, but not limited to, naloxone, as may be further determined by rules and regulations, shall be transmitted with controlled substances in schedule II, III, IV, and V. Provided, information collected regarding dispensing of opioid antagonists shall be for statistical, research, or educational purposes only. The department's rules and regulations shall require the removal of patient, recipient, or prescriber information that could be

used to identify individual patients or recipients of opioid antagonists.

(3) A practitioner may shall sign and transmit electronic prescriptions for controlled substances in schedules II, III, IV and V to a pharmacy in accordance with rules and regulations as shall be promulgated by the department and which shall require electronic transmission no sooner than January 1, 2020, and a pharmacy may dispense an electronically transmitted prescription for these controlled substances in accordance with the code of federal regulations, 21 C.F.R., pt. 1300, et seq.

(e) <u>Subject to the rules and regulations promulgated by the department pursuant to §21-28-3.18(d)(3)</u>, A <u>a</u> prescription for a schedule II narcotic substance to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous, or intraspinal infusion may be transmitted by the practitioner, or practitioner's agent, to the pharmacy by facsimile. The facsimile will serve as the original prescription.

22 (f) Subject to the rules and regulations promulgated by the department pursuant to §21-23 28-3.18(d)(3), A a prescription for a schedule II substance for a resident of a long-term-care BUDHUBA Page 5 OI 8

facility may be transmitted by the practitioner, or the practitioner's agent, to the dispensing pharmacy by facsimile. The facsimile serves as the original prescription.

(g) Subject to the rules and regulations promulgated by the department pursuant to §21-28-3.18(d)(3), A a prescription for a schedule II narcotic substance for a patient residing in a hospice certified by Medicare under title XVIII of the Social Security Act, 42 U.S.C. § 1395 et seq., or licensed by the state, may be transmitted by the practitioner, or practitioner's agent, to the dispensing pharmacy by facsimile. The practitioner, or the practitioner's agent, will note on the prescription that the patient is a hospice patient. The facsimile serves as the original, written prescription.

(h) An apothecary, in lieu of a written prescription, may sell and dispense controlled substances in schedules III, IV, and V to any person upon an oral prescription of a practitioner. In

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issuing an oral prescription, the prescriber shall furnish the apothecary with the same information as is required by subsection (a) of this section and the apothecary who fills the prescription shall immediately reduce the oral prescription to writing and shall inscribe the information on the written record of the prescription made. This record shall be filed and preserved by the proprietor of the pharmacy in which it is filled in accordance with the provisions of subsection (c). In no case may a prescription for a controlled substance listed in schedules III, IV, or V be filled or refilled more than six (6) months after the date on which the prescription was issued and no prescription shall be authorized to be refilled more than five (5) times. Each refilling shall be entered on the face or back of the prescription and note the date and amount of controlled substance dispensed and the initials or identity of the dispensing apothecary.

- (i) In the case of an emergency situation as defined in federal law, an apothecary may dispense a controlled substance listed in schedule II upon receiving an oral authorization of a prescribing practitioner provided that:
- (1) The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period and dispensing beyond the emergency period must be pursuant to a written prescription signed by the prescribing practitioner.
- (2) The prescription shall be immediately reduced to writing and shall contain all the

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information required in subsection (a).

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- (3) The prescription must be dispensed in good faith in the normal course of professional practice.
- (4) Within seven (7) days after authorizing an emergency oral prescription, the prescribing practitioner shall cause a prescription for the emergency quantity prescribed to be delivered to the dispensing apothecary. The prescription shall have written on its face "Authorization for emergency dispensing" and the date of the oral order. The prescription, upon receipt by the apothecary, shall be attached to the oral emergency prescription that had earlier been reduced to writing.
  - (j) (1) The partial filling of a prescription for a controlled substance listed in schedule II is permissible, if the apothecary is unable to supply the full quantity called for in a prescription or emergency oral prescription and he or she makes a notation of the quantity supplied on the face of the prescription or oral emergency prescription that has been reduced to writing. The remaining portion of the prescription may be filled within seventy-two (72) hours of the first partial filling, however, if the remaining portion is not, or cannot be, filled within seventy-two (72) hours, the apothecary shall notify the prescribing practitioner. No further quantity may be supplied beyond seventy-two (72) hours without a new prescription.

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- (2) (i) A prescription for a schedule II controlled substance written for a patient in a long-term-care facility (LTCF), or for a patient with a medical diagnosis documenting a terminal illness, may be filled in partial quantities to include individual dosage units. If there is a question whether a patient may be classified as having a terminal illness, the pharmacist must contact the practitioner prior to partially filling the prescription. Both the pharmacist and the prescribing practitioner have a corresponding responsibility to assure that the controlled substance is for a terminally ill patient.
  - (ii) The pharmacist must record on the prescription whether the patient is "terminally ill" or an "LTCF patient." A prescription that is partially filled, and does not contain the notation "terminally ill" or "LTCF patient", shall be deemed to have been filled in violation of this chapter.
    - (iii) For each partial filling, the dispensing pharmacist shall record on the back of the

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12	prescription (or on another appropriate record, uniformly maintained, and readily retrievable),
13	the:
14	(A) Date of the partial filling;
15	(B) Quantity dispensed;
16	(C) Remaining quantity authorized to be dispensed; and
17	(D) Identification of the dispensing pharmacist.
18	(iv) The total quantity of schedule II controlled substances dispensed in all partial fillings
19	must not exceed the total quantity prescribed.
20	(v) Schedule II prescriptions for patients in a LTCF, or patients with a medical diagnosis
21	documenting a terminal illness, are valid for a period not to exceed sixty (60) days from the issue
22	date, unless sooner terminated by the discontinuance of medication.
23	(k) Automated, data-processing systems. As an alternative to the prescription record
24	keeping provision of subsection (h) of this section, an automated, data-processing system may be
25	employed for the record-keeping system if the following conditions have been met:
26	(1) The system shall have the capability of producing sight-readable documents of all
27	original and refilled prescription information. The term "sight readable" means that an authorized
28	agent shall be able to examine the record and read the information. During the course of an on-
29	site inspection, the record may be read from the CRT, microfiche, microfilm, printout, or other
30	method acceptable to the director. In the case of administrative proceedings, records must be
31	provided in a paper printout form.
32	(2) The information shall include, but not be limited to, the prescription requirements and
33	records of dispensing as indicated in subsection (h) of this section.
34	(3) The individual pharmacist responsible for completeness and accuracy of the entries to
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1	the system must provide documentation of the fact that prescription information entered into the
2	computer is correct. In documenting this information, the pharmacy shall have the option to
3	either:
4	(i) Maintain a bound logbook, or separate file, in which each individual pharmacist
5	involved in the dispensing shall sign a statement each day attesting to the fact that the prescription

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information entered into the computer that day has been reviewed and is correct as shown. The book or file must be maintained at the pharmacy employing that system for a period of at least two (2) years after the date of last dispensing; or

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- (ii) Provide a printout of each day's prescription information. That printout shall be verified, dated, and signed by the individual pharmacist verifying that the information indicated is correct. The printout must be maintained at least two (2) years from the date of last dispensing.
- (4) An auxiliary, record-keeping system shall be established for the documentation of refills if the automated, data-processing system is inoperative for any reason. The auxiliary system shall ensure that all refills are authorized by the original prescription and that the maximum number of refills is not exceeded. When this automated, data-processing system is restored to operation, the information regarding prescriptions filled and refilled during the inoperative period shall be entered into the automated, data-processing system within ninety-six (96) hours.
- (5) Any pharmacy using an automated, data-processing system must comply with all applicable state and federal laws and regulations.
- (6) A pharmacy shall make arrangements with the supplier of data-processing services or materials to ensure that the pharmacy continues to have adequate and complete prescription and dispensing records if the relationship with the supplier terminates for any reason. A pharmacy shall ensure continuity in the maintenance of records.
- (7) The automated, data-processing system shall contain adequate safeguards for security of the records to maintain the confidentiality and accuracy of the prescription information. Safeguards against unauthorized changes in data after the information has been entered and verified by the registered pharmacist shall be provided by the system.
- (I) Prescriptions for controlled substances as found in schedule II will become void unless dispensed within ninety (90) days of the original date of the prescription and in no event shall more than a thirty-day (30) supply be dispensed at any one time.
- (1) In prescribing controlled substances in schedule II, practitioners may write up to three
   (3) separate prescriptions, each for up to a one-month supply, each signed and dated on the date
   written. For those prescriptions for the second and/or third month, the practitioner must write the

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1	earliest date each of those subsequent prescription may be filled, with directions to the pharmacist
2	to fill no earlier than the date specified on the face of the prescription.
3	(m) The prescriptions in schedules III, IV, and V will become void unless dispensed
4	within one hundred eighty (180) days of the original date of the prescription. For purposes of this
5	section, a "dosage unit" shall be defined as a single capsule, tablet, or suppository, or not more
6	than one five (5) ml. of an oral liquid.
7	(1) Prescriptions in Schedule III cannot be written for more than one hundred (100)
8	dosage units and not more than one hundred (100) dosage units may be dispensed at one time.
•	(2) Prescriptions in Schedule IV and V may be written for up to a ninety-day (90) supply
10	based on directions. No more than three hundred and sixty (360) dosage units may be dispensed
1	at one time.
2	(n) A pharmacy shall transmit prescription information to the prescription-monitoring
3	database at the department of health within one business day following the dispensing of an
4	opioid prescription.
5	(o) The pharmacist shall inform patients verbally or in writing about the proper disposal
6	of expired, unused, or unwanted medications, including the location of local disposal sites as
7	listed on the department of health website.
8	(p) The pharmacist shall inform patients verbally or in writing in the proper use of any
9	devices necessary for the administration of controlled substances.
0	SECTION 2. This act shall take effect upon passage.
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# **EXPLANATION**

## BY THE LEGISLATIVE COUNCIL

OF

# AN ACT

# RELATING TO FOOD AND DRUGS -- UNIFORM CONTROLLED SUBSTANCES ACT --

# **ELECTRONIC PRESCRIPTION OF CONTROLLED SUBSTANCES**

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- 1 This act would amend the statute governing prescriptions of controlled substances by
- 2 making reference to regulations issued by the department of health.
- 3 This act would take effect upon passage.

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## Public Act No. 17-131

# AN ACT PREVENTING PRESCRIPTION OPIOID DIVERSION AND ABUSE.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

Section 1. Subsection (j) of section 21a-254 of the general statutes is amended by adding subdivision (11) as follows (*Effective from passage*):

- (NEW) (11) The commissioner may provide controlled substance prescription information obtained in accordance with subdivisions (3) and (4) of this subsection to other state agencies, pursuant to an agreement between the commissioner and the head of such agency, provided the information is obtained for a study of disease prevention and control related to opioid abuse or the study of morbidity and mortality caused by overdoses of controlled substances. The provision of such information shall be in accordance with all applicable state and federal confidentiality requirements.
- Sec. 2. Section 21a-262 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective from passage*):
- (a) The Commissioner of Consumer Protection may receive, take into custody or destroy excess or undesired controlled substances and may in his <u>or her</u> discretion deliver, upon application, to any hospital, laboratory, incorporated college, scientific institution or any state or

municipal agency or institution not operated for private gain, any controlled substances that have come into his or her custody by authority of this section. In the case of a care-giving or correctional or juvenile training institution having an institutional pharmacy, the Commissioner of Consumer Protection shall deliver such controlled substances only to the licensed pharmacist in charge of such pharmacy. The Commissioner of Consumer Protection may receive and take into custody excess or undesired controlled substances from pharmacists, manufacturers and wholesalers or any other registrant. Said commissioner shall keep a full and complete record of all substances received and of all substances disposed of, showing the exact kinds, quantities and forms of such substances, the persons from whom received and to whom delivered, by whose authority received, delivered and destroyed, and the dates of the receipt, disposal or destruction. Controlled substances and preparations shall at all times be properly safeguarded and securely kept. Minimum security and safeguard standards for the storage, manufacture, sale or distribution of all controlled substances shall be established by regulations adopted hereunder. Controlled substances seized or held as contraband or controlled substances, the title to which cannot be resolved, which controlled substances are not held by law enforcement agencies or court officials as evidence in criminal proceedings, shall be, upon the order of the court, destroyed by the seizing authority or delivered to the Commissioner of Consumer Protection as soon as possible upon resolution of the case or upon ascertaining the status of the unclaimed substance. The agent of the Commissioner of Consumer Protection shall issue a receipt for all such substance obtained. Any loss, destruction or theft of controlled substances shall be reported by a registrant within seventy-two hours to the Commissioner of Consumer Protection as follows: (1) Where, through breakage of the container or other accident, otherwise than in transit, controlled substances are lost or destroyed, the person having title thereto shall make a signed statement as to the kinds and quantities of controlled substances lost or

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destroyed and the circumstances involved, and immediately forward the statement to the Commissioner of Consumer Protection. A copy of such statement shall be retained by the registrant; (2) where controlled substances are lost by theft, or otherwise lost or destroyed in transit, the consignee shall, immediately upon ascertainment of the occurrence, file with the Commissioner of Consumer Protection a signed statement of the facts, including a list of the controlled substances stolen, lost or destroyed and documentary evidence that the local authorities were notified. A copy of the statement shall be retained by the registrant. As used in this section, "care-giving institution", "correctional or juvenile training institution", "institutional pharmacy" and "pharmacist" have the same meanings as provided in section 20-571.

- (b) For each long-term care facility, two or more of the following persons may jointly dispose of excess stock of controlled substances: A nursing home administrator, a pharmacist consultant, a director of nursing services or an assistant director of nursing services. Such facility shall maintain documentation of any such destruction and disposal for a period of three years and such documentation shall be maintained in a separate log and on a form prescribed by the department.
- (c) For each outpatient surgical facility, as defined in section 19a-493b, two or more of the following persons may jointly dispose of excess stock of controlled substances: An administrator, a clinical director or chief of staff, or a nursing supervisor. Such facility shall maintain documentation of any such destruction and disposal for a period of three years and such documentation shall be maintained in a separate log and on a form prescribed by the department.
- (d) A registered nurse licensed by the Department of Public Health and employed by a home health care agency, as defined in section 19a-490, may, with the permission of a designated representative of the

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patient, oversee the destruction and disposal of the patient's controlled substances, using the recommendations for the proper disposal of prescription drugs on the Internet web site of the Department of Consumer Protection. Such registered nurse shall maintain written or electronic documentation for a period of three years of any such destruction and disposal on a form prescribed by the Commissioner of Consumer Protection. Such written or electronic documentation shall be maintained with the patient's medical record. Nothing in this subsection shall prevent the registered nurse and patient's designated representative from depositing the patient's controlled substances in a statutorily authorized prescription drug drop box.

- Sec. 3. Section 21a-249 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective January 1, 2018*):
- (a) All prescriptions for controlled drugs shall include (1) the name and address of the patient, or the name and address of the owner of an animal and the species of the animal, (2) whether the patient is an adult or a child, or his specific age, (3) the compound or preparation prescribed and the amount thereof, (4) directions for use of the medication, (5) the name and address of the prescribing practitioner, (6) the date of issuance, and (7) the Federal Registry number of the practitioner. No prescription blank containing a prescription for a schedule II substance shall contain more than one prescription. No prescription or order for a controlled substance issued by a practitioner to an inanimate object or thing shall be considered a valid prescription within the meaning of this chapter.
- (b) [Written prescriptions shall be written in ink or in indelible pencil or by typewriter. No duplicate, carbon or photographic copies and no printed or rubber-stamped orders shall be considered valid prescriptions within the meaning of this chapter. No prescription or order for any controlled substance issued by a practitioner to an inanimate object or thing shall be considered a valid prescription

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within the meaning of this chapter.] Each prescribing practitioner, as defined in section 20-14c, who the Department of Consumer Protection authorizes to prescribe controlled substances, within the scope of practice of his or her license, shall electronically transmit the controlled substance prescription to a pharmacy. Electronically transmitted prescriptions shall be promptly printed out in hardcopy or created as an electronic record and filed by the prescriber. Electronically transmitted prescriptions shall be consistent with the requirements of the federal Controlled Substances Act, 21 USC 801, as amended from time to time. All records shall be kept on file for three years at the premises of the licensed practitioner and maintained in such form as to be readily available for inspection by the commissioner, his or her authorized agent or other persons, as authorized in section 21a-265, at reasonable times. For purposes of this subsection and subsections (c), (d) and (e) of this section, the term "electronically transmit" means to transmit by computer modem or other similar electronic device.

(c) A licensed practitioner shall not be required to electronically transmit a prescription when:

(1) Electronic transmission is not available due to a temporary technological or electrical failure. In the event of a temporary technological or electrical failure, the practitioner shall, without undue delay, reasonably attempt to correct any cause for the failure that is within his or her control. A practitioner who issues a prescription, but fails to electronically transmit the prescription, as permitted by this subsection, shall document the reason for the practitioner's failure to electronically transmit the prescription in the patient's medical record as soon as practicable, but in no instance more than seventy-two hours following the end of the temporary technological or electrical failure that prevented the electronic transmittal of the prescription. For purposes of this subdivision, "temporary technological or electrical failure" means failure of a computer system, application or device or

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the loss of electrical power to such system, application or device, or any other service interruption to such system, application or device that reasonably prevents the practitioner from utilizing his or her certified application to electronically transmit the prescription in accordance with subsection (b) of this section;

- (2) The practitioner reasonably determines that it would be impractical for the patient to obtain substances prescribed by an electronically transmitted prescription in a timely manner and that such delay would adversely impact the patient's medical condition, provided if such prescription is for a controlled substance, the quantity of such controlled substance does not exceed a five-day supply for the patient, if the controlled substance was used in accordance with the directions for use. A practitioner who issues a prescription, but fails to electronically transmit the prescription, as permitted by this subsection, shall document the reason for the practitioner's failure to electronically transmit the prescription in the patient's medical record;
- (3) The prescription is to be dispensed by a pharmacy located outside this state. A practitioner who issues a prescription, but fails to electronically transmit the prescription, as permitted by this subsection, shall document the reason for the practitioner's failure to electronically transmit the prescription in the patient's medical record;
- (4) Use of an electronically transmitted prescription may negatively impact patient care, such as a prescription containing two or more products to be compounded by a pharmacist, a prescription for direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion, a prescription that contains long or complicated directions, a prescription that requires certain elements to be included by the federal Food and Drug and Administration, or an oral prescription communicated to a pharmacist by a health care practitioner for a patient in a chronic and convalescent nursing home, licensed pursuant to chapter 368v; or

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(5) The practitioner demonstrates, in a form and manner prescribed by the commissioner, that such practitioner does not have the technological capacity to issue electronically transmitted prescriptions. For the purposes of this subsection, "technological capacity" means possession of a computer system, hardware or device that can be used to electronically transmit controlled substance prescriptions consistent with the requirements of the federal Controlled Substances Act, 21 USC 801, as amended from time to time.

(d) Any prescription issued in a form other than an electronically transmitted prescription pursuant to subsection (c) of this section may be issued as a written order or, to the extent permitted by the federal Controlled Substance Act, 21 USC 801, as from time to time amended, as an oral order or transmitted by facsimile machine. Such oral order or order transmitted by facsimile machine shall be promptly reduced to writing on a prescription blank or a hardcopy printout or created as an electronic record and filed by the pharmacist filling it. No duplicate, carbon or photographic copies and no printed or rubber-stamped orders shall be considered valid prescriptions within the meaning of this chapter.

[(c)] (e) Prescriptions for schedule II substances [, if in writing,] shall be [signed] electronically transmitted by the prescribing practitioner at the time of issuance and previously signed orders for such schedule II substances shall not be considered valid prescriptions within the meaning of this chapter. No practitioner shall prescribe, dispense or administer schedule II sympathomimetic amines as anorectics, except as may be authorized by regulations adopted by the Departments of Public Health and Consumer Protection acting jointly. To the extent permitted by the federal Controlled Substances Act, 21 USC 801, as from time to time amended, in an emergency, the dispensing of schedule II substances may be made upon the oral order of a prescribing registrant known to or confirmed by the filling pharmacist.

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The filling pharmacist shall promptly reduce such oral order to writing on a prescription blank, provided such oral order shall be confirmed by the proper completion and mailing or delivery of a prescription prepared by the prescribing registrant to the pharmacist filling such oral order within seventy-two hours after the oral order has been given. Such prescription of the registrant shall be affixed to the temporary prescription prepared by the pharmacist and both prescriptions shall be maintained on file as required in this chapter. The Department of Public Health and the Department of Consumer Protection, acting jointly, may adopt regulations, in accordance with chapter 54, allowing practitioners to prescribe, dispense or administer schedule II sympathomimetic amines as anorectics under certain specific circumstances. Nothing in this subsection shall be construed to require a licensed pharmacist to determine the diagnosis of a patient prior to dispensing a prescription for such substances to a patient.

- I(d) To the extent permitted by the federal Controlled Substances Act, 21 USC 801, as from time to time amended, a prescribing practitioner may issue an oral order or an electronically transmitted prescription order and, except as otherwise provided by regulations adopted pursuant to sections 21a-243, 21a-244 and 21a-244a, such oral order or electronically transmitted prescription order shall be promptly reduced to writing on a prescription blank or a hardcopy printout or created as an electronic record and filed by the pharmacist filling it. For the purposes of subsections (d) and (h) of this section the term "electronically transmitted" means transmitted by facsimile machine, computer modem or other similar electronic device.
- (e) To the extent permitted by the federal Controlled Substances Act, in an emergency the dispensing of schedule II substances may be made upon the oral order of a prescribing registrant known to or confirmed by the filling pharmacist who shall promptly reduce the oral order to writing on a prescription blank, provided, in such cases

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such oral order shall be confirmed by the proper completion and mailing or delivery of a prescription prepared by the prescribing registrant to the pharmacist filling such oral order within seventy-two hours after the oral order has been given. Such prescription of the registrant shall be affixed to the temporary prescription prepared by the pharmacist and both prescriptions shall be maintained on file as required in this chapter.]

- (f) All prescriptions for controlled substances shall comply fully with any additional requirements of the federal food and drug laws, the federal Controlled Substances Act, and state laws and regulations adopted under this chapter.
  - (g) Repealed by P.A. 82-419, S. 46, 47.
- (h) Except when dispensed directly by a practitioner, other than a pharmacy, to an ultimate user, a controlled substance included in schedule III or IV, which is a prescription drug as determined under federal food and drug laws, shall not be dispensed without a written, electronically transmitted or oral prescription of a practitioner. The prescription shall not be filled or refilled more than six months after the date thereof or be refilled more than five times, unless renewed by the practitioner.
- (i) A controlled substance included in schedule V shall not be distributed or dispensed other than for a medical purpose.
- (j) A pharmacy may sell and dispense controlled substances upon the prescription of a prescribing practitioner, as defined in subdivision (22) of section 20-571.
- (k) Pharmacies shall file filled prescriptions for controlled substances separately from other prescriptions. All schedule II prescriptions shall be filed in a separate file or in an electronic file. All schedule III, IV and V prescriptions shall be filed in another separate

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file or in an electronic file, except as otherwise provided for in regulations adopted pursuant to section 21a-243, 21a-244 or 21a-244a. All written controlled substance prescriptions shall, immediately upon filling, be filed chronologically and consecutively.

- (I) Any pharmacy may transfer prescriptions for controlled substances included in schedules III, IV and V to any other pharmacy in accordance with the requirements set forth in the federal Controlled Substances Act 21 USC 801 et seq. and the regulations promulgated thereunder, as from time to time amended.
- (m) A practitioner authorized to prescribe controlled substances shall not prescribe anabolic steroids for the sole purpose of enhancing a patient's athletic ability or performance.
- (n) Each pharmacy, as defined in section 20-571, shall accept an electronically transmitted prescription for a controlled substance from a practitioner, as defined in section 21a-316. All records shall be kept on file for three years at the premises of the pharmacy and maintained current and separate from other business records in such form as to be readily available at the pharmacy for inspection by the Commissioner of Consumer Protection, his or her authorized agent or other persons, as authorized in section 21a-265, at reasonable times. Prescription records received from the practitioner electronically may be stored electronically, provided the files are maintained in the pharmacy computer system for not less than three years. If the electronically transmitted prescription is printed, it shall be filed as required in subsection (k) of this section.
  - Sec. 4. (NEW) (Effective October 1, 2017) (a) As used in this section:
- (1) "Opioid drug" has the same meaning as provided in 42 CFR 8.2, as amended from time to time;
- (2) "Prescribing practitioner" has the same meaning as provided in *Public Act No. 17-131*10 of 20

section 20-14c of the general statutes; and

- (3) "Voluntary nonopioid directive form" means a form that is voluntarily filed by a patient with a prescribing practitioner that indicates such patient's request to not be issued a prescription or medication order for an opioid drug.
- (b) The Department of Public Health, in consultation with the Departments of Consumer Protection and Mental Health and Addiction Services, shall establish a voluntary nonopioid directive form and publish such form on its Internet web site for public use. Any person who does not wish to be issued a prescription or medication order for an opioid drug may file such form with a prescribing practitioner. Upon receipt of a voluntary nonopioid directive form, a prescribing practitioner shall document such receipt in the patient's medical record.
- (c) The voluntary nonopioid directive form established by the Department of Public Health shall allow a patient to appoint a duly authorized guardian or health care proxy to override a previously recorded voluntary nonopioid directive form. Such patient, duly authorized guardian or health care proxy may revoke the directive, orally or in writing, for any reason, at any time.
- (d) An electronically transmitted prescription to a pharmacy shall be presumed to be valid for the purposes of this section and a pharmacist shall not be held in violation of this section for dispensing a controlled substance in contradiction to a voluntary nonopioid directive form.
- (e) No prescribing practitioner acting with reasonable care shall be liable for damages in a civil action, subject to criminal prosecution or deemed to have violated the standard of care for such prescribing practitioner for refusing to issue a prescription or medication order for an opioid pursuant to a voluntary nonopioid directive form.

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- (f) No person acting in good faith as a duly authorized guardian or health care proxy shall be liable for damages in a civil action or subject to criminal prosecution for revoking or overriding a voluntary nonopioid directive form.
- (g) A prescribing practitioner who wilfully fails to comply with a patient's voluntary nonopioid directive form may be subject to disciplinary action pursuant to section 19a-17 of the general statutes.
- (h) No emergency department prescribing practitioner, acting either as the patient's practitioner or as the medical control officer for emergency medical services personnel, and acting with reasonable care shall be liable for damages in a civil action, subject to criminal prosecution or deemed to have violated the standard of care for a prescribing practitioner for issuing a prescription for or administering a controlled substance containing an opioid to a person who has a voluntary nonopioid directive form, when, in such prescribing practitioner's professional medical judgment, a controlled substance containing an opioid is necessary and such prescribing practitioner had no knowledge of the patient's voluntary nonopioid directive form at the time of issuance or administration.
- Sec. 5. Section 20-140 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective July 1, 2017*):
  - (a) As used in this section:
- (1) "Opioid drug" has the same meaning as provided in 42 CFR 8.2, as amended from time to time;
  - (2) "Adult" means a person who is at least eighteen years of age;
- (3) "Prescribing practitioner" has the same meaning as provided in section 20-14c;

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- (4) "Minor" means a person who is under eighteen years of age;
- (5) "Opioid agonist" means a medication that binds to the opiate receptors and provides relief to individuals in treatment for abuse of or dependence on an opioid drug;
- (6) "Opiate receptor" means a specific site on a cell surface that interacts in a highly selective fashion with an opioid drug;
- (7) "Palliative care" means specialized medical care to improve the quality of life of patients and their families facing the problems associated with a life-threatening illness; and
- (8) "Opioid antagonist" has the same meaning as provided in section 17a-714a, as amended by this act.
- (b) When issuing a prescription for an opioid drug to an adult patient for the first time for outpatient use, a prescribing practitioner who is authorized to prescribe an opioid drug shall not issue a prescription for more than a seven-day supply of such drug, as recommended in the National Centers for Disease Control and Prevention's Guideline for Prescribing Opioids for Chronic Pain.
- (c) A prescribing practitioner shall not issue a prescription for an opioid drug to a minor for more than a [seven-day] <u>five-day</u> supply of such drug. [at any time. When issuing a prescription for an opioid drug to a minor for less than a seven-day supply of such drug, the prescribing practitioner shall discuss the risks associated with use of an opioid drug, including, but not limited to, the risks of addiction and overdose associated with opioid drugs and the dangers of taking opioid drugs with alcohol, benzodiazepines and other central nervous system depressants, and the reasons why the prescription is necessary with (1) the minor, and (2) the custodial parent, guardian or other person having legal custody of the minor if such parent, guardian or other person is present at the time of issuance.]

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- (d) Notwithstanding the provisions of subsections (b) and (c) of this section, if, in the professional medical judgment of a prescribing practitioner, more than a seven-day supply of an opioid drug is required to treat an adult patient's acute medical condition, or more than a five-day supply of an opioid drug is required to treat a minor patient's acute medical condition, as determined by the prescribing practitioner, or is necessary for the treatment of chronic pain, pain associated with a cancer diagnoses or for palliative care, then the prescribing practitioner may issue a prescription for the quantity needed to treat the acute medical condition, chronic pain, pain associated with a cancer diagnosis or pain experienced while the patient is in palliative care. The condition triggering the prescription of an opioid drug for more than a seven-day supply for an adult patient or more than a five-day supply for a minor patient shall be documented in the patient's medical record and the practitioner shall indicate that an alternative to the opioid drug was not appropriate to address the medical condition.
- (e) The provisions of subsections (b), (c) and (d) of this section shall not apply to medications designed for the treatment of abuse of or dependence on an opioid drug, including, but not limited to, opioid agonists and opioid antagonists.
- (f) When issuing a prescription for an opioid drug to an adult or minor patient, the prescribing practitioner shall discuss with the patient the risks associated with the use of such opioid drug, including, but not limited to, the risks of addiction and overdose associated with opioid drugs and the dangers of taking opioid drugs with alcohol, benzodiazepines and other central nervous system depressants, and the reasons the prescription is necessary, and, if applicable, with the custodial parent, guardian or other person having legal custody of the minor if such parent, guardian or other person is present at the time of issuance of the prescription.

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Sec. 6. (Effective July 1, 2017) On or before October 1, 2017, the Department of Public Health shall post information on its Internet web site concerning the ability of a prescribing practitioner, as defined in section 20-14c of the general statutes, to obtain certification to prescribe medicine indicated for treatment of opioid use disorder that a patient may take at home. Such information shall include, but need not be limited to, a list of educational requirements, available courses and information regarding waivers from such requirements.

Sec. 7. (NEW) (Effective July 1, 2017) (a) As used in this section:

- (1) "Health care provider" means any person or organization that furnishes health care services and is licensed or certified to furnish such services pursuant to chapters 370, 372, 373, 375, 376, 376a, 376b, 377, 378, 379, 380, 383, 383a, 383b and 383c of the general statutes, or is licensed or certified pursuant to chapter 368d of the general statutes:
- (2) "Pharmacist" means a pharmacist licensed pursuant to chapter 400j of the general statutes;
- (3) "Opioid drug" has the same meaning as provided in section 20-140 of the general statutes, as amended by this act; and
- (4) "Opioid antagonist" has the same meaning as provided in section 17a-714a of the general statutes, as amended by this act.
- (b) On or before October 1, 2017, the Alcohol and Drug Policy Council, established under section 17a-667 of the general statutes, shall develop (1) a one-page fact sheet that includes, in clear and readily understandable language in at least twelve-point font size, the risks of taking an opioid drug, the symptoms of opioid use disorder and services available in the state for persons who experience symptoms of or are otherwise affected by opioid use disorder, and (2) strategies to encourage health care providers and pharmacists to disseminate the one-page fact sheet. Such one-page fact sheet shall be made available

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on the Internet web site of the Department of Mental Health and Addiction Services for use by health care providers and pharmacists to disseminate to any person (A) whom such provider treats for symptoms of opioid use disorder, (B) to whom such provider issues a prescription for or administers an opioid drug or opioid antagonist, or (C) to whom such pharmacist dispenses an opioid drug or opioid antagonist or issues a prescription for an opioid antagonist.

- (c) (1) The Alcohol and Drug Policy Council shall examine the feasibility of the following:
- (A) Developing a marketing campaign and making monthly public service announcements on the Internet web sites and social media accounts of the appropriate state agencies, as designated by the council, and any radio station and television station broadcasting to persons in the state, regarding (i) the risks of taking opioid drugs, (ii) symptoms of opioid use disorder, (iii) the availability of opioid antagonists in the state, and (iv) services in the state for persons with or affected by opioid use disorder; and
- (B) Establishing a publicly accessible electronic information portal, in the form of an Internet web site or application, as a single point of entry for information regarding the availability of (i) beds at a facility in the state for persons in need of medical treatment for (I) detoxification for potentially life-threatening symptoms of withdrawal from alcohol or drugs, and (II) rehabilitation or treatment for alcohol dependency, drug dependency or intoxication, and (ii) slots for outpatient treatment using opioid medication that is used to treat opioid use disorder, including methadone and buprenorphine. Such examination shall include the ability of the portal to (I) provide real-time data on the availability of beds and slots, including, but not limited to, the types of beds and slots available, the location of such beds and slots and the wait times, if available, for such beds and slots, and (II) be accessible to the public.

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- (2) Not later than January 1, 2019, the council shall report, in accordance with the provisions of section 11-4a of the general statutes, to the joint standing committee of the General Assembly having cognizance of matters relating to public health on the outcome of such examination.
- (d) The Alcohol and Drug Policy Council shall convene a working group to advise the council of any recommendations for statutory or policy changes that would enable first responders or health care providers to safely dispose of a person's opioid drugs upon their death. Not later than February 1, 2018, the council shall report, in accordance with the provisions of section 11-4a of the general statutes, to the joint standing committee of the General Assembly having cognizance of matters relating to public health regarding the recommendations of the working group.
- (e) The Alcohol and Drug Policy Council shall convene a working group to study substance abuse treatment referral programs that have been established by municipal police departments to refer persons with an opioid use disorder or seeking recovery from drug addiction to substance abuse treatment facilities. The working group shall (1) examine such referral programs, (2) identify any barriers faced by such referral programs, and (3) determine the feasibility of implementing such programs on a state-wide basis. Not later than February 1, 2018, the council shall report, in accordance with the provisions of section 11-4a of the general statutes, to the joint standing committees of the General Assembly having cognizance of matters relating to public health and public safety and security regarding the findings of the working group.
- Sec. 8. (NEW) (Effective January 1, 2018) Each insurance company, hospital service corporation, medical service corporation, health care center, fraternal benefit society or other entity that delivers, issues for delivery, renews, amends or continues in this state an individual *Public Act No. 17-131*17 of 20

health insurance policy providing coverage of the type specified in subdivision (1), (2), (4), (11) or (12) of section 38a-469 of the general statutes that provides coverage to an insured or enrollee who has been diagnosed with a substance use disorder, as described in section 17a-458 of the general statutes, shall cover medically necessary, medically monitored inpatient detoxification services and medically necessary, medically managed intensive inpatient detoxification services provided to the insured or enrollee. For purposes of this section, "medically monitored inpatient detoxification" and "medically managed intensive inpatient detoxification" have the same meanings as described in the most recent edition of the American Society of Addiction Medicine Treatment Criteria for Addictive, Substance-Related and Co-Occurring Conditions.

Sec. 9. (NEW) (Effective January 1, 2018) Each insurance company, hospital service corporation, medical service corporation, health care center, fraternal benefit society or other entity that delivers, issues for delivery, renews, amends or continues in this state a group health insurance policy providing coverage of the type specified in subdivision (1), (2), (4), (11) or (12) of section 38a-469 of the general statutes that provides coverage to an insured or enrollee who has been diagnosed with a substance use disorder, as described in section 17a-458 of the general statutes, shall cover medically necessary, medically monitored inpatient detoxification services and medically necessary, medically managed intensive inpatient detoxification services provided to the insured or enrollee. For purposes of this section, "medically monitored inpatient detoxification" and "medically managed intensive inpatient detoxification" have the same meanings as described in the most recent edition of the American Society of Addiction Medicine Treatment Criteria for Addictive, Substance-Related and Co-Occurring Conditions.

Sec. 10. (NEW) (Effective July 1, 2017) An alcohol or drug treatment

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facility, as defined in section 19a-490 of the general statutes, shall use the criteria for admission developed by the American Society of Addiction Medicine for purposes of assessing a person for admission to such facility in consideration of (1) the services for which the facility is licensed, and (2) the appropriate services required for treatment of such person.

Sec. 11. Subsection (e) of section 17a-714a of the general statutes is repealed and the following is substituted in lieu thereof (*Effective July 1, 2017*):

(e) Not later than October 1, [2016] 2017, each municipality shall amend its local emergency medical services plan, as described in section 19a-181b, to ensure that [the emergency responder] at least one emergency medical services provider, as defined in the regulations of Connecticut state agencies pertaining to emergency medical services, who is likely to be the first person to arrive on the scene of a medical emergency in the municipality, including, but not limited to, emergency medical services personnel, as defined in section 20-206jj, or a resident state trooper, [who is likely to be the first person to arrive on the scene of a medical emergency in the municipality] is equipped with an opioid antagonist and such person has received training, approved by the Commissioner of Public Health, in the administration of an opioid [antagonists] antagonists.

Sec. 12. (NEW) (Effective October 1, 2017) (a) A prescribing practitioner, as defined in section 20-14c of the general statutes, who is authorized to prescribe an opioid antagonist, as defined in section 17a-714a of the general statutes, as amended by this act, and a pharmacy may enter into an agreement for a medical protocol standing order at such pharmacy allowing a pharmacist licensed under part II of chapter 400j of the general statutes to dispense an opioid antagonist that is (1) administered by an intranasal application delivery system or an autoinjection delivery system, (2) approved by the federal Food and Drug

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Administration, and (3) dispensed to any person at risk of experiencing an overdose of an opioid drug, as defined in 42 CFR 8.2, or to a family member, friend or other person in a position to assist a person at risk of experiencing an overdose of an opioid drug.

- (b) Any such medical protocol standing order shall be deemed issued for a legitimate medical purpose in the usual course of the prescribing practitioner's professional practice. The pharmacy shall provide the Department of Consumer Protection with a copy of every medical protocol standing order agreement entered into with a prescribing practitioner under this section.
- (c) A pharmacist may only dispense an opioid antagonist pursuant to a medical protocol standing order if the pharmacist has been trained and certified as part of a program approved by the Commissioner of Consumer Protection.
- (d) A pharmacist who dispenses an opioid antagonist pursuant to a medical protocol standing order shall (1) provide appropriate training regarding the administration of such opioid antagonist to the person to whom the opioid antagonist is dispensed, (2) maintain a record of such dispensing and the training required pursuant to chapter 400j of the general statutes, and (3) send a copy of the record of such dispensing to the prescribing practitioner who entered into an agreement for a medical protocol standing order with the pharmacy.
- (e) A pharmacist who dispenses an opioid antagonist in accordance with the provisions of this section shall be deemed not to have violated any standard of care for a pharmacist.
- (f) The commissioner may adopt regulations, in accordance with chapter 54 of the general statutes, to implement the provisions of this section.

Approved June 30, 2017

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Date

Robert D. Orrock, Sr., Chairman House Committee on Health, Welfare, and Institutions

Stephen D. Newman, Chairman Senate Committee on Education and Health

Re: Interim Progress Report, HB2165

Dear Chairmen:

Pursuant to HB2165, passed during the 2017 General Assembly Session, a workgroup was convened on August 2, 2017 and on August 29, 2017 to review actions necessary for implementation of the mandatory issuance of electronic prescriptions for controlled substances containing an opiate, effective July 1, 2020. Transmitting prescriptions for opiates electronically can potentially reduce medication errors, prescription theft, and forgery, assist prescribers and pharmacists in obtaining electronic prior authorizations when necessary, and integrate prescription records directly into a patient's electronic health record. The workgroup evaluated hardships on prescribers and the inability of prescribers to comply with the deadline for electronic prescribing. Additionally, it developed recommendations to the General Assembly for any extension or exemption processes relative to compliance or disruptions due to natural or manmade disasters or technology gaps, failures, or interruptions of services. The workgroup was comprised of representatives from the Board of Pharmacy; Virginia Pharmacists Association; National Association of Chain Drug Stores, Medical Society of Virginia; Virginia Hospital and Health Care Association; Surescripts; Virginia Dental Association; Virginia Veterinary Medical Association; Drug Enforcement Administration; and, the Virginia Association of Health Plans. A complete listing of the workgroup members is enclosed. David Brown, DC, Director of the Department of Health Professions (DHP) chaired the workgroup meetings.

Data provided by Surescripts to the members represented two types of prescribers: Active E-prescribers (prescribers who have sent e-prescriptions to pharmacies using Surescripts network in the last 30 days using the EHR software applications) and Active E-Prescribers EPCS Enabled (prescribers who use an EHR software that is Electronic Prescriptions for Controlled Substances certified and audit approved. As of June 2017, 56.8% of Virginia prescribers are active E-prescribers with 6.3% EPCS enabled. Nationally, 17.1% of prescribers are EPCS enabled. Additionally, 97.5% of Virginia pharmacies are active eRx pharmacies (pharmacies that are ready

and processing e-prescriptions from prescribers' applications) and that 90.3% are EPCS enabled pharmacies (pharmacies with certified and audit approved software ready to receive EPCS transactions from prescribers). The percentage of EPCS enabled pharmacies for Virginia reflects favorably with the national number of 90.5%.

The workgroup briefly reviewed federal requirements passed in 2010 authorizing electronic prescriptions for controlled substances in Schedules II-V and the Board of Pharmacy regulation authorizing electronic prescriptions for controlled substances in Schedules II-VI, and discussed similar mandates implemented in other states, particularly New York. The workgroup was informed that seven other states have passed legislation requiring electronic prescriptions for certain types of controlled substances. New York was the first state to mandate electronic prescriptions, effective March 2016, for all controlled and non-controlled substances.

While there was no expressed direct opposition to the mandate, there was general consensus among the workgroup members that exceptions to the mandate were needed. A review of passed legislation from other states revealed that most states have identified in Code various exceptions to the mandate, with one state authoring the promulgation of regulation on the subject. Therefore, the workgroup recommends a legislative amendment to identify exceptions to the mandate that prescriptions for controlled substances containing an opiate must be issued as an electronic prescription, which could include: a prescriber who dispenses the opiate directly to the patient or patient's agent; a prescriber who orders a controlled substance to be administered in a hospital, nursing home, hospice facility, outpatient dialysis facility, or residential healthcare facility; a prescriber who experiences temporary technological or electrical failure or other temporary extenuating circumstance that prevents the prescription from being transmitted electronically, provided the prescriber documents the reason for this exception in the patient's medical record; a prescriber who writes a prescription to be dispensed by a pharmacy located on federal property or out-of-state, provided the prescriber documents the reason for this exception in the patient's medical record, prescriptions issued by a veterinarian; prescriptions with complicated directions; prescriptions with directions longer than 140 characters or for compounded drugs containing two or more drugs if the software application cannot accommodate the required number of characters; prescriptions containing attachments required by the Food and Drug Administration; approved protocols authorized in law; and, prescriptions that cannot be issued in a timely manner and the patient's condition is at risk.

Because various exceptions to the mandate were deemed necessary by the workgroup, there was general consensus that pharmacists would not be able to readily determine if an otherwise valid prescription was transmitted in compliance with an exception. New York and North Carolina support and have acknowledged this understanding. Therefore, the workgroup recommends a legislative amendment to strike in 54.1-3410 E, "No pharmacist shall dispense a controlled substance that contains an opiate unless the prescription for such controlled substance is issued as an electronic prescription." and insert "A dispenser is not required to verify that a prescriber properly falls under one of the exceptions specified in Code prior to dispensing a controlled substance containing an opiate. A dispenser may continue to dispense controlled substances from valid written, oral, or facsimile prescriptions that are otherwise consistent with applicable laws."

There was additional discussion regarding whether an allowance for prescribers to apply for a temporary waiver should also be implemented. New York has such a provision wherein prescribers may apply annually for a temporary waiver of the mandate due to economic hardship, technological limitations that are not reasonably within the control of the prescriber, or other exceptional circumstance demonstrated by the prescriber. During the first year of implementation, New York granted approximately 6,200 waivers for approximately 19,000 prescribers. The following year, the number of approved waivers reduced to approximately 3,120. The most commonly approved waiver in the first year were for institutions and large group practices that were in the process of upgrading their software applications to comply with the mandate. North Carolina did not include a waiver provision in its 2017 legislation mandating electronic prescribing of "targeted controlled substances", i.e., Schedule II drugs containing opiates. The workgroup concluded that it is unnecessary to create a process for approving temporary waivers.

New York also exempts prescribers from the mandate if they certify that they do not issue more than twenty-five prescriptions during a twelve-month period. Prescriptions in both oral and written form are included in determining whether the prescriber will reach the limit of twenty-five prescriptions. Approximately 1,000 New York prescribers have certified that they will not issue more than twenty-five prescriptions during a twelve-month period. The workgroup discussed the need for allowing a certification process for low volume prescribers. It concluded that an exception for low volume prescribers of no more than twenty-five controlled substances containing an opiate within one calendar year should be included in the aforementioned legislative amendment to create a list of exceptions to the mandate.

Other identified challenges included costs for procuring or upgrading a software application that may transmit electronic prescriptions compliant with federal requirements. Cost will vary greatly depending on the chosen application and actions necessary to enable proper functions. It was stated that many providers utilize an application capable of electronically transmitting prescriptions in compliance with federal rules, but have not activated the function for various reasons. Additionally, during staff's research, a New York colleague indicated the purchasing of an electronic health record is not required for electronically transmitting prescriptions and that lesser expensive stand-alone applications exist which enable e-prescribing. Professional associations could potentially assist providers in identifying the best and most affordable software applications to meet the providers' needs. The workgroup recommends exploring the possibility of using Hi-tech grant funding to assist prescribers and pharmacists in obtaining a software application capable of electronically transmitting controlled substances in compliance with federal and state requirements.

The workgroup discussed the need for prescribers, who are not currently complying with federal requirements for transmitting electronic prescriptions, to obtain a two-factor credential and complete identity proofing in order to electronically sign a prescription. It appears a prescriber may incur a cost for this process, unless the employer subsidizes the cost. Additionally, there appeared to be concern for educating prescribers, particularly those working in solo or small practices, on how to complete the process. The workgroup recommends that the relevant professional associations and related boards could assist providers in educating them on how to obtain a two-factor credential.

The appropriateness of the effective date for the mandate, July 1, 2020, was discussed. While some members thought the deadline could be moved up to an earlier date, others thought 2020 provided the necessary amount of time to potentially obtain funding and software.

The appropriateness of the mandate exclusively addressing controlled substances containing an opiate was briefly discussed by the workgroup. One member supported a potential expansion of the mandate to other abuseable drugs given the addiction crisis. Others thought a possible expansion to other drug classifications would likely impact a greater number of prescribers and could complicate the implementation process for meeting the 2020 effective date.

No additional meetings of the workgroup are scheduled at this time. A final report shall be submitted to you by November 1, 2018. Please feel free to contact Caroline Juran at (804) 367-4456 or me, should you have any questions.

Respectfully,

David Brown, DC Director

Enclosure