HHR/DHP E-Prescribing Workgroup

Wednesday, August 29, 2018

Perimeter Center, 2nd Floor Conference Center, Board Room 2 Henrico, Virginia

DRAFTMEETING MINUTES

In Attendance:

Workgroup Conveners

Daniel Carey, MD Secretary of Health and Human Resources

David Brown, DC
Department of Health Professions, Director

Caroline Juran
Board of Pharmacy, Executive Director

Workgroup Members

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

Christina Barrille Virginia Pharmacists Association

Ellen Byrne, DDS, PhD Virginia Dental Association, Alternate Member

Lannie W. Cropper Virginia Association of Chain Drug Stores

Carol Forster, MD Kaiser Permanente Kelly Gottschalk, DVM Virginia Veterinary Medical Association

Doug Gray

Virginia Association of Health Plans

Richard Grossman Virginia Council of Nurse Practitioners

Scott Johnson HCA Hospitals

Ralston King Medical Society of Virginia

Jodi Manz, MSW Assistant Secretary of Health and Human Resources

R. Brent Rawlings Virginia Hospital & Healthcare Association

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

Staff

Laura Z. Rothrock

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

Sheralee Copeland Board of Pharmacy, Executive Assistant

Absent:

Ruth A. Carter

Drug Enforcement Administration

Opening Remarks and Approval of Agenda:

David E. Brown, DC, Director, Department of Health Professions Daniel Carey, MD, Secretary of Health and Human Resources

The meeting was called to order at 9:11am. Dr. Brown welcomed everyone, provided emergency egress information, and asked that the members introduce themselves.

Secretary Carey provided brief remarks concerning the purpose of the workgroup and announced he would leave the meeting around 10am due to a previous commitment.

Dr. Brown asked if there were any comments on or changes to the agenda; there were none.

NOTE: In addition to the agenda package, there were additional documents provided to the workgroup members:

- Statement from the U.S. Drug Enforcement Administration (DEA) entitled "Use of Mobile Devices in the Issuance of EPCS" (electronic prescriptions for controlled substances).
- Three (3) items provided by Ken Whittemore of Surescripts, LLC:
 - o Status of E-Prescribing in Virginia & Active E-Rx Mandate States
 - VA EPCS Prescriber and Pharmacy Enablement Status July 2018
 - o H.R. 6 Support for Patients & Communities Act

Call for Public Comment:

Dr. Brown asked if anyone in the audience wished to make comments. Michele Thomas, Pharmacy Services Manager, Virginia Department of Behavioral Health & Developmental Services (DBHDS) commented that DBHDS is moving toward one platform with implementation potentially in 2023 - 2025.

Review of Law and Workgroup's Past Actions:

Dr. Brown turned the meeting over to Ms. Juran who reviewed HB 2165 which was passed by the General Assembly in 2017 and mandates the electronic prescribing (e-prescribing) of prescriptions for controlled substances containing opiates.

HB2165 contains two enactment clauses (page 6 of agenda package):

1. Delayed implementation until July 1, 2020; and

2. Workgroup to be convened by the Secretary of Health and Human Resources 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, the inability of prescribers to comply with the 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.

The interim report was submitted to the General Assembly last fall and is included in the agenda package starting at page 7.

Ms. Juran indicated several states have passed legislation mandating e-prescribing. She then reviewed the exceptions noted in the interim report (page 8). She noted that the exceptions pertaining to "...prescriptions with complicated directions; prescriptions with directions longer than 140 characters or for compounded drugs...," would not be included in the draft legislation as these will soon be resolved.

A question arose as to whether "extenuating circumstances" for an exception which would be documented in the patient's records would also need to be noted on the prescription. It was determined that if exceptions are created then it would be near impossible for a pharmacist to determine if a prescriber has complied with the mandate. Therefore, it was determined that it is not the pharmacist's responsibility to determine if the prescriber has complied with the law and thus, the extenuating circumstance does not need to be documented on the prescription. Recommended amendments of §54.1-3410(E) are included in the draft legislation (page 30).

Recommend Legislation to Implement Mandate:

Waiver Process

There was discussion regarding whether a waiver process should be implemented. New York allowed waivers due to economic hardship, technological issues not in the control of the practitioner, or other exceptional circumstance. It was noted that New York had a significant gap between passage of the law and implementation and that the number of waivers decreased by almost half in the second year following implementation.

It was also noted that the DEA has data showing that the use of e-prescribing has had a positive effect on preventing fraud and drug diversion, and this data would help policy makers to move in the direction of mandating e-prescribing.

The workgroup determined that the legislation should include a requirement to review the implementation of the mandate and any approved exceptions.

There was concern that a waiver, particularly regarding economic hardship, could become permanent. It was stated that this is not the intent, as e-prescribing should become the standard of care. When a waiver is granted, there should be a plan on how it will be addressed to further implementation.

A question arose as to whether data could be used to determine if a waiver is working the way it was proposed. Dr. Brown requested that Ralph Orr, Director of the Virginia Prescription Monitoring Program (PMP), who was in the audience, address the question. Mr. Orr indicated that currently aggregated, deidentified information can be obtained. Also, in the event of an investigation of a prescriber, PMP data can be used. The PMP would need to clear with program counsel whether PMP data could be used related to review of a waiver. Mr. Orr noted that it is not currently possible to identify which prescribers work for a particular institution. Secretary Carey inquired as to whether it would be possible to view PMP data to determine the method of transmission of a prescription. Mr. Orr noted it is possible to track the method of transmission. The workgroup decided that PMP data would not be applicable in verifying a waiver based on economic hardship. However, it could be used to confirm that someone is a low prescriber (one of the exceptions in the draft legislation).

Exceptions Listed in Draft Legislation (page 28)

- 1. A prescriber who dispenses the opiate directly to the patient or patient's agent
- 2. A prescriber who orders a controlled substance to be administered in a hospital, nursing home, hospice facility, outpatient dialysis facility, or residential healthcare facility
- 3. 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 the exception in the patient's medical record
- 4. 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
 - It was decided to delete the term "out-of-state" as 94.5% of U.S. pharmacies are compliant.
- 5. A prescriber who writes a low volume of prescriptions, defined as less than twenty-five prescriptions during a twelve-month period with a maximum of a 7-day supply for each prescription

The numbers were discussed, and it was decided to leave as is with the addition of "most recent" before "twelve-month period."

- 6. A prescription issued by a veterinarian
- 7. A prescription containing attachments required by the Food and Drug Administration

This pertains to a drug with risk evaluation and mitigation strategies [see the Federal legislation (vii) on pages 18 and 19]. It was determined that the Federal language should be used in the draft legislation.

8. Approved protocols authorized in law

Ms. Juran indicated this pertains to standing orders.

At 10:42am before continuing, Dr. Brown announced that the workgroup would take a break and asked that the members not discuss this subject until the group has reconvened. At 11am the workgroup resumed discussions.

Ms. Juran went through the Federal legislation items (v) and (vi) on page 18. It was recommended to use Virginia's language when the Governor declares an emergency. The workgroup decided to strike #8 and replace it with the Federal language.

9. A prescription that cannot be issued electronically in a timely manner and the patient's condition is at risk

Before moving on to the next agenda item, Ms. Juran shared information from Mr. Orr pertaining to Item #2 in the draft legislation exceptions. An "administered" drug would not be reported to the PMP; a "dispensed" drug would be reported to the PMP. The Federal language in item (viii) on page 19 does not use either verb. Ms. Juran recommended that the words "to be administered" be removed and wording similar to the Federal language (e.g., resides in or receives care from) be used. The workgroup decided to use "administered by a person as authorized per Code §3401" and leave the remaining wording.

Next Steps:

Ms. Juran inquired of the workgroup as to whether to introduce legislation in 2019 with the recommended exceptions and amendments or wait and monitor the Federal legislation and

introduce legislation in 2020. After a brief discussion, the workgroup decided to proceed with introducing legislation in 2019 and amending in 2020, if necessary.

Dr. Brown inquired as to whether the workgroup felt there were any other items which needed clarification.

For exception #1, Mr. Gray inquired as to whether there is anything which should be noted in the process of obtaining the drugs to be dispensed. Ms. Juran discussed the standards wholesale distributors must follow in reporting suspicious transactions.

Pertaining to the exception in the interim report (page 8) regarding directions longer than 140 characters, Mr. Whittemore provided that the national e-prescribing standard is changing to 1,000 characters. Dr. Brown thanked Mr. Whittemore for the data that helped to inform the group's work during this meeting and last year's meetings.

Ms. Juran addressed the handout entitled "Use of Mobile Devices in the Issuance of EPCS." It is a clarifying statement from DEA which may be shared with other stakeholder groups for informational purposes.

Mr. Rawlings inquired as to how waivers would be incorporated into the draft legislation. Ms. Juran indicated that a separate paragraph would be added.

Dr. Brown expressed appreciation for the time that everyone invested into these meetings and thanked Ms. Juran, Ms. Rothrock, and Elaine Yeatts (DHP Senior Policy Analyst who assisted in preparing the draft legislation for the work group's consideration). Ms. Juran also thanked everyone for their work since last year and taking the time to review the interim report.

Adjourn:	
With no further business to discuss, Dr. Brown	n adjourned the meeting at 11:45am.
David E. Brown, DC Director	Date