COMMONWEALTH of VIRGINIA

Office of the Governor

William A. Hazel, Jr., MD
Secretary of Health and Human Resources

October 12, 2017

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

The Honorable Stephen D. Newman
Chairman
Senate Committee on Education and Health

Re: Interim Progress Report, E-Prescribing Workgroup (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; Virginia Council of Nurse Practitioners; 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 was provided by Surescripts to the members. Surescripts self-reports that it operates the nation's largest clinical health information network, serving providers in all 50 states and D.C. The company's network connects to over 98 percent of all retail pharmacies, most mail order pharmacies, and over one million U.S. providers. The Surescripts data 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%. During the workgroup discussions, a member noted that there are hundreds of EPCS enabled physicians practicing within healthcare systems that do not utilize Surescripts, e.g. Kaiser Permanente, that are not included in the Surescripts data. Additionally, it should be noted that the Surescripts data regarding EPCS enabled prescribers does not include most dentists.

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 (Note: it is purported that these two issues may be addressed in an upcoming NCPDP version and therefore, may no longer require exemption from the mandate.); 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, along with federal bill HR3528 introduced July 28, 2017, 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 did not determine that it is necessary to create a process for approving temporary waivers, but acknowledge that additional review may be necessary.

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. There was discussion regarding how best to define "low volume". While New York defines the term as a specified number of prescriptions per year, there was concern that even a few prescriptions written for large quantities could be problematic. It was suggested that "low volume" be defined as a maximum number of prescriptions per year with a restriction for the allowable maximum day supply for each prescription. The workgroup concluded that an exception for low volume prescribers should be included in the aforementioned legislative amendment to create a list of exceptions to the mandate and that a definition for low volume will need to be defined.

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 opioid prescriptions in compliance with federal rules, but have not activated the function for various reasons. Surescripts estimates that 95% of the active e-prescribers in Virginia use systems that are certified and approved for EPCS, and therefore, further estimates

that 54% of all Virginia prescribers could become enabled to transmit EPCSs in a relatively short period of time by working with their application vendor to download and/or install the EPCS functionality in their EHR. 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.

Subsequent to the workgroup's meetings, Board of Pharmacy staff was reminded of the following pharmacist observations with current utilization of e-prescribing which may need to be addressed prior to implementation of the mandate: prescribers practicing within a large healthcare system, wherein the prescriber may practice in multiple offices, often use a default address or telephone number for the healthcare system on the e-prescription, instead of the address number and telephone number associated with the site from which the prescription was issued, which creates challenges for the pharmacist contacting the prescriber with questions or concerns related to the dispensing of the prescription; occasionally prescribers will choose the default directions in the e-prescribing system, but then enter different directions in a text field thus creating opportunities for medication errors and confusion regarding the intended use of the drug; coupons or rebate opportunities associated with the cost of the drug will occasionally be included on the e-prescription which obscures the pharmacist's ability to read important prescribing information for dispensing the drug; and, while DEA allows the "forwarding" of an unfilled electronically transmitted prescription to another pharmacy should the patient choose to have the prescription filled at another pharmacy or if the prescriber transmits the prescription to

the wrong pharmacy, it has not provided information on how a pharmacist completes this process and the current NCPDP does not allow for such a transaction.

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 Dr. David Brown at (804) 367-4450, should you have any questions.

Respectfully,

William A. Hazel, Jr., MD

Enclosure

HHR/DHP E-Prescribing Workgroup

Member List – August 29, 2017

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