33 W Monroe, Suite 1700
Chicago, IL 60603
swillis@ehra.org
Phone: 312-915-9518
Twitter: @EHRAssociation

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Scott Gottlieb, M.D.
Commissioner of Food and Drugs
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Dear Dr. Gottlieb,

Members of the Association noted with interest your recent public statements on the opioid crisis, and in particular your statements in support of expanded use of prescription drug monitoring databases (PDMPs), as well as the importance of electronic health record (EHR) integration in that process.

Sadly, no one is immune from the opioid epidemic and its devastating effects, which is why, when the Electronic Health Record Association asked for volunteers to join a new Opioid Crisis Task Force in January 2018, numerous members stepped forward, sharing both their personal and their companies' experiences and expertise. For the past year, the Task Force has been looking into how EHRs and other health information and technology (IT) can best be part of the solution.

The EHR Association's 35 member companies serve the vast majority of hospitals and ambulatory care organizations that use electronic health records (EHRs) and other health information and technology to deliver high quality, efficient care to their patients. The Opioid Crisis Task Force began its work knowing that powerful tools like EHRs, PDMPs, Electronic Prescribing of Controlled Substances (EPCS) and health data exchange hold some of the keys to attacking substance abuse.

However, when we began researching how individual states were utilizing these tools, we learned that public policy can be an impediment to doing the right thing.

We share with you our detailed compilation of state-by-state rules and regulations for PDMPs. The disparity and sometimes even conflict between different states is striking,

and it has a direct bearing on our work as technologists and the work of our collective clients to apply the power of data to the challenge. Following is a summary of those findings, and our recommendations.

Prescription Drug Monitoring Programs

The EHR Association's Opioid Crisis Task Force has recommended expanded PDMP access beyond view-only throughout the EHR, within the clinical workflow and accessible to CDS tools to assist in decision making. This requires integration steps taken by both EHR companies and PDMP vendors, knowing that information access within the workflow will minimize provider burden as this process becomes more commonplace.

Like a lot of things, however, this isn't straightforward. For example, while many states utilize the same vendor to manage their PDMPs, they still are not able to easily share data. Although it seems common sense that states would share information to identify problematic drug-shopping behavior, some states prohibit PDMP checks from providers in other states, dramatically increasing the chances of cross-state drug purchases.

Other examples of variance in state regulations that restrict PDMPs from achieving their full potential in the U.S. include:

- the provider types that are allowed to, required to or prohibited from checking the PDMP;
- rules against saving PDMP data into the EHR as structured data;
- the Classes of drugs that must be reported to the PDMP;
- the period of time within which dispensers must report a controlled substance script to the PDMP; and
- the data points that can be exchanged.

Every state has a different approach. What we're left with are inconsistent workflows for providers, a higher cost to ensure compliance, and opportunities for drug seekers to cross state lines when they know that state databases don't talk to each other. The result is that the PDMP, a tool that could have a major positive impact on efforts to stem the opioid epidemic in the U.S., is not able to be utilized to its fullest potential.

We encourage states to take a more standardized approach to the exchange of opioid data, making access to the relevant patient data available across jurisdictions. This may take the form of common access capabilities using industry standards and common privacy policies, or promoting a national PDMP database. We welcome the FDA's efforts to contribute to this effort to reduce disparities and move towards greater integration of PDMP data into the EHR.

Electronic Prescribing of Controlled Substances

As you know, EPCS results in reduced prescription fraud and theft, as well as a greater level of accuracy in controlled substance prescription. These are critical factors that widespread adoption of EPCS could

address. EPCS is embedded in most EHRs, but the EHR Association's research identified several barriers to wider use of EPCS technology, such as disparate approaches to authentication, and lagging adoption by physicians.

Clinical Decision Support (CDS)

It is widely recognized that the incorporation of pain management CDS tools into the EHR, at the point at which prescribing decisions are being made, has an impact on providers' prescribing behavior. In November, the Opioid Crisis Task Force published a guide to assist healthcare organizations in efforts to incorporate the CDC opioid prescribing guideline into their EHR. The new *CDC Opioid Guideline – Implementation Guide for Electronic Health Records* focuses on how clinical practice guidelines can be efficiently and effectively operationalized within the EHR to improve opioid stewardship in clinical practice.

Although it is often cited by care professionals who treat pain, the CDC Guideline is seldom and inconsistently utilized in clinical practice. One reason often cited to explain low adoption of clinical decision support tools, like the CDC Guideline, is the lack of content available within a provider's EHR workflow. In this implementation guide, EHRA provides insights on the role technology can play in operationalizing each of the 12 CDC recommendations, as well as a menu of specific options for implementing these solutions, noting that each should be tailored to each organization's practice, protocols and state laws.

Given our consultation with several leading provider organizations, we expect it to deliver strong value to the Association's member companies and our collective clients.

Also, we are collaborating with the ECRI Institute to define a "virtuous cycle" of performance measurement and EHR-enabled safer opioid prescribing, such as health IT-enabled approaches for healthcare organizations to assess opioid prescribing; enabling safer opioid prescribing practices via CDS, e-prescribing and PDMP data; and including patient and clinician education as an element of CDS.

Public Health Monitoring

Tracking patterns of opioids prescribed electronically at the organizational or individual provider level is already widely feasible; those prescriptions are captured in EHRs (which can be used to run reports) and are increasingly transmitted through intermediaries (such as Surescripts) to the pharmacy. Prescriptions initiated within the EHR but printed (where electronic transmission is not legal or otherwise enabled) are also reportable from the EHR. Additionally, in states with PDMP or EPCS systems already live, those centralized data warehouses are capable of identifying prescribing patterns.

The EHR Association is highly committed to doing whatever we can to support the country's war on opioids. We have created several useful tools for the industry, and we are interested in conversing with policymakers and others central to the effort about what we have learned, as well as our recommendations on optimal next steps. We would appreciate the opportunity to further discuss our

data and recommendations with you and your staff. Please contact Sarah Willis-Garcia, EHRA Program Manager, at swillis@ehra.org.

Sincerely,

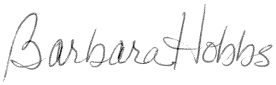
Cherie Holmes-Henry
Chair, EHR Association
NextGen Healthcare

Sasha TerMaat
Vice Chair, EHR Association
Epic

HIMSS EHR Association Executive Committee

David J. Bucciferro
Foothold Technology

Hans J. Buitendijk
Cerner Corporation



Barbara Hobbs
MEDITECH, Inc.

Rick Reeves, RPh
Evident

Emily Richmond, MPH
Practice Fusion

Courtney E. Tesvich, RN
Nextech

About the EHR Association

Established in 2004, the Electronic Health Record (EHR) Association is comprised of more than 30 companies that supply the vast majority of EHRs to physicians' practices and hospitals across the United States. The EHR Association operates on the premise that the rapid, widespread adoption of EHRs will help improve the quality of patient care as well as the productivity and sustainability of the healthcare system as a key enabler of healthcare transformation. The EHR Association and its members are committed to supporting safe healthcare delivery, fostering continued innovation, and operating with high integrity in the market for our users and their patients and families.

The EHR Association is a partner of HIMSS. For more information, visit www.ehra.org.