



July 10, 2017

Commissioner Scott Gottlieb, M.D.
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Submitted Electronically

Re: Docket No. FDA-2017-N-1094: Training Health Care Providers on Pain Management and Safe Use of Opioid Analgesics – Exploring the Path Forward

Dear Commissioner Gottlieb:

Health IT Now (HITN) appreciates your attention to and focus on the prescription drug and opioid abuse crisis and utilizing innovative practices and solutions in the fight against this epidemic. HITN is a diverse coalition of health care providers, patient advocates, consumers, employers, and payers who support the adoption and use of health IT to improve health outcomes and lower costs and are pleased to offer comments on Docket No. FDA-2017-N-1094: Training Health Care Providers on Pain Management and Safe Use of Opioid Analgesics – Exploring the Path Forward.

According to the Drug Enforcement Administration (DEA), deaths from prescription drug abuse have outpaced those from cocaine and heroin combined in the last 14 years. According to the Centers for Disease Control (CDC), from 2000 to 2015 nearly half a million people died from drug overdoses and the most recent statistics show that each day 91 Americans die from an opioid overdose. Through its regulatory authority, the FDA has many of the tools necessary to reduce instances of addiction while also ensuring those with a legitimate need maintain access.

Education and training for health care providers is one of those previously mentioned tools, but it will be reinforced and exponentially more effective when that education is paired with comprehensive and real-time data of the patient's controlled substance prescription history. In order for those pieces to coordinate, Prescription Drug Monitoring Programs (PDMPs) need to be interoperable across state lines, real-time, and within the workflow of prescribers and dispensers.

Compiling information from all operating state PDMPs is also needed to prevent cross-border shopping activity. Pharmacies already use transaction standards developed by the Standards Development Organization, the National Council for Prescription Drug Programs (NCPDP), and technology to glean information from electronic claims forms to achieve these purposes. On the provider side, NCPDP's HIPPA-compliant standards are also used in conjunction with Electronic Health Records (EHR) systems to provide the information regarding which medications are prescribed for the patient.

One way to promote interoperability is through a Patient Safety Network which stitches together the existing PDMPs through the utilization of current standards to provide comprehensive and complete

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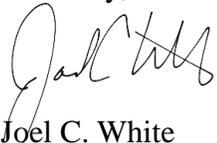
information to prescribers and dispensers, allowing these health care professionals to make an informed clinical decision with the benefit of data, as well as increased education. As described in the most recent version of NCPDP's white paper, *NCPDP's Recommendations for an Integrated, Interoperable Solution to Ensure Patient Safe Use of Controlled Substances*, this solution would use:

- A data facilitator to aggregate information into a central data repository that would house the data while individual state PDMPs would maintain control over the access of that information;
- Alerts similar to the alerts in use under the Drug Utilization Review (DUR) program to make a risk score known to the prescriber or dispenser;
- The enhanced program to cover all dispensed controlled substances, regardless of the method of payment; and
- HIPAA-compliant existing standards providing for the real-time information to be included within the workflow to reduce the burden at the points of prescribing and dispensing.

Utilizing existing interoperable standards that are employed throughout the industry today will ensure seamless implementation for providers by bringing PDMP information into their workflow and provide for the exchange of PDMP information in real-time at both the point of prescribing and dispensing. Enhancing the existing PDMP structure through the use of proven technology is a commonsense and proactive approach to reducing the instances of addiction and death ultimately caused by the abuse of prescription drugs and opioids.

We appreciate your consideration of our comments and look forward to working with the FDA to curb the opioid abuse crisis facing the country today.

Sincerely,



Joel C. White
Executive Director