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Suite 900
Washington, D.C. 20024

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To Whom It May Concern,

On behalf of the American Psychiatric Association (APA), the medical specialty society representing over 37,800 physicians who specialize in the treatment of mental illnesses, including substance use disorders, thank you for the opportunity to provide comments for consideration by the Food and Drug Administration's (FDA) Opioid Policy Steering Committee (OPSC). We appreciate the FDA's urgency in responding to this national public health crisis.

The APA is committed to working with the Administration and the states to help provide education, training, and support to address the crisis. Currently, we are an active partner in the Substance Abuse and Mental Health Services Administration's (SAMHSA) [Providers' Clinical Support System](#). Through this program, we train thousands of psychiatrists and physicians on the most effective approaches to medication assisted treatment for opioid use disorder.

We are pleased to submit the following feedback in response to the OPSC's request for comments regarding prescribing interventions.

Prescriber Documentation

As we address the current crisis, we recognize that we must strike a balance in assessing the risks of opioids, while also maintaining access for patients with acute pain who benefit from these drugs. The APA strongly supports increasing education and training opportunities for providers, and we recommend that the FDA work with specialty medical societies to develop specific guidelines on appropriate prescribing.

Additionally, the existing Risk Evaluation and Mitigation Strategy (REMS) Program currently addresses the safe use of opioids for providers, and at the state level, many medical boards have already implemented an opioid education requirement as a Maintenance of Licensing condition. We encourage the FDA to defer to the educational standards being set at the state level to avoid creating confusion and unnecessary federal overlap. We also recommend that the Agency work with medical schools to continue to enhance their curricula on opioid prescribing and the risk of developing a substance use disorder.

Additional REMS Approaches

Proper prescribing and dispensing of opioids can make a significant impact to reduce opioid misuse. To this end, we support the expansion of Prescription Drug Monitoring

Programs (PDMPs) and the availability of PDMPs to share information across state lines but would like to underscore that any effort should build upon the existing state-built PDMPs. Forty-nine states and the District of Columbia currently operate PDMPs¹ tailored to their specific state needs, and we encourage the Agency to work with state leaders to leverage the local infrastructure for better communication across state lines. Many states are already sharing information across state lines, and for providers who serve patients in areas with easy access to bordering states, this interoperability is critical.

However, one concern we have about the current reporting standards in PDMPs is that not all dispensed medications have to be reported. Medications that are ordered and directly dispensed from federally licensed opioid treatment programs, which legally include only methadone and buprenorphine, may not be reported. In contrast, methadone and buprenorphine prescribed are reported in other settings. If a provider does not realize that such information is not included, and the provider does not obtain a full history from the patient, the provider may inadvertently prescribe medication that could interact with the medication not reported in the PDMP and harm the patient. We recommend that all PDMPs include a notice to providers that clearly states which medications are excluded from PDMP reporting, so they can better understand the limitations of the reported information.

Additionally, we recommend that FDA consider an approach that integrates PDMP reporting more seamlessly with the flow of clinical practice to avoid adding obstacles for practicing physicians. One potential hurdle to implementing this requirement is that the current interoperability landscape between EHR systems, registries, and other health information technology is currently more aspirational than actualized. One primary reason for this is the tendency for HIT software companies to engage in “information blocking” (otherwise known as “data hoarding”) in order to protect proprietary software specifications—mainly for financial and other business-related reasons. However, the 21st Century Cures Act contains provisions that should help to mitigate information blocking and help the FDA to navigate ways in which a REMS approach to creating a system that utilizes a nationwide prescription history database to facilitate safe use of opioids.

The relevant statutory language of 21st Century Cures, Section 4004(a), reads that health IT vendors, exchanges, networks must avoid information blocking to the following extent: (A) except as required by law or specified by the Secretary pursuant to rulemaking under paragraph (3), is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information; and (B)(i) if conducted by a health information technology developer, exchange, or network, such developer, exchange, or network knows, or should know, that such practice is likely to interfere with, prevent, or materially discourage the access, exchange, or use of electronic health information; or (ii) if conducted by a health care provider, such provider knows that such practice is unreasonable and is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information.

Under this statute, a REMS solution might be for FDA to work with major electronic prescribing networks (e.g., SureScripts, AllScripts) to potentially create a nationwide prescription history database that is interoperable with most EHR and clinical data registries systems.

¹ Vestal, Christine. [“In Opioid Epidemic, States Intensify Prescription Drug Monitoring.”](#) December 2017.

Additional Considerations

Regarding the creation of an FDA requirement that sponsors take additional measures to ensure education on safe storage and disposal and the risks of misuse, abuse, and addiction associated with opioids, we encourage the Agency to consider the existing opportunities within the statutory authority of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) and within the scope of the regulatory requirements of MIPS' "Patient Electronic Access" measure (ACI_PEA_2). The MIPS eligible clinician must use clinically relevant information from certified EHR technology to identify patient-specific educational resources and provide electronic access to those materials to at least one unique patient seen by the MIPS eligible clinician." While the 2017 and now the 2018 performance year reporting requirements for this MIPS ACI measure were and are to provide patient education for only one unique patient, a REMS requirement for providers to offer educational materials (via their EHR systems) could help MIPS eligible clinicians who electronically prescribe controlled substances to become accustomed to engaging in this activity regularly. This might help some psychiatrists—who already struggle to find and disseminate germane patient-centered educational materials within EHRs—to earn additional performance score percentage points under MIPS ACI category while offering valuable educational materials on opioids to those who need them.

Lastly, the latest National Survey on Drug Use and Health reported that among people aged 12 or older in 2016 who misused prescription pain relievers in the past year, the most common source for the last pain reliever that was misused was from a friend or relative.² The APA encourages the Administration to continue to engage the public on safe disposal education, such as the Drug Enforcement Agency's Take Back Days, where people can turn in unused or expired prescription medications for safe disposals. Given the growing participation from year to year, we know that these designated days serve as a reminder to people about the importance of proper disposal and provides communities across the country an opportunity to prevent addiction and overdose deaths. In communities where local health departments partner with law enforcement, these designated days also present an opportunity to engage individuals about substance use disorder treatment.

The APA stands at the ready to join the FDA in its efforts to combat this public health crisis and we thank you for your ongoing efforts. If you have questions, or if we can be of further assistance, please contact Michelle Dirst, Director of Practice Management and Delivery Systems Policy, at mdirst@psych.org or 703-907-8586.

Sincerely,



Saul Levin, MD, MPA, FRCP-E
CEO and Medical Director

² Rebecca Ahrnbrak et al., "[Key Substance Use and Mental Health Indicators in the United States: Results from the 2016 National Survey on Drug Use and Health.](#)" September 2017.