October 2, 2018

Leslie Kux
c/o Bakul Patel
Associate Commissioner for Policy
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

RE: Fostering Medical Innovation: A Plan for Digital Health Devices; Software Precertification Pilot Program

Dear Associate Commissioner Kux:

The American Psychiatric Association (APA), the medical specialty society representing more than 37,800 psychiatrists who treat mental health disorders, including substance use disorders, appreciates the opportunity to submit feedback to the Food and Drug Administration's (FDA's) Fostering Medical Innovation: A Plan for Digital Health Devices; Software Precertification Pilot Program.

The APA is mindful that creating too many regulatory barriers has the potential to stifle innovative products that may benefit mental health patients in the rapidly-evolving digital health ecosphere. However, some regulation is necessary when developing a framework by which mobile applications may be regulated. This is especially true for the FDA's pre-certification program. As currently framed, the APA is concerned that the FDA's proposed regulatory process for Software as a Medical Device (SaMD) is heavily industry-driven, with prospective pre-certified vendors effectively monitoring their own apps for safety and effectiveness via the real-world data performance surveillance component. The APA urges the FDA to ensure a transparent regulatory process around the development, deployment, and self-evaluation of vendor and vendor products seeking pre-certification and re-certification. A transparent process is the cornerstone to creating products that adhere to high clinical standards and ensure patient safety—the latter being crucial when developing software used by highly vulnerable patients with mental health and substance use disorders and their physicians.

One aspect of the FDA's pre-certification program where regulatory transparency is essential is the use of real-world performance surveillance data as a contingency for maintenance of or recertification for product developers. Medical specialty societies, like the APA, can offer the FDA and participating vendors a wealth of guidance in this process, including expertise in measurement-based care, clinical content resources (e.g., clinical practice guidelines), and member experts (e.g., on diagnostic assessment standards and clinical practice ethics). Moreover, psychiatrists with experience in healthcare administration, who are the ultimate

decision-makers for how and when quality data are used in clinical care and for reimbursement, can also offer guidance on the use of healthcare data gleaned from apps, ensuring that app data is ecologically validated as a component of the SaMD real-world performance data recertification process.

Further, the pre-certification program could ensure greater transparency during the real-world performance data collection and review process by leveraging specialty societies' qualified clinical data registries (QCDRs). While a process for coordinating and connecting to these registries for the purposes of collecting mobile application data and utilizing it as a part of vendor re-certification would have to be delineated, use of QCDRs can potentially provide a concrete mechanism for the FDA and for vendors to demonstrate the reliability, validity, and clinical utility of these apps in a fundamentally transparent way.

In the future, APA could leverage our QCDR, PsychPRO, with the FDA and a mental health app developer, to provide a platform with transparency demonstrating the program's evaluation of real-world performance surveillance data. In addition to ensuring transparency, delineating a process to leverage specialty societies' QCDRs would also offer a way to track patient outcomes for the purposes of measuring overall use of the apps (a factor which recent research has demonstrated as being predictive in app effectiveness[1]) and any patient-centered harms and burdens associated with said use. The APA is particularly concerned that lack of transparency during the pre-certification and re-certification process might jeopardize patient-safety, which is especially troubling considering that patients who utilize some of these apps by pre-certified vendors will be diagnosed with substance use disorders, mood disorders, and other mental health conditions that place them at risk for self-injurious behavior, suicidality, and overdose.

In addition to QCDRs being used to enhance transparency in the pre-certification program, they also align with the goals of the Administration around using health IT meaningfully. Indeed, the Administration's current emphasis on using APIs as outlined in the Office of the National Coordinator's Request for Information on the Electronic Health Record certification program, and in the Centers for Medicare and Medicaid Services' (CMS') "Promoting Interoperability" performance category of the Merit-based Incentive Payment System, provides an opportunity for the FDA to ensure that data from patient-centered apps have an onramp into programs and systems that use patient-reported outcomes.

Finally, the APA has developed a Mobile App Evaluation Model[2], a tool to help psychiatrists evaluate apps for use in practice. The Model offers guidance on ascertaining an app's overall risk, privacy/security and data issues, clinical evidence base, patient usability, and

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[1] Torous J, Staples P, Slaters L, Adams J, Sandoval L, Onnela JP, Keshavan M. Characterizing Smartphone Engagement for Schizophrenia: Results of a Naturalist Mobile Health Study. Clinical Schizophrenia & Related Psychoses. 2017 Aug 4.
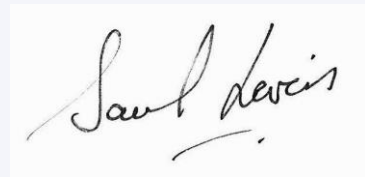
[2] https://www.psychiatry.org/psychiatrists/practice/mental-health-apps/app-evaluation-model

interoperability. While many of these factors are represented in aspects of the FDA's pre-certification pilot program, the APA encourages the FDA to review the APA's App Evaluation Model through the lens of the discerning practitioner: oftentimes, physicians have little background in medical/health app use and design, and APA's Model represents the level and types of information that doctors need when selecting apps to use with patients. We believe the model provides several concrete examples of the degree of transparency that should be considered in developers' Excellence Appraisal and Review Pathway Determination, especially around issues of Product Quality, Patient Safety, and Cybersecurity Responsibility.

The APA appreciates the opportunity to provide feedback to the FDA on the pre-certification pilot program. While the pre-certification program is designed with multiple medical conditions in mind, the use of apps in the context of mental health and substance use disorders is especially unique, and we encourage the FDA to be mindful of the aforementioned issues regarding data transparency and patient safety. As this work moves forward, please use APA's expertise to ensure SaMD products are clinically valid and reliable by ensuring that pre-certification and re-certification processes are transparent to the psychiatric clinician community.

If you have any questions, please feel free to contact Nathan Tatro, Health Information Technology Specialist, at (202) 559-3680, or ntatro@psych.org.

Sincerely,

Saul Levin, M.D., M.P.A.
CEO and Medical Director