AMERICAN
PSYCHIATRIC
ASSOCIATION

800 Maine Avenue, S.W.
Suite 900
Washington, D.C. 20024

June 3, 2019

Donald Rucker, MD
National Coordinator for Health Information Technology
Office of the National Coordinator for Health Information Technology
US Department of Health and Human Services
330 C Street, SW, Floor 7
Washington, DC 20201

RE: 21st Century Cures Act: Interoperability, Information Blocking, and the ONC
Health IT Certification Program

Dear Dr. Rucker:

The American Psychiatric Association (APA), the national medical specialty society
representing more than 38,500 physician psychiatrists who treat mental health and
substance use disorders, appreciates the opportunity to submit feedback to the Office
of the National Coordinator for Health Information Technology's (ONC) proposed rule,
"21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT
Certification Program." The APA is fully supportive of the myriad ways in which the
ONC has endeavored in recent years to attain the "Triple Aim" of enhancing the patient
experience, improving population health, and reducing costs. We also appreciate the
move by the ONC to include improving the work life of health care providers (the
"Quadruple Aim") among its priorities. The APA is hopeful that the successful
implementation of many of the provisions detailed in this proposed rule will advance
interoperability and support the access, exchange, and use of electronic health
information for psychiatrists and other providers across the United States.

Our comments are organized below by specific questions of the Rule; however, we
would also like to highlight some general concerns. First, while the APA is supportive
of efforts for physicians to have access to a complete and accurate patient record,
there is some concern that by requiring all data ("EHI"), regardless of relevance, to be
sent and received by all systems, this might lead to "information overload" of
physicians. With so much information available to them—with limited capacity to filter
it usefully in most EHR systems—there is a question of how much utility these data
would offer to care providers, as well as a potential for critical health information to
be overlooked. Sorting through all information would also place undue burden on
physician workflows, which are already overwhelmed with the requirements of the
various CMS' Quality Payment Programs.

Further, there is also a concern regarding the implementation timeline for the proposed rule. We have frequently heard from developers at HL7 that it requires a substantial amount of time and effort when new certification criteria are issued to bring them from development to in vivo use. This was especially true for the original Meaningful Use program, which saw many EHR vendors failed to keep pace with the frequent updates to CEHRT. The adoption and deployment of open APIs, as detailed in this Rule, raises similar concerns. Adopting APIs, implementing them within EHRs, and having physicians and staff trained on them, all make the ONC's proposed 24-month timeline insufficient for these stakeholders to adopt the new standards and adhere to the new Rule—especially when physicians would be required to immediately respond to requests under the Information blocking provision.

The APA requests that the timeline be extended to a 36-month period, and that an interim final rule be released in advance of the final rule. The scope of this Rule is vast and touches every patient and provider in the United States. An interim final rule, with comment period, as well as additional implementation time after the final rule is released, would provide developers, patients, and physicians the opportunity to acclimate to the new regulation.

Recognition of Food and Drug Administration Process

The APA recognizes the need for regulation surrounding the burgeoning software as a medical device (SaMD) commercial space, especially as it relates to the use of mobile applications ("apps") by patients and physicians. Similarly, 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, we have some concerns around the FDA's Pre-Certification Pilot Program as a regulatory mechanism to address this need. As currently framed, we are 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.

This real-world data performance surveillance component appears to lack transparency around vendors' self-evaluation processes—especially as it pertains to data validity and the medical expertise required in assessing the efficacy of a SaMD and how this relates to 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. **While the APA does not recommend that the ONC create its own regulatory process around regulating SaMD, we do suggest that the ONC work with the FDA and physician subject matter experts to revise future iterations of the Pre-Certification Pilot Program to increase transparency in developers' Excellence Appraisal and Review Pathway**

Determination, especially around issues related to the program's components of Product Quality, Patient Safety, and Cybersecurity Responsibility.

Electronic Prescribing

APA supports the adoption of the National Council for Prescription Drug Programs (NCPDP), Script Standard Implementation Guide, Version 2017071. Requiring this standard for ONC certification will improve interoperability between EHRs and Prescription Drug Monitoring Program (PDMPs) software. However, the current criteria do not appear to be able to handle medication assisted treatment for opioid use disorder (OUD) and other long-acting medications, which is crucial to clinical care and patient safety. **The APA recommends that the ONC include this ability within its revised 2015 certification criteria.**

Data Segmentation for Privacy – Send & Receive

The APA supports the ONC's decision to update the DS4P's send and receive standards to require capability for security tagging at the document, section, and entry levels. This enhanced capability could support more practice settings and use cases (e.g., pediatric psychiatric care, inpatient/outpatient substance abuse treatment facilities), reduce the use of burdensome workarounds by providers, and potentially increase care efficiency while reducing costs. Limited CEHRT options with DS4P especially is burdensome for psychiatrists, who must consider the sensitivity or even legal implications (e.g., 42 CFR Part 2) of their patients' health data when sending and receiving patient records electronically. **The APA recommends that the ONC identify incentives for CEHRT developers to include this currently optional standard within their products.**

Request for Information on Health IT and Opioid Use Disorder Prevention and Treatment

The APA supports the ONC's focus on health IT to continue to enhance clinicians' access to PDMPs and expand access to addiction treatment and recovery support services. The expanded use of open APIs for the ONC's certification program holds promise, but we are concerned that a completely market-driven solution around API connectivity with EHRs may not fully address clinicians' lack of access to OUD and other substance abuse data.

Specifically, there is still confusion among providers around 42 CFR Part 2 data and whether/when/how this information may be shared. For example, there might be a proliferation of mobile health apps that collect Part 2 data, but it is unclear whether hospitals will decide to enter into business associate agreements with these apps. Thus, this information would still not be shared among providers for whom it would be essential knowledge in treating patients with OUD. Further, the quality of these apps and the data collected is not guaranteed to be helpful, consistent, or used uniformly among patients. **The APA recommends that the ONC develop a regulatory process that would outline minimum standards around app privacy, security, and quality, to validate that the API is communicating information between providers and systems in uniformly and securely** (e.g., perhaps a registration process for the app developer with the ONC).

This would also provide an opportunity for patients to confirm that the app meets a minimum standard of quality and, at the least, will not cause them harm.

"Clinical information reconciliation and incorporation" criterion: APA has heard from its membership the myriad problems that exist around medication reconciliation. Specifically, that medication reconciliation between providers and EHR systems is often plagued with misinformation. This is due to multiple sources of information, the timing of when information is shared, familiarity with the clinician who initially entered data into the problem list, and whether the clinician accessing the record can identify and communicate with the clinician who originally entered this information. Our primary concern with adding the "clinical information reconciliation and incorporation" standard to CEHRT is that this will introduce an overwhelming amount of new clinical information into the problem list within the patient record, and it is not guaranteed that it will be done in a clinically useful way. Moreover, this standard may result in more errors than accurately reconciled information. **The APA recommends that this standard include a requirement that allows for commenting on the problem list so that the source of the information can be identified at the point-of-care in order to clarify any underlying confusion regarding the problem list.**

Application Programming Interfaces – Condition and Maintenance of Certification

In the Rule, the ONC details the numerous ways in which an API developer can recoup the cost for developing, testing, and updating APIs to interact with EHRs. Moreover, the Rule prohibits end-users (physicians) from passing any of these costs to the patient. The APA appreciates that the Rule provides rules around how and when developers can do so (e.g., "Ensure that fees are based on objective and certifiable criteria that are uniformly applied for all substantially similar or similarly situated classes of persons and requests"), but is concerned that the vagueness of the language may lead to inflated costs passed onto physicians, which would be a financial burden—especially to those operating in solo practice. **The APA recommends that the ONC, in cooperation with the Office of the Inspector General, develop a surveillance or feedback mechanism that could monitor this aspect of the Maintenance of Certification of CEHRT. This could be done in tandem with the forthcoming EHR Reporting Program on the usability of EHRs.**

Information Blocking

The APA appreciates the efforts undertaken in this rule to promote interoperability by setting parameters around information blocking between EHRs and between vendors and clients. Many of our members have notified us that, when transitioning from an old to a new EHR system, their legacy vendor does not readily provide an electronic copy of their data in a usable format; or the vendor attempts to charge them exorbitant fees to do so. The APA is optimistic that this part of the Rule will serve to curtail these behaviors on the part of vendors.

However, we do seek additional clarification around two of the **Exceptions to Information Blocking**, namely, the "Preventing Harm," and the "Promoting the Privacy of Electronic Health Information" exceptions. We appreciate that the Rule delineates the conditions under which actors—as defined in the Rule—qualify for these exceptions; however, we are concerned that some physicians may broadly misinterpret whether

certain scenarios encountered in practice qualify for these Exceptions. For example, we have heard overwhelmingly from our membership that physicians in many areas of practice—from primary care to substance abuse treatment—generally (and falsely) believe that HIPAA prevents them from sharing any or all mental health/substance use disorder data with other care providers. We are concerned that the misinterpretation of these two exceptions may compound this effect, inadvertently resulting in massive information blocking of data pertaining to psychiatric treatment in multiple care settings. For example, some care providers may interpret the exception to believe that releasing *any* piece of a psychiatric record may fall within the qualifying scope of "Preventing Harm" or "Promoting the Privacy of Electronic Health Information," simply because of the sensitive nature of mental health data.

Similarly, there is still widespread confusion around when a patient's substance use disorder record may be shared with another care provider. We are also concerned that the two above exceptions may further compound this confusion, resulting in fewer SUD records being shared between treatment settings. This would severely hinder care for this patient population at a time when the United States is in the midst of an opioid use disorder epidemic.

The APA recommends that the ONC—in concert with the Office of Civil Rights—develop training materials for physicians and educational materials for patients that provide an overview of these Exceptions, including illustrative examples and scenarios of when and how they apply. Such training materials could focus on specialties and be disseminated through the ONC's Health IT Playbook.

Definitions – Electronic Health Information

The Rule defines Electronic Health Information, in addition to HIPAA's electronic Protected Health Information (ePHI) as: "Any other information that identifies the individual, or with respect to which there is a reasonable basis to believe the information can be used to identify the individual and is transmitted by or maintained in electronic media, as defined in 45 CFR 160.103, that relates to the past, present, or future health or   condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual." The APA is concerned that this definition may be too all-encompassing in an era where patients, physicians, and systems are generating, sending, and storing a vast array of data between and within multiple systems, including EHRs (CEHRT or not), QCDRs, SaMD, mobile health apps that connect to EHRs, and so on. Such a broad definition may result in confusion among stakeholders about what data falls under EHI. This uncertainty also applies to the Rules definition of a Health Information Exchange and Health Information Network, and therefore would be subject to the Information Blocking Exceptions. This is particularly concerning for specialty society registries, like APA's PsychPRO, and the registry's vendor, FigMD. **The APA seeks clarification on whether registries fall under the definition of EHI, HIN, and HIE, under the Information Blocking Provision, and would therefore be required to comply with the Rule.**

Request for comment regarding price information (Department of Health and Human Services)

APA acknowledges the increased urgency for price transparency within healthcare, given soaring costs combined with new points of access and innovative solutions emerging within a competitive marketplace. New psychopharmacological treatments that contain microchips that pair with a smart phone to track medication compliance for those with serious mental illness (SMI), telepsychiatry, and alternative payment models all are example of an evolving healthcare landscape that provides patients with numerous treatment options.

APA is concerned that patients presented treatment options on a computer screen with little-to-no context may result in patients reaching decisions based on cost alone rather than the treatment that best suits their diagnosis and other life circumstances. Further information is needed on how price transparency would include various diagnostic and other use cases, including how algorithms would incorporate social and behavioral health data. Additionally, in a marketplace where dozens of payers with multiple insurance plans would affect cost for individuals in very different ways, it is often unknown what the final cost to a patient would be with respect to downstream effects. The technical and operational challenges would create significant burden on physician workflows if physicians were required to provide this information for every patient, for every treatment. It should not be the responsibility of the provider to ensure that any pricing information provided via the EHR is correct. **The APA recommends that the ONC review the possibility of including a price transparency standard in future iterations of CEHRT.**
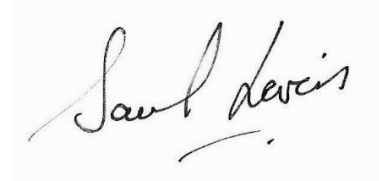
Patient Matching Request for Information – Opportunities to Improve Patient Matching

Accurate and standardized data capture and exchange and optimized algorithm performance are critical components to accurate patient matching. Better patient matching is paramount to quality of care, as it improves patient safety, care coordination, and advances efforts around interoperability. Unfortunately, much of patient matching still occurs manually, with providers reviewing patient demographics (name, date of birth, address) from different sources of information—EHRs, practice management software, information received by fax, paper intake forms, and PDMPs. This is burdensome and—in the case of PDMPs—potentially dangerous.

Many organizations have attempted to find solutions to better patient matching, including the ONC's own Gold Standard and Algorithm Testing pilot study; the Sequoia Project's "A Framework for Cross-Organizational Patient Identity Management," the College of Healthcare Informatics Executives' (CHIME) National Patient ID Challenge, among others. While these efforts showed some success, **the APA is generally supportive of efforts for a national patient unique identifier.** While we understand that this is the purview of Congress and would require a change in federal statute, we hope that, by highlighting this position in our letter, we can add our voice to the chorus of medical societies' who also maintain this position.

Thank you again for the opportunity to respond to this proposed rule. We welcome the opportunity to continue this conversation and ask that you contact Nathan Tatro, Associate Director of Digital Health, at ntatro@psych.org if you have questions.

Sincerely,

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