



AMERICA'S ESSENTIAL HOSPITALS

June 3, 2019

Don Rucker, MD
Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Suite 729D
200 Independence Ave. SW
Washington, DC 20201

Ref: RIN 0955-AA01: 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program

Dear Dr. Rucker:

Thank you for the opportunity to submit comments on the above-captioned proposed rule. America's Essential Hospitals welcomes the Office of the National Coordinator for Health Information Technology's (ONC's) work to promote interoperability and facilitate the access, exchange, and use of electronic health information. We appreciate that the agency is viewing its policies through the prism of reduced burden and costs associated with the use of health information technology (IT). Essential hospitals are committed to using health IT to improve the lives of their patients, including through population health efforts, telehealth to reach patients who face transportation barriers, and electronic health record (EHR) data to reduce unnecessary readmissions and improve outcomes. Despite these successes, burdensome regulatory requirements drain staff time and resources that hospitals could better spend on delivering high-quality, patient-centered care. As ONC establishes policies to implement 21st Century Cures Act ("Cures Act") provisions facilitating information exchange, we encourage the agency to consider that a variety of stakeholders are responsible for information sharing, and we urge the agency to provide realistic parameters for implementing exchange requirements.

America's Essential Hospitals is the leading champion for hospitals and health systems dedicated to high-quality care for all, including the vulnerable. Filling a vital role in their communities, our 300 member hospitals provide a disproportionate share of the nation's uncompensated care and three-quarters of their patients are uninsured or covered by Medicare or Medicaid. Our members provide state-of-the-art, patient-centered care while operating on margins one-fifth that of other hospitals—1.6 percent

on average compared with 7.8 percent for all hospitals nationwide.¹ Essential hospitals' commitment to serving all people, regardless of income or insurance status, and their diverse patient mix pose unique challenges. A disproportionate number of their patients face sociodemographic challenges to accessing electronic patient information, including poverty, homelessness, language barriers, connectivity, and low health literacy.

We appreciate ONC developing certification criteria that will ensure EHR products are capable of exchanging and exporting information, and we welcome the additional details about what constitutes information blocking under the Cures Act. We urge the agency to reduce excessive regulatory burdens on providers so they can direct their resources to patient care. Below, we offer recommendations that will reduce burden on providers and ease their ability to exchange information with patients as well as other providers and entities.

Deregulatory Actions for Previous Rulemakings

1. ONC should keep randomized surveillance requirements in place to ensure IT products remain compliant with certification requirements.

ONC should maintain robust testing and surveillance of EHR products to ensure these products offer the functionalities required by the certification criteria. The ONC certification program requires EHR developers to have their products certified and tested before they are listed on the certified health IT product list (CHPL) website. For EHR developers to offer their IT products to providers for use in the Medicare and Medicaid Promoting Interoperability Programs (PIPs), these products must be the certified to the 2015 edition certification criteria. Increasingly, other government and nongovernment programs also have adopted or referenced the certification criteria in their program requirements.² An EHR developer's responsibilities do not end when their product is approved and listed on the CHPL—once these products are certified, ONC oversees their use in health care settings. Field surveillance is critical to ensuring EHR products function as intended and do not present safety or health risks.

Certification requirements mandate both reactive field surveillance in response to specific complaints filed by providers, as well as randomized field surveillance performed by ONC authorized certification bodies (ACBs). In 2017, ONC used its enforcement discretion to announce it was easing the randomized field surveillance requirements and making them voluntary.³ Under the proposed rule, ONC would

¹ Clark D, Roberson B, Ramiah K. *Essential Data: Our Hospitals, Our Patients—Results of America's Essential Hospitals 2017 Annual Member Characteristics Survey*. America's Essential Hospitals. April 2019. www.essentialdata.info/. Accessed April 12, 2019.

² *Programs Referencing ONC Certified Health IT*. The Office of the National Coordinator for Health Information Technology. <https://www.healthit.gov/topic/certification-ehrs/programs-referencing-onc-certified-health-it>. Accessed May 17, 2019.

³ ONC exercises enforcement discretion with respect to implementation of randomized surveillance. The Office of the National Coordinator for Health Information Technology. September 21, 2017. https://www.healthit.gov/sites/default/files/ONC_Enforcement_Discretion_Randomized_Surveillance_8-30-17.pdf. Accessed May 17, 2019.

remove the regulatory language mandating that ACBs conduct randomized surveillance, noting that this will reduce burden for ACBs and for providers.

Surveillance of certified products is an important safeguard in the ONC certification program. While providers can report deficiencies to ACBs as part of reactive surveillance, ONC should conduct randomized surveillance in tandem with reactive surveillance to ensure that certified products continue to conform to the certification requirements when used in health care settings. There are real examples of certified EHR products that, when implemented in health care settings, function in a way that could imperil patient safety. For example, an EHR that has a faulty electronic prescribing or computerized provider order entry functionality could result in incorrect dosages of medication. These types of discrepancies can be addressed through randomized surveillance. **We are sympathetic to the concerns about burden on providers, and we therefore urge the agency to provide guidance to ACBs to conduct randomized surveillance in a way that is least disruptive to providers, such as by offering ample notice of randomized surveillance and performing surveillance in an expeditious manner.**

2015 Certification Criteria/Electronic Health Information Export

- 1. ONC should revise its electronic health information export certification criterion to ensure certified EHR technology (CEHRT) is capable of exporting data without excessive burden.**

While America’s Essential Hospitals supports the development of robust criteria for electronic health information (EHI) export, we urge ONC to develop and enforce these criteria in a way that minimizes strain on provider EHR systems and providers’ staff. In the proposed rule, ONC makes numerous updates and additions to the 2015 edition certification criteria. ONC proposes to develop a new certification criterion that will enable a provider to export all EHI within the EHR in a timely manner without requiring subsequent developer assistance. The new export criterion would be effective 25 months from the issuance of the final rule. This criterion is intended to apply to two specific use cases. First, it will allow a provider to export all EHI for a single patient in an electronic and computable format. Second, the criterion will enable a provider to export a database of all EHI for data transfer purposes, such as in a case where a provider is changing EHR products and needs to move all patient data contained from its existing EHR to a new product.

This criterion supports key functionalities that will enable the exchange of information between a provider and its patients, as well as the free flow of information across different platforms. We support the agency’s development of the criterion but are concerned about the strain large data queries can place on a provider’s IT system. Given the breadth of EHI in the export criterion, the proposed rule would require multiple data export queries involving dedicated hospital staff to process and perform these requests. In addition, the sheer volume of the data inevitably will burden and could disrupt provider IT systems. The criterion, as proposed by ONC, would require that EHRs be capable of exporting all data that the system “produces and electronically

manages.” This is not limited to clinical data; it includes administrative and billing data, imaging data, and data stored in data warehouses. For a given patient, this data includes all data on the patient, regardless of the date it was produced or the format. ONC should ensure adequate testing of these functionalities and consider the burden this proposal could place on provider systems. The agency should work with developers to provide guidance to make the export a process that is manageable for IT systems and the providers using these systems.

2. ONC should provide a transition period from the data export to the new EHI export criterion.

ONC’s proposed new EHI export criterion would replace the existing data export criterion in the 2015 edition certification regulations, which the agency proposes to remove upon the effective date of the final rule. **America’s Essential Hospitals encourages the Department of Health and Human Services (HHS) to establish a transition period so providers can export data from their EHRs while developers work on EHR products that will be compliant with the new EHI export criterion.** Due to the importance of data transfer capabilities and patient access to health information, it is critical to ensure providers’ systems can export data during this transition period. Immediately removing the data export criterion will leave a two-year gap during which developers will not be bound by any certification criteria relating to data export. Providers should continue to have data export functionalities in any updated or new products they acquire until the new EHI export criterion takes effect. **Thus, we urge the agency to leave the existing data export criterion in place until developers begin to offer products certified to the new EHI export criterion.**

Request for Information on Opioid Use Disorder Prevention and Treatment

ONC requests feedback on the use of health IT to address opioid use disorder. Essential hospitals are on the front lines of treating patients most affected by the opioid crisis and have implemented innovative strategies to reduce opioid dependence. As leaders in population health, essential hospitals continue to develop programs that prevent opioid misuse among the most vulnerable populations. They partner with pharmacies, public health departments, law enforcement, emergency medical services, and other community providers to combat the crisis. As key stakeholders in combating the opioid crisis, essential hospitals stand ready to implement practices that have proved effective in reducing opioid dependence. Notwithstanding the successes that essential hospitals have realized in addressing the opioid crisis, there still are substantial technological and regulatory barriers that prevent the flow of information across the care continuum. ONC can address these barriers in collaboration with other federal agencies and stakeholders to ensure that providers coordinate care for patients battling opioid use disorder.

- 1. ONC should develop standards to integrate prescription drug monitoring programs (PDMPs) into EHRs and ensure clinicians can access PDMPs with minimal workflow disruption.**

In the proposed rule, ONC notes barriers to the exchange of PDMP data and integration of such programs into EHRs. ONC should work with other agencies and stakeholders to ensure there are adequate standards and criteria for the integration of EHRs into PDMPs. This integration is even more vital now that providers will be required to query PDMPs for prescription drug history. The Centers for Medicare & Medicaid Services (CMS) added PDMP and opioid treatment agreement measures to PIPs that are voluntary in 2019 but required beginning in 2020. **ONC should facilitate the development of standards and criteria that will enable providers to report on the PIP measure to use data from CEHRT to query a PDMP.**

PDMPs are not fully integrated into health IT, and the use of PDMPs cause workflow disruptions when practitioners check a patient's opioid medication history. Our members have indicated to us that accessing PDMPs can be an arduous process that requires the provider to close the EHR and provide credentials to log on to a state PDMP website. In other words, a provider cannot always seamlessly access information from a PDMP from within the EHR when electronically prescribing a medication.

PDMPs lack uniform adoption across states and providers. Due to varying state requirements governing PDMPs, their use is uneven across the country. Not all states require the use of PDMPs and one—Missouri—does not even have a PDMP. Additionally, platforms differ by state, creating a lack of uniformity in accessing PDMP data and difficulty in establishing standards for the use of EHRs to access PDMP data. There are no standards or certification criteria governing the use of PDMPs, so hospitals have no guarantee that their certified EHR technology will include the functionality to query a PDMP. Due to the lack of uniform adoption across states and varying levels of provider and pharmacist use of PDMPs, PDMPs often contain incomplete information about patients' medication history. **ONC should develop standards and criteria for PDMPs that will allow providers to benefit from accessing and logging data with minimal workflow disruption.**

- 2. ONC should work with policymakers to clarify and lift restrictions related to substance use disorder confidentiality requirements to facilitate related health information exchange.**

Essential hospitals deploy innovative approaches to treat patients with opioid and substance use disorders, but they continue to face operational challenges. When patients visit doctors and hospitals, most assume providers have a complete medical history and an awareness of addictions or substance use to factor into treatment and prescribing. However, requirements imposed by 42 CFR Part 2 (Part 2) limit providers' use of patient substance use records for certain substance use treatment programs. Obtaining multiple consents from a patient is challenging and creates barriers to whole-person, integrated approaches to care. As a result, many providers often learn of addiction problems only after an adverse event or an overdose. Part 2 regulations might

lead to a physician writing prescriptions for opioid pain medication for an individual without knowing that patient had a substance use disorder. Confidentiality requirements under Part 2 also pose barriers to the completeness of information in PDMPs. For example, pharmacists dispensing medications as a part of medication-assisted treatment to treat substance use disorder are sometimes unsure of whether they can log these prescriptions into a PDMP. This results in an incomplete record of a patient's medication history that can lead to prescribing errors and harmful drug interactions. Separation of a patient's addiction record from the rest of their medical record creates several problems and impedes safe, effective, high-quality substance use treatment and coordinated care.

Part 2 must better align with the Health Insurance Portability and Accountability Act (HIPAA) so health care providers can ensure comprehensive, coordinated substance use treatment and care. Specifically, Part 2 should align with HIPAA for the purposes of treatment, payment, and health care operations. It is unrealistic for ONC and CMS to expect to realize the full potential of interoperability when there are substantial barriers to the exchange of information on patients with substance use disorder. The barriers to exchange are not limited to information specifically covered by Part 2. When a patient's medical record contains information covered by both HIPAA and Part 2, this also creates a barrier to the exchange of information unrelated to substance use disorder. Even if a provider needs to exchange information in the medical record unrelated to the substance use disorder, the provider will have to carve out the Part 2 data, which is not always feasible with EHR systems. We provide additional recommendations on data segmentation issues in the section below, on information blocking.

In 2018, the Substance Abuse and Mental Health Services Administration released a final regulation, as well as informational materials and fact sheets on its website, clarifying how Part 2 relates to the exchange of information between providers. However, these steps do not go far enough to mitigate provider concerns. **ONC should work with lawmakers to modify Part 2, allowing appropriate levels of access for providers to ensure they have a complete picture of their patients' health.**

3. ONC should work with providers to incorporate the most relevant prescribing guidelines into EHRs and clinical decision support tools.

In the proposed rule, ONC notes the importance of evidence-based guidelines in treating substance use disorder, as well as the potential for EHRs to guide physicians with patient-specific clinical support through clinical decision support tools in the EHR, such as alerts, reminders, and guidelines that can present recommendations to the physician based on the patient's specific clinical factors and health history. We recommend ONC work with providers who have firsthand experience to determine the appropriate guidelines and resources to develop and incorporate into EHRs. ONC notes the possibility of using the Centers for Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain. Providers have voiced concerns about how limitations imposed by the CDC guideline can interfere with a clinician's judgment of the most appropriate treatment for a specific patient. As a result, CDC recently issued a clarifying letter emphasizing that the decision to prescribe opioids is best made by the

physician based on their assessment of a particular patient's needs.⁴ This underscores the importance of working with providers to ensure any tools or resources are valuable to providers and are meant only as aids that do not replace the role of clinical judgment in prescribing decisions.

Information Blocking

Essential hospitals are committed to exchanging health information both within their health care systems and with other providers to ensure patients receive coordinated, holistic care. The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) requires providers in the PIPs to attest they did not knowingly and willfully engage in information blocking by interfering with the interoperability of their CEHRT. Hospitals participating in the PIPs, as well as clinicians participating in the Merit-based Incentive Payment System of the Quality Payment Program, are required to provide detailed attestations that they did not engage in information blocking. The Cures Act further restricted information blocking, by both defining the term and prohibiting providers, developers, networks, and exchanges, from engaging in the practice. The legislation also gave HHS enforcement authority over information blocking and deferred to the agency to delineate “reasonable and necessary activities” exempted from the definition. In the proposed rule, ONC outlines seven proposed exceptions and defines EHI for the purposes of information blocking.

America's Essential Hospitals is committed to and has previously voiced support for an interoperable learning health system. Essential hospitals realize the need for patients' health information to be readily accessible by providers across the care continuum. However, there are many obstacles—most of which are outside of the control of hospitals—that prevent a hospital from seamlessly exchanging information. ONC recognizes some of these obstacles in delineating the exceptions to information blocking. However, work remains for the agency and other stakeholders to develop an interoperable health system, such as the development of the Trusted Exchange Framework and Common Agreement. Below, we provide recommendations that will ease providers' transition to complying with the information blocking provisions and exceptions.

1. ONC should delay implementation for the information blocking provisions.

ONC should delay the implementation date of the information blocking provisions to at least 18 months from the publication of the final rule. ONC proposes to put its information blocking provisions into effect with publication of the final rule. Providers and other entities governed by the new provisions will require time to assess their systems and update their internal processes to be able to comply with the information blocking provisions and the exceptions. ONC outlines seven detailed exceptions, each with multiple sub-exceptions and requirements that must be met. Providers will need

⁴ Finnegan J. CDC clarifies opioid prescribing guideline, says doctors should use their 'clinical judgment.' *FierceHealthcare*. April 10, 2019. <https://www.fiercehealthcare.com/practices/cdc-clarifies-opioid-prescribing-guideline-say-doctors-should-use-their-clinical>. Accessed April 18, 2019.

lead time to train their staff about the provisions of the final rule and how to determine whether a given activity qualifies for an information blocking exception. Providers also will have to develop internal policies to capture and document relevant information to justify their use of an exception. Given the punitive nature of the information blocking provision—which contains monetary penalties for most entities and other disincentives for health care providers, including the public posting of information on entities that are deemed to be information blocking—ONC must delay the implementation of the information blocking provisions by at least 18 months.

2. ONC should exclude health care providers from the definition of health information network (HIN).

ONC should revise the definition of HIN to explicitly exclude health care providers because they already are covered by the information blocking provisions of the Cures Act. The Cures Act applies the information blocking prohibition to health IT developers, exchanges, networks, and health care providers. In the proposed rule, ONC broadly defines an HIN as an individual or entity that enables, facilitates, or controls the movement of information between or among different individuals or entities that are unaffiliated. Specifically, the proposed regulatory text states that an HIN is an individual or entity that:

- determines, oversees, administers, controls, or substantially influences policies or agreements that define business, operational, technical, or other conditions or requirements for enabling or facilitating access, exchange, or use of EHI between or among two or more unaffiliated individuals or entities; or
- provides, manages, controls, or substantially influences any technology or service that enables or facilitates the access, exchange, or use of EHI between or among two or more unaffiliated individuals or entities.

The way ONC defines HIN is overly broad and would include certain health providers engaged in the exchange of data with other entities. ONC provides an example of a health system that uses health IT to facilitate the exchange of EHI with other, smaller health care providers. ONC's definition of HIN potentially would encompass a variety of health care providers who manage and share data outside of their health system, both with other health care providers and with social service agencies, government agencies, data clearinghouses, public health agencies, and other entities. As large, integrated health systems responsible for patients' care inside their four walls but also upon discharge, these systems have a vested interest in coordinating care by exchanging information not just with other providers but, in many cases, with local community organizations and social service organizations. ONC's inclusion of these providers in the definition of HIN could disincentivize information sharing by imposing additional penalties.

The Cures Act authorizes the Office of Inspector General to levy \$1 million civil monetary penalties (CMPs) on HINs and other entities for each violation of the information blocking provisions, while imposing separate penalties on health care providers. By including certain health care providers in the definition of HINs, ONC

subjects them to CMPs, in addition to the separate penalty for health care providers. Because providers already are covered by separate penalties under the Cures Act, certain providers' inclusion in the definition of HIN would inappropriately subject them to two penalties. **For these reasons, ONC should clarify the regulatory language to carve out health care providers from the definition of HIN.**

3. ONC should narrow the definition of EHI used in determining what constitutes information blocking.

ONC proposes a very expansive definition of EHI that encompasses clinical, administrative, and payment data. Specifically, ONC proposes that EHI would include:

- electronic protected health information; and
- any other information that—
 - is transmitted by or maintained in electronic media, as defined in 45 CFR 160.103;
 - 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
 - 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 types of information included in this definition include data not produced in CEHRT itself but from external sources, including information about insurance eligibility, as well as information received from the patient, an employer, a university, or a school. Storing, compiling, and sharing this data will be cumbersome for providers, as they will have to collect data from various sources and verify they are not missing information provided by an external source that is not incorporated into the EHR. This data would likely be unstructured and not subject to data standards, further compounding existing issues with information exchange that stem from a lack of standardization.

A more reasonable definition of EHI would limit it to the United States Core Data for Interoperability (USCDI) standard, which is the core dataset that ONC proposes to require in 2015 CEHRT. ONC has determined and states in the preamble to the proposed rule that requiring this standardized dataset in CEHRT will “achieve the goals set forth in the Cures Act by specifying a common set of data classes for interoperable exchange.”⁵ ONC already is building certification criteria based on the USCDI, which contains standardized data useful to patients and other providers requesting information from another provider, including clinical notes, laboratory tests, immunizations, medications, vital signs, and patient demographics. **ONC should limit the definition of EHI for information blocking purposes to the USCDI dataset because health IT products will be certified to the USCDI and, at a minimum, will contain this information.**

⁵ 84 Fed. Reg. 7424, 7441 (March 4, 2019).

4. **ONC should exclude price information from the definition of EHI.**

In defining EHI, ONC proposes to explicitly include information on the “*past, present, or future payment* for the provision of health care to an individual.” As noted in the previous section, we urge ONC to limit the information to the USCDI, which would exclude payment information. Expecting providers to search their records for data on past payment, without any limitation on how far back the provider must search, is unreasonable and onerous. Included in the agency’s rationale for the inclusion of price information is that “the availability of price information could help increase competition that is based on the quality and value of services patients receive.”⁶ Hospitals already face a multitude of quality reporting requirements through Medicare and other payers, which is displayed publicly and intended to improve quality and reduce costs. These measures include specific metrics on quality of care and the value of care, so imposing additional price information requirements to achieve these goals is redundant. Moreover, CMS began requiring hospitals to post price information online, so additional price information requirements are unnecessary. **Before implementing new price information requirements, ONC should consider the full scope of reporting requirements with which hospitals already comply and should explicitly exclude payment and price information.**

ONC seeks comment on the parameters of including price information for services that a provider offers. The types of data on which ONC seeks comment underscore the complexity of sharing price information. For example, ONC asks about the inclusion of patient out-of-pocket costs, charge master prices, and negotiated rates. Hospitals are not independently responsible for setting patient out-of-pocket costs, which are dependent on the patient’s insurance company. The final amount paid by patients often is dependent on insurance benefit design, including deductibles, coinsurance, copayments, out-of-pocket maximum amounts, and how the payer has negotiated a contract with the provider. Patient out-of-pocket costs are dependent on financial assistance offered under a hospital’s financial assistance policies, which can cover the patient’s copays and deductibles if the patient meets certain financial criteria. These determinations are not always made at the point-of-service and often take time to process while the hospital reviews information submitted by the patient on eligibility for financial assistance. Therefore, any price given to a patient up-front will be subject to change and not reflective of the final patient liability amount. Chargemaster prices are no more useful for patients without insurance, as these patients are often eligible for hospital charity care policies or other significant discounts. No single list at an institution can capture this information.

Essential hospitals strive to ensure their patients receive the most timely and accurate information regarding the cost of their care, including through their charity care programs. Essential hospitals, all of which are public or nonprofit institutions, already share information with their parents on the cost of care. Public hospitals that are fully or partially governed by state or local governments, are, by definition, more transparent than most other hospitals. Public hospitals often are subject to more stringent

⁶ 84 Fed. Reg. 7424, 7513 (March 4, 2019).

requirements under state and/or local laws intended to increase accountability to the public. For example, public hospitals often must periodically report to local government entities and government audits; conform to open meeting and open records laws; take part in competitive bidding before entering contracts; and follow stringent procurement requirements to ensure appropriate spending of public dollars.

In addition, other essential hospitals (including some public hospitals) are nonprofit organizations under section 501(c)(3) of the Internal Revenue Code. In 2009, Congress and the Internal Revenue Service implemented reforms on nonprofit hospitals to ensure greater transparency in their activities. These transparency requirements include the creation of the IRS Form 990, Schedule H, which requires nonprofit hospitals disclose financial assistance and means-tested government program information and other benefits to their communities. Section 501(r) also requires nonprofit hospitals to publicize their financial assistance policies and limit the amount they charge patients who are eligible for financial assistance. Nonprofit hospitals face the very real threat of losing their tax-exempt status if they do not comply with these requirements.

In addition to federal regulations, hospitals face transparency requirements from their state and local governments. In some states, data on hospital prices for common procedures are posted online to allow consumers to compare potential charges at hospitals in their area. Given these existing requirements on price transparency, ONC should not include this requirement in the information blocking provision.

5. In implementing its exceptions to information blocking, ONC should consider technological barriers that inhibit the segmentation of confidential patient data from the rest of a patient's medical record.

The first of the seven informational blocking exceptions, preventing harm, would exempt practices that are reasonable and necessary to prevent harm to a patient or another individual. One example that ONC provides of potential patient harm is the risk of sharing EHI that is corrupted or inaccurately entered into the EHR. ONC notes, however, that sharing EHI that is incomplete due to federal and state laws that prohibit sharing certain information in the medical record does not qualify as preventing harm. In other words, a provider who possesses EHI that contains certain confidential data protected by state or federal confidentiality laws is not precluded from sharing the rest of the patient's medical record with another provider. For example, in the case of information protected by Part 2, ONC suggests a provider who has not received the appropriate consents from the patient to share the Part 2-protected data can share the rest of the medical record with the provider requesting the data. In practice, this is not feasible, because EHR systems do not readily allow for this type of data segmentation (in which a provider can isolate the Part 2 protected information from other information in the medical record). **ONC should work with developers to ensure they build the requisite functionalities that would allow for such data segmentation before expecting providers to carve out this data.** Absent the capability in providers' IT systems, this would require extensive manual effort on the part of the provider's staff.

America's Essential Hospitals appreciates the opportunity to submit these comments. If you have questions, please contact Senior Director of Policy Erin O'Malley at 202-585-0127 or eomalley@essentialhospitals.org.

Sincerely,

Bruce Siegel, MD, MPH
President and CEO