COLLEGE of AMERICAN PATHOLOGISTS

June 3, 2019

Donald Rucker, MD
National Coordinator
Office of the National Coordinator for Health Information Technology
200 Independence Avenue, SW
Washington, DC 20201

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

Submitted via Electronic Submission to www.regulations.gov

Dear Dr. Rucker:

The College of American Pathologists (CAP) appreciates the opportunity to comment on the Office of the National Coordinator for Health Information Technology's (ONC) proposed rule to implement certain provisions of the 21st Century Cures Act (the Cures Act), including the information blocking provisions. As the world's largest organization of board-certified pathologists and leading provider of laboratory accreditation and proficiency testing programs, the CAP serves patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide. Pathologists are physicians whose timely and accurate diagnoses drive care decisions made by patients, primary care physicians, and surgeons. When other physicians need more information about a patient's disease, they often turn to pathologists who provide specific diagnoses for each patient. The pathologist's diagnosis and value is recognized throughout the care continuum and many patient encounters.

Certified Health Information Technology and Laboratory Information Systems

This proposed rule refers to the term "certified health IT" which includes the full range of potential technologies, functions, and systems for which the Department of Health and Human Services (HHS) has adopted standards, implementation specifications, and certification criteria under the ONC Health IT Certification Program. However, the vast majority of Laboratory Information Systems (LISs), in which pathologists practice, are not Certified Electronic Health Record Technology (CEHRT).

Pathologists and their laboratories have long relied on LISs to support the work of analyzing patient specimens and generating test results, and it is via an LIS that EHR or enterprise-wide clinical information systems exchange laboratory and pathology data. Since LISs do not currently have a pathway to be considered certified under the ONC's Health IT Certification Program, LISs not being CEHRT presents a barrier in the interoperable exchange of data. **The CAP believes that the ready exchange of laboratory data between different practice settings is crucial for the improvement**

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of quality of care and patient safety as well as the reduction of costs. As such, the CAP hopes that the ONC proposals will incentivize the interoperable exchange of laboratory data.

The proposed rule also proposes to establish seven Conditions and Maintenance of Certification requirements for HIT developers and their certified HIT modules as required by the Cures Act. Any noncompliance would be subject to ONC review, corrective action, and enforcement procedures under the ONC HIT Certification Program. Some of these proposed Conditions of Certification include that HIT developers not take any action that constitutes information blocking and ensure that health care providers can access, exchange, and use Electronic Health Information (EHI) for quality improvement and population health management activities. ONC also proposes Conditions of Certification related to health IT developers not prohibiting or restricting communications on the usability, interoperability, security, and user experience of their products, as well as information about the business practices of developers of health IT related to exchanging EHI. **The CAP supports ONC's proposed Conditions of Certification and believes that this would be a step in the right direction toward promoting transparency and improving usability of laboratory EHI and the interoperability of health IT regardless of it being certified health IT.**

Updates to the ONC 2015 Certification Edition Criteria

ONC is proposing to remove and modify certain existing criteria as well as to add new criteria to the 2015 Edition Certification. This includes adoption of the US Core Data for Interoperability (USCDI) which will include a new required data class of clinical notes to include laboratory and pathology report narrative. ONC is also proposing to modify, remove, and/or add to the 2015 base EHR definition. Some of the removals include:

Problem List § 170.315(a)(6)
Medication List § 170.315(a)(7)
Medication Allergy List § 170.315(a)(8)
Smoking Status § 170.315(a)(11)

The CAP met with ONC in October 2018 to explore whether/how LIS might become CEHRT so that pathologists are not disadvantaged in federal payment programs such as the Quality Payment Program (QPP) that require use of CEHRT. In addition, this proposed rule underscores the need for certification so that LIS vendors are held to the same standards of not engaging in Information Blocking activities and meeting Conditions of Certification as other certified EHR vendors. At the meeting, ONC indicated that it likely has some statutory leeway in changing the base definition of a qualified EHR. The CAP determined (and has indicated in a follow-up letter to ONC) that LISs would not meet all the ONC criteria, but further analysis is needed to determine which criteria LISs could meet.

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However, with the proposed changes to the ONC's existing five 2015 Edition Base EHR certification criteria, the CAP seeks clarification on how the proposed modifications impact our ongoing work with ONC. The CAP continues to believe that additional flexibility is needed to not penalize pathologists because they are not practicing in CEHRT but instead in LISs. **The CAP hopes to continue its conversations with ONC and CMS for broader interpretation of the agencies' EHR criteria so that LISs can be deemed CEHRT under that criteria. This would go a long way in supporting pathologists' efforts in promoting the electronic exchange of health information across LIS and EHRs and would enable pathologists to not be further penalized in federal quality reporting programs because of their lack of CEHRT.**

Health IT for Multiple Medical Specialties and Practice Settings

In response to the requirements set forth in section 4001 of the Cures Act, ONC has developed recommendations for the voluntary certification of health IT for pediatric care that does NOT include a separate certification program for pediatric care and practice settings. ONC has also identified current and proposed new 2015 Edition certification criteria that support pediatric care and practice settings. The CAP hopes that ONC can use this as a model to focus on non-regulatory initiatives that are nimble and responsive to stakeholders, including development of informational resources to support setting-specific implementation that aligns with the ONC Health IT Certification Program.

ONC also proposes an approach for identifying HIT Certification Criteria and Standards to support multiple care and practice settings. **The CAP asks whether ONC could use this proposal as a model for voluntary certification of LISs for pathologists.** The CAP urges ONC to **a**nalyze certification criteria and to focus on real-time evaluation of standards in the ONC HIT Certification Program to determine and ensure broad applicability to multiple medical specialties including pathologists. The CAP believes that there is a need for implementation of voluntary certification of LISs in order to support pathologists' efforts in promoting the electronic exchange of health information across LIS and EHRs to enable pathologists to not be further penalized in federal quality reporting programs because of their lack of CEHRT**. The CAP hopes that these proposals further facilitate our ongoing collaboration with ONC to advance the effective implementation of certified LISs.**

Interoperability and Registries Request for Information

Section 4005(a) of the Cures Act requires that EHRs be capable of transmitting data to and, where applicable, receiving and accepting data from clinician-led clinical data registries, in accordance with standards recognized by ONC. The CAP appreciates ONC's attention to exploring multiple approaches to advancing the ability of EHRs to exchange data with registries. Access to patient information from EHRs/LISs is crucial for registries to achieve their mission of improving quality of care through the collection, analysis, and benchmarking of data on health care diagnoses, treatments, and outcomes. The free flow of data between registries and EHR and LIS vendors is also

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critical to reducing administrative burden for clinicians and to ensuring the success of payment for performance under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA).

It is essential that ONC address both the ability of EHR and LIS vendors to exchange EHI, as well as the usability of the exchanged information. For example, it is imperative that the data shared with QCDRs be sufficient for quality measurement and include the data elements needed to calculate specialty-specific quality measures relevant to the physicians using the EHR or LIS and participating in a registry. Lack of interoperability between EHRs/LISs and registries impedes the collection and analysis of data needed to accurately assess and appropriately improve quality of care. A regulatory framework that focuses on improving the exchange of EHI with registries and the usability of such data will assist efficient exchange of information, reduce administrative burdens for both registries and their clinician participants, and allow clinicians to more effectively make use of registries for reporting under MIPS.

In the Proposed Rule, ONC specifically seeks information about how ONC's proposed new standards and capabilities for certified application programming interfaces (APIs) to aid bidirectional exchange of data with registries, as well as use cases where an API using FHIR Release 4 might support improved exchange between a provider and a registry. **The goal of semantic interoperability through APIs, however, will only go so far without natural language processing or human curation of clinical notes, both of which are resource intensive and often unsuccessful. We urge ONC and CMS to show more caution in the selection and development of data standards.** The selection of data standards ideally should be based on published, peer-reviewed studies and/or implementation metrics and success stories supported by verifiable and relevant quantitative data on advantages, disadvantages, costs and burdens for implementation and maintenance.

While FHIR comprises several data transmission standards (i.e., API plus data payload definitions), it is not a data-capture standard. FHIR focuses on exchange of clinical data from clinical text records. Often discretized, standardized data captured in the laboratory is restated in non-structured fashion within the managing physician's successive narratives. For complex data such as cancer reporting, this could result in interoperability issues. Without constraining the way that information enters and leaves EHRs will lead to a never-ending maintenance burden because unmanaged data capture approaches will inevitably diverge. This very problem is perpetuated by the FHIR observations model and older HL7 approaches including C-CDA. **For many types of complex medical data, especially data generated by pathology laboratories, we believe that CMS and ONC should work with professional medical organizations like the CAP to develop best practices for data capture, particularly the capture of standardized and structured data.** We have not been successful in our attempts to have these needs recognized when working through HL7 and FHIR, but we have had success working with IHE.

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While FHIR may be an appropriate first step for some stable consensus-based clinical data structures (e.g., lists of problems, medications, immunizations, etc.), it is likely unsuitable where consensus has not been reached or where the medical content is complex and/or rapidly changing, such as molecular diagnostic results, surgical pathology reports, imaging reports, etc. The problem is particularly severe for pathology and oncology where several professional groups have been working with FHIR for several years with very little progress to create usable expert-consensus resources. This area of FHIR's greatest weakness is precisely the area where the CAP and others have had the most success with IHE Structured Data Capture (SDC). Specifically, assuming a one-size-fits-all approach and that FHIR is a suitable long-term solution for pathology data could be a serious and costly error that will be difficult to correct. At the same time, IHE SDC is ready to tackle many of the more complicated problems of standardized and structured data elements and their transmission, and therefore SDC should also receive emphasis from CMS and ONC, in particular as it applies to the larger, more granular data required to maintain a patient's timeline of diagnosis and treatment and required achieve the promise of interoperability and precision medicine.

Information Blocking

In addition to enhancing the ability of clinical data registries to access patient information from EHR and LIS vendors, it is just as critical that ONC develop policies for policing information blocking by EHR and LIS vendors that otherwise have the capability to share their data with clinical data registries. The CAP supports ONC's proposed definition of information blocking, as this definition is consistent with Section 4004 of the Cures Act. **The CAP encourages ONC to publish additional examples of practices that may constitute information blocking through sub-regulatory guidance.**

The CAP supports the Physician Clinical Registry Coalition (PCRC) in its significant concerns about ONC's proposed definitions of health information networks ("HINs") and health information exchanges ("HIEs"). Specifically, the concern is that the breadth of ONC's proposed definitions of HINs and HIEs is inconsistent with the meaning and intent of the information blocking provisions adopted by Congress. The Cures Act creates "clinician-led clinical data registry" as a defined term. Yet this term is conspicuously not included in the actors that Congress explicitly listed as covered by the information blocking provisions. **If Congress wished to apply the information blocking provisions to clinical data registries, it would have done so. Instead, Congress applied the information blocking provisions to health IT developers, HINs, HIEs, and health care providers. Any definition of HIN or HIE adopted by ONC must reflect Congress's intent by not including clinical data registries.**

As ONC recognizes in the Proposed Rule and as the CAP has experienced, EHR and LIS vendors continue to create barriers to access patient information and thus impeding the integration of EHR and LIS data into clinical data registries. These barriers further interfere with and materially discourage physician and patient access to information. **The CAP's experience through its Pathologists Quality Registry has been that some**

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EHR and LIS vendors make it difficult for the transfer of patient information to clinical data registries. While some EHR and LIS vendors have negotiated with physicians and third-party software companies, other EHR vendors tack on large fees to send data from the EHR to clinical data registries or to even connect to a HIE. While certified EHR vendors are required to acknowledge the existence of fees, they are not required to publish the actual dollar amount, or even list a range of costs. Other barriers to the exchange of information from EHR and LIS vendors include limited access to data, and a lack of common technical profiles and standards across health IT systems. **These barriers interfere with and materially discourage access to information, as well as violate the letter and the spirit of the provisions of the Cures Act that prohibit information blocking.** Imposing these impediments to the exchange of data are particularly inappropriate given that EHR and LIS vendors are just holding the data for the health care providers who seek to submit the same data to clinical data registries. The EHR and LIS vendors have no inherent right to withhold that data from such registries.

In addition, pathologists participating in MIPS need to report performance on quality measures. As CMS eliminates claims-based measures, pathologists become disadvantaged in the program because it is difficult or impossible to access data from hospitals' electronic health records and LIS. Pathologists need hospital-owned data to support their ongoing participation in MIPS. As pathologists working in and supporting hospitals, we should have access to all the patient's data from the hospital's EHR and LIS. However, in many cases, this does not occur or is made extremely difficult. For example, a large number of pathologists that use the CAP's clinical data registry, the Pathologists Quality Registry, to report quality measures do not receive any data from their hospitals.

Data from hospitals could include critical information such as laboratory tests and utilization, turnaround times, blood product utilization, cancer diagnostic workups, etc. Without these data elements, the measures cannot be fully calculated and scored. Hospitals claim that they cannot share the data for privacy and security purposes, but CMS has indicated that there are no regulations that impede hospitals from doing so. In addition, each hospital has its own legal framework for potentially accessing data, so this becomes a significant resource issue for pathologists, registries, and the hospitals themselves (since presumably several specialties approach the hospitals for data). The lack of data availability from hospitals is a significant resource problem for the system as a whole (nobody wins), and a particular problem for pathologists.

Since this is a serious issue for hospital-based clinicians, we encourage both ONC and CMS to come up with potential solutions to help improve the flow of information between hospital EHRs, LISs, and registries.

While the CAP appreciates that ONC has defined information blocking, it is essential that ONC's proposed exceptions to the information blocking prohibition be narrowly tailored to the purpose that ONC seeks to achieve and not

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inappropriately interfere with Congress's goals in including the information blocking provision in the Cures Act. The CAP cautions ONC against creating broad exceptions that undermine the rules against information blocking and absolve health IT vendors from being subject to civil penalties and other disincentives under the law. In addition, for each of these exceptions, the CAP encourages ONC to publish additional examples of practices that may fall within each exception through sub-regulatory guidance. The CAP supports the PCRC in its comments regarding concerns that if the exceptions to information blocking are not defined properly, health IT vendors may attempt to use proposed exceptions as loop holes to continue to engage in information blocking as detailed below.

i. Proposed Exception: Preventing Harm (§ 171.201)

The CAP supports ONC's exception to the information blocking prohibition for practices necessary to prevent harm to patients. The CAP further supports ONC's definition of "harm" to include corrupt or inaccurate data being recorded or incorporated into a patient's electronic health record, as well as the misidentification of a patient's EHI. It is essential to the work of registries that the information included in a patient's electronic health record be accurate.

ii. Proposed Exception: Promoting Privacy of EHI (§ 171.202)

The CAP supports ONC's efforts to promote the privacy of EHI. The CAP is concerned, however, that EHR and LIS vendors may inappropriately deny access to their health care provider outcomes data based on the false premise that such transfer of data somehow violates the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Accordingly, the CAP urges ONC to advise EHR and LIS vendors that HIPAA compliance is not a justification for withholding data from clinical data registries and other similar parties if such registries are in compliance with all applicable HIPAA Rules. The CAP further requests that ONC urge parties to work together in good faith to address any privacy concerns.

iii. Proposed Exception: Promoting Security of EHI (§ 171.203)

As with the proposed exception to promote the privacy of EHI, the CAP supports ONC's efforts to promote the security of EHI, but is concerned that EHR and LIS vendors may inappropriately deny access to their health care provider outcomes data based on the false premise that such transfer of data somehow violates HIPAA. As above, the CAP urges ONC to advise EHR and LIS vendors that HIPAA compliance is not a justification for withholding data from clinical data registries and other similar parties if such registries are in compliance with all applicable HIPAA Rules. The CAP further requests that ONC urge parties to work together in good faith to address any security concerns.

iv. Proposed Exception: Recovering Costs Reasonable Incurred (§ 171.204)

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As stated earlier, unreasonably high fees charged by EHR and LIS vendors are one of the principle impediments to the exchange of information between registries and EHRs/LISs. The CAP supports ONC's proposal to limit an actor's ability to charge fees to the recovery of costs reasonably incurred to provide access, exchange, or use of EHI, based on objective and verifiable criteria that are uniformly applied for all substantially similar or similarly situated classes of persons and requests. The CAP further supports ONC's efforts to prohibit the charging of fees based in any part on whether the requestor or other person is a competitor, potential competitor, or will be using the EHI in a way that facilitates competition with the actor.

The CAP is concerned, however, that EHR and LIS vendors may attempt to use this proposed exception as a loop hole to continue to charge unreasonably high fees. Unreasonably high fees are one of the biggest problem areas when working with EHR and LIS vendors. The CAP also notes that there is currently significant variation among the fees charged by EHR and LIS vendors. The CAP urges ONC to require actors to disclose the methodology behind their fees.

v. Proposed Exception: Declining to Provide Access, Exchange, or Use of EHI in a Manner that is Infeasible (§ 171.205)

The CAP cautions ONC that EHR and LIS vendors may attempt to use this proposed exception to inappropriately deny access to EHI for registries. As a result, the CAP urges ONC to strongly enforce the requirement that an actor timely respond to all requests relating to access, exchange, or use of EHI and, in the event that the actor determines that providing EHI in a particular manner is not feasible, provide the requestor with a detailed written explanation of the reasons why the actor cannot accommodate the request. The CAP further strongly encourages ONC to enforce its proposed requirement that the actor work with the requestor in a timely manner to identify and provide a reasonable alternative means of accessing, exchanging, or using the EHI.

vi. Proposed Exceptions: Licensing Interoperability Elements (§ 171.206)

The CAP supports ONC's proposal to require actors to negotiate with requestors in a reasonable and non-discriminatory fashion to identify any interoperability elements that are needed and offer an appropriate license with reasonable and non-discriminatory terms. The CAP cautions, however, that the ability to charge reasonable royalties to license interoperability elements may present an opening for EHR and LIS vendors to charge unreasonably high fees for exchanging information with registries. As a result, the CAP urges ONC to require actors to disclose the methodology behind their fees.

vii. Proposed Exceptions: Maintaining and Improving Health IT Performance (§ 171.207)

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The Coalition supports an actor's ability to make health IT under its control temporarily unavailable in order to perform maintenance or improvements to the health IT, provided that the practice is for a period of time no longer than necessary and implemented in a consistent and non-discriminatory manner. The CAP urges ONC to require that, if feasible, actors provide advance notice that health IT will be temporarily unavailable in order to perform maintenance or improvements.

Price Transparency Request for Information

This proposed rule emphasizes that the "fragmented and complex nature of pricing within the health care system has decreased the efficiency of the health care system and has had negative impacts on patients, health care providers, [and] other key health care stakeholders." Indeed, many provider groups have acknowledged that a lack of information about the cost of health care services can be an impediment to transparency and patient empowerment. To that point, the CAP agrees with the AMA that when scheduling services for patients, providers should be transparent about their own anticipated charges, and insurers should be transparent about the amount of those charges they will cover.[1] However, the CAP expresses serious concern about requiring pathologists to inform patients about out-of-pocket costs for a service before patients are furnished that service, as there is significant risk for patient harm from any delays. Pathologists understand how access to facility cost information prior to services may be useful for some patients and provider care, but the CAP opposes adding additional administrative requirements on physicians that interfere with or impair the patient's medical diagnosis and care.

Further, there is significant difficulty in determining the cost of pathology services in advance of services conducted by the pathologist. For instance, a surgical or invasive diagnostic procedure performed by a dermatologist, surgeon, gastroenterologist, urologist, or other clinician may result in no specimens obtained or it may result in multiple specimens requiring anatomic evaluation. Additionally, anatomic pathology services typically involve a pathologist performing microscopic analysis of tissue or body fluids to determine whether cancer or other disease is present and, if so, its characteristics. The type of specimen or complexity of the analysis is often not known in advance of the initial microscopic analysis conducted by the pathologist, making it impossible to provide a reliable estimate of charges or costs.

Relatedly, while recent efforts to increase access to charge information are well-intentioned, pricing data posted online by hospitals is often incomprehensible and unusable by patients. Even where a patient can determine the appropriate item from the chargemaster, which must now be posted online by the hospital, that charge differs from the cost to the patient and likely does not accurately represent patient out-of-pocket costs. As this proposed rule notes, there is a variety of pricing information that could be

[1]https://www.acponline.org/acp_policy/letters/joint_letter_to_ways_and_means_committee_on_surprise_billing_2019.pdf

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made available, including "negotiated prices, pricing based on CPT codes or DRGs, bundled prices, and price to payer," in addition to out-of-pockets costs that may include "deductibles, copayments and coinsurance." Out-of-pocket costs to the patient are most relevant and meaningful of these options, but it should be noted that the only accurate information on these patient-specific calculations is held by the enrollee's health plan. Further, any efforts to increase the availability of price information for patients would have to be accompanied with significant education efforts to ensure patients understand the information provided, including the fact that that price alone does not determine the value of care or services. Moreover, the CAP stresses that Medicare is not an appropriate reference price as a comparison tool for use by patients. Medicare's payment methodology artificially adjusts payments to accommodate budget neutrality and does not always reflect the market rates for physician services. This would only serve to further confuse patients who do not understand this fundamental difference and who may falsely assume that Medicare payments represent the costs to patients in the commercial marketplace.

Surprise billing is an important issue that cannot be addressed through price transparency alone. The CAP's goal is to keep patients out of the middle of any billing disputes, ensure network adequacy and fewer out-of-network services, and if an out-of-network physician provides services to patients, that the physician receives a fair market payment for the service provided. The best way to achieve this is through congressional action that would protect patients from surprise bills and employ alternative dispute resolution together with fair reimbursement rates and network adequacy standards. Importantly, bundled billing or contracting regulation is not an appropriate solution. This approach requires an ever-increasing complex array of stakeholders, including physicians, lawyers, administrative staff, and others to define the services and duration of the bundle. The bundle then needs to be appropriately priced, maintained for technological and medical advances, and ensured that any financial relationships adhere to state and federal laws. Further, in addition to uncertainty and variation issues,[2] requiring physicians to contract with hospitals/facilities for payment for their services leaves physicians with little protection against abusive or exploitive business behavior by payers and hospitals that threatens the independent practice of medicine. The CAP applauds the administration's focus on the issue of surprise billing but would urge caution and stakeholder involvement in the development of any solutions.

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Thank you for the opportunity to submit these comments. The CAP looks forward to working with ONC as it implements the Cures Act. Please direct questions on these comments to Loveleen Singh at (202) 354-7133 or lsingh@cap.org.

[2] See https://www.aha.org/system/files/media/file/2019/04/040219-aha-fah-ama-to-reps-foxx-scott-on-surprise-billing-proposal.pdf

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