![College of American Pathologists logo]

January 28, 2019

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

Subject: Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs, Draft for Public Comment

Submitted via Electronic Submission to www.healthIT.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) Draft Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs. 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.

The 21st Century Cures Act requires the Secretary to address specific sources of clinician burden that will require coordinated action on the part of a variety of stakeholders across the health care system, including clinical societies and electronic health record (EHR) developers. The CAP is particularly interested in burden reduction associated with the alignment and simplification of quality measures across federal quality initiatives, including EHR reporting for the Merit-Based Incentive Payment System (MIPS) and Alternative Payment Models (APMs) as established under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). In addition, the CAP encourages ONC to acknowledge the value of clinical data registries, particularly the important role that Qualified Clinical Data Registries (QCDRs) play in enhancing quality improvement activities and reducing administrative burden for clinicians.

Certified Health Information Technology and EHR Reporting

This draft strategy 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 significant barrier to pathologists' full participation in the Center for Medicare & Medicaid Services' (CMS) Quality Payment Program (QPP) that comprises MIPS and APMs as well as other federal quality reporting programs. While the CAP appreciates the ongoing work of CMS and ONC toward interoperability of health IT systems, we 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.

Burden Reduction in the Quality Payment Program Related to Health IT and EHRs

The CAP urges CMS to continue burden reduction related to EHR reporting via alignment of Promoting Interoperability (PI) programs across healthcare settings, including the PI program for hospitals and the QPP. Pathologists can currently participate in only two of the four categories of MIPS. This means that 85% of the MIPS final score for pathologists is based on quality measures which places a disproportionate amount of weight on that category. While we appreciate the recognition of the non-applicability of the PI category to pathologists by CMS, the CAP is continuing to explore alternatives for pathologists to engage and more fully participate in the QPP. As the CAP responded in its comment letters to the CMS Request for Information included in the 2019 Inpatient Prospective Payment System (IPPS) and the Outpatient Prospective Payment System (OPPS) proposed rules, **one possible burden reduction mechanism for EHR reporting would be to allow hospital-based eligible clinicians such as pathologists to earn points in the PI category of MIPS through their hospital's participation in the PI program, for example, if more than 50% of the Medicare Part B payments for that clinician are generated at a particular facility.** This would be similar to eligible clinicians' use of facility-based measurement in MIPS beginning in CY 2019. This would support hospital-based MIPS eligible pathologists' efforts in promoting the electronic exchange of health information across LIS and hospital EHRs, while ensuring their participation in the PI category is not administratively burdensome.

In addition, the CAP strongly encourages CMS to consider leveraging QCDR reporting of measures for more than the Quality category of MIPS. Awarding credit across multiple MIPS performance categories would reduce administrative burden to allow physicians to spend less time on reporting and more time with patients and on improving care. **To this end, the CAP believes that CMS should allow clinicians who submit quality measures through a QCDR using end-to-end reporting, either via CEHRT or via another health IT system such as an LIS, to earn full credit in the Improvement Activities and Promoting Interoperability categories of MIPS.** Not only would this encourage the use of QCDRs as intended by CMS, it would also leverage health information technology in a more meaningful way while reducing clinician burden.

The Importance of Qualified Clinical Data Registries

Clinical data registries play an essential role in promoting quality of care. The CAP is concerned that ONC's draft strategy claims that most registries are public health registries supported by the Centers for Disease Control (CDC) and other federal and state entities, while omitting any discussion of the important work done by QCDRs supported by nonprofit medical societies and other nonprofit entities. QCDRs provide timely and actionable feedback to providers on their performance, speeding and enhancing quality improvement opportunities. In addition, QCDRs allow for patient-centered, statistically valid, and timely inter-practice and national benchmarking and comparisons. The measures developed by QCDRs are meaningful and relevant to participating providers and their patient populations.

The CAP appreciates the Department of Health and Human Services' previous efforts, through CMS, to encourage the use of QCDRs for electronically reporting data across quality improvement activities. **To that end, the free flow of data between QCDRs and EHR/LIS vendors is critical to reduce administrative burden for clinicians and to ensure the success of payment for performance under MACRA.** The ability of QCDRs to access patient information from EHRs and LISs is crucial for such registries to achieve their mission of improving quality of care and to provide useful analysis to the federal government for quality improvement activities and other purposes. When EHR and LIS vendors erect barriers to sharing information with QCDRs, physicians cannot efficiently report data for the purposes of MIPS.

Interoperability between EHRs and Qualified Clinical Data Registries

The CAP experiences that EHR and LIS vendors continue to create barriers to access patient information. These barriers interfere with and materially discourage physician and patient access to information. The CAP's experience through its Pathologists Quality Registry has been that some 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 health information exchange (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. 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.

Essentially, "fitting a round peg into a slightly round hole" allows vendors to assert they are conforming to a standard while still stretching the standard's flexibility to fit their own business needs—effectively curbing data access, use, and exchange. The CAP is concerned that, without the appropriate transparency, testing, and assurances, EHR vendors will extend current interoperability issues into their next generation products. Clinicians have little influence or capability to fix these interoperability issues and should not be held liable for issues outside their control.

The lack of interoperability between EHRs and QCDRs is a serious impediment to data collection and creates significant administrative burdens for both registries and their clinician participants. As ONC recognizes in its draft strategy, hindrances to interoperability increase administrative burden and expenses for clinicians and divert precious clinical and financial resources from patient care. This lack of interoperability also reduces the value of the information that QCDRs can provide to their clinician participants. It is essential that ONC's strategy address both the ability of EHR and LIS vendors to exchange electronic health information, as well as 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. **In conjunction with ONC's forthcoming rules to implement the information blocking requirements in the Cures Act, a strategy that focuses on improving how EHRs and LISs exchange electronic health information with QCDRs, and the usability of such data will assist efficient exchange of health information and allow providers and clinicians to most effectively make use of QCDRs for reporting under the MIPS Program, as well as the promotion of research, public health, and quality improvement activities by QCDRs generally.**

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Thank you for the opportunity to submit these comments. The CAP looks forward to working with ONC to identify a path for Laboratory Information Systems to be more fully considered in the implementation of the Cures Act. Please direct questions on these comments to Loveleen Singh at (202) 354-7133 or lsingh@cap.org.