



COLLEGE of AMERICAN PATHOLOGISTS

January 2, 2024

The Honorable Micky Tripathi, PhD, MPP
National Coordinator
Office of the National Coordinator for Health Information Technology (ONC)
U.S. Department of Health and Human Services
330 C St SW
Floor 7
Washington, DC 20201

The Honorable Chiquita Brooks-LaSure, MPP
Administrator
Centers for Medicare & Medicaid Services (CMS)
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Subject: RIN 0955-AA05 – 21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking

Submitted via Electronic Submission to www.regulations.gov

Dear National Coordinator Tripathi and Administrator Brooks-LaSure:

The College of American Pathologists (CAP) appreciates the opportunity to comment on the Office of the National Coordinator for Health Information Technology's (ONC) and the Centers for Medicare & Medicaid Service's (CMS) 21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking Proposed Rule. 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 are recognized throughout the care continuum and many patient encounters.

The CAP supports empowering patients by facilitating patients' access to their health information, including laboratory and pathology reports. Providing patients with direct and immediate access to laboratory and pathology reports has advantages. Nevertheless, there are very real barriers, challenges and potential safety issues that



exist with the current rule. The CAP will detail those issues and focus our comments on the following provisions included in the proposed rule:

1. Request for Information (Section IV)
2. General Provisions for Applications of Disincentives (Section III.B.2)
3. Medicare Promoting Interoperability Program for Eligible Hospitals and Critical Access Hospitals (CAHs) (Section III.C.2)

1. Request for Information (Section IV)

In this section, the CAP would like to iterate that it supports empowering patients by facilitating access to their health information, including laboratory and pathology reports. However, providing patients with direct and immediate access to laboratory and pathology reports has very real barriers, challenges, and potential safety issues. This proposed rule does not do enough to mitigate ONC's information blocking regulations in this regard.

The CAP requests that the ONC reduce potential patient harm and improve care coordination by allowing for greater flexibility and more expansive use of the legal exceptions to the information blocking regulations. Some CAP members have expressed concerns about psychological harm caused by the immediate release of distressing reports. Pathologists are most concerned about the myriad of situations in which automatic release of final reports to a patient portal can have disastrous psychological and practical consequences, and case-by-case implementation of an exception is impractical or unworkable. Specifically, patients may already have accessed results before a physician realizes that the result may be harmful to the patient and/or the patient's family, particularly when the diagnosis or result produced by a pathologist, or the laboratory was not anticipated.

The immediate release of pathology reports through the electronic health record available to the public notably runs the risk of harm because pathology reports are designed to communicate to clinical providers, not patients.¹ This is enough of an issue that the CAP has been working on how a patient-centered pathology report would be structured, with two consecutive grants from the Council of Medical Specialty Societies

¹ <https://www.captodayonline.com/results-release-new-steps-under-new-rules/?print=pdf> ("Once the Cures Act results reporting requirements went into place at the University of Washington, "there were definitely a couple of specific cases where providers contacted the lab—upset, or surprised at least—that their patient had received results ahead of their ability to discuss them with the patient," says Noah Hoffman, MD, PhD, director of the Informatics Division and co-director of the next-generation sequencing and analytics laboratory, UW Department of Pathology and Laboratory Medicine. ... The text of laboratory reports in anatomic pathology presents two distinct dimensions of problem. "Obviously, you're going to use different language to describe results to providers and patients," Dr. Hoffman says. When providers look at some results, they might say, "This is a completely uninterpretable wall of text. What's the patient possibly going to do with this?").



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to support this work.

In addition to more expansive exceptions in the information blocking rule, particularly applicable to pathologists and clinical laboratories, the CAP urges ONC to consider allowing a delay for the release of test results available to the public through the electronic health record for involved clinicians to create an integrated response before patient communication for the best care coordination.

It is burdensome to expect physicians to anticipate, on a patient-by-patient basis, each result that could possibly result in harm to a patient if it is released immediately to a patient. Indeed, the regulations create an unnecessary burden on pathologists and patient care physicians by requiring them to anticipate and attempt to mitigate (by multiple methods) harms that are enabled purely by the regulations. Put differently, it is not practical to identify cases for exceptions in real time, and there are a limited number of problematic case types that can be predicted and set up ahead of time appropriately if there is adequate flexibility. It is also worth noting that the regulations do not provide detailed mitigation strategies, so these responses will probably vary by locale in confusing ways.

The CAP urges the ONC to allow for blanket exceptions to the information blocking rule so that the Electronic Health Record (EHR) administrators can delay patient test result release consistent with the needs of clinicians to protect patients from the emotional distress attendant to dire diagnostic findings. Some patient portals or similar apps may be incapable of suppressing blocked reports when selected for the harm exception. There are complex situations that patient portals cannot handle: most patient portals are limited in their ability to display or hide or restrict result views for a particular patient based on certain patient or situational criteria. For example, some states may require that all sexually transmitted infection results and pregnancy tests can only be shown to the adolescent between the ages of 13 and 18. Some patient portals do not have the flexibility to hide some results from those who have proxy access while showing them to the patient. Some portals also cannot toggle displaying vs. not displaying results in a portal based on the patient's age or presence of proxy access into the account. For example, a sexually transmitted infection result, if hidden from patients 0-17 years of age, would also be hidden from that same patient when they become an adult with no proxy access. Some LIS/EHR systems do not adequately handle the concept of preliminary reports. This could cause premature release of non-validated results to a portal. Very few LISs or EHRs use sufficient coding for noting whether results are preliminary versus final. It is not clear that EHRs are set to exclude results with an HL7 result status of "preliminary" from a patient portal or other result distribution system. Patient portals might show preliminary results due to this issue, and as we all know, this could be very harmful to patients. In addition, patient portals have difficulty navigating conflicting state and federal reporting requirements, especially in the context of special rules for pediatric patients. The work required to make these changes in current installed



systems would be significant and, in some cases, technically infeasible.

The CAP would also like to reiterate that some patient portals or similar apps may be incapable of suppressing blocked reports in accordance with a patient's wishes. This presents problems for providers as they may be forced to violate their patient's wishes to comply with the Information Blocking rule as written. To improve the availability and accessibility of solutions supporting health care providers' and other information blocking actors' efforts to honor patients' expressed preferences regarding their EHI, the CAP would also like to reiterate that the ONC can help by allowing some blanket delays for specific kinds of tests.

2. General Provisions for Application of Disincentives (Section III.B.2)

In this section of the proposed rule, the ONC and CMS note that following the application of a disincentive, a health care provider may have the right to appeal administratively a disincentive if the authority used to establish the disincentive provides for such an appeal, and that any right to appeal administratively a disincentive, if available, would be provided through notice and comment rulemaking. This is because the Cures Act did not provide instruction regarding appeals of disincentives for health care providers.

The CAP urges the ONC and CMS to delay implementing disincentives on providers until there is a guaranteed appeals process for providers. There are difficulties and ambiguities with how providers may comply with the information blocking rule, and providers should consequently have a means to contest disincentives. For example, as we explained earlier in response to the proposed rule's request for information, it is difficult for physicians to anticipate, on a patient-by-patient basis, each result that could possibly result in harm to a patient if it is released immediately to a patient. As previously stated, such results that could result in harm include sexually transmitted infection results and pregnancy tests for adolescents. A provider accused of committing information blocking, may, in good faith, have believed that they were complying with the information blocking rule's preventing harm exception.² Consequently, providers should have a guaranteed means of appealing disincentives. Indeed, the proposed rule even notes that there are procedures for appeals available for developers of health IT and, health information networks, and health information exchanges accused of information blocking.

3. Medicare Promoting Interoperability Program for Eligible Hospitals and Critical Access Hospitals (CAHs) (Section III.C.2)

In this section of the proposed rule, the ONC and CMS note that if a hospital eligible to

² § 171.201.



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participate in the Medicare Promoting Interoperability program or a critical access hospital (CAH) are determined to have engaged in information blocking, that the eligible hospital or CAH would be determined to not be a meaningful EHR user in an applicable EHR reporting period. An eligible hospital would lose 75 percent of the annual market basket increase, while a CAH subject to the disincentive would have payments reduced to 100 percent of reasonable costs instead of the 101 percent of reasonable costs associated with successful participation.

With the way that this proposed rule is written, a provider—who has not committed information blocking—may be penalized for a different provider’s behavior if the latter provider has committed information blocking and if both providers work at an eligible hospital or a CAH. Similarly, a provider may be penalized if their employer—the eligible hospital or CAH—committed information blocking, even if the provider themselves did not commit information blocking. **The CAP opposes this section of the proposed rule as it is unfair that a provider may be penalized for another provider’s actions.** Such an arbitrary penalty structure does not disincentivize providers from committing information blocking and may punish providers for the actions of their employer.

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Thank you for the opportunity to submit these comments. The CAP looks forward to working with ONC and CMS and always stands willing to work with government agencies, industry, pathologists, and other stakeholders to support high quality laboratory operations and medical care. Please direct questions on these comments to Han Tran at htran@cap.org.