December 21, 2023

The Honorable Micky Tripathi
National Coordinator for Health Information Technology
Office of the National Coordinator for Health Information Technology
330 C St. SW, 7th Floor
Washington, DC 20024

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244

Dear National Coordinator Tripathi and Administrator Brooks-LaSure:

On behalf of the American College of Physicians (ACP), I am pleased to share our comments on the Department of Health and Human Services' *21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking* proposed rule. ACP is the largest medical specialty organization and the second largest physician membership society in the United States. ACP members include 161,000 internal medicine physicians, related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge, clinical expertise, and compassion to the preventive, diagnostic, and therapeutic care of adults across the spectrum from health to complex illness.

While ACP applauds ONC and CMS on their collaboration in the development of disincentives that apply to physicians and other clinicians who knowingly engage in practices that are likely to interfere with the access, exchange, or use of health information, the College has some concerns about the proposed regulatory approaches as laid out throughout the proposed rule. Generally, many of these concerns are rooted in the College's continued belief that the information blocking regulations and exceptions are particularly complicated and remain confusing to the physician community.

The College continues to have significant concerns regarding the complexity of the information blocking provisions and how that complexity will affect our members in their daily practice. Not only are the information blocking provisions, exceptions, and sub-exceptions complicated in and of themselves, they can overlap with requirements under the Health Insurance Portability and Accountability Act, making it difficult to understand what information a clinician is permitted versus required to share for any given individual patient. Furthermore, there are varying state

laws around health information privacy which are not preempted by these federal regulations, adding more complexity and burden to complying with these regulations.

The College reiterates our previous comments expressing concern about the lack of clarity on what physicians will be required to implement and document in order to effectively comply with the information blocking provisions. To address these concerns, ACP continues to request that the Office of Inspector General (OIG), in coordination with ONC and the Office for Civil Rights, develop clear guidance materials providing physicians with a baseline for what is required to comply with health data requests to ensure physicians are not inadvertently blocking information. These additional educational resources and guidance should also include examples of the types of documentation needed should physicians be subject to an information blocking claim or investigation. Furthermore, a detailed explanation of how the knowledge requirement for information blocking by health care providers would be evaluated should be included as well.

Regarding enforcement and the application of disincentives, the College previously advocated that instead of penalties, enforcement should focus more on providing clinicians with education if they are found to be information blocking—much like what CMS has done with their auditing process for billing. If physicians are found to be information blockers, they should be provided educational tools and resources to better understand the issue prior to any disincentives. We reiterate this position in response to the disincentives proposed in this rule.

We also reiterate our previous comments related to the timeline of enforcement and implementation of an educational period. The College is opposed to enforcement starting immediately, upon finalization of the proposals. We believe there should be at least a two-year delay in enforcement following the publication of the final disincentives rule to allow for educational efforts to ensure that physicians fully understand the scope of possible disincentives. We previously stated, and it remains the case, that it will take a significant amount of time and resources to develop and implement internal policies around the types of application programming interface queries the health system or physician practice will allow into their system.

An additional and important element of this compliance will be to make sure physician practices are able to appropriately document or record that they took the necessary steps to share electronic health information appropriately and are not accidentally blocking information, or included in an information blocking claim that is not within their control. This burden will disproportionately disadvantage independent physician practices as they are not likely to have the resources to employ information security or health information management departments to assist them in deciphering the regulations and overlaps with existing privacy and security regulations. For these reasons, ACP continues to recommend that ONC, CMS, and OIG allow for graduated enforcement that includes an initial education period for physicians. This educational period should focus on assessing the information blocking claims received to better understand real-world information blocking scenarios and implications for physician workflows. At a

minimum, the official enforcement date for physicians, after the educational or pilot period, should be no sooner than two years after the publication of the disincentives final rule.

Alternatively, the College believes that OIG should consider implementing a notice (or "warning") process with a proposed corrective action plan instead of (or prior to) the imposition of disincentives. For example, if a clinician is still found to be information blocking after a sufficient period (e.g., 6 months) following their receipt of notice and/or corrective action plan, then the College would support the possibility of imposing disincentives of the kind proposed in this rule.

Appropriate Disincentives for Health Care Providers

ONC and CMS propose that if an eligible hospital, critical access hospital (CAH), or a Merit-based Incentive Payment System (MIPS) eligible clinician is found by OIG to have committed information blocking, CMS would determine that they were not a meaningful EHR user for an applicable reporting or performance period under the Promoting Interoperability Program and the MIPS track of the Quality Payment Program (QPP).

Eligible hospitals subject to this disincentive would not be able to earn the three quarters of the annual market basket increase associated with qualifying as a meaningful EHR user, thereby reducing the inpatient prospective payment system payment that the eligible hospital could have otherwise earned had it met the other requirements of the Medicare Promoting Interoperability Program.

CAHs subject to this disincentive would have payments reduced from 101 percent of their reasonable costs to 100 percent of reasonable costs, thereby reducing the reimbursement a CAH could have received had it met the other requirements of the Medicare Promoting Interoperability Program.

MIPS-eligible clinicians subject to this disincentive would receive a score of "zero" in the Promoting Interoperability performance category (one of four MIPS performance categories) which is typically worth 25 percent of the entire MIPS score. Depending on the performance threshold, such a disincentive could make it impossible for the clinician to earn a positive adjustment, as would be the case with the current performance threshold of 75%. With this threshold, the maximum such a clinician could receive is a neutral payment adjustment if they earned perfect scores in the three other performance categories.

Under the Medicare Shared Savings Program (SSP), CMS proposes to screen ACOs, ACO participants, and ACO providers/suppliers for an OIG determination of information blocking and deny the addition of such a health care provider as an SSP participant for at least one year. The phrase 'health care provider' is defined in the proposed rule as including hospitals, nursing facilities, federally qualified health centers, group practices, pharmacists, laboratories, and rural health clinics, in addition to other types of practitioners and entities. ACO applicants would be denied participation in the SSP for the upcoming performance year and ACOs already

participating in the program could have their participation agreement terminated for the upcoming performance year.

The College opposes several aspects of the proposed approach to the application of disincentives. First, ACP opposes the application of disincentives under authorities that do not provide CMS with discretion to adjust or tailor the monetary impact of a disincentive to fit the gravity or severity of the information blocking conduct a health care provider has been determined to have committed. As ONC and CMS acknowledge, the actual monetary impact resulting from the application of the disincentives proposed may vary across health care providers. The College applauds ONC and CMS for considering the possibility of proposing an alternative approach under which the monetary impact of a disincentive could be tailored based on the severity of the conduct in which the health care provider engaged. However, we are disappointed that alternative approaches or authorities allowing for such flexibility and discretion were not identified. We encourage ONC and CMS to continue to examine and seek alternative authorities under which disincentives may be imposed that allow for discretion according to the severity of information blocking conduct.

Notably, ONC and CMS have proposed such a mechanism as an alternative policy for the Shared Savings Program. Under the alternative policy, the Shared Savings Program would consider OIG's referral of an information blocking determination "in light of the relevant facts and circumstances" before taking an enforcement action. According to ONC and CMS, under this alternative policy, relevant facts and circumstances could include: (1) the nature of the health care provider's information blocking, (2) the health care provider's diligence in identifying and correcting the problem, (3) the time since the information blocking occurred, (4) the time since the OIG's determination of information blocking, and (5) other factors. The College is supportive of this alternative policy and believes that these relevant facts and circumstances should similarly be considered in the application of disincentives for all health care providers. ACP believes other factors could include the size of the practice and number of eligible clinicians in the practice.

CMS explains 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." Therefore, there is no guaranteed right to an appeal a disincentive should a physician believe the disincentive was unjustly imposed or unwarranted under a specific set of facts and circumstances. The College strongly opposes the lack of an appeals process, particularly considering the continued widespread confusion and uncertainty among physicians regarding the information blocking regulations. The College believes that physicians should always have a right to appeal the imposition of such disincentives, regardless of whether the authority used to establish a disincentive provides for the right to appeal.

Additionally, ONC and CMS are proposing to include information about information blocking practices, actors who committed information blocking, and any settlements of liability, civil money penalties levied, and disincentives administered on ONC's website. The College strongly opposes and protests proposals to publish information about information blocking

determinations and enforcement. The College is particularly opposed to the publication of any information identifying physicians who have committed information blocking. The College believes such a practice would be unnecessarily punitive and would risk penalizing the wrong individuals for actions or inactions outside of their control, particularly given that physicians rarely have full, final control over their institutions' information sharing protocols and practices. Therefore, the College urges ONC and CMS not to finalize these proposals.

If ONC and CMS should choose to finalize these proposals, ACP reiterates our views, as shared in a May 2019 letter to CMS, that there should be proper mechanisms for physicians to review and contest publicly reported information. Physicians should be able to review before publishing, appeal, and request consideration of any publicly reported measure to ensure accurate information is being provided.

Finally, ACP is concerned that these proposals may have the unintended effect of impacting practice choices that could harm patient access to care, especially for vulnerable and underserved populations. Medicare payment rates have not kept pace with inflation, resulting in downward pressure on practice resources and making access to care for Medicare beneficiaries more tenuous. The proposed disincentives exacerbate the strain that physicians are under, especially those in independent practices and have limited administrative or information technology support. Additionally, CMS and the broader health care community, including ACP, have a shared goal of promoting participation in value-based care models. Layering in the risks posed by the proposed disincentives could discourage participation in the CMS programs under which disincentives have been proposed. For some clinicians, for instance, the high likelihood of receiving a negative or neutral payment adjustment if they were determined to have committed information blocking could be enough to push them away from participating in these programs.

The College appreciates the opportunity to share our perspective and provide feedback on this proposed rule. While we oppose some aspects of the proposed enforcement approach, ACP believes that the deterrence of information blocking that interferes with patient care and access is essential and applauds ONC and CMS on their collaboration in developing disincentives. We hope that ONC and CMS will consider our feedback and continue to engage with our organization in future deliberations. Please contact Nadia Daneshvar, JD, MPH, Associate, Health IT Policy, at ndaneshvar@acponline.org or (202) 261-4586 with comments or questions about the content of this letter.

Sincerely,

Deepti Pandita, MD, FACP, FAMIA
Chair, Medical Informatics Committee
American College of Physicians