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December 21, 2023

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Ave. SW
Washington, DC 20201

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

Dear Secretary Becerra,

The American Academy of Neurology (AAN) is the world's largest neurology specialty society representing more than 40,000 neurologists, clinical neuroscience professionals, and students. The AAN is dedicated to promoting the highest quality patient-centered neurologic care. A neurologist is a doctor with specialized training in diagnosing, treating, and managing disorders of the brain and nervous system. These disorders affect one in six people and include conditions such as Alzheimer's disease, stroke, migraine, multiple sclerosis, concussion, Parkinson's disease, and epilepsy.

The AAN greatly appreciates the opportunity to provide feedback to the Department of Health and Human Services (HHS), the Office of the National Coordinator for Health Information Technology (ONC), and the Centers for Medicare and Medicaid Services (CMS) regarding proposed disincentives for providers found by the Office Inspector General (OIG) to have committed information blocking. We note that this rulemaking implements provisions of the 21st Century Cures Act (Cures Act) which requires providers found to have engaged in information blocking "to be subject to appropriate disincentives using authorities under applicable Federal law, as the Secretary sets forth through notice and comment rulemaking."[1] Further, the AAN notes that ONC has already defined exceptions to the statutory prohibition on information blocking in previous rulemaking.[2] We appreciate the thoughtful consideration of the appropriateness of various potential disincentives, as well as how disincentives can be incorporated into existing federal programs. The AAN appreciates that HHS is not proposing to establish new civil monetary penalties at this time, nor is the agency creating new programs to ensure compliance with the prohibition on information blocking.

<u>Appropriate Disincentives</u>

[1] 88 Fed. Reg. at 74947
[2] 45 C.F.R. § 171.200.

HHS notes that the Cures Act "does not specify or provide illustrations for the types of disincentives that should be established."[3] Additionally, the term "appropriate" "is likewise not defined in PHSA section 3022, nor are illustrations provided."[4] As such, HHS proposes the following definition for an appropriate disincentive under the Cures Act to be "a disincentive for a health care provider that OIG has determined to have committed information blocking may be any condition, established through notice and comment rulemaking, that would, in our estimation, deter information blocking practices among health care providers subject to the information blocking regulations."[5] HHS clarifies that the "disincentives provision does not limit the number of disincentives that an appropriate agency can impose on a health care provider."[6] Further the agency proposes "that a health care provider would be subject to each appropriate disincentive that an agency has established through notice and comment rulemaking and is applicable to the health care provider. Imposing cumulative disincentives, where applicable, would further deter health care providers from engaging in information blocking."[7]

While the AAN recognizes both the agency's authority to impose appropriate disincentives and the need to ensure that disincentives adequately deter providers from engaging in information blocking, the AAN is deeply concerned with the overly broad nature of this proposed definition, as well as the cumulative application of disincentives, noting that the agency does not place any substantive limits on what may be deemed appropriate, as long as applying such a disincentive would, in the agency's estimation, deter information blocking. In the AAN's view any penalty proposed by an appropriate agency and applied to a provider could theoretically meet this standard. Further, the allowance of cumulative application effectively allows as many individual disincentives as are identified in any future rulemaking to be applied to a single provider. The AAN does not believe a potential unlimited quantity of disincentives, without any restriction either in quantity or potential impact, can be reasonably viewed as appropriate. Regardless of any future plans by any agency to implement disincentives beyond those proposed in this rulemaking, the AAN urges HHS to refine this definition so that it is reflective of the underlying statute's requirement that disincentives be appropriate.

<u>Appropriate Disincentives for Health Care Providers</u>

HHS identifies three distinct authorities under which to propose appropriate disincentives for health care providers found to have committed information blocking.

- Under existing authority for the hospital Medicare Promoting Interoperability Program for eligible hospitals, and critical access hospitals (CAHs), CMS proposes that an eligible hospital or CAH would not be a meaningful electronic health record (EHR) user in an EHR reporting period if OIG refers, during the calendar year of the reporting period, a determination that the eligible hospital or CAH committed information blocking under the existing definition. As a result, an eligible hospital 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, while a CAH subject to this disincentive would have its payment reduced to 100 percent of reasonable costs, from the 101 percent of reasonable costs it might have otherwise earned, in an applicable year.

[3] 88 Fed. Reg. at 74951
[4] Id.
[5] Id.
[6] Id.
[7] Id.

- Under existing authority for the Promoting Interoperability performance category of the Merit-based Incentive Payment System (MIPS), CMS proposes that a health care provider that is a MIPS eligible clinician would not be a meaningful EHR user in a performance period if OIG refers, during the calendar year of the reporting period, a determination that the MIPS eligible clinician committed information blocking under the existing definition. CMS also proposes that the determination by OIG that a MIPS eligible clinician committed information blocking would result in the MIPS eligible clinician, if required to report on the Promoting Interoperability performance category of MIPS, not earning a score in the performance category (a zero score), which is typically a quarter of the total final composite MIPS performance score.
- Under existing authority for the Medicare Shared Savings Program (Shared Savings Program), CMS proposes that a health care provider that is an accountable care organization (ACO), ACO participant, or ACO provider/supplier, if determined by OIG to have committed information blocking, would be barred from participating in the Shared Savings Program for at least one year. This may result in a health care provider being removed from an ACO or prevented from joining an ACO; and in the instance where a health care provider is an ACO, this would prevent the ACO's participation in the Shared Savings Program.

The AAN's comments on the proposed disincentives are as follows:

Medicare Promoting Interoperability Program for Eligible Hospitals and Critical Access Hospitals (CAHs)

The AAN appreciates CMS's clarification that in estimating the portion of hospitals' payments subject to the market basket increase, the agency used data from CMS Hospital Cost Reports to subtract out disproportionate share hospital and indirect medical education and graduate medical education payments. While the AAN recognizes that CMS has an interest in ensuring that appropriate disincentives have the effect of deterring information blocking, given ongoing challenges associated with the neurology workforce and the physician workforce as a whole, the AAN believes it is critical to protect payments associated with medical education to ensure that access to training is not impacted by this rulemaking.

It is estimated that by 2025, the demand for neurologists will exceed the number of practitioners in the United States by 19 percent and recently published data indicates that 20 percent of neurology patients must travel more than 50 miles to see a neurologist.[8] Further, the United States is facing a shortage of between 54,100 and 139,000 physicians by 2034 which will likely be exacerbated by rising rates of physician burnout and early retirement due to the COVID-19 pandemic.[9] In addition, the population of Americans over 65 years old is expected to double to 95 million by 2060,[10] and a dramatic rise in neurodegenerative disease is expected with incidence of stroke rising 20 percent by

[8] Dall, Timothy M et al. "Supply and demand analysis of the current and future US neurology workforce." Neurology vol. 81,5 (2013): 470-8. doi:10.1212/WNL.0b013e318294b1cf

[9] American Academy of Medical Colleges, The Complexities of Physician Supply and Demand: Projections From 2019 to 2034, June 2021, https://www.aamc.org/media/54681/download?attachment

[10] Mather, Mark, et al. Fact Sheet: Aging in the United States, Population Reference Bureau, 15 July 2019, www.prb.org/resources/fact-sheet-aging-in-the-united-states/.

2030,[11] prevalence for Parkinson disease doubling by 2040,[12] and incidence of Alzheimer's disease and related disorders doubling by 2050.[13] This is further compounded by increased demand for neurologists stemming from the aging population and recent approvals for monoclonal antibody therapies directed against amyloid for the treatment of Alzheimer's disease. For neurologic patients, prompt access to care is essential to minimize risks of dangerous complications and side effects. Holding payments supporting medical education harmless from penalties for engaging in information blocking is critical to ensuring a sufficient pipeline of trained neurologists to meet the access challenges faced by neurologic patients.

Promoting Interoperability Performance Category of the Medicare Merit-based Incentive Payment System (MIPS)

The AAN supports establishing appropriate disincentives for MIPS-eligible clinicians found to have engaged in information blocking through the existing MIPS program, rather than establishing a new compliance or reporting mechanism. While the AAN is supportive in principle, we strongly believe that such disincentives must not threaten patient access to care or practice sustainability. The AAN also believes that providers should not be subject to sanctions that are disproportionate or overly burdensome when compared to those faced by other actors covered under the information blocking statute. The AAN recognizes that establishing such disincentives is statutorily mandated and appreciates the agency's explanation of how information blocking relates to the requirement that MIPS eligible clinicians are "using certified EHR technology in a meaningful manner."[14] The AAN concurs with CMS that knowingly and willfully engaging in information blocking substantially undermines the meaningful use of certified EHR technology.

The AAN notes that the impact of CMS's proposed disincentive on MIPS eligible clinicians' Medicare payments will vary from year to year, based on policies established in the annual updates to the Medicare Physician Fee Schedule. The Promoting Interoperability performance category has typically represented 25 percent of the total MIPS score and the performance threshold for 2024 has been finalized at 75 points.[15] As such, a clinician found to have engaged in information blocking, would therefore receive a score of zero for the Promoting Interoperability performance category, and could therefore achieve a maximum overall MIPS score of 75 points. Under the performance threshold finalized for 2024, a MIPS-eligible clinician found to have engaged in information blocking could at best receive a neutral MIPS payment adjustment and would likely receive a penalty, as MIPS eligible clinicians are unlikely to achieve a perfect score on all other MIPS components. In any year in which the performance threshold is set above 75 points, MIPS eligible clinicians found to have engaged in information blocking will definitively receive a negative payment adjustment, which could be as high as 9 percent of total Medicare payments.[16]

By contrast, hospitals and CAHs found to have engaged in information blocking are not subject to penalties and instead receive a reduced payment increase in years in which they are sanctioned for

[11] Ovbiagele, Bruce et al. "Forecasting the future of stroke in the United States: a policy statement from the American Heart Association and American Stroke Association." Stroke vol. 44,8 (2013): 2361-75. doi:10.1161/STR.0b013e31829734f2

[12] Kowal, Stacey L et al. "The current and projected economic burden of Parkinson's disease in the United States." Movement disorders: official journal of the Movement Disorder Society vol. 28,3 (2013): 311-8. doi:10.1002/mds.25292

[13] Alzheimer's Association. 2015 Alzheimer's disease facts and figures. Alzheimers Dementia. 2015;11(3):332-384. doi:10.1016/j.jalz.2015.02.003

[14] 88 Fed. Reg. at 74958

[15] 88 Fed. Reg. at 79376

[16] 88 Fed. Reg. at 79379

engaging in information blocking. The AAN does not believe it is appropriate for providers to receive more stringent penalties than hospitals and CAHs, which have substantially greater resources to engage in compliance activities than the typical provider, for engaging in the same detrimental practice. While the AAN appreciates that small practices are exempt from the proposed disincentives, due to reweighting of the promoting interoperability performance category, the AAN urges CMS to consider strategies to ensure fairness in the application of appropriate disincentives for engaging in information blocking. These may include, given the weight of the promoting interoperability performance category, maintaining stability in the MIPS performance threshold at 75 points in all future years of the program. Alternatively, CMS could consider additional incentives within the promoting interoperability performance category to promote the flow of electronic health information and to deter information blocking.

Further, the AAN is concerned that the proposed disincentive does not account for actions taken by providers to correct practices identified as information blocking. The AAN recommends that CMS consider a reduction in the applicable disincentive for providers who have adequately demonstrated to CMS and the OIG that they have taken corrective action to address the root cause of the information blocking practice and provided sufficient assurance that it will not reoccur.

CMS is requesting comments regarding the agency's approach to applying disincentives in cases in which the OIG has determined that information blocking occurred in multiple calendar years. As CMS is proposing to apply penalties in the payment year applicable to the performance year in which the conduct occurred, this creates a potential scenario in which a provider receives greater sanction for an instance of information blocking that spanned multiple calendar years, even if that practice did not last for more than 12 months. The AAN does not believe it is appropriate that a provider receive greater sanction for a practice that lasted for the same number of days, simply because the information blocking occurred from December through January as opposed to April through May. The AAN does not believe that it would be appropriate to apply sanctions in two MIPS payment years unless a practice spanned longer than 12 months and urges the agency to apply equal disincentives for conduct of equal length.

The AAN requests clarification regarding CMS's proposed policy concerning groups and virtual groups. CMS is proposing "if data for the MIPS Promoting Interoperability performance category is submitted as a group or virtual group then the application of the disincentive would be made at that level."[17] The AAN notes that MIPS-eligible clinicians can report both as an individual and as a group in the same performance year and receive a payment adjustment based on the higher of the two scores. In instances in which a MIPS-eligible clinician who is found to be information blocking reports both as a group and as an individual, the AAN has several questions:

- Would the disincentive still be applied to the whole group, or would it be applied at the individual level?
- How will this policy be applied to subgroups when a subgroup is identified?
- Will the appropriate disincentive be applied to the whole group, regardless of whether the information blocking practice was limited to a particular subgroup?

The AAN is concerned that CMS's proposed approach is overly punitive and may implicate Medicare payments for clinicians who did not engage in information blocking. Addressing this issue is of high importance to neurologists given the high and growing prevalence of neurologic patients in the

[17] 88 Fed. Reg. at 74962

Medicare population. As such, we strongly urge the agency to consider limiting the application of appropriate disincentives to the actual pool of clinicians who engaged in information blocking and apply disincentives at the individual or subgroup level when doing so is feasible.

Medicare Shared Savings Program

The AAN supports CMS's proposal to bar participation in the Medicare Shared Savings Program for a period of at least one year for a health care provider found to have engaged in information blocking. The AAN concurs with CMS that "information blocking runs contrary to the care coordination goals of the Shared Savings Program."[18] The AAN appreciates CMS's clarification that the agency "would be unlikely to impose a disincentive greater than 1 year if the information blocking occurred in the past and there was evidence that the information blocking had stopped and whether safeguards have been put in place to prevent the information blocking that was the subject of OIG's determination."[19] The AAN believes that this approach is appropriate and consistent with the application of disincentives to other clinicians covered by this proposed rulemaking.

The AAN shares CMS's concerns regarding the duplication of penalties in cases in which a provider was previously subject to a disincentive under another program, such as MIPS, for the same information blocking behavior. Given the prospective application of the penalty, it is possible that a clinician may not apply to participate in the Medicare Shared Savings Program until many years after the information blocking behavior has been identified and corrected. The AAN supports an approach under which "a health care provider could participate in the Shared Savings Program if a significant amount of time (for example, 3 to 5 years) had passed between the occurrence of the information blocking and OIG's determination, and the provider had given assurances in the form and manner specified by CMS that the issue had been corrected and appropriate safeguards had been put in place to prevent its reoccurrence."[20] The AAN shares CMS's concern that the prospective application of this penalty may incentivize clinicians who have engaged in information blocking to apply to participate in the Medicare Shared Savings Program as soon as possible, regardless of their actual intention to participate in a given year, so as to have the disincentive applied, to avoid being barred from participation in a future year in which the clinician actually intends to participate. The AAN believes that such a disincentive structure does not actually deter information blocking and is likely to increase administrative burden for ACO participants, ACOs, and CMS.

Request for Information

HHS recognizes that the proposed disincentives do not apply to all healthcare providers for which the information blocking prohibition is applicable. The agency believes it is critical for HHS to establish appropriate disincentives that would apply to all providers, including those not covered by this rulemaking. As such, the agency requests information from the public on additional appropriate disincentives that should be considered in future rulemaking, particularly disincentives that would apply to health care providers that are not implicated by the disincentives proposed in this rule.

The AAN recognizes that aside from those in small practices, the vast majority of neurology providers will be subject to the disincentives proposed in this rulemaking. Given the AAN's above

[18] 88 Fed. Reg. at 74964
[19] 88 Fed. Reg. at 74965
[20] Id.

cited concerns regarding the overly broad definition of appropriate proposed in this rulemaking, the AAN urges HHS to both refine this definition and to ensure that any additional disincentives are not applied to providers already subject to sanction under this rulemaking. The AAN is particularly concerned regarding overly burdensome and cumulative penalties, beyond those proposed in this rule, being applied to neurology providers in small practices. Unlike larger institutions, small practices have fewer resources to devote to compliance, auditing, and legal services, as well as fewer auxiliary staff to devote to non-clinical activities. The AAN believes that for small practices in particular, the focus should be on remediating information blocking itself, rather than implementing financial disincentives that are likely to threaten the viability of small practices, many of whom are already struggling financially. Further any additional proposed disincentives should not create an undue burden on providers or exacerbate access to care issues faced by patients.

Conclusion

The AAN appreciates the opportunity to comment on the various provisions of this proposed rule. The AAN is committed to working with HHS, CMS, and ONC to minimize burdens faced by providers and to promote the seamless sharing of electronic health information across the healthcare system. Please contact Matt Kerschner, the AAN's Director, Regulatory Affairs and Policy at mkerschner@aan.com with any questions or requests for additional information.

Sincerely,

Carlayne E. Jackson, MD, FAAN
President, American Academy of Neurology