AMA
AMERICAN MEDICAL ASSOCIATION

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

Micky Tripathi, PhD
National Coordinator for Health Information Technology
Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
330 C Street SW, Floor 7
Washington, DC 20201

Re: Response to the "Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking" Proposed Rule [RIN 0955-AA05]

Dear Administrator Brooks-LaSure and National Coordinator Tripathi:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am writing in response to the Centers for Medicare & Medicaid Services (CMS) and Office of the National Coordinator for Health Information Technology (ONC) proposals related to the establishment of disincentives for health care providers that have committed information blocking (RIN 0955-AA05), published in the Federal Register on November 1, 2023 (the Proposed Rule). The AMA and its physician members have long recognized how greater health data sharing is an integral component of improved care for patients. Physicians are pioneers in harnessing health information technology (health IT) to enhance patient care, patient engagement, quality, and efficiency.

The AMA strongly opposes the persistent and egregious practice of information blocking, which not only contravenes the spirit of open and collaborative health care, but also undermines patient trust and safety. Deliberate obstruction of vital health information access is antithetical to the principles of modern health care, which prioritize patient-centered care and data interoperability. Flagrant information blocking practices impede the seamless flow of critical health data and significantly hamper the ability of physicians to provide timely, effective, and coordinated care.

Since the early days of the electronic health record (EHR) Incentive (or Meaningful Use) Program, we have been working to achieve the promise of EHRs and other health IT by promoting interoperability and ensuring that safe and usable technology is incorporated into the physician workflow in practices, large and small, in both urban and rural areas. Our support has not wavered on the best ways to expand the nationwide exchange of health data that can be converted into actionable information for physicians as they care for patients. We continue to see the benefits of information sharing and improved outcomes for patients and will keep moving forward in advocating for an even more interoperable health care infrastructure that supports physicians and patients.

We understand that the 21st Century Cures Act (the Act) set forth a bifurcated enforcement structure for information blocking, subjecting health IT developers of certified health IT and health information

networks/exchanges (HINs/HIEs) to civil monetary penalties and subjecting health care providers to "appropriate disincentives."[1]

We have serious concerns, however, that the proposed disincentive construct will:

1. **Unfairly and arbitrarily penalize physicians;**
2. **Result in punishments that are not proportional to the underlying alleged misconduct;**
3. **Lack a meaningful mechanism for physicians to address allegations or appeal adverse determinations; and**
4. **Ultimately – and counterproductively – discourage participation in Medicare quality and value-based care programs and compound existing Medicare payment shortfalls.**

We strongly believe that a provider disincentive construct that does not include opportunities for education and corrective action, does not consider the severity of the underlying alleged misconduct, and does not provide meaningful appeal rights cannot be considered "appropriate," as required by statute. In our detailed comments below, we highlight several specific areas of concern with the proposed disincentives. We also provide our recommendations to enhance information blocking compliance while ensuring that physician practices do not face undue financial hardships, which could disproportionately impact small, safety net, rural, and other less-resourced practices that often serve underserved patient communities.

**Most importantly, we recommend that CMS and ONC (the Agencies), along with the Department of Health and Human Services (HHS) Office of Inspector General (OIG), prioritize education for physicians related to perceived information blocking and work with practices to facilitate corrective action, rather than imposing harsh punishments that are not calibrated to the underlying alleged misconduct.** Starting with notice and corrective action is consistent with enforcement approaches undertaken in various other HHS efforts, especially when the underlying regulatory scheme is novel and complex.

**We also strongly urge the Agencies to clarify the significant open questions that remain about the proposed disincentives through supplemental notice-and-comment rulemaking *before* any enforcement begins.** Without any past experience in enforcement of the information blocking prohibition and corresponding exemptions, many of our member physicians are still unclear about what HHS might view as constituting prohibited practices, despite investing significant time and effort into understanding the information blocking framework.

To this end, we make the following recommendations, which are further explained in our comments that follow:

[1] Unlike the authority to levy civil monetary penalties for information blocking violations committed by health information technology (health IT) developers of certified health IT and by health information exchanges and networks, Section 4004 of the 21st Century Cures Act requires HHS OIG to refer health care providers that OIG determines to have committed information blocking to the "appropriate agency to be subject to appropriate disincentives using authorities under applicable Federal law" as set forth through notice-and-comment rulemaking.

**Disincentives:**

- The Agencies should prioritize physician education and opportunities for corrective action over the imposition of harsh financial disincentives. Before imposing a disincentive, the Agencies should first provide educational resources and work with the physician or practice to establish a formal corrective action plan, which would then be closely monitored.

- Any disincentive construct should be predictable, should take into consideration the severity of the alleged misconduct, and should not result in arbitrary financial impacts.

- Any disincentive construct should be centrally administered by HHS to ensure coordination and minimize potential errors that will ultimately fall upon the physician to navigate and resolve, increasing the already overwhelming administrative burden placed on physicians and further detracting from patient care.

- Information blocking disincentives should be carefully designed in close collaboration with interested parties so as not to have the unintended effect of discouraging participation in Medicare quality and value-based care programs.

- The Agencies should propose supplemental rulemaking to address how the proposed disincentives interact with existing, complex quality reporting program rules – and the resulting additional and downstream implications for physicians – *before* any disincentive construct is finalized and *before* any enforcement activity begins.

**Enforcement:**

- Physicians' appeal rights should not vary arbitrarily based on the disincentive's underlying program.

- Physicians should have meaningful opportunities to address allegations of information blocking and should be able to challenge and appeal any determination of information blocking prior to the imposition of any disincentive.

- The Agencies should clarify important details regarding the disincentives' effective dates, potential look-back periods, and time limits for information blocking referrals.

**Transparency:**

- Physicians subject to education or a corrective action plan should not be listed publicly as information blockers. Similarly, physicians should not be listed publicly as information blockers until *after* they have had an opportunity to appeal the determination and any associated disincentives.

- The Agencies should also establish a process to confirm the accuracy of the information being posted *before* a physician's name or practice entity is publicly displayed.

**Detailed Explanation of Recommendations**

## I. Disincentives

### A. The Agencies should prioritize physician education and opportunities for corrective action over the imposition of harsh financial disincentives. Before imposing a disincentive, the Agencies should first provide educational resources and work with the physician or practice to establish a formal corrective action plan, which would then be closely monitored.

When the Act was signed into law in 2016, it promised more efficient data exchange and much-needed privacy protections for patients in an increasingly technology-driven health care system. Physicians were especially supportive of provisions that promised to bring about long-overdue interoperability of EHRs. The AMA has developed many robust resources to help inform and educate the physician community on the development of the Act's information blocking provisions and physician responsibilities and expectations for data sharing, including action-oriented reports and playbooks[2] that describe what information blocking is; the specifics around access, exchange, and use of health information; how patient access to data is impacted; and intersections with the Health Insurance Portability and Accountability Act (HIPAA) of 1996 and state law.

As information blocking moved into the regulatory phase of development, we continued to educate physicians on which "Health Care Providers" are designated as regulated actors, the difference in knowledge standards amongst the actors, and when the exceptions apply. We also continue to assist physicians in interpreting ONC's answers to stakeholder inquiries included in the 50+ Frequently Asked Questions on Information Blocking.[3] Despite our best efforts, there remains a lack of understanding about what constitutes information blocking across the physician community. Physicians in over-burdened and under-resourced practices have a particularly difficult task in trying to understand the regulations' complexities and nuances. Finally, the information blocking regulations continue to evolve, with substantial changes to the information blocking exceptions just recently finalized in December 2023.

The information blocking prohibition (and various corresponding exemptions) is extremely complicated, and many of our member physicians are still unclear whether certain practices would be considered unreasonable and thus potentially within the scope of the information blocking prohibition. **Given the complexity of the information blocking regulations, and the lack of previous enforcement action, physicians should be given a meaningful opportunity to better understand the prohibited conduct and to self-correct *before* the Agencies begin imposing disincentives that can have significant financial impacts.**

As the OIG discussed in its information blocking civil monetary penalty (CMP) final rule issued earlier this year, HHS has the ability "to conduct individualized education and corrective action plans when an actor has committed information blocking."[4] **We strongly believe that this would be the most**

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[2] *See* sample AMA information blocking educational resources, available here.
[3] See the Information Blocking Frequently Asked Questions, available here.
[4] 88 FR 42824, discussing HHS's ability under the Public Health Service Act (PHSA) and other regulations to engage in education and to establish corrective action plans in response to information blocking, and also stating

**appropriate first step in establishing disincentives for physicians and would likely improve future compliance with the information blocking requirements**. Without such outreach, we are concerned that many physicians and other actors will fail to fully understand and learn how to avoid instances of information blocking, may have limited ability to actively work with HHS to address questions and uncertainty regarding conduct, and will ultimately face penalties that could be avoided.

Importantly, an approach that emphasizes a ramp-up period of education and self-correction aligns with the enforcement of other legal constructs, especially those that impose new requirements.[5] As proposed, however, the rule skips this important step and moves immediately to establishing disincentives that can have significant financial impacts. If this were the intent of the underlying statute, we believe the Act would have simply used the words "payment adjustment" or "penalty," as is used consistently in other statutory payment reductions. Instead, the terminology of the law affords HHS an opportunity to establish what it believes would be an appropriate disincentive to information blocking, recognizing existing authority.

HHS itself notes its existing authority to use corrective action in the MSSP context in the Preamble of the Proposed Rule, but then does not discuss how corrective action could be used for the other disincentive constructs. Outreach, education, and learning periods are embedded in each of the quality reporting programs HHS now proposes to intertwine with the disincentives. The Proposed Rule, however, fails to recognize these important existing components of each program. In sum, the statute outlines that an actor should be referred "to the appropriate agency to be subject to appropriate disincentives using authorities under applicable Federal law," but **the Proposed Rule does not recognize the full authority already vested in HHS and its quality reporting programs to establish transitional learning periods and to allow for appropriate ramp-up periods.**

Furthermore, while the Agencies characterize the proposed disincentives as relatively insignificant on average, **the financial impact would in fact be economically significant for many physician practices and could be catastrophic for some.** For example, the proposed disincentive for Merit-based Incentive Payment System (MIPS)-eligible clinicians fails to acknowledge that CMS has historically increased the MIPS performance thresholds over time. The proposed negation of the clinician's promoting interoperability (PI) performance category score could, as a result, levy increasingly large penalties against MIPS participants who would no longer meet the overall performance score threshold, even with perfect scores in the remaining performance categories. In addition, if an Accountable Care Organization (ACO) is suspended from the MSSP for a year (or more), or if a large ACO Participant is removed from the ACO, the resulting financial impact could be the loss of millions of dollars in potential shared savings revenue. Depending upon the financial condition of the ACO, such a penalty could result in the ACO collapsing completely.

We are concerned that **an overly punitive approach will negatively impact already struggling physicians and practices working with limited resources and will discourage participation in Medicare quality and value-based care programs. To put the proposed disincentives in context, Medicare physician pay has fallen 26 percent since 2001, threatening the viability of physician**

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that "OIG may refer an allegation to ONC to address under its direct review authority, under which ONC could impose a corrective action plan."

[5] For example, CMS has established corrective action for a denial or revocation of a provider's Medicare billing privileges to address compliance with Medicare coverage, coding, and billing rules; and enforcement of the new price transparency requirements provided for an extended period of learning and self-correction.

**practices and patient access to care.**[6] Further reductions to physician payment will severely hamper access to care for Medicare patients. The Medicare Trustees have explicitly warned that access to Medicare-participating physicians could be seriously compromised in the long-term if payment rates continue to decline. Delays in care, particularly in underserved populations, are associated with worse health outcomes and inequitable health care delivery. Practices that serve a larger proportion of Medicare beneficiaries will be disproportionately impacted by the proposed disincentives. Small, rural, and safety net practices – already working with fewer resources and on thinner margins – will be particularly unable to absorb additional financial penalties.

The Proposed Rule would create additional financial distress for physicians in the Medicare program and would further discourage physicians from serving Medicare beneficiaries. We strongly believe that CMS policies should enhance access to care and improve health outcomes for our nation's seniors and people with disabilities, not further discourage physician participation in the Medicare program. **Given the potentially severe impacts of the proposed disincentives, and the significant and continuing erosion of Medicare payment to physicians, we strongly urge the Agencies to prioritize inclusion of individualized education and corrective action steps prior to the imposition of disincentives.**

**B. Any disincentive construct should be predictable, should take into consideration the severity of the alleged misconduct, and should not result in arbitrary financial impacts.**

In the Proposed Rule, the Agencies would establish disincentives that result in negative financial impacts based on the type of provider and the provider's Medicare reimbursement, effectively creating arbitrarily different punishments for different types of providers. The severity of the penalty being imposed would, in many instances, be an arbitrary function of the type of provider and their Medicare reimbursement rather than a function of the severity of the provider's alleged misconduct. In other words, **the monetary impact of the proposed disincentives is not directly tied to the severity of the underlying purported offense.**

For example, the Proposed Rule proposes that an information blocking determination would result in a MIPS-eligible clinician[7] receiving a "zero" score for the PI performance category. Automatically imposing a maximum reduction to the PI category of a physician's MIPS score, regardless of the severity of the physician's conduct, is not sound policy and risks serious consequences as MIPS penalties are now as severe as a -9 percent payment adjustment. Under the proposed disincentive for the MSSP, an ACO found to have committed information blocking would be suspended from the program for at least one year. The effective penalty amount for the ACO would vary based on the potential savings foregone for that performance year, not based on the severity of the ACO's conduct.

Additionally, the proposed disincentives for an eligible hospital or critical access hospital (CAH) would result in the loss of 75 percent of the annual market basket increase tied to the meaningful user designation for hospitals and in a payment reduction from 101 percent of reasonable costs to 100 percent of reasonable costs for CAHs. Accordingly, the effective financial penalty amounts would vary based on the volume of the hospital's/CAH's Medicare reimbursement, not based on the severity of the underlying

[6] For additional information on overall Medicare payment reductions to physicians, please see our analysis here.
[7] We also note that not all MIPS participants are required to report the PI performance category, including exceptions for facility-based and hospital-based clinicians. Clinicians who do not have to report a PI performance category score would not be subject to any disincentives under this proposal, while similarly situated clinicians would be subject to the disincentive.

offense. **We are extremely concerned that the magnitude of the proposed disincentives is not proportional to the severity of the underlying alleged misconduct and, instead, seemingly results in arbitrary financial impacts based on the physician's Medicare reimbursement.**

We are also concerned that **the imposition of the disincentives appears to be binary and that all purported offenses would have equal weight, regardless of the facts or circumstances surrounding the alleged misconduct.** Under the Proposed Rule, an OIG referral that contains a single instance of information blocking could have the same impact as an OIG referral that contains multiple instances of information blocking perpetrated over an extended time period. For example, under the proposed hospital/CAH disincentive and the MIPS-eligible clinician disincentive, regardless of whether multiple information blocking violations were identified as part of OIG's determination, each referral would affect a hospital's/CAH's or a MIPS-eligible clinician's status as a meaningful user for the affected reporting/performance period.

In other words, **multiple instances of alleged information blocking would trigger the same disincentive as one instance of alleged information blocking.** Similarly, we are concerned that the proposed disincentives would not differentiate between kinds of purported violations, implying that all practices and instances of information blocking are equally egregious. Moreover, penalizing providers without considering the number or magnitude of offenses would minimize the proposed policy's effectiveness at disincentivizing more egregious information blocking offenses.

While we recognize that OIG has stated that it plans to prioritize investigations based on certain factors (which can include the number of claims made against a provider and the duration of the conduct), OIG has also emphasized that this announced enforcement plan is non-binding.[8] Further, OIG has acknowledged that the investigative factors alone are insufficient to ensure appropriately calibrated penalties.[9] Under the CMP construct, which applies to information blocking conduct committed by developers of certified health IT and HINs/HIEs, the penalties **are scaled based on consideration of several mitigating and aggregating factors. Physicians, however, cannot avail themselves of the same individualized consideration and scaling of the disincentives under the Proposed Rule.**

We are not aware of any statutory bar that would prevent the Agencies from establishing disincentives that result in penalties that scale to the severity of the underlying alleged misconduct and that take into consideration the facts and circumstances of the case at hand. Although the Act requires the disincentives to be made "using authorities under applicable Federal law," such language could permit different disincentive thresholds, scaling, or other ways to establish and appropriately calibrate financial penalties. We also note that the Agencies have already proposed many principles (included in proposals for a potential MSSP ACO alternative policy) that would seem to suggest that scaling measures and added discretion in applying a disincentive would be within the Agencies' authority to apply to *all providers*.[10] Under the Proposed Rule, physicians could also be subjected to *multiple* disincentives based simply on their participation in multiple programs, not based on the culpability of their conduct.[11] **We are**

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[8] *See* Preamble discussion of the OIG's stated enforcement priorities at 88 FR 74951-52.

[9] For example, two cases may trigger the same investigatory factors and lead to investigations, but different CMP amounts may be appropriate based on the application of the mitigating and aggravating factors for CMPs.

[10] *See* discussion of the alternative MSSP ACO policy at 88 FR 74966.

[11] The Proposed Rule states that a "health care provider would be subject to each appropriate disincentive that an agency has established" and that "imposing cumulative disincentives, where applicable, would further deter health care providers from engaging in information blocking" at 88 FR 74951.

**concerned that physician participation in multiple programs would open the physician to more information blocking enforcement risk.** The Proposed Rule also notes but does not adequately address potential intersection with HIPAA and other enforcement efforts and the potential for significant overlap across different authorities. As noted, we are concerned that subjecting physicians to multiple disincentives would further undermine participation in important programs. **We are also extremely concerned that there does not appear to be a process in place to reconcile the multiple disincentives being applied and to ensure that the resulting punishment is not unfair and disproportionate to the provider's behavior.** We strongly believe that physicians should not be subjected to multiple disincentives for the same conduct based simply on the fact that they have chosen to participate in multiple programs. Accordingly, the Agencies should establish a disincentive clearinghouse process to ensure the disincentives applied are not duplicative, arbitrary, and unduly punitive.

Overall, we are concerned that **a disincentive construct that varies based on provider type will punish physicians unequally for the same alleged misconduct.** If the Agencies continue to develop additional disincentives based on this proposed approach, these differential punishments will continue to be amplified. We are also concerned that the proposed construct is binary and does not take into consideration any mitigating factors before the disincentive is applied. Accordingly, **we urge the Agencies to establish regulations that enable the provider disincentives to be scaled in a manner that considers, among other things, the severity of the underlying alleged misconduct and the facts and circumstances of the case.**

One such approach could be to adopt the proposed alternative MSSP ACO policy and extend these same flexibilities to other types of physicians. The proposed alternative MSSP ACO policy would, among other flexibilities: (1) permit CMS to decline to apply the disincentive in certain circumstances despite an OIG information blocking determination; and (2) enable CMS to consider an information blocking determination in light of the relevant facts and circumstances – including the nature of the conduct, the provider's diligence in identifying and correcting the problem and in establishing "appropriate safeguards" to prevent future information blocking, and the time that has passed since the information blocking occurred.[12] **This proposed alternative appropriately accounts for important factors and takes a much more balanced approach, prioritizing progress toward information sharing over punitive policies. We strongly support the flexibilities included in this proposed alterative approach, and we encourage the Agencies to adopt these flexibilities, to consider other flexibilities raised during this rulemaking, and to apply these types of flexibilities and added discretion consistently across all physicians.**

### C. Any disincentive construct should be centrally administered by HHS to ensure coordination and minimize potential errors that will ultimately fall upon the physician to navigate and resolve, increasing the already overwhelming administrative burden placed on physicians and further detracting from patient care.

We are concerned about the complexity of the proposed disincentives and the fact that implementation will involve multiple offices across HHS. The Proposed Rule only notes referral to CMS without acknowledging which Center (e.g., the Center for Medicare, the Center for Clinical Standards and Quality) or other entity will ensure appropriate implementation of the disincentives. The proposed

[12] The Agencies noted particular concerns about applying disincentives in situations when many years had passed since the information blocking occurred and such issues had long been remediated.

disincentives are built upon existing Medicare programs, which will continue to evolve and change, typically on a yearly basis. Such complexity and compartmentalization will increase the opportunity for coordination and communication breakdowns, and **we are extremely concerned that the burden of navigating and resolving problems will ultimately fall upon physicians.** For example, within MIPS, clinicians already face a complex framework of different categories, measures, and program requirements for scoring the overall MIPS program and addressing reconsideration of the final score.

We strongly believe that any disincentive construct should not increase physician administrative burden and should not take more time away from patient care. To that end, **we recommend that HHS establish a centralized coordinating entity dedicated to implementing the information blocking disincentives and providing a main and effective point of contact for physicians** to gather information about the disincentive implementation process and to resolve any discrepancies easily. The lack of detail or discussion in the Proposed Rule on this matter, we believe, would necessitate supplemental rulemaking before finalizing any permanent structure for the disincentives.

**D. Information blocking disincentives should be carefully designed in close collaboration with interested parties so as not to have the unintended effect of discouraging participation in Medicare quality and value-based care programs.**

We are concerned that the Proposed Rule will unintentionally discourage participation in Medicare quality and value-based programs. As a starting point, only a subset of Medicare physicians (and then only a subset of *those* physicians) is potentially subject to the proposed disincentives. **Physicians who have larger Medicare payments, and who treat more Medicare beneficiaries, are disproportionately and negatively impacted under the proposed construct.** We strongly believe that HHS policies should encourage physician participation in Medicare, not use a physician's degree of Medicare participation to expose them to greater financial risk.

Similarly, we are very concerned that the proposed disincentive for MIPS-eligible clinicians will compound the well-documented problems with the MIPS program. Under the proposal, the effect of the disincentive would be that any physician found to have committed information blocking would automatically have their PI score set to "zero," likely resulting in a downward payment adjustment *even if* the clinician received a nearly perfect score in the other three performance categories (including improvement activities, quality, and cost). As HHS is aware, dealing with "all-or-nothing" approaches in the past has resulted in diminished physician confidence and buy-in to the program, harming progress on achieving program goals. We are concerned that the proposed disincentive will worsen the arbitrariness of penalties under MIPS and, as a result, would potentially lower stakeholder engagement in MIPS overall.

Additionally, under the MIPS-related proposal, **an information blocking determination for one physician would affect the score of the entire practice group** if the group reports the PI performance category at the group-level. Group practices will have less of an incentive to report at the group-level if a single physician's conduct, outside the other physicians' control, could result in the penalty being levied against the entire group.[13] This would be even more problematic for virtual group practices that are more

[13] For example, the median estimated disincentive amount for an individual is $686. The estimated median group disincentive amount (based on a group of six clinicians) is $4,116. The estimated range of the disincentive amount (for groups ranging from two to 241 clinicians) is $1,372 to $165,326. Applying the disincentive at the group-level, rather than at the individual-level, could have *significant* financial consequences; in the worst-case scenario, application of the disincentive at the group-level would be a difference of nearly $165,000.

loosely associated and with physicians who may practice in different physical locations and may use different EHR systems. The added complexity of determining whether to report at the group-level (and potentially suffer a group-wide penalty for the conduct of one physician) **would further complicate MIPS reporting, directly contravening CMS' stated goal of reducing administrative burden within the MIPS program.**[14]

Application of the disincentive at the group-level may also discourage physicians from joining larger practice groups or reporting through groups and virtual groups, designed to reduce burden and coordinate quality reporting. Additionally, punishing the entire group for the behavior of one individual – in other words, guilt by association – appears to be contrary to the Act definitions at 42 U.S.C. § 300jj-52(a)(6), which effectively state that information blocking, with respect to an individual, does not include an act or practice committed by another individual.[15] As an alternative to the proposed policy, **individual physicians found to be information blockers could be excluded from the group data or be required to report and be assessed separately.**

In addition to complicating participation in MIPS, **we are also very concerned that the Proposed Rule will discourage physicians from participating in the MSSP and could undermine improvements in patient care.** Under the MSSP-related disincentive, if an ACO entity is found to have committed information blocking (and is consequently suspended from MSSP for at least a year), all of the clinicians practicing under that ACO would also effectively be banned for a year. If physicians happen to choose the "wrong" ACO, they would lose an entire year of alternative payment model (APM) experience and potential shared savings revenue. Ultimately, this blunt application of the disincentive could upend ACO operations, undermine care coordination, and diminish needed resources that MSSP ACOs use to improve patient care.

Additionally, suspension from the MSSP may also make the ACO ineligible for the APM bonus payments that ACOs rely on to cover initial investment costs and ongoing care coordination costs. Also, as the Agencies would not be able to remove individual National Provider Identifiers from the ACO, and would instead suspend the entire ACO or suspend an ACO Participant at the Tax Identification Number (TIN) level, the suspensions could have outsized consequences. For example, implementation at the TIN-level could have significant negative impacts on attribution calculations and could negatively impact the beneficiaries who were receiving services from that entity. The results of a TIN- or ACO-level suspension could cause financial hardships that could result in outsized hardships for existing ACOs up to and including the ACO collapsing.

MSSP and other ACO participants are already accountable for significant financial risks, and these added potential penalties could greatly compound the financial instability of the ACO entity and participating physician practices. Accordingly, the added uncertainty could discourage physicians from joining MSSP ACOs, significantly undercutting the Administration's stated goal of having all traditional Medicare beneficiaries in a care relationship with a provider who is accountable for quality and total cost of care by 2030.[16] As a result, **we strongly urge the Agencies to revise the proposed disincentives to mitigate these negative effects on physician participation in Medicare quality and value-based programs.**

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[14] Some groups may also be transitioning to subgroup reporting for MIPS Value Pathways (MVPs) and must elect MVP and subgroup reporting even earlier than the data submission window, creating additional complications.

[15] 42 U.S.C. § 300jj-52(a)(6) states, "[t]he term "information blocking", with respect to an individual or entity, shall not include an act or practice other than an act or practice committed by such individual or entity."

[16] *See* the *CMS Innovation Center Strategy Refresh* at 13, available here.

**E. The Agencies should propose supplemental rulemaking to address how the proposed disincentives interact with existing, complex quality reporting program rules – and the resulting additional and downstream implications for physicians – *before* any disincentive construct is finalized and *before* any enforcement activity begins.**

We are concerned that the proposed disincentives' interactions with complicated, existing program rules, and the resulting downstream consequences for physicians, are not fully explained in the Proposed Rule. Differing initial and downstream consequences that stem from the disincentive's underlying program will further exacerbate unequal and unpredictable punishments across provider types. **Given the serious ramifications these interactions could have for physicians, we strongly urge the Agencies to address these open questions through additional notice-and-comment rulemaking before the proposed provider disincentives are finalized.**

While there are certainly additional interactions with existing program rules that will become more apparent as we further consider the proposals, there are several significant issues that are immediately apparent and that will require additional clarification. For example, the PI program has established hardship exemptions, but the Proposed Rule does not address specifically how those interact with the proposed disincentives. It is also unclear how the Agencies plan to handle the attestation requirement currently required by the MIPS program to not engage in information blocking. Additionally, it is unclear how the two-year (or longer) delay in payment under MIPS would correlate with an occurrence of information blocking that could have occurred *several years* prior.

The Proposed Rule also fails to consider that CMS will be requiring MSSP ACO Participants to report the PI Program starting in 2025 (unless further changes are made in rulemaking).[17] It is unclear how this change would impact the proposed disincentive for MSSP ACOs: (1) Would the proposed disincentive only be active for one year and then be changed to a disincentive that more closely resembles the hospital/CAH and MIPS-eligible provider disincentives?; or (2) Could an MSSP ACO be at risk in the future for *multiple disincentives* that stem from the same determination as a result? We note that the Proposed Rule states that a "health care provider would be subject to each appropriate disincentive that an agency has established" and that "imposing cumulative disincentives, where applicable, would further deter health care providers from engaging in information blocking."[18] **We are extremely concerned that physicians could be subject to multiple disincentives, and that there does not appear to be a process to ensure that physicians are not unfairly and disproportionately punished based simply on the fact that they participate in (and are therefore subject to the disincentives associated with) multiple programs.**

Additionally, it is unclear how the proposed MSSP ACO-related disincentive would interact with other complicated, existing program rules. The suspension of an ACO Participant/provider would seem to have significant effects, for example, on the ACO's attributed lives, but the Proposed Rule does not provide details on this key impact. Similarly, the Proposed Rule does not appear to address how such a suspension

[17] There are many reasons why we continue to believe that MSSP ACOs should not be required to report the PI Program. Instead of imposing additional reporting burden, we believe that CMS should actively seek opportunities to alleviate regulatory burdens for ACOs that have already taken responsibility for outcomes and costs. For more detail, please see our comments (beginning on pg. 72) submitted in response to the Calendar Year 2024 Physician Fee Schedule Proposed Rule (88 FR 52262, Aug. 7, 2023), available here.

[18] 88 FR 74951.

would affect providers with respect to the MSSP rules allowing providers to remain in one-sided risk for a certain period of time or otherwise advance through the program.

**We are also concerned about the differing effects of individual- and entity-level enforcement and the lack of clarity regarding the factors that would affect the choice of enforcement level.** For example, when an MSSP ACO *entity* is found to have committed information blocking – and is thus suspended from MSSP participation for at least one year – it is unclear what downstream effects that would have on the ACO's participating providers. It would appear that, if the ACO entity is found to have committed information blocking, all of the providers participating in that ACO would also effectively be suspended for at least a year. Those providers would have to find another ACO to join for a short time period, assuming that the deadlines to join a different ACO have not yet passed. **We are concerned that this will lead to counterproductive and unnecessary instability in the MSSP program**, undercutting CMS' efforts to encourage physicians to move into value-based models.

As noted, the Proposed Rule would also impose the MIPS-related disincentive on the entire practice group when the group reports the PI performance category at the group- or virtual group-level. The application of the disincentive at the entity-level, based only on the fact that the group has chosen to reduce administrative burden by reporting at that level, arbitrarily increases the financial risk for physicians in those groups. Rather than correcting the individual physician who has committed information blocking, the disincentive would apply to the whole group based on the decision to report as a group, a decision that is entirely unrelated to the information blocking conduct and a decision that CMS has encouraged to reduce overall MIPS reporting burden.

We are also concerned that the perpetually changing nature of the underlying programs will complicate the implementation of the proposed disincentives and will require physicians to continually monitor these changes, taking even more time away from patient care. For example, CMS updates the quality program requirements on a yearly or more frequent basis (including increasing the minimum performance scores), and **it is unclear how the Agencies will constantly monitor these updates, (re)align the disincentives accordingly, and communicate important changes and implications to physicians.** We are concerned that the potential for the disincentives to evolve over time, and to become more punitive over time, has not been fully considered. **We believe the significant implications of these open questions necessitate further clarification through supplemental notice-and-comment rulemaking *before* any provider disincentives are finalized.**

## II. Enforcement

### A. Physicians' appeal rights should not vary arbitrarily based on the disincentive's underlying program.

Under the Proposed Rule, physicians would have differing appeal rights depending on the program through which the disincentive is imposed. If the disincentive's underlying program does not provide for appeal rights, physicians subject to that disincentive would have no appeal rights at all. **We are extremely concerned that physicians would have different appeal rights that vary arbitrarily based on the disincentive being applied, and that many physicians would have no right to appeal a disincentive**. Under the CMP construct, health IT developers and HINs/HIEs all have appeal rights. It is unfair and arbitrary that physicians would not have the same or comparable appeal rights under the proposed disincentive construct.

Additionally, any programmatic appeal rights that might be available to a physician are so late in the proposed process that they do not provide a meaningful opportunity for physicians to correct an adverse determination before the disincentive is applied. In the Proposed Rule, HHS appears to take the position that any appeal rights would apply *only to the application of the disincentive itself*, meaning that **a physician would be able to challenge only how the disincentive was calculated and applied.** Under the proposals, **a physician would not be able to challenge the underlying OIG information blocking determination**. We are extremely concerned that, under the proposed construct, physicians would have different appeal rights and that these appeal rights (if available) would only enable a physician to challenge the application of the disincentive. Accordingly, **we urge the Agencies to establish a meaningful appeals process that is available to all providers** and that addresses both the underlying information blocking determination (discussed further below) and the application of the disincentive.

**B. Physicians should have meaningful opportunities to address allegations of information blocking and should be able to challenge and appeal any determination of information blocking prior to the imposition of any disincentive.**

The Proposed Rule largely omits discussion of the underlying investigative process, including whether OIG's process will include an opportunity for physicians to respond to an ongoing investigation and explain why their conduct either did not implicate the information blocking prohibition, met an exception, was otherwise lawful, or was actually the result of information blocking by *another* regulated actor.[19] We believe that it would be in the best interests of both physicians and HHS to allow physicians to respond to allegations of information blocking much earlier in the process.

Providing an earlier opportunity to resolve allegations would save valuable time and resources for OIG and for physicians. **We strongly recommend that HHS confirm that there will be, and formalize, an opportunity for physicians to engage with OIG before it makes an information blocking determination.** Specifically, many of the information blocking exceptions depend on fact-specific circumstances. To assess whether an exception is met, we believe OIG will need detailed information about the patient and care provided along with the circumstances surrounding care decisions. To that end, prior to OIG completing its investigation and making a determination of information blocking, OIG should timely notify the physician and provide an opportunity to gather these fact-specific circumstances, assess each case's unique situation, and respond to the underlying allegations.

As noted above, the Proposed Rule also does not appear to provide for an appeal mechanism through which physicians could challenge OIG's determination of information blocking. The varying appeal rights only allow physicians to challenge the disincentive itself. **We are extremely concerned that the Proposed Rule does not provide physicians an opportunity to engage with OIG during the investigation process and does not grant or identify an express right for physicians to challenge an adverse OIG determination.** We do not believe that Congress intended to create a more punitive enforcement process, with no rights to appeal information blocking determinations, for health care providers relative to other regulated actors. If anything, the creation of "disincentives" for providers, rather than the imposition of direct penalties, would seem to signal Congressional intent to establish a

[19] 42 U.S.C. § 300jj-52(a)(6) and (7) state that "[t]he term "information blocking", with respect to an individual or entity, shall not include an act or practice other than an act or practice committed by such individual or entity" and that "the Secretary shall ensure that health care providers are not penalized for the failure of developers of health information technology or other entities offering health information technology to such providers to ensure that such technology meets the requirements to be certified under this subchapter."

more lenient and flexible enforcement process for providers, not one that would foreclose opportunities for education, corrective action, and meaningful appeal rights.

We believe that patients are more likely to identify their physician, rather than the underlying health IT system, as contributing to information blocking because the patient may not know what EHR system is being used or the technological limitations that may prevent adequate access. Accordingly, the physician may be named as the default bad actor simply because the patient most closely associates their physician with their care concerns. As the vast majority of potential information blocking complaints made thus far identify health care providers,[20] it is imperative that HHS provide fair and meaningful opportunity for physicians to **(1) address allegations of information blocking conduct during the investigation process and prior to a determination of information blocking, (2) appeal adverse determinations made by the OIG, (3) have an opportunity to correct conduct before facing disincentives, and (4) be able to appeal the application of the disincentive regardless of the underlying program.** This requires both an opportunity to engage with OIG before it makes a determination that information blocking has occurred and an opportunity to administratively appeal any such determination.

### C. The Agencies should clarify important details regarding the disincentives' effective dates, potential look-back periods, and time limits for information blocking referrals.

Several important details regarding the proposed enforcement timeline are not entirely clear under the Proposed Rule and could have significant implications for physicians' information blocking liability. We respectfully request that the Agencies: (1) identify an enforcement date (occurring *after* the issuance of a final rule for disincentives) similar to how OIG identified an enforcement date in its CMP final rule; (2) confirm that disincentives will not be imposed for conduct occurring prior to that enforcement date; and (3) confirm that HHS has only six years from the date an actor committed a practice that constitutes information blocking to impose a disincentive (similar to the time period within which OIG must impose a CMP for information blocking).

## III. Transparency

### A. Physicians subject to education or a corrective action plan should not be listed publicly as information blockers. Similarly, physicians should not be listed publicly as information blockers until *after* they have had an opportunity appeal the determination and any associated disincentives.

We are concerned that physicians could potentially be "named and shamed" on the ONC's information blocking website before they have had a meaningful opportunity to appeal an adverse information blocking determination. Under the proposals, information about regulated actors would be posted to the ONC's website, including: the information blocking practice; the actors involved; and any settlements of liability, civil monetary penalties levied, and disincentives administered. **We strongly believe that physicians who are engaged in individualized education efforts or corrective action plans should not be publicly shamed as information blockers,** as they are taking appropriate steps to understand the

[20] As of October 2023, ONC and OIG had received 835 possible claims of information blocking; 699 of those claims (nearly 84%) were against health care providers. *See* https://www.healthit.gov/data/quickstats/information-blocking-claims-numbers. We note that the current information blocking reporting statistics support the fact that physicians are likely often incorrectly blamed for "blocking" because physicians are on the front lines of delivering patient care while other regulated actors (who may have actually caused the information delay) are not.

information blocking regulations and remedy alleged problematic practices. **Physicians should also not be included on such a list if they are undergoing appeal.** The Agencies should give physicians an opportunity to learn and take responsible corrective action, and to appeal an adverse determination and any associated disincentive, *before* physicians are added to any such list.

Additionally, **the Agencies should establish a reasonable threshold for including a physician or practice on the information blocking list**, similar to HIPAA breach notification rules requiring breach of a certain number of patient records. For example, a physician should not ultimately be included on the information blocking list if the underlying referral contained a single instance of information blocking that did not adversely impact patient care. **The Agencies should also establish a reasonable time period for which a physician or practice could be included on the information blocking list.** We strongly believe that physicians and practices should not be "named and shamed" in perpetuity on the information blocking list.

**B. The Agencies should also establish a process to confirm the accuracy of the information being posted *before* a physician's name or practice entity is publicly displayed.**

Unfortunately, our past experience with Care Compare and other publicly posted information about health care providers demonstrates how easily inaccurate information can be posted, and how difficult it can be for the provider to remove or otherwise remedy the inaccurate information. In the most concerning cases, the *wrong* individual has been identified on public websites – requiring the physician to expend significant time and resources to have the harmful and inaccurate information removed. **We are extremely concerned that physicians and practices could be erroneously "named and shamed" and that the burden to correct any inaccurate postings would fall upon the physician or practice after the fact.**

**We are also concerned that HHS could further use the posted information to apply additional disincentives or to bar the physician from participation in other programs.** We strongly believe that additional notice-and-comment rulemaking would be required if HHS plans to use the "information blocking list" in such a manner, particularly given the possibility for inaccurately posted information. As the potential damage to a physician's reputation is extremely high, and as the administrative burden to correct inaccurate information would take even more time away from patient care, **we urge the Agencies to establish a clear process to confirm the accuracy of the information being posted *before* a physician's name or practice entity is publicly displayed.**

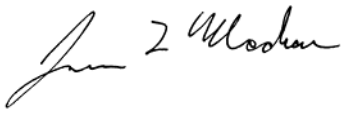
**Conclusion**

The AMA appreciates the opportunity to comment on proposals that will have a significant impact on our physician members. **We are most concerned that the proposed disincentives are not proportional to the severity of the underlying alleged misconduct and that physicians do not appear to have equal and meaningful appeal rights compared to other information blocking actors.** As physicians work on the front lines of care delivery and often bear the brunt of frustrations outside their control, physicians will likely continue to be the target of the vast majority of information blocking complaints by default, especially if patients do not know the EHR or other health IT system used related to their care. Small, rural, and safety net practices – which often serve some of America's most vulnerable communities – would also be particularly harmed by the imposition of additional financial hardships. As a result, **it is essential that HHS prioritize physician education and opportunity for corrective action over the imposition of harsh financial disincentives.** We also strongly urge the Agencies to **clarify the**

**significant open questions that remain about the proposed disincentives through supplemental notice-and-comment rulemaking** *before* any enforcement begins.

We are happy to discuss our comments and recommendations in more detail as the Agencies continue to develop information blocking policy. If you have any questions or need any additional information, please do not hesitate to contact Margaret Garikes, Vice President of Federal Affairs, at margaret.garikes@ama-assn.org. The AMA looks forward to working together with you and your staff to enhance health information sharing while ensuring that physicians are not subjected to harsh and arbitrary financial hardships that risk undermining progress and exacerbating existing inequities.

Sincerely,



James L. Madara, MD

cc: The Honorable Christi A. Grimm