January 2, 2024

The Honorable Micky Tripathi, Ph.D.
National Coordinator for Health Information Technology
Office of the National Coordinator for Health Information Technology
330 C Street SW, 7th Floor
Washington, DC 20201

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

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

Dear National Coordinator Tripathi and Administrator Brooks-LaSure:

On behalf of our member medical group practices, the Medical Group Management Association (MGMA) is pleased to provide the following comments in response to the Office of the National Coordinator for Health Information Technology's (ONC's) and Centers for Medicare and Medicaid Services' (CMS') proposed rulemaking on establishing disincentives for healthcare providers that have committed information blocking. MGMA appreciates the agencies' attention to information blocking as our members are dedicated to promoting interoperability and appropriately sharing health information to enhance patient care.

With a membership of more than 60,000 medical practice administrators, executives, and leaders, MGMA represents more than 15,000 group medical practices ranging from small private medical practices to large national health systems, representing more than 350,000 physicians. MGMA's diverse membership uniquely situates us to offer the following policy recommendations.

MGMA members are committed to utilizing health information technology (IT) to reduce administrative burden and advancing the provision of high-quality, cost-effective care. We have supported efforts to increase the flow of health information throughout this nation's health IT ecosystem and understand the potential for improvement that interoperability brings. While we recognize the need for ONC and CMS to establish appropriate disincentives for providers who commit information blocking under the *21st Century Cures Act*, we harbor significant concerns with the proposed rule and its impact on medical groups. MGMA offers the following recommendations to help support medical groups advance interoperability.

Key Recommendations

- **Utilize corrective action plans and education to effectively remedy information blocking allegations instead of significant financial penalties**. A corrective action process that allows for providers to rectify offending conduct would most efficiently promote interoperability without dissuading providers from participating in Medicare due to severe financial disincentives. Properly allowing providers to correct offending conduct by using education and guidance would best facilitate information sharing.
- **Institute an equitable and accessible appeals process for all providers.** A straightforward appeals process would allow providers wrongly accused of information blocking the due process considerations to address the situation without suffering considerable financial harm.
- **Do not institute punitive disincentives for providers participating in the Merit-based Incentive Payment System (MIPS) by zeroing out the promoting interoperability (PI) category.** The substantial administrative burden and difficulties medical groups face under the MIPS program will be exacerbated should the agencies move forward with this penalty.
- **Do not move forward with removing accountable care organizations (ACOs) and providers participating in ACOs from the Medicare Shared Savings Program (MSSP).** In addition to causing significant administrative and financial barriers, this proposal goes against the agencies' intention to promote value-based care and undermines providers ability to succeed in MSSP.
- **Increase transparency throughout the process and coordinate with other federal agencies to ensure there is a comprehensive strategy that would best promote information sharing by providing guidance and technical assistance to providers.** More clarity is needed about how the program operates, the applicability of exceptions, and how it intersects with state laws.

Use Corrective Action Plans and Education to Remedy Information Blocking

MGMA urges the agencies to consider the unintended consequences to its proposed approach for provider disincentives related to information blocking. As currently constructed, providers would be subject to potentially significant administrative and financial penalties if they are found to be information blocking. **Instituting a process using corrective action plans — similar to how CMS already uses them in other circumstances — would go a long way to preventing information blocking and accomplish the agencies' interoperability goals**.

Before any financial penalties may be levied, providers must understand the offending conduct and have the opportunity to correct any information blocking allegations. The terminology "appropriate disincentives" in the *21st Century Cures Act* contemplates a broader range of actions than just financial penalties, and there is precedent for the agencies using corrective action plans to great effect. The proposed rule discusses policies similar to corrective action plans in the MSSP disincentive section — we believe the agencies should follow this path and allow for remedial action prior to any financial penalty being applied.

Guidance and education would be invaluable not only to offending parties, but to prevent information blocking before it occurs. MGMA urges the agencies to provide clarity around the various facets of the information blocking regulations, scenarios when an exception would apply, and provide FAQs, technical resources, and other educational material to providers before any financial disincentives are implemented. Should the agencies move forward with the proposed rule without implementing a corrective action process, we ask for further rulemaking related to questions raised in this letter, or a delay on the effective date of enforcement to allow providers to understand the disincentive process.

Increase Transparency Throughout the Information Blocking Disincentive Process

The proposed rule reviews OIG's anticipated priorities related to information blocking investigations of healthcare providers while noting that it is for information purposes only and not a regulatory proposal. It goes on to discuss the recent OIG rule finalizing information blocking civil monetary penalties for health IT developers of certified health IT or other entities offering certified health IT, health information exchanges (HIEs), and health information networks (HINs). OIG expects to use four of the priorities laid out in that final rule: 1) resulted in, are causing, or have the potential to cause patients harm; 2) significantly impacted a provider's ability to care for patients; 3) were of long duration; and 4) caused financial loss to Federal health care program, or other government or private entities. Prior to making a referral, OIG will coordinate with the appropriate agency to which OIG plans to refer its determination of information blocking.

While we appreciate the discussion of OIG's investigation process, this section is not offered as a binding regulatory proposal. MGMA suggests OIG focus on allegations of information blocking that were intentional or done with actual knowledge given the complexity of the information blocking regulations and exceptions. Many instances of information blocking would likely result from providers attempting to comply or believing that an exception is applicable to their situation given the myriad considerations involved such as HIPAA privacy and security concerns. **Disincentives should be scaled based on severity of the information blocking, and mitigating factors should be taken into account during the investigation, as these regulations may disproportionately impact smaller or less-resourced practices.**

Increased transparency for this opaque process would be welcomed as providers would not receive notification of the information blocking complaint until after OIG has made a determination of information blocking and referred it to the appropriate agency to enforce penalties. Further, the way the current investigation process is set up will result in penalties being levied years after the offending conduct has occurred. Providers should have the opportunity to address information blocking allegations earlier in the process to avoid cascading negative impacts that would result from financial penalties that could have been avoided. This proposal further demonstrates the need for the use of corrective action plans that are more dynamic than the proposed rule.

MGMA recommends the Department of Health and Human Services maintain central oversight of all aspects of information blocking and coordinate actions between the different agencies. This would help prevent confusion and the dissemination of competing information from various agencies, and ensure uniformity in how the regulations are enforced. Lastly, we recommend that the investigation of information blocking claims begin with complaints received after the effective date of the final rule —this is how OIG structured its enforcement for health IT developers and we believe the same logic applies here.

Establish an Appropriate Appeals Process

The proposed rule states that healthcare providers "may have the right to appeal administratively a disincentive if the authority used to establish the disincentives provides for such an appeal." It then goes on to distinguish between the civil monetary penalties from health IT developers established under the *21st Century Cures Act* which had language about the appeals process from its proposal for providers. An ACO may be able to appeal the application of an information blocking disincentive, but the underlying information blocking determination made by OIG would not be subject to this reconsideration process.

MGMA urges ONC and CMS to ensure there is a fair and equitable appeals process available to all providers who may be accused of information blocking. Given the intricacy of the information blocking regulations, coupled with competing privacy laws, and the interaction of electronic health record (EHR) vendors, instituting a fair appeals process is essential to ensuring providers are afforded proper due process considerations.

This appeals process should be impartial and equally accessible to all providers despite the Medicare program they participate in and allow for a determination within a timely manner before any financial penalties may be imposed. Providers should be able to appeal both the determination of information blocking and the application of the disincentive. The agencies should look to their recent appeals process established for health IT developers, HINs, and HIEs, as well as other Medicare programs, to institute a fair process.

Proposed Merit-based Incentive Payment System (MIPS) Disincentives

The proposed rule establishes that a healthcare provider who is a MIPS eligible clinician would not be considered a meaningful EHR user in a performance period when OIG refers a determination that the clinician committed information blocking. CMS defines MIPS eligible clinicians as including groups and virtual groups. The MIPS eligible clinician, if required to report on the promoting interoperability (PI) performance category in MIPS, would receive a score of zero in PI performance category.

CMS will apply the proposed disincentive to the MIPS payment year associated with the calendar year in which OIG referred its determination to CMS. If data is submitted for the MIPS PI performance category at the group or virtual group level, then application of the disincentive would be made at the same level. The MIPS eligible clinician would be notified by CMS following referral from OIG after its investigation and determination.

By enforcing a penalty of zero points in the PI category, CMS is ensuring that groups participating in MIPS will likely receive a downward payment adjustment on their performance score. CMS initially proposed an increase to the 75-point MIPS performance threshold to 82 points for 2024. The agency estimated that a majority of MIPS eligible clinicians would receive a negative adjustment and ultimately decided to maintain the current 75-point performance threshold. At 75 points, a MIPS eligible clinician would automatically receive at minimum a neutral adjustment due to this policy if they have a perfect score in every other performance category; should the performance threshold increase in future years, this would result in an automatic negative adjustment.

Given the difficulty practices are currently seeing in their ability to avoid a negative adjustment due to the well-documented issues with MIPS, and the ever-changing nature of the program, this automatic adjustment is unnecessarily punitive and would diminish the financial resources available to practices. Medicare reimbursement is already not keeping up with inflation and costs, and practices face a 3.4% cut the conversion factor in 2024. Without significant change, this added financial penalty may dissuade groups from participating in Medicare, while amplifying the difficulties medical groups face reporting under MIPS.

The proposed rule doesn't distinguish between providers found to be information blocking within a group and those who may not have violated any information blocking rules. This proposal could end up harming innocent actors given the lack of differentiation in groups and virtual groups, and end up penalizing the whole group for the actions of potentially a single provider. In addition to disproportionately penalizing the group, this proposal may deter clinicians from joining groups or virtual groups due to the threat of

receiving a financial penalty for conduct outside of their control. We urge the agency not to move forward with this proposal in its current form.

Proposed Medicare Shared Savings Program (MSSP) Disincentives

CMS proposes to establish disincentives for healthcare providers that are an accountable care organization (ACO), ACO participant, or ACO provider/ supplier if the OIG determines they have committed information blocking. The offending provider would be barred from participating in the MSSP for at least one year and may be removed from an ACO or prevented from joining an ACO. For an ACO, this would prevent the ACO's participation in the program.

Removing ACOs, or providers participating in an ACO, from MSSP works against CMS' intention of having all Medicare beneficiaries in an accountable care relationship by 2030. There are myriad negative effects that would result from exclusion such as harming the ability of ACOs to leverage their infrastructure to reduce costs and improve care, damaging vital data collection, increased administrative and financial burdens, and more. **Excluding practices and ACOs from participating in MSSP runs counter to the transition to value-based care and undercuts the ability of providers within the ACO framework to succeed. MGMA urges the agencies not to move forward with its proposal as it would ultimately impact Medicare patients.**

There are ambiguities in the proposed rule as it is unclear how the exclusion of providers from MSSP would impact patient attribution and other MSSP regulations. It appears that exclusion would apply at the Taxpayer Identification Number (TIN) level and not the National Provider Identifier (NPI) level, thereby excluding the full practice for conduct from a single provider. If an ACO entity is found to be information blocking, it is uncertain how that will impact providers participating in that ACO — it appears that every provider be excluded from MSSP participation for a year, thereby penalizing providers for violations unrelated to their practice. These approaches are unnecessarily harsh and may dissuade providers from participating in MSSP.

Further, providers may potentially be subject to dual penalties if they participate in both MIPS and MSSP, thereby magnifying a negative financial impact that other providers would not be subject to. The agencies should clarify that providers reporting under MIPS and MSSP are not subject to excessive double penalties. (We have similar concerns about excessive penalties in the hospital and Critical Access Hospital disincentive proposal that ties the amount of the financial penalty to the volume of Medicare payment, not the severity of the information blocking conduct.) Excluding ACOs and providers from MSSP would likely occur years after the offending information blocking has happened, resulting in penalties for long-since halted conduct.

Viewed in totality, these concerns necessitate the establishment of a corrective action process to address information blocking. CMS contemplates an alternative disincentive policy where the agency would inform an ACO that remedial action could be taken before denying the addition of an ACO participant. The specific circumstances surrounding the information blocking allegation could be taken into account such as the provider's attempts to fix the alleged conduct, and other considerations. **We support the adoption of corrective action plans not only for MSSP disincentives but for all providers discussed in the proposed rule.**

Publicly Posting Information Blocking Offenders

ONC is proposing to publicly post on its website information about actors that have been found to commit information blocking after a penalty has been imposed. The agency would post the provider's name, business address, the practice found to have been information blocking, the disincentives applied, and where to find additional information. ONC believes this is needed to promote transparency about how information blocking is impacting the nation's health IT infrastructure.

Should ONC move forward with this provision, MGMA urges that any information not be publicly reported until providers have been able to avail themselves of an equitable appeals process. There should be a proper time limit on having this information publicly posted so that it is not indefinitely available for conduct that occurred many years in the past that may negatively impact the financial viability of providers. As discussed in the proposed rule, providers should have a chance to review any information prior to it being publicly posted to confirm its accuracy, especially in light of negative consequences that stem from erroneous information being made public. While MGMA supports transparency, as currently proposed, we have significant concerns about the public reporting of any information about information blocking offenders without significant adjustments to the proposed rule as detailed above.

Conclusion

MGMA thanks the agencies for their leadership and attention to information blocking. We urge the utilization of corrective action plans and education to best prevent information blocking while avoiding unintended consequences. If you have any questions, please contact James Haynes, associate director of government affairs, at jhaynes@mgma.org or 202-293-3450.

Sincerely,

/s/

Anders Gilberg
Senior Vice President, Government Affairs