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National Coordinator for Health Information Technology
Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services

Attention: RIN 0955-AA05
Submitted electronically to http://www.regulations.gov

RE: 21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking

Dear Administrator Brooks-LaSure:

The National Association of ACOs (NAACOS) appreciates the opportunity to submit comments in response to the proposed rule, 21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking. NAACOS represents more than 400 accountable care organizations (ACOs) in Medicare, Medicaid, and commercial insurance working on behalf of health systems and physician provider organizations across the nation to improve quality of care for patients and reduce health care cost. NAACOS members serve over 9 million beneficiaries in Medicare value-based payment models, including the Medicare Shared Savings Program (MSSP) and the ACO Realizing Equity, Access, and Community Health (REACH) Model, among other alternative payment models (APMs).

A critical component of participation in value-based care models is the ability to share data to better coordinate a patient's care. Therefore, ACOs already have a strong incentive to share data and report information blocking as it represents an obstacle to an ACO's success. NAACOS is concerned with the proposal to prohibit participation in the MSSP as a disincentive for health care providers that have committed information blocking. Value-based care models are meant to improve care for patients through better coordinated, high quality care. Imposing penalties that prohibit participation in these models is counterintuitive and penalizes patients. Any approach that prohibits participation in value-based care is overly punitive and inappropriate. Our comments below reflect concerns of our members and our shared goals to increase quality and lower costs for Medicare patients.

Key Recommendations

NAACOS recommends the Centers for Medicare and Medicaid Services (CMS) and the Office of the National Coordinator for Health IT (ONC):

- Do not apply penalties that prohibit participation in value-based care models. Instead, CMS and ONC should look to ACOs as partners in advancing interoperability and assisting in identifying and remediating cases of information blocking.
- When information blocking is found to have taken place, CMS and ONC should apply a Corrective Action Plan rather than imposing financial penalties.
- CMS and ONC should focus first on establishing a joint CMS-ONC educational campaign to increase awareness among health care providers in regard to what constitutes information blocking.
- CMS and ONC should avoid double penalizing health care providers found to have committed information blocking. Applying multiple penalties is duplicative, overly punitive and will create undue confusion and complexity.
- CMS and ONC must more clearly outline the appeals rights of ACOs and the clinicians in an ACO, which should be aligned with those afforded to health IT developers and vendors.

Information Blocking Penalties for Medicare Shared Savings Program (MSSP) ACOs

CMS and ONC's proposals implementing provisions of the 21st Century Cures Act to create disincentives for health care providers committing information blocking are overly punitive, duplicative and have the unintended consequence of diminishing ACOs' efforts to improve patient care. CMS and ONC propose ACOs who are health care providers as well as ACO providers/suppliers who are engaged in information blocking would be removed from or denied approval to participate in the MSSP. CMS and ONC also propose other additional penalties for clinicians and hospitals who are engaged in information blocking. **NAACOS strongly opposes any penalty approach that prohibits participation in value-based care models**. CMS and ONC should instead see ACOs as partners in identifying instances of information blocking and help flag instances of information blocking for ACOs to remediate. A critical component of participation and success in value-based care models is the ability to share data to better coordinate a patient's care. Therefore, ACOs already have a strong incentive to share data and report information blocking, as it represents an obstacle to an ACO's success. Imposing penalties that prohibit participation in value-based care models is counterintuitive and penalizes patients. CMS and ONC should look to ACOs as partners in advancing interoperability and assisting in identifying and remediating cases of information blocking.

Rather than imposing financial penalties, CMS and ONC should apply a Corrective Action Plan when information blocking is found to have taken place. There is very little understanding currently regarding the definition of information blocking and the eight defined exemptions. As described in more detail below, more education should be done first before moving to a penalty phase. CMS and ONC note in the proposed rule, that if the ACO reapplies for participation in the MSSP in a subsequent year it was found to have committed information blocking, CMS will review whether the Office of Inspector General (OIG) had any subsequent determinations of information blocking, as well as any evidence that indicated whether the issue had been corrected and appropriate safeguards had been put in place to prevent reoccurrence, as part of the application process. This is an approach that should be used initially in all cases of information blocking, as it allows for consideration of the frequency, severity and intent of the information blocking action(s) and allows for remediation.

Further, as proposed CMS and ONC would be applying multiple duplicative penalties to clinicians in ACOs, this is overly punitive and will create undue confusion and complexity. CMS could penalize an individual clinician in multiple ways, such as through the individual penalties aimed at their Merit-Based Incentive Payment System (MIPS) Promoting Interoperability score and in addition through their

participation in the MSSP. Additionally, it is not clear how CMS would implement the proposed penalties for MSSP ACOs given the full Tax Identification Number (TIN) participation requirements of the program. For example, if an individual clinician was found to be information blocking and therefore prohibited from participation in the MSSP, it is not clear how CMS and the ACO would be able to remove a single clinician from participation. Instead, CMS would need to prohibit participation of the full TIN, or group practice, based on the actions of one clinician. This approach is overly punitive and will reduce the number of clinicians participating in value-based care models. Likewise, the ACO Entity would not be the entity involved in information blocking, therefore it would be inappropriate to prohibit an entire ACO from participation in a value-based care model based on the actions of an individual.

We recommend that CMS and ONC only apply fines at the individual clinician/group levels, rather than the ACO entity. This would allow CMS to utilize the MIPS and PI penalties as currently proposed, without creating a duplicative penalty. For those clinicians in advanced APMs who are exempt from MIPS and PI (i.e., qualified professionals or QPs), CMS should consider penalties that reduce the advanced APM incentive payment or higher conversion factor that is awarded to these clinicians. The amount of the fine to the advanced APM incentive or higher conversion factor should be comparable to the fines clinicians receive under MIPS.

Further, as proposed CMS and ONC also note all health care providers and ACOs may also meet the definition of a health information network or health information exchange, or the definition of a health IT developer of certified health IT. If it is found by OIG that the health care provider or entity (such as an ACO) meets either definition, then they would be subject to a different intent standard and civil monetary penalties would be administered by the OIG (88 FR 42828). CMS and ONC must do more education across the health care industry to ensure clinicians, ACOs and health IT developers and vendors have a clear understanding of these expectations.

Education

The Cures Act was designed to accelerate the discovery, development, and delivery of 21st Century cures. Section 3022(a)(1) of the Public Health Service Act (PHSA) defines information blocking as a practice, that except as required by law or specified by the Secretary pursuant to rulemaking, is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information. To date there has been little education for providers and the health care industry at large as to what constitutes information blocking and what real world scenarios may fall into one of the eight established exclusions. **CMS and ONC should focus first on establishing a joint CMS-ONC educational campaign to increase awareness among health care providers in regard to what constitutes information blocking**.

There has been little outreach and education to clinicians and ACOs regarding what real world examples constitute information blocking, both for health IT developers and vendors as well as health care clinicians. CMS and ONC must first focus on education and communication of real-world examples and actions that would be deemed to be information blocking before moving to a penalty implementation phase. ACOs still lack an understanding of whether and how they should report information blocking for health IT developers and vendors, indicating there is more to be done before moving enforcement focus to health care providers. Further, CMS and ONC should provide more detailed information about the information blocking reporting that has taken place thus far as currently there is very limited summary information available.

Appeals

An ACO may be able to appeal the application of an information blocking distinctive in the MSSP, if not prohibited from administrative or judicial review under 42 CFR 425.800, by requesting a reconsideration review by CMS. **CMS and ONC must more clearly outline the appeals rights of ACOs and the clinicians in an ACO, which should be aligned with those afforded to health IT developers and vendors.** The proposed rule briefly discusses the OIG enforcement priorities for implementing this rule, however this is lacking key details regarding the process and the opportunities for ACOs and clinicians to dispute and/or discuss the key aspects of the investigation including whether and how an exception did or did not apply. This should be aligned with requirements for health IT developers and vendors who have appeals rights when a determination of information blocking has been made. We urge CMS and ONC to clearly articulate the appeals process that will be afforded to clinicians and ACOs.

CONCLUSION

Thank you for the opportunity to provide feedback on the proposed rule, 21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking. NAACOS and its members are committed to providing the highest quality care for patients while advancing population health goals for the communities they serve. We look forward to our continued engagement on advancing interoperability to ensure patients can receive high quality, coordinated care. If you have any questions, please contact Aisha Pittman, senior vice president, government affairs at aisha_pittman@naacos.com.

Sincerely,

Clif Gaus, Sc.D.
President and CEO
NAACOS