December 13, 2023

Administrator Chiquita Brooks-LaSure
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

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

Re: RIN 0955–AA05

Dear Administrator Brooks-LaSure and Coordinator Tripathi,

On behalf of the CARIN Alliance, we want to thank you for providing the opportunity to comment on your joint rule regarding the establishment of disincentives for Providers committing Information Blocking. As you know, consumer access to information has long been a bipartisan priority for Congress and multiple administrations. We appreciate the ongoing work you have done to facilitate consumer access to information.

As you are aware, the CARIN Alliance is a multi-sector group of stakeholders representing numerous hospitals, thousands of physicians, and millions of consumers and caregivers. We are committed to providing consumers and their authorized caregivers access to health information. Specifically, we are promoting the ability for consumers and their authorized caregivers to gain digital access to their health information via the open APIs and the ability to use that information in any third-party application they choose.

Again, we appreciate your consideration of our comments. Please do not hesitate in contacting me if you have any further questions.

Ryan Howells
Leavitt Partners
On behalf of the CARIN Alliance

Applicability

CMS and ONC propose to establish disincentives for some health care providers that are engaged in patient care across the country. Impacted providers are limited, however, to those participating in various Medicare-related programs. Providers included in this regulation include hospitals and Critical Access Hospitals (CAHs) engaged in the Promoting Interoperability Program (PIP), clinicians participating in the Merit-based Incentive Payment System (MIPS), and organizations participating in the Medicare Shared Savings Program (MSSP). Penalties across the programs range from reductions in payment to expulsion from the MSSP.

While CARIN is supportive of the intent from CMS and ONC to cast a wide net for disincentives, and to provide appropriate disincentives across regulated programs, we are concerned that numerous providers that do not engage in these Medicare programs are not included in this proposed rule. We also are concerned that various provider types (*e.g.*, labs, pharmacies, and ambulance service providers) are not included in this rule. While recognizing the limitations that CMS and ONC may have within the PIP, MIPS, and MSSP programs, and the stated goal to conduct future rulemaking, we encourage the agencies to expand their vision and consider ways of expanding the reach of this rule to ensure that consumers or other health care actors are not denied access to information that they need simply because the data source they are seeking does not participate in these programs.

This rule will have great benefit to Medicare beneficiaries, but CARIN is concerned that other patient populations will be disadvantaged if providers subject to disincentives are limited to those engaged in the Medicare program. When Congress passed the *21st Century Cures Act*, we believe they intended for all providers to be subject to information blocking disincentives. Congress wanted, and we support the desire for, information to flow freely between providers and from providers to consumers. This intention was not limited to Medicare providers or for consumers who happen to be Medicare beneficiaries. Consumers are now often using various insurance products or engaging with providers that are exclusively cash-pay. CARIN believes all providers should be subject to disincentives for information blocking and that all consumers deserve access to their information. We again encourage CMS and ONC to consider additional mechanisms for establishing disincentives for providers that do not participate in these Medicare programs.

Enforcement Prioritization

In this proposed rule, ONC and CMS note the expertise that the Office of the Inspector General (OIG) within HHS has in pursuing intent-based infractions across HHS programs and the further expertise that exists within OIG to prioritize investigations of actors who are committing information blocking infractions. CARIN agrees with ONC and CMS that OIG has extensive expertise in investigations and that current civil monetary penalty regulations and guidance are useful in understanding how OIG will prioritize various enforcement activities.

Lack of Transparency into the Information Blocking complaint resolution process

CARIN is also concerned about the lack of transparency and significant length of time we believe it will take to enforce an information blocking complaint. As we note below, we have several questions about this process, which we encourage CMS, ONC, and OIG to clarify. However, we

believe, from reading the regulations, the steps for enforcing information blocking complaints and levying a fine against someone who is deemed an information blocker roughly include the following steps:

1. Information blocking complaints are initially reported to ONC on their website.
2. The ONC investigates and refers the complaints that appear to merit further investigation on to the OIG.
3. The OIG then makes a decision as to which complaints are worth pursuing and opens an investigation.
    - How long does this process take?
    - What criteria does the OIG use to determine which complaints are worthwhile pursuing and which ones are not? Will that information be made public to inform future complaint submissions?
    - How will the public be informed if OIG takes a different approach/enforcement decision than ONC recommends?
4. OIG then completes their investigation, renders a judgement, and if OIG believes the entity was engaged in information blocking, they will refer the case to CMS to levy a monetary penalty.
    - How long does this process take?
    - How will the public know once an OIG inquiry is complete?
    - Where will OIG refer those complaints to within CMS?
5. If the entity desires to appeal, CMS (or OIG?) allows for the appeals process to occur.
    - Which entity will handle an appeal?
    - How long could the appeals process take?
    - How will the public know once the appeals process is complete?
6. Once the appeals process is complete, a monetary injunction is levied.
    - Is this the only time the public will know the results of the various government agencies investigations and the fine levied?
    - How long will this entire process take? It appears to the CARIN community it could take years but hopefully that's not the case.

CARIN strongly believes this process is onerous, non-transparent, and lengthy especially in situations where entities are clearly and repeatedly performing actions that are deemed to be information blocking. We would strongly encourage ONC, OIG, and CMS to be more transparent in providing specifics to the public on how the complaints will be handled to ensure stakeholders have transparency into knowing where their complaint is in the process and when they should expect a final decision. Without public transparency into the process, stakeholders, including the public, will never understand if complaints they have lodged are being acted upon.

Need to develop a 'Complaint Clearinghouse' for providers and payers

In addition, we have heard feedback from providers and payers they are very hesitant to lodge complaints against each other (even if it is done anonymously) because of their concern over

retaliation, retribution, or at a minimum, that it will impose harm to their business relationship. Single complaints, even if submitted anonymously, can be tied back to the submitter, and cause undue harm to a working business relationship. Therefore, the providers and payers in the CARIN community believe it will be highly unlikely they will be submitting individual complaints themselves. Current published ONC metrics[1] show that out of 923 complaints filed, over 754 (82%) were filed by patients, on behalf of patients, or by an attorney rather than filed by providers or payers themselves.

We believe a solution to this problem is for ONC to allow for **'complaint clearinghouses'** to exist where providers or payers can send in their complaints to an independent, private sector third party who would aggregate those complaints over time. Once there are enough complaints against a specific bad actor to eliminate attribution to any one organization, those complaints can be aggregated and submitted together as a group to the ONC or other federal agency, thus helping to ensure the complaints are unattributed to specific business working relationships. We believe doing this will help providers and payers submit more examples of where information blocking exists in health care. This process would need to be in addition to, not as a replacement for, the current submission process. It would also need to be specific enough to address the details of the information blocking behavior that needs to be changed. The complaint clearinghouse process would also need to show a pattern of information blocking over time like what the current process requires. Finally, the complaint clearinghouse model needs to ensure the entity who is in the role of the complaint clearinghouse is authorized to act for and on behalf of the organizations who are reporting complaints to them.

We continue to encourage CMS and ONC to continue to work with the Office for Civil Rights (OCR) within HHS and with OIG to ensure that instances where a HIPAA Covered Entity or a regulated provider under the information blocking regulations is not providing timely access to consumers are pursued and that appropriate penalties are pursued. As noted above, one of the primary goals of the Congress in passing the *21st Century Cures Act* was to guarantee that individuals could create and access a longitudinal health record for their personal use. Ensuring that limited enforcement resources are used to press this consumer right is critical.

Technical Nonconformance as Information Blocking

We've heard feedback from application developers that adoption of open APIs has been hampered by these API's lack of technical conformance with the published implementation guides. This results in additional work and delay on behalf of the application developers to handle these poorly-implemented APIs, which, in turn, results in greater barriers to adoption by consumers and their authorized caregivers. While this type of nonconformance is likely not intentional in most cases, it nonetheless has a similar impact as other types of information blocking, and providers and payers do not have strong incentives to fix these issues once their initial APIs have been deployed.

[1] SOURCE: https://www.healthit.gov/data/quickstats/information-blocking-claims-numbers; Information current as of 12/7/2023

We encourage ONC and CMS to consider ways to hold providers, payers, and technology vendors accountable not only for providing an open API per the current rules, but also ensuring that these APIs are compliant with the published implementation guides. For example, encouraging voluntary use of Inferno and Lantern could highlight the providers and payers who are already conformant. Evaluation via Lantern could be improved through the adoption of a standard "test patient" that every provider and payer could deploy in a test account to enable more consistent results from this type of evaluation.

Conclusion

Again, CARIN thanks ONC and CMS for their ongoing work to advance data interoperability, data mobility, and consumer access to information. Your work over the last several years is critical to advancing care coordination, consumerization, and cost reduction in the health care system.