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Submitted electronically via: www.regulations.gov

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

The Honorable Micky Tripathi
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 St SW
Floor 7
Washington, DC 20201

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

Dear Administrator Brooks-LaSure and Dr. Tripathi,

Vizient, Inc. appreciates the opportunity to comment on the proposed rule entitled "21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking" (hereinafter, "Proposed Rule") issued by the Centers for Medicare and Medicaid Services (CMS) and the Office of the National Coordinator for Health Information Technology (ONC) at the Department of Health and Human Services (HHS). Many of the proposed policies have a significant impact on our members and the patients they serve, and we urge ONC and CMS to refrain from finalizing the Proposed Rule, as the disincentives proposed are excessive. We encourage CMS, ONC and the Office of the Inspector General (OIG) to provide additional clarity regarding several policies under consideration.

Background

Vizient, Inc. provides solutions and services that improve the delivery of high-value care by aligning cost, quality, and market performance for more than 60% of the nation's acute care providers, which includes 97% of the nation's academic medical centers, and more than 20% of ambulatory providers. Vizient provides expertise, analytics, and advisory services, as well as a contract portfolio that represents more than $130 billion in annual purchasing volume, to improve patient outcomes and lower costs. Headquartered in Irving, Texas, Vizient has offices throughout the United States.

Recommendations

Vizient applauds ONC for its ongoing efforts to promote interoperability, support advancements in the use of health information technology, and prevent information blocking, which can significantly impact a patient's healthcare experience. Vizient remains committed to working with providers to support their utilization of health information technology to provide high-quality care for their patients. As this Proposed Rule builds on prior regulation related to information blocking, Vizient appreciates CMS and ONC's acknowledgement of various stakeholder feedback throughout the process. Vizient is concerned, however, that the proposed disincentives are excessive, particularly given the limited information available regarding the enforcement process.

Further, ONC has multiple regulations in various stages of the rulemaking cycle related to information blocking,[1] as well as a Request for Information (RFI) in the Proposed Rule that will inform future rulemaking related directly to disincentives for healthcare providers. In addition, within the Proposed Rule, there are several statements related to the OIG's expected prioritization of practices for enforcement and OIG is soliciting comments. Yet, it is unclear whether the Proposed Rule is the avenue through which OIG is soliciting comments, since OIG is not listed as an agency like in other OIG-initiated rulemaking related to information blocking, or whether additional opportunities for comment are forthcoming.[2,3] As a result of these uncertainties, in addition to the concerns noted above, Vizient recommends CMS refrain from finalizing the Proposed Rule. Instead, Vizient encourages ONC to consider stakeholder feedback regarding the Proposed Rule's RFI and to work with OIG to better clarify stakeholder opportunities to comment on future regulations or guidance related to information blocking.

Proposed Disincentives for Information Blocking

CMS and ONC propose to use three existing mechanisms to disincentivize information blocking among healthcare providers. The agencies note that these mechanisms will not reach all healthcare providers, but CMS and ONC believe that these programs provide appropriate and relevant activities to promote information sharing. As detailed below, Vizient has concerns with all of the proposed disincentives because the financial harm is excessive and would negatively impact patient access to care.

Disincentivizing Information Blocking through the Meaningful Use of Electronic Health Record (EHR) in the Medicare Promoting Interoperability Program
CMS proposes to revise the definition of "Meaningful EHR User" to provide that an eligible hospital is not a meaningful EHR user in an EHR reporting period if OIG refers to an appropriate agency, during the calendar year of the reporting period, a determination that the eligible hospital committed information blocking. This would result in a reduced payment for facilities paid under the inpatient prospective payment system (IPPS) by reducing payments by three quarters of the annual market basket update applied to the payment year that occurs two years after the year in which the OIG determination is made.[4]

As hospitals continue to face financial difficulties, workforce challenges, and increasing expenses, a loss of 75% of the market basket update for IPPS payments would have a substantial effect on hospitals' financials that might impact their ability to be fully operational. As noted in the Proposed Rule, some penalties would be approximately $2.4 million, which is $1.4 million above the civil monetary penalty (CMP) finalized by OIG[5] for information blocking by health information technology (IT) providers, health information exchanges, health information networks and vendors

[1] See final rules https://www.federalregister.gov/documents/2023/07/03/2023-13851/grants-contracts-and-other-agreements-fraud-and-abuse-information-blocking-office-of-inspector; https://www.federalregister.gov/documents/2020/05/01/2020-07419/21st-century-cures-act-interoperability-information-blocking-and-the-onc-health-it-certification. See rules pending review https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202310&RIN=0955-AA03.
[2] *See* https://www.federalregister.gov/documents/2023/07/03/2023-13851/grants-contracts-and-other-agreements-fraud-and-abuse-information-blocking-office-of-inspector which lists the Agency as "Office of Inspector General (OIG), Department of Health and Human Services (HHS)."
[3] The Proposed Rule indicates, "The following information regarding OIG's anticipated approach to information blocking investigations of health care providers is not a regulatory proposal and is provided for information purposes only. This preamble discussion of investigation priorities for health care provider information blocking claims is not binding on OIG and HHS. It does not impose any legal restrictions related to OIG's discretion to choose which health care provider information blocking complaints to investigate.", *available at:* https://www.federalregister.gov/d/2023-24068/p-83
[4] CMS projects that the median disincentive amount under this proposal would be $394,353. CMS also states that the market basket decrease would be larger in dollar terms for hospitals with greater base IPPS payments.
[5] https://www.federalregister.gov/documents/2023/07/03/2023-13851/grants-contracts-and-other-agreements-fraud-and-abuse-information-blocking-office-of-inspector

(collectively, “other actors”). Given hospitals could have financial penalties far exceeding other actors’ information blocking CMPs, Vizient believes the proposed disincentive for hospitals paid under IPPS is excessive and could negatively impact patient access to care.

Additionally, the delay in the application of penalties creates operational challenges. Under this proposal, a payment reduction may not occur for several years after a complaint is made to OIG, placing a hospital in a constant state of uncertainty regarding future anticipated payments, as penalties could be imposed at any given time and without the opportunity for an appeal. Vizient recommends CMS and ONC identify disincentives that would help ensure hospitals more promptly correct the behavior that led to the information blocking finding.

Disincentivizing Information Blocking through the Medicare Shared Savings Program
CMS proposes to disincentivize information blocking by denying an Accountable Care Organization (ACO) determined to have committed information blocking from the Medicare Shared Savings Program (MSSP) for at least one performance year. However, the Proposed Rule includes an alternative proposal where CMS would not apply a disincentive in certain circumstances, despite an OIG determination that information blocking occurred. In this scenario, CMS would consider OIG’s determination in light of the facts and circumstances surrounding the nature of the provider’s information blocking, including the provider’s diligence in identifying and correcting the problem, the time since the information blocking occurred, the time since OIG’s determination of information blocking, and other factors. Vizient agrees with the need for CMS to have flexibility regarding the imposition of a disincentive based on the circumstances and we believe this flexibility should exist for all proposed disincentives.

Also, under proposals related to MSSP, an ACO would be able to appeal the termination decision through the existing regulations for ACO termination but would not be able to appeal the determination of information blocking, which may be relevant to any future program integrity analyses CMS performs. Again, Vizient reiterates our suggestion that CMS and ONC work with OIG to develop an appeals process for the initial information blocking determination, in addition to allowing appeals through existing regulations.

Vizient is also concerned about the potential impact to an ACO, and beneficiaries assigned to that ACO, should providers and facilities within an ACO be ineligible to participate in MSSP. Given ACOs’ aim to ultimately benefit patients while lowering costs, Vizient is concerned this proposed policy is unnecessarily burdensome and would harm patients who benefit from more coordinated and better-quality care. We urge CMS to refrain from finalizing this potential disincentive, as it is excessive and would negatively impact patients.

Disincentivizing Information Blocking through the Merit-Based Incentive Payment System (MIPS) Performance Improvement Score
CMS and ONC propose that MIPS eligible clinicians and groups that OIG determines committed information blocking would not be considered meaningful EHR users for that performance period. This would result in the clinician or group receiving a zero score in the Promoting Interoperability (PI) performance category, which is typically a quarter of the total final score, potentially resulting in either a neutral or negative payment adjustment.[6]

[6] The total points for a MIPS payment year can vary based on the year. For example, the performance threshold for the 2026 MIPS payment year is 82 points. If a clinician was determined to have committed information blocking for the 2026 MIPS payment year, the most points the clinician could receive would be 75, resulting in an automatic negative payment adjustment even with perfect scores in the other three categories. If CMS finalizes a performance threshold at 75 points, the highest possible score would result in a neutral payment adjustment in years where the performance threshold is above 75.

Vizient has several concerns about the application of this policy to the MIPS program. In the Proposed Rule, CMS and ONC indicate that the disincentive applies only to MIPS eligible clinicians participating in Traditional MIPS and does not reference MIPS Value Pathways (MVPs),[7] which CMS is utilizing and developing as it plans to sunset traditional MIPS. The Proposed Rule also does not clarify what would happen to those MIPS eligible clinicians who transition from traditional MIPS to MVPs sometime during the OIG investigation or whether penalties would be imposed given different participation options within the MVPs. Vizient is concerned that this policy overlooks the current landscape of the MIPS and MVP programs and would lead to unnecessary confusion and implementation challenges if finalized.

Additionally, the Proposed Rule notes that disincentives can be applied at the individual clinician level or at the group and virtual group level. Vizient is concerned that the penalties at the group or virtual group level would unfairly impact clinicians, including those working in large groups that could be penalized for actions beyond their control. Further, the Proposed Rule does not outline how decisions would be made regarding the level to penalize, particularly as participation may change over time. These operational issues are another reason why CMS and ONC should consider disincentives other than those proposed.

Selection of Disincentive

Finally, Vizient recommends CMS and ONC clarify how and which entities (e.g., ONC, CMS, or OIG) determine disincentives for a given case of information blocking. The Proposed Rule states that "[d]uring an investigation of information blocking by a health care provider, but prior to making a referral, OIG will coordinate with the appropriate agency to which OIG plans to refer its determination of information blocking… Once OIG has concluded its investigation and is prepared to make a referral, it will send information to the appropriate agency indicating that the referral is made."[8] Based on this information, it is unclear whether OIG will be determining which disincentive will be applied or if CMS or another agency would have this authority. For example, if OIG receives a complaint that a provider engaged in information blocking and that this provider participated in an ACO, would the scope of OIG's investigation potentially be expanded to include the ACO or other ACO participants? Also, would OIG's referral to multiple groups within CMS or ONC prompt multiple penalties or would a single referral be made to CMS for a more coordinated approach to select disincentives based on circumstances of the referral? Vizient encourages clarification regarding how disincentives will be selected, as this information could also impact stakeholder perspectives regarding the appropriateness of the proposed disincentives.

Appeals for Disincentives

In any proposal for disincentives, Vizient urges CMS and ONC to include processes for hospitals and other providers to appeal the application of a disincentive. As drafted, the Proposed Rule does not consistently provide an appeals process for the disincentives contemplated, but does clarify an appeals process would exist under the MSSP disincentive. Given that OIG's enforcement priorities remain unclear and that there is limited information currently available regarding information blocking violations, Vizient believes providers should be able to appeal their disincentives to CMS and ONC.

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[7] "However, for a given performance period/MIPS payment year, a MIPS eligible clinician does not include an eligible clinician who meets one of the exclusions set forth in 42 CFR 414.1310(b), including being a Qualifying APM participant, Partial Qualifying APM Participant that does not elect to participate in MIPS, or does not exceed the low volume threshold (as these terms are defined in 42 CFR 414.1305)." See Proposed Rule.

[8] https://www.federalregister.gov/documents/2023/11/01/2023-24068/21st-century-cures-act-establishment-of-disincentives-for-health-care-providers-that-have-committed

Notice and Public Posting After a Determination of Information Blocking

CMS proposes to publicly post information on all actors determined to have committed information blocking on the ONC website, including information about the type of information blocking, the actors involved, and any settlements or liability. Vizient notes that this public posting also serves as a disincentive against information blocking, yet it is unclear if ONC and CMS recognize this action as a disincentive. Thus, should the proposal for public posting be retained, we suggest that it be considered a disincentive.

Timeline and Investigation Procedure for Imposition of Penalties

Across all three proposed disincentives, CMS notes that penalties will not be issued in the year in which the complaint is made, but instead the penalty will be based on the year in which the OIG determination is made, and payments will be adjusted based off that performance year.[9] Based on these proposals, there is no projected or specified timeline in which OIG is required to investigate and make a determination of information blocking. Unlike the rules related to CMPs for information blocking, which specify that OIG must make a determination of information blocking within six years of the complaint, the Proposed Rule does not include details regarding a timeline or procedure for OIG to investigate and make a determination of information blocking. The Proposed Rule provides additional detail about the process by which a health care provider that has committed information blocking would be subject to appropriate disincentives, but CMS also notes that nothing in the Proposed Rule outlining this process constitutes a regulatory proposal, creating more confusion and uncertainty.[10] Vizient urges CMS not to finalize policies related to the imposition of substantial financial disincentives without ensuring that OIG's process and procedure for investigations – including the establishment of a timeline for investigations and an appeals process – is concurrently established.

Vizient also recommends that HHS periodically review the data from the information blocking complaints and aggregate data on the complaints and OIG determinations of information blocking. Such information will help stakeholders identify areas for improvement and may help inform future guidance regarding OIG enforcement priorities.

Process for Appeals of a Determination of Information Blocking

Vizient is also concerned that there is no procedure for appealing a determination of information blocking outlined in the Proposed Rule. Neither the Proposed Rule or Final Rule for investigation of information blocking claims provides an appeals process for providers through OIG or HHS once an information blocking determination is made. Vizient is concerned that providers will not be afforded the opportunity to defend or explain their actions if accused of information blocking or once an information blocking determination is initially made by OIG. Vizient believes this information should be clarified as it could impact comments on appropriate disincentives.

Additionally, it appears that under current regulations, an appeals process exists for the imposition of CMPs, as well as through the existing administrative process for appealing a termination of an

[9] Each of the relevant timelines is specific to how payments are made under the guidelines of the program in question, which vary from each other.

[10] The Proposed Rule indicates, "The following information regarding OIG's anticipated approach to information blocking investigations of health care providers is not a regulatory proposal and is provided for information purposes only. This preamble discussion of investigation priorities for health care provider information blocking claims is not binding on OIG and HHS. It does not impose any legal restrictions related to OIG's discretion to choose which health care provider information blocking complaints to investigate.", *available at:* https://www.federalregister.gov/d/2023-24068/p-83

MSSP. While Vizient supports CMS adopting processes that are familiar to facilities, Vizient is concerned that because there is no existing mechanism for administrative appeal of a zero score under the MIPS program or a revocation of a hospital's meaningful EHR use classification, the disincentives applied to providers and facilities under these programs would not be equitable with other penalties for information blocking.

Conclusion

Vizient membership includes a wide variety of hospitals ranging from independent, community-based hospitals to large, integrated health care systems that serve acute and non-acute care needs. Additionally, many are specialized, including academic medical centers and pediatric facilities. Individually, our members are integral partners in their local communities, and many are ranked among the nation's top health care providers. In closing, on behalf of Vizient, I would like to thank CMS and ONC for providing us the opportunity to comment on this important Proposed Rule. Please feel free to contact me, or Emily Jones at Emily.Jones@vizientinc.com, if you have any questions or if Vizient may provide any assistance as you consider these recommendations.

Respectfully submitted,

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