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United States Senate

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS WASHINGTON, DC 20510-6300

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July 10, 2024

VIA ELECTRONIC TRANSMISSION

The Honorable Christi A. Grimm Inspector General U.S. Department of Health and Human Services 330 Independence Avenue, S.W. Washington, D.C. 20201

The Honorable Micky Tripathi
National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
330 C Street SW, Floor 7
Washington, D.C. 20201

Dear Inspector General Grimm and Dr. Tripathi:

Congress directed the Office of the National Coordinator for Health Information Technology (ONC) in the 21st Century Cures Act to publish rules to prohibit health data information blocking. The purpose of the prohibition is to facilitate unimpeded exchange of health information, improving interoperability of electronic health records and enabling better care coordination and outcomes. Congress also directed the Office of Inspector General (OIG) of the Department of Health and Human Services (HHS) to implement an enforcement framework for the prohibition. Eight years later, we still receive reports of information blocking.

OIG did not issue a proposed rule outlining information blocking enforcement until 2021 and did not finalize this proposed rule until July 2023. Further, a proposed rule to prohibit information blocking by providers was only published last month. Despite this multi-year delay, ONC has received 1,052 claims of information blocking, 982 were found to be potentially valid claims. ONC, however, has not provided information around the alleged conduct identified or how these claims have been resolved.

¹ *Information Blocking Claims: By the Numbers*, Office of the National Coordinator for Health Information Technology (May 2024), https://www.healthit.gov/data/quickstats/information-blocking-claims-numbers.

It is imperative that the Administration fully implement the statutory prohibition on information blocking that Congress established in 2016. Without data, we cannot have an informed patient population, find cures, or drive down costs – the goals of the law we passed nearly a decade ago.

This process has taken years to implement and it is still not clear whether OIG and ONC's actions have actually reduced cases of information blocking. To that end, I ask that you answer the following questions on a question-by-question basis by <u>July 24, 2024</u>:

- 1. How do ONC and OIG conduct audits and monitor compliance with the information blocking prohibition?
- 2. Please provide detailed examples of any enforcement actions taken by OIG, including any penalties imposed or corrective measures required?
- 3. How does OIG prioritize which cases to investigate, and what criteria are used to determine the severity of information blocking violations?
- 4. OIG's enforcement of the information blocking prohibition by health information technology (IT) developers, health information exchanges (HIEs), and health information networks (HINs) became effective on September 1, 2023. How is OIG working with ONC to determine whether allegations of information blocking prior to that date are investigated using other authorities OIG may have?
- 5. In its final rule, OIG did not specifically outline penalty amounts for certain levels of conduct, instead relying on, "facts and circumstances that must be assessed individually." Why did OIG take this approach to assessing fines and how will it provide clarity to impacted entities about how individual fines are calculated?
- 6. How does OIG take ONC's Frequently Asked Questions (FAQs) guidelines into consideration when evaluating allegations of information blocking?³
- 7. What educational resources do ONC and OIG plan to provide to entities subject to the information blocking prohibition to ensure clarity about compliance? How will ONC and OIG coordinate to ensure consistency in these materials? How will ONC and OIG collaborate with other agencies, specifically CMS?
- 8. What metrics are used to evaluate the effectiveness of the current information blocking regulations in improving interoperability and patient care?

² Grants, Contracts, and Other Agreements: Fraud and Abuse; Information Blocking; Office of Inspector General's Civil Money Penalty Rules, Office of Inspector General (July 3, 2023), https://www.govinfo.gov/content/pkg/FR-2023-07-03/pdf/2023-13851.pdf, Page 42823.

^{2023-07-03/}pdf/2023-13851.pdf, Page 42823.

³ See Frequently Asked Questions, Office of the National Coordinator for Health Information Technology, https://www.healthit.gov/fags.

Sincerely,

Bill Cassidy, M.D.
Ranking Member

U.S. Senate Committee on Health,