HL7® International

June 23, 2020

Aaron S. Zajic
Office of Inspector General
Department of Health and Human Services
Attention: OIG-2605-P
Cohen Building
330 Independence Avenue, SW, Room 5527
Washington, DC 20201

Re: Proposed Rule on Grants, Contracts, and Other Agreements: Fraud and Abuse; Information Blocking; Office of Inspector General's Civil Money Penalty Rules RIN 0936–AA09 Submitted electronically at http://www.regulations.gov

Dear Mr. Zajic:

Health Level Seven (HL7®) is pleased to submit comments on the Proposed Rule on Grants, Contracts, and Other Agreements: Fraud and Abuse; Information Blocking; Office of Inspector General's (OIG) Civil Money Penalty Rules. These comments focus on the amendment by the 21st Century Cures Act (Cures Act) of the Public Health Service Act (PHSA), 42 U.S.C. 300jj-5, authorizing the OIG to investigate claims of information blocking and providing the Secretary (Secretary) of Health and Human Services (HHS) authority to impose Civil Monetary Penalties (CMPs) for information blocking. HL7 as a key driver in global interoperability, is increasingly at the forefront of the patient care revolution with its comprehensive framework and related interoperability standards, including the rapidly evolving Fast Healthcare Interoperability Resources (HL7® FHIR®), the Consolidated Clinical Document Architecture (C-CDA®), and the widely used V2 messaging standards.

We appreciate the efforts of OIG to summarize and codify its responsibilities for information blocking enforcement. We share your goal of improving health through enhanced electronic access to patients' health information.

Our comments reflect our responsibilities and perspectives as an ANSI-accredited Standards Development Organization (SDO). As you know, HL7 has developed the standards that will be expected to be used by Actors responding to request for Electronic Health Information (EHI). HL7 FHIR is the standard specified by ONC for use in application programming interfaces (APIs) to be used by healthcare organizations, other authorized entities and individuals, and apps and other applications requesting EHI. Use of such APIs and apps, as well as data exchange using other HL7 standards, will be central to achieving the goals of the Cures Act and the prevention of information blocking.

As such, it is essential that all stakeholders, including Actors (i.e., providers, certified EHR developers, and HIEs/HINs) specified by Cures and the ONC Final Rule, have clear expectations about information blocking enforcement. Actors' compliance responsibilities must be clearly understood by them and not provide an undue burden that conflicts with their core responsibilities, especially those related to patient care.

From this perspective, we offer the following five suggestions:

1. Given the overwhelming burdens on providers and other Actors created by the COVID-19 pandemic, we ask OIG to push out the earliest enforcement date to 6 months after publication of the OIG final rule, rather than two months as proposed. The additional four months should be used for an OIG advisory process with actors, using real-world examples.

2. We urge OIG to work with ONC to ensure maximum clarity and guidance for Actors and others on their obligations and associated compliance and enforcement requirements. The public health community feels a special urgency, for example given the COVID-19 pandemic, for clarity regarding when public health programs could fall under the ONC Final Rule definition of an HIE/HIN.

3. We urge OIG, in its Final Rule (preamble, regulatory text, and sub-regulatory guidance) to provide clearer criteria on the determination of single vs multiple violations. A clear and reasonable approach to such criteria will be essential for compliance by Actors that is as non-disruptive and cost-effective as possible. We urge OIG to avoid an approach under which consistent application of a single policy developed by an Actor could spawn tens of thousands of separate violations (e.g., one violation for each patient affected) at up to $1 million per violation. Such an approach could create disincentives for efficient and automated policies that facilitate exchange "without special effort".

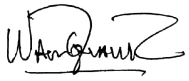
4. We urge OIG to adopt, to the greatest extent possible, an approach that uses a Corrective Action Plan model in lieu of or in addition to imposition of CMPs. Such an approach could help ensure that Actors acting in good faith can make needed changes to their technology, policies, and procedures that result in more access to EHI.

5. Finally, we recognize that health care providers are not subject to the imposition of Civil Money Penalties under the Cures Act and, therefore understand OIG's statement that the proposed rule is not applicable to health care providers. OIG does state that once a process is established through a separate and forthcoming notice and comment rulemaking as required by the Cures Act, "OIG will coordinate with, and send referrals to, the agency or agencies identified in future rulemaking by the Secretary that will apply the appropriate disincentive for health care providers that engage in information blocking". There is significant uncertainty in the provider community, and other communities, about how OIG will handle complaints it receives about potential information blocking by providers, especially before completion of the follow-on rulemaking. We urge OIG, as it finalizes this current proposed rule, to be explicit on how it will handle such complaints of provider information blocking and whether these will be referred to other agencies.

Thank you for consideration of these comments. Please contact me at cjaffe@HL7.org or 734-677-7777 if you have any questions. We look forward to continuing this discussion with you.

Sincerely,

Charles Jaffe, MD, PhD
Chief Executive Officer
Health Level Seven International



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