

June 23, 2020

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

Re: Comments to OIG-2605-P

Dear Mr Zajic,

On behalf of CommonWell Health Alliance, we are pleased to submit comments on the Office of Inspector General's Proposed Rule to amend and update HHS Civil Money Penalty rules of the Department of Health and Human Services.

CommonWell Health Alliance is a not-for-profit trade association made of various health IT and health care stakeholders. As a membership-based trade association, we provide an environment to openly work on interoperability improvements across many cornerstones of health care including but not limited to technology companies, payers, State and Federal agencies, providers, clearing houses, and patients. When the Alliance launched seven years ago, we started with services centered around Care Treatment and provided the ability for providers to query across other provider systems and retrieve data about a given patient. We have and continue to be a patient-centered network available nationwide and are proud to have added Patient Access use cases to give individuals the ability to find and access their data through patient portals, personal health records and other patient-centric applications.

CommonWell has a simple vision: health data should be available to individuals and caregivers regardless of where care occurs. Additionally, access to this data must be built into health IT at a reasonable cost for use by a broad range of health care providers and the people they serve. At CommonWell, together with our service provider and members, we have created and deployed a vendor-neutral platform that breaks down the technological and process barriers that inhibit effective health data exchange. We leverage existing standards and policies in order to enable scalable, secure and reliable interoperability as easily as possible for our members and their customers across the nation. We believe the ONC's Strategic Plan aligns with our mission and vision.

Note on Our Comments

These comments are reflective of the opinions of the Alliance and its members in regard to the objectives of CommonWell. It is not intended to represent the individual comments of each of our Members. Comments made here are not intended to represent the view of any particular member; and we expect some of our members to submit their own comment letters.

Timing and Effective Dates

In response to the following request for comment at <https://www.federalregister.gov/d/2020-08451/p-84>

We solicit comment on these proposed approaches for the effective date of OIG's information blocking CMP regulations, which would subsequently determine the start of OIG's information blocking enforcement. We are considering alternative effective dates that are sooner or later than October 1, 2020, and are interested in comments on potential dates and explanations about why parties would need a longer or shorter time period to come into compliance with the ONC Final Rule.

While ONC has not changed the compliance dates and timeframes in the ONC Final Rule, it has decided to exercise its discretion in enforcement to allow health care participants to focus on addressing the COVID-19 pandemic. We support ONC's enforcement discretion and the opportunity it affords Alliance Members to address the pandemic effectively while working in parallel on any work necessary to support the ONC rule. We recommend the OIG adjust its enforcement timelines to align with the ONC's Enforcement Discretion Dates and Timeframes.

Appeals Process

In response to the following request for comment at <https://www.federalregister.gov/d/2020-08451/p-89>:

We solicit comment, for purposes of a final rule, on the proposed incorporation of the information blocking regulations into 42 CFR part 1003, and the proposed application of the existing CMP procedures and appeal process in parts 1003 and 1005 to the information blocking CMP.

We support the inclusion of an appeal process. We believe information blocking claims should have the same process as other claims that come into OIG.

Violation Definitions and Examples

In response to the request for comment at <https://www.federalregister.gov/d/2020-08451/p-97> and this subsequent example:

The A health IT developer (D1) connects to a health IT developer of certified health IT (D2) using a certified API. D2 decides to disable D1's ability to exchange information using the certified API. D1 requests EHI through the API for one patient of a health care provider for treatment. As a result of D2 disabling D1's access to the API, D1 receives an automated denial of the request. This would be considered a single violation.

We would appreciate clarification on when a single violation would or would not become multiple violations. For example, if the same developer (D1) came back and requested EHI on 4 more individual patients for a total of 5, and they were subsequently denied in the same automated fashion each of those additional times, would this count as 5 violations in total and therefore 5 different practices, or would this still equate to a single practice/violation?"

Regarding request for comment at <https://www.federalregister.gov/d/2020-08451/p-102>:

We solicit comments on the proposed definition of "violation," for purposes of the final rule, as it pertains to proposed subpart N of 42 CFR part 1003. The examples are offered solely to illustrate OIG's current understanding of what constitutes a single violation versus multiple violations.

However, as previously stated, these examples are non-exhaustive and our understanding of single versus multiple violations will be informed by OIG's experience enforcing the information blocking CMP authority.

While we appreciate it is difficult to document every variation of all potential violations the examples included thus far have been helpful to understand the approach of the OIG. We suggest additional clarification on some examples made thus far, as illustrated in our previous comment, and the addition of more examples either through the rule itself or via additional guidance documents.

§ 1003.1420 Determinations regarding the amount of penalties

While the factors listed seem appropriate, there are no details on the extent any or all of the factors would be used with regard to a violation. One solution could be a weighted scoring system that outlines the potential impact of the factors listed optimally with minimum and maximum effects to the overall likelihood of the maximum assessable penalty of \$1M. Another would be to enhance the violation examples already documented to include these factors and provide an estimate of the like penalty for each.

Final Comments

The Alliance remains committed to patient-centric interoperability on a national scale with the goal of ubiquitous, secure exchange of clinical data to the benefit of providers, patients, payers, public health and all other stakeholders in health care and beyond. We support the mission and vision HHS has constructed with its recent interoperability rulemaking and further appreciate the challenge of developing appropriate penalties. We believe transparency is the key to an efficient and effective regulatory environment and look forward to any additional clarification that can be included in the final rule and any associated guidance documents.

On behalf of CommonWell Health Alliance, thank you again for the opportunity to comment on the Office of Inspector General's Proposed Rule on Civil Money Penalty. For any clarification or comments, please feel free to contact me at paul@commonwellalliance.org.

Sincerely,



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