



January 31, 2022

Christi A. Grimm, Principal Deputy, Inspector General
Office of Inspector General (OIG)
Department of Health and Human Services (HHS)
Attention: OIG-0922-N
330 Independence Avenue, SW
Washington, DC 20201

RE: OIG-0922-N: OIG Modernization Initiative To Improve Its Publicly Available Resources—
Request for Information, published in Vol. 86 No. 183 (53072-53079) on September 24, 2021

Submitted electronically via <http://www.regulations.gov>

Dear Principal Deputy Grimm,

UnityPoint Health appreciates this opportunity to provide comments on OIG Modernization Initiative To Improve Its Publicly Available Resources—Request for Information (RFI). UnityPoint Health is one of the nation’s most integrated health care systems. Through more than 34,000 employees and our relationships with more than 480 physician clinics, 40 hospitals in urban and rural communities, and 14 home health agencies throughout our 9 regions, UnityPoint Health provides care throughout Iowa, central Illinois and southern Wisconsin. On an annual basis, UnityPoint Health hospitals, clinics, and home health agencies provide a full range of coordinated care to patients and families through more than 8.4 million patient visits.

UnityPoint Health respectfully offers the following input on select questions posed in this RFI.

SECTION A. OIG RESOURCES: GENERAL QUESTIONS

OIG seeks input on its general approach to providing publicly available resources that may improve the usefulness, timeliness, usability, and accessibility of OIG’s resources across categories.

1. *What OIG resources have you or your organization found most useful, and why are they most useful? Why have you and your organization found some resources more useful than others?*

Comment: UnityPoint Health uses the following resources available on the OIG website:

- The OIG Work Plan, Fraud Alerts, Corporate Integrity Agreements, and enforcement-related materials help identify risks. These website resources are monitored for recent developments and incorporated within compliance programming.
- The intentional compilation of statutes, regulations, advisory opinions, etc.—creating a one-stop shop—is helpful.

- Interpretive guidance through Special Advisory Bulletins is informational, and UnityPoint Health would encourage OIG to produce more of these.
- UnityPoint Health utilizes many of the resources for training purposes. For example, UnityPoint Health refers to newsroom articles for purposes of preparing training materials; distributes the link to “Practical Guidance for Health Care Governing Boards on Compliance Oversight” to our Board Members; and references “A Roadmap for New Physicians” when training our physicians.

The training materials and toolkits are particularly useful, especially when these materials are in the PowerPoint format or can be readily integrated into the PowerPoint format.

2. *What types of arrangements or practices, topical areas, or industry segments should OIG consider addressing in future resources? From your perspective, which of these are most important or urgent for OIG to address?*

Comment: As an integrated health care system, UnityPoint Health encourages OIG’s consideration of developing resources in the following topic areas:

- Telehealth
- Joint Ventures
- Innovation
- Fraud and Abuse issues in data sharing or transfer agreements
- Pandemic—now and after
- Compliance Effectiveness (with specific emphasis on metrics)
- Behavioral Health

3. *What other forms or formats should OIG consider adopting in future compliance resources? Possible form and format of guidance and resource materials could include, for example, interactive content tools, guidance published in the Federal Register, video trainings, or podcasts. What do you suggest are effective ways for OIG to seek input from industry stakeholders and the public when developing resource materials?*

Comment: Interactive content tools that could be readily incorporated into training materials would be helpful, as would video trainings, and trainings in PowerPoint format. Frequently produced video clips (1-2 minutes in length) on specific topics that could be posted on our stakeholder websites or embedded in periodic communication pieces would also serve as a tool that would aid message distribution. As interpretive guidance (e.g., through Special Advisory Bulletins) has proven to be valuable to daily operations, OIG should consider more frequent distribution of these resources.

In addition to this RFI through a formal notice and comment period, roundtables at conferences and webinars with major health care systems and state associations are possible avenues for obtaining industry and stakeholder input. Specifically, OIG could reach out to organizations such as the Health Care Compliance Association (HCCA) and American Health Lawyers Association (AHLA) who can compile ideas from their membership.

4. *In addition to OIG’s annual solicitation of new safe harbors and special fraud alerts, do you have any suggestions for another formal mechanism for industry stakeholders and the public to request OIG guidance or resources on specific topics or for a particular industry sector?*

Comment: Consideration should be given to setting up a web-based portal to accept questions and ideas.

5. *What type of data or other information could OIG provide to the health care industry to facilitate compliance and program integrity efforts?*

Comment: Toolkits are helpful, but those currently available may benefit from a recurring schedule for review and updating. The Physician Roadmap tools model stakeholder-friendly resources because they include a publication, a PowerPoint, and speaker notes for the PowerPoint. Compliance professionals utilize these resources with flexible formats and standard messaging for training purposes.

6. *Please provide any suggestions to help improve accessibility and usability of our content for individuals with disabilities.*

Comment: If not done so already, Consumer Alerts should be made available in an audible format for those with visual impairment and through a TTY line for those with hearing impairments.

SECTION B. OIG ADVISORY OPINIONS

Pursuant to section 1128D of the Social Security Act, HHS, through OIG, publishes advisory opinions regarding the application of the Federal anti-kickback statute and the safe harbor provisions, as well as OIG's administrative sanction authorities, to parties' proposed or existing arrangements.

2. *If you have ever considered submitting an advisory opinion request and elected not to do so, why did you not submit a request? What concerns, if any, do you have about the process and how might OIG address those concerns?*

Comment: The request process needs to include an opportunity for an organization to adjust the original proposal short of withdrawal and submission of a new request.

3. *OIG advisory opinions currently include a thorough explanation of the facts and circumstances of the proposed or ongoing arrangement and a detailed analysis that comprehensively assesses the arrangement or proposed arrangement under the relevant authorities. In the past, OIG has received informal feedback that the advisory opinion process may be too restrictive, slow, or cumbersome. We are seeking your input on how to balance the value and utility of including detailed analyses in advisory opinions— which necessitates a more involved and time-consuming process—with the value and utility of a more expeditious process that does not necessarily include a detailed legal analysis in each published opinion. Please share your feedback on the approach that would be most valuable for you and your organization. For example, would a short-form advisory opinion that answers the legal questions posed to OIG without providing a comprehensive legal analysis be useful to you and your organization? If so, should OIG implement short-form advisory opinions: (i) for all advisory opinions; (ii) for unfavorable advisory opinions only; (iii) for any request for which the requesting party or parties elected, at the beginning of the advisory opinion process, to receive a short-form opinion; or (iv) for other categories of opinions?*

Comment: The legal analysis with the Advisory Opinions is helpful. There is a presumption that instituting a short form would save time; however, given that the analysis would still need to be completed to reach a conclusion, this presumption should be questioned. A key consideration should be the value of the Advisory Opinion to other organizations. While an Advisory Opinion only relates

to the party submitting the opinion, other organizations look to Advisory Opinions when structuring their own relationships. In this regard, documentation of the legal analysis is important.

5. *When requesting parties make significant modifications to the facts presented in the advisory opinion request during the advisory opinion process, such modifications can delay the process and result in the expenditure of additional OIG resources. To address this, OIG could require requesting parties to withdraw (with the opportunity to resubmit) a request when requesting parties make significant modifications to the facts presented in the initial request. Alternatively, OIG could restrict requesting parties from making any modifications to the original advisory opinion request. Please share your perspectives on the benefits or drawbacks of each approach.*

Comment: UnityPoint Health would support the development of a mechanism to make modifications as part of the original submission. While this could extend the process, overall efficiencies in allowing modifications will likely result. As an initial step, OIG could consider reasonable modification limitations, such as limiting parties to one set of modifications.

SECTION C. FRAUD ALERTS

With respect to special fraud alerts, pursuant to section 1128D(c) of the Social Security Act, “any person may present a request at any time to [OIG] for a [special fraud alert that would inform] the public of practices [that OIG] considers to be suspect or of particular concern under Medicare or a State health care program.”

1. *Which fraud alerts, if any, have you or your organizations used as a resource, and how have you used them?*

Comment: The OIG’s Consumer Fraud Alerts are excellent. Fraud Alerts targeting providers are particularly useful in that they can be communicated to affected populations within a health care entity as reminders or as the basis for additional training. For example, the Fraud Alert on Speaker Programs was a helpful communication for physicians.

2. *What could OIG do differently to make our fraud alerts more meaningful, useful, or timely?*

Comment: OIG should consider placing more emphasis on Fraud Alerts in the provider space, including more frequent publication.

SECTION D. SPECIAL ADVISORY BULLETINS

Special advisory bulletins cover a variety of topics, including discussions regarding: (i) Potentially abusive health care industry practices, similar to those described in special fraud alerts, but where OIG may lack the enforcement experience necessary to substantiate a special fraud alert; (ii) the importance of robust compliance measures, as applied to specific types of arrangements; (iii) arrangements that potentially implicate the Federal anti-kickback statute and OIG’s administrative enforcement authorities; and (iv) the scope and effect of certain legal prohibitions.

1. *Which special advisory bulletins, if any, have you or your organization used as a resource and how have you used them?*

Comment: The Special Advisory Bulletins are important tools for Compliance Professionals as they provide additional commentary and guidance on specific regulatory issues. One example is the Special Advisory Bulletin on the Effect of Exclusion from Participation in Federal Health Care Programs. Special Advisory Bulletins address a topic more comprehensively than a Fraud Alert, and unlike an Advisory

Opinion, they are not limited to a special set of facts or the party(ies) requesting the opinion. As with the Fraud Alerts (Section C above), Special Advisory Bulletins are practical as their content can be readily communicated to affected populations within a health care system as reminders or as the basis for additional training.

2. *What could OIG do differently to make our special advisory bulletins more meaningful, useful, or timely?*

Comment: UnityPoint Health urges OIG to produce Special Advisory Bulletins more frequently and on additional topics.

3. *If OIG were to update existing special advisory bulletins or publish additional special advisory bulletins on certain topic areas, how should OIG best obtain stakeholder input on areas in need of new guidance or refinements to existing guidance?*

Comment: UnityPoint Health encourages OIG to consider the following: (i) Setting up a web-based portal to solicit questions and ideas; and (ii) Reaching out to organizations such as the Health Care Compliance Association (HCCA) and American Health Lawyers Association (AHLA) who can compile ideas from their membership.

SECTION E. COMPLIANCE PROGRAM GUIDANCE

As a general matter, Compliance Program Guidance (CPGs) set forth OIG's views on the value and fundamental principles of a compliance program, in addition to elements for consideration when developing and implementing an effective compliance program. CPGs are intended to encourage the voluntary development and use of internal controls to monitor adherence to applicable statutes, regulations, and program requirements.

1. *How, if at all, do you or your organization use the CPGs to understand beneficial compliance practices or relevant risk areas?*

Comment: These are foundational documents used to implement UnityPoint Health's Compliance Program. CPGs are frequently referenced, and their maintenance should continue to be a priority for OIG.

2. *If OIG published additional or supplemental CPGs, or resources similar to CPGs, what industry segments would you find most useful for us to address?*

Comment: OIG should consider the following:

- Relationships involving more than one type of entity (e.g., physician-hospital relationships, joint ventures)
- Telehealth
- Behavioral Health

3. *If OIG were to update or publish additional or supplemental CPGs, how should OIG best solicit stakeholder input about risk areas or other features to update or supplement?*

Comment: With respect to the existing documents, using the Request for Information public notice and comment period format is a preferred method to efficiently gather comments specific from industry-wide and stakeholder groups and individuals to areas of the Guidance documents.

In addition, OIG may want to have stakeholder meetings with the trade associations like the American Hospital Associations to get specific feedback and examples from the industry. Individual hospitals and providers may not necessarily feel comfortable coming to the OIG with specific examples due to OIG's enforcement authorities.

4. *What suggestions, if any, do you have for the form, format, or content for CPGs to make them as useful, relevant, and timely as possible? For example, instead of a static document, would it be more useful, relevant, and timely to have a mobile-friendly web page that is updated at regular intervals to describe compliance best practices and current risk areas?*

Comment: UnityPoint Health supports the use of a format that can be more easily updated and is mobile-friendly. Presently, some redundancy of information exists within the Compliance Guidance Documents (e.g., basic elements of a compliance program), which could be consolidated. Application of these basic concepts to specific types of providers could be addressed in separate documents (or webpages). For example, a discussion of the basic elements of a compliance program could be discussed in one document or webpage, and specific information applicable to hospitals, physician groups, etc. could be detailed in separate documents or webpages.

SECTION F. FAQs

In response to the COVID-19 public health emergency, OIG developed a process to respond to inquiries from health care industry stakeholders regarding the application of the Federal anti-kickback statute and OIG's administrative enforcement authorities to arrangements directly connected to the COVID-19 public health emergency.

1. *How, if at all, do you or your organization use the COVID-19 FAQ responses in assessing or structuring arrangements directly connected to the COVID-19 public health emergency that potentially implicate OIG's administrative enforcement authorities? Do you have any feedback on how OIG can make the COVID-19 FAQ responses more useful?*

Comment: The website is not user friendly. From a user experience perspective, it would be beneficial to have all the FAQs available in single PDF or web-based text that can be copied and pasted. Currently, a user must click on each question to get the answer. Thus, if someone is trying to get a general sense for a topic or wanting to read all the FAQs, the person would need to click each question every time the person visits the website. Also, consolidating all FAQs into one location—similar to how the Office for Civil Rights manages privacy FAQs—is a recommended approach.

SECTION G. OTHER COMPLIANCE GUIDANCE AND RESOURCES

OIG has published numerous other compliance-related documents that target various segments of the health care industry.

1. *How, if at all, do you and your organization use OIG's other compliance resources, like our video trainings and podcasts? If you or your organization do not use these resources, please explain why.*

Comment: The training materials are helpful, but some are outdated. For example, the podcast on Medical Documentation does not reflect the use of EMRs. OIG should revisit the format of these resources. Having materials available only in PDF format is limiting. Slides should be made available in alternative formats, including PowerPoint.

2. *What, if anything, could OIG do to make our other compliance resources more useful, relevant, and timely?*

Comment: The 2011 HEAT Provider Training Material is useful but should be reviewed, updated, and expanded. Materials should be available in PowerPoint format. In addition to existing videos and podcasts, short (1-2 minute) podcasts on specific topics geared toward physicians (e.g., speaker bureaus, copy and paste, supervising residents, etc.) should be considered to engage providers. Existing PDF documents under “Presentation Materials” should be incorporated into webpages. In addition, consideration should be given to having an FAQ section divided by topics. FAQs are currently found in various places and in various documents (e.g., Understanding Program Exclusions). Consolidating FAQs into one area would be preferred and create efficiencies.

SECTION H. CORPORATE INTEGRITY AGREEMENTS

OIG negotiates Corporate Integrity Agreements (CIAs) with individuals and entities as part of the settlement of Federal health care program investigations arising under a variety of civil false claims statutes.

1. *How do you or your organization use the information in publicly available CIAs?*

Comment: UnityPoint Health uses CIAs to understand issues and arrangements that may be problematic and to identify potential risk areas.

2. *What types of search capabilities for CIA documents (e.g., search by provider type) would be most useful for you or your organization?*

Comment: The ability to search CIAs by provider type would be the most useful.

SECTION I. LIST OF EXCLUDED INDIVIDUALS/ENTITIES

OIG has the authority to exclude individuals and entities from federally funded health care programs pursuant to section 1128 of the Act (and from Medicare and State health care programs under section 1156 of the Act) and maintains a list of all currently excluded individuals and entities called the List of Excluded Individuals/Entities (LEIE).

1. *How can OIG best provide access to the LEIE? For example, if OIG publishes an API for the LEIE, would that be useful to you or your organization? Are there other access options or data formats that would make using the LEIE easier?*

Comment: With respect to an Application Programming Interfaces (API), it would be ideal if users could upload an excel file containing provider names, National Provider Identifiers (NPIs), and Social Security Numbers (SSNs) that would result in the generation of a report showing a listing of potential exceptions. Being able to check a large number of providers in this way is more efficient than the current system which is limited to only a few providers per submission.

OIG should also consider additional LEIE search fields: middle name, NPI, and SSN (or Tax Identification Number (TIN)). These additional fields will help identify potential matches. For example, if a provider legally changed their last name, their SSN or NPI would not change. Having the SSN or NPI available would help correctly identify the individual, particularly for individuals with common surnames.

2. *What software or application, if any, do you currently use to check the LEIE? Is that software or application developed internally or by a third party? Does the software or application automate the process of checking the LEIE?*

Comment: UnityPoint Health uses tools developed by a third-party vendor, Crowe. Specifically, the Crowe “look-up” tool is used for initial checks, while the Crowe Continuously Monthly Monitoring tool is used for ongoing checks. Through these products, Crowe simultaneously “pings” OIG, System for Award Management (SAM), SSN death master, and all state Medicaid Sanction listings, creating great efficiencies. Further efficiencies could result if users could search the LEIE directly as a one-stop shop, which would also include state databases.

3. *Do you integrate the results of the LEIE with other information, such as information related to provider onboarding, licensure, credentialing, or privileging? If yes, please explain how.*

Comment: Yes. LEIE results are reported to the UnityPoint Health Credentialing Verification Office when a sanction match is identified. For monthly exclusion checks, those results are included within the UnityPoint Health credentialing/privileging database.

SECTION J. AUDITS AND EVALUATIONS

OIG audits examine the performance of HHS programs and/or its grantees, contractors, or providers in carrying out their respective responsibilities and provide independent assessments of HHS programs and operations. OIG also conducts national evaluations to provide HHS, Congress, the public, and other stakeholders with timely, useful, and reliable assessments of HHS programs and operations.

4. *Please share any feedback on accessing OIG audit and evaluation reports. For example, how easy is it for you to find specific reports when you look for them? How well does the downloadable PDF format work for you? Are there other file types or web-based formats that would be more accessible or useful to you?*

Comment: This area presents an opportunity for improvement.

- Accessing OIG audit and evaluation reports directly from the OIG website is difficult. Currently, the audits/evaluations are available by agency and then sorted by time. Also, if the audit predates 2018, users must go to a separate webpage to view.
- The two ways that are generally used to access reports are a link from a third-party news article or the OIG’s press release, which is not ideal and could benefit from a centralized OIG webpage.
- The search function is not intuitive. If users are trying to find a specific or older report without the date or the audit/evaluation number, users must generally resort to doing a site search of <https://oig.hhs.gov> via Google.

5. *Please share any feedback on the ways we present information in OIG audit and evaluation reports, including our more standard reporting templates and our alternative formats, such as data briefs and data snapshots. For example, what types of information (e.g., key takeaways, findings, recommendations, methodology) are most useful to you? How easy is it to find and understand that information? What suggestions, if any, do you have for making our reports more useful or user friendly in their presentation?*

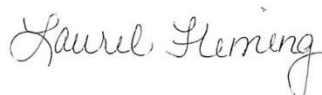
Comment: The inclusion of key takeaways, best practices, and potential next steps for providers resulting from the audit or evaluation would be beneficial and should be considered.

8. *As OIG develops our searchable repository of recommendations for our public website, we would appreciate any feedback you have on how to make this repository most useful to you or your organization. For example, what types of queries would you want to run, what types of information might you be looking for, and what functionalities would you want this system to have?*

Comment: Any search functions should have both Boolean Operators and Proximity Operators. A Boolean search is a search that uses the logical (i.e. Boolean operators (AND, OR, NOT) in addition to the keywords. Proximity Operators allows users to specify searches where one word is near, next to, or in the vicinity of another word.

We are pleased to provide input on this RFI and its impact on our health care system, our patients, and communities served. To discuss our comments or for additional information on any of the addressed topics, please contact Cathy Simmons, Executive Director, Government & External Affairs at (319) 361-2336 or cathy.simmons@unitypoint.org.

Sincerely,



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