manatt

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VIA ELECTRONIC UPLOAD (HTTP://WWW.REGULATIONS.GOV)

U.S. Department of Health & Human Services
Office of Inspector General
330 Independence Avenue, SW
Washington, DC 20201

Dear Sir or Madam:

Manatt, Phelps & Phillips, LLP ("Manatt") appreciates the opportunity to comment on the Office of Inspector General's ("OIG") September 24, 2021 Request for Information ("RFI") addressing potential avenues for modernizing OIG's various guidance mechanisms. Manatt has a long history of representing clients across all segments of the health care industry, including hospitals and health systems, physician practices, post-acute care companies, and other providers and suppliers; pharmaceutical, medical device, digital health, and other life sciences companies; health plans, including those that administer the Medicare Part C and D programs; and state Medicaid programs. The contents of this letter represent feedback from organizations of all sizes and levels of maturity, ranging from large, well-established health care companies to smaller start-up companies.

We appreciate that OIG is taking steps to solicit input from industry participants on ways to ensure its guidance is as accessible, useful, and relevant as possible. In light of Manatt's extensive experience working with health care clients, including in-house counsel and compliance officers who routinely rely on OIG's publicly available resources, we are pleased to submit the following comments and suggestions. Please note that this submission does not address all topical areas and questions in the RFI, but rather those that we prefer OIG to focus on and prioritize as part of this important modernization effort.

I. OIG Advisory Opinions (RFI Section III.B)

OIG's advisory opinion process is viewed as a critical mechanism for parties to obtain certainty around the legality of proposed arrangements under the Anti-Kickback Statute ("AKS"), beneficiary inducement provisions of the Civil Monetary Penalties Law ("CMPL"), and other OIG administrative authorities. More broadly, industry stakeholders rely extensively on advisory opinions for guidance on how OIG might analyze similar arrangements that they may be considering implementing and to develop appropriate safeguards to ensure such arrangements remain in compliance. At present, the advisory opinion process represents the only established mechanism for parties to obtain feedback from OIG on whether an arrangement might implicate the fraud and abuse laws. Accordingly, it is especially important that the advisory opinion process be timely and nimble, particularly in light of the rapidly evolving health care landscape as recognized in the RFI.

We are encouraged by OIG's recent decision to *sua sponte* amend its regulatory bases for rejecting an advisory opinion request, thereby enabling issuance of an advisory opinion under circumstances where the same or substantially similar conduct may be the subject of a pending

investigation or legal proceeding.[1] However, there are other opportunities to streamline and refine the OIG's advisory opinion process to render it more user-friendly and accessible to health care stakeholders. To that end, our comments and suggested areas for reform are as follows:

3. *Advisory Opinion Formats*

As OIG acknowledges in the RFI, the most frequently cited barrier to parties utilizing the advisory opinion process is the long lead time for issuance of a final advisory opinion. With new technologies emerging and health care payment and delivery systems constantly evolving, parties are often under time-sensitive pressure to implement new business arrangements in response to customer, patient, and payor demands; competitive variables; and other factors. Development of a truncated, short-form advisory opinion process could help address these challenges and significantly expedite the timeframe for parties to receive feedback from OIG. If such a process is created, parties should be given the choice whether they wish to receive a short-form advisory opinion or the traditional advisory opinion containing a comprehensive legal analysis. This will provide parties that simply seek OIG's view on the material question as to whether OIG would seek to impose administrative penalties a timelier, but still binding response, while preserving parties' ability to request and have the benefit of OIG's more fulsome analysis of the underlying arrangement should they prefer.

OIG might also consider allowing parties to bifurcate a request involving multiple arrangements. For example, a requestor might seek an advisory opinion on an arrangement that substantially mirrors an arrangement discussed in one or more prior advisory opinions, as well as a more novel arrangement on which OIG has never opined. In the former case, the requestor might be satisfied with – and it presumably would be a more efficient use of OIG's resources to issue – a short-form opinion. However, for any arrangement that presents issues of first impression, the requestor might well desire – and the industry at large would certainly benefit from – the traditional long-form advisory opinion containing OIG's complete legal analysis.

6. *Advisory Opinion Fee Structure*

We appreciate that OIG is considering revising its advisory opinion fee structure and propose that, in connection with doing so, OIG evaluate the feasibility of and its legal authority to adopt a paradigm conceptually similar to the U.S. Food & Drug Administration's ("FDA") user fee models. The goal of this model would be to allow OIG to generate additional fees that can be applied to hiring additional staff to review and process advisory opinions, thereby resulting in reduced wait times and increased efficiencies for all requesting parties. Specifically, OIG could assess tiered fees tied to the complexity of the request (*e.g.*, "Low," "Medium," "High"). The assigned level of complexity could be determined based on: (i) the novelty of the issues; (ii) the proposed arrangement's similarity to other arrangements covered by prior advisory opinions; (iii) the number of distinct legal questions presented

[1] *See* 87 Fed. Reg. 1,367 (Jan. 11, 2022) (eliminating 42 C.F.R. § 1008.15(c)(2)).

by the request; and (iv) other objective factors influencing the anticipated resources required to appropriately evaluate the request, consult with other agencies, and prepare a final advisory opinion.

As OIG is aware, the FDA's user fee models recognize exceptions whereby the standard fee may be waived or reduced. To ensure that the advisory opinion process is accessible and open to all, we envision that OIG could adopt a similar structure allowing for exceptions or reduced fees where the requestor is, for example, a non-profit entity or a small start-up company submitting its first advisory opinion request. As with the FDA's statutorily authorized user fee models, it would be well-received by the industry for OIG to commit to meeting certain performance goals (*e.g.*, issuance of an advisory opinion within a specified timeframe) in exchange for the fees assessed. Moreover, to the extent an advisory opinion request is withdrawn prior to issuance of a published advisory opinion, we would encourage OIG to consider refunding or waiving fees on a pro rata basis, with the specific amount determined based on the stage at which the request is withdrawn.

7. *Oversight of Issued Advisory Opinions*

In the RFI, OIG states the agency is considering whether to set "expiration dates" for advisory opinions or, in the alternative, require parties to periodically recertify that the facts presented in the advisory opinion are still true and correct and constitute a complete description of the facts in order for the advisory opinion to remain in effect. In assessing these proposals, we urge OIG to bear in mind that requestors heavily rely on favorable advisory opinions when investing resources, manpower, and capital in the implementation of an arrangement. Providing for automatic "expiration dates" will likely create a disincentive to using the advisory opinion process as parties understandably may not wish to expend the time, effort, energy, and cost to obtain an advisory opinion that will be rendered invalid – even absent material changes in the law or underlying facts – after a defined point in time.

Similarly, requiring parties to periodically recertify that all of the facts included in a published advisory opinion remain accurate or risk nullification of the opinion may be too harsh a tool to accomplish OIG's objectives. We note that the background sections of advisory opinions often contain extensive recitations of the facts and circumstances surrounding the parties, the context for the arrangement, and the terms of the arrangement. Only some of these facts are critical to OIG's analysis, as evidenced by the fact that only select pieces of information are repeated and relied upon in the analysis section of the opinion. To the extent OIG were to require some form of periodic recertification by requestors, we caution against requiring parties to attest that all of the facts – whether or not material to the legal analysis and outcome – remain accurate. At minimum, any recertification requirement should be coupled with OIG's commitment to identify to requestors which facts were considered material to the analysis and require attestation only as to those facts.

Notwithstanding the above, the preferable course of action would be for OIG to continue its current practice of allowing requestors to self-police their arrangements' adherence to the terms of a published advisory opinion.

II. Fraud Alerts & Special Advisory Bulletins (RFI Sections III.C, III.D)

Special Fraud Alerts ("SFAs") and Special Advisory Bulletins ("SABs") provide important guidance to the industry on the types of practices, arrangements, or conduct that OIG views as suspect; how OIG interprets or applies its administrative authorities; and other topics. Compliance officers and attorneys frequently rely on SFAs and SABs to guide organizations on how to structure arrangements and new business proposals in a compliant fashion. These resources also serve as key evidence of the government's thinking in a particular area when engaging with organizational leaders and business personnel on a proposed course of action.

At the same time, as recognized in the RFI, SFAs and SABs have been only infrequently issued, and often after the industry is aware of a particular risk area. False Claims Act matters and OIG investigations tend to stay under seal or otherwise remain non-public for significant periods of time. Thus, it can be several years before the industry is on-notice of a new enforcement risk or practice that the government has long questioned or viewed as problematic. Once such enforcement actions do become public, the incremental value added by an SFA or SAB is somewhat limited.

2. *Making SFAs & SABs More Meaningful, Useful, or Timely*

To maximize the relevance and usefulness of SFAs and SABs, OIG might consider developing a regular cadence for publication of these resources. For example, OIG could commit to publishing either an SFA or SAB on a quarterly or semi-annual basis. The primary purpose of the SFAs or SABs could be to highlight new risk areas in close to real-time, as the OIG identifies them. OIG could also use SABs to: (i) more fulsomely address common questions raised about compliance topics or OIG's interpretation of its administrative authorities; or (ii) proactively offer guidance to the industry on select compliance topics, including based on work conducted by other OIG components (*e.g.*, the Office of Audit Services, Office of Evaluation and Inspections). Finally, in lieu of a one-time, limited duration annual solicitation of potential topics, OIG could provide a dedicated mechanism for parties to submit suggestions or proposals for new SFAs or SABs in real-time through its website.

Apart from periodically developing new guidance, we respectfully suggest that OIG also adopt a formal mechanism for retiring SFAs or SABs that may no longer be applicable and create unnecessary confusion for stakeholders. By way of example, the SAB on Contractual Joint Ventures has been on the books since April 2003. However, to our knowledge, this guidance has not served as the basis for any material enforcement activity or been further interpreted or clarified by OIG. Ultimately, this guidance has been a source of confusion for parties seeking to structure contract-based arrangements, as the principles set forth therein are incredibly broad and challenging to work with in practice. As part of this process, we strongly encourage OIG to solicit input from health care industry participants on other guidance documents that have potentially been more harmful than helpful, or which are no longer relevant, and should be retired.

III. Compliance Program Guidance (RFI Section III.E)

3. *Solicitation of Industry Feedback on Updating or Publication of New CPGs*

As the OIG acknowledges in the RFI, its voluntary Compliance Program Guidance ("CPG") documents are all nearly twenty (20) years old, and the most recent update to the CPGs – for nursing facilities – dates back to 2008. Updating the CPGs to ensure they remain timely, relevant, and useful for various industry sectors is essential. We note that the seven essential elements of an effective compliance program are well-ingrained across the health care industry, and some of the topics addressed in the CPG documents are perennial risk areas on which the government continues to focus. That being the case, perhaps the greatest opportunities to "refresh" and update the CPGs are with respect to new and emerging risk areas; the use of data analysis and technology to support compliance efforts; and removal of concepts that no longer remain pertinent, including due to changes in health care payment and delivery models over time.

When considering updates to the CPG documents, we encourage OIG to engage with and solicit feedback from the industry. Ideally, this would be done through multiple avenues, including in-person or teleconference roundtables and surveys. Because there may be wide variability in perspectives within an individual industry sector, OIG could consider having break-out roundtable sessions based on company size, non-profit versus for-profit status, geographic location, or subspecialization within a broader provider or supplier category. To secure the broadest possible participation and level of input, we also suggest that OIG consider hosting at least some roundtables at industry conferences or other events likely to be well-attended by compliance professionals, attorneys, consultants, health care leaders, and other interested stakeholders.

4. *Form, Format & Content of CPGs*

In light of the dynamic pace at which health care evolves, we believe the industry would be supportive of OIG moving away from static CPG documents. Instead, it would be more useful, relevant, and timely for OIG to adopt its proposal of having a mobile-friendly website that is regularly updated to address new compliance best practices and emerging risk areas. To encourage broad public engagement with the CPGs, OIG might also consider having a form on its website whereby parties can submit suggestions or requests on an ongoing basis for additional compliance-related topics or issues that OIG might incorporate into the CPGs.

IV. Frequently Asked Questions (RFI Section III.F)

2. *Establishment of FAQ Process Outside the COVID-19 Pandemic*

As a general matter, health care industry participants of all varieties will be receptive to and welcoming of additional opportunities to substantively and meaningfully engage with OIG on regulatory and compliance topics. Prior to establishment of the COVID-19 FAQ process, the inability

to obtain feedback from OIG outside the rigorous contours of the advisory opinion process has been a source of frustration for stakeholders. While we appreciate that the level of fraud and abuse risk presented by an arrangement necessarily depends on the nuanced facts and circumstances, in some cases parties simply want to understand OIG's position on an issue as a conceptual matter. Where, for example, parties do not have a clear understanding of the arrangement they wish to pursue or the facts are too fluid to make the advisory opinion process viable, it may be sufficient to the parties – and of value to the industry – to obtain a more generalized answer from OIG that will inform the parties' course of action. Further, where a party is aware of competitors engaging in a potentially problematic practice, the ability to submit an FAQ and have OIG publicly respond could have a sentinel effect by putting an end to, or in the first instance averting, fraudulent or abusive behavior.

Given the above, we strongly support the establishment of a permanent FAQ process along the lines of what OIG has done in the context of the COVID-19 pandemic. While the current COVID-19 FAQs page is user-friendly and easily navigable, if this process is continued on a go-forward, we encourage OIG to consider developing a sorting feature that allows parties to search FAQs by legal issue and provider, supplier, or other health care organization type. We also envision that the FAQ process could be expanded to address not only the AKS or CMPL implications of a particular arrangement, but also inquiries about compliance program effectiveness, the effect of exclusion from participation in the Federal health care programs, and general compliance best practices. In the end, we believe this could be an invaluable tool for health care stakeholders to obtain OIG input in a manner that is nimble, accessible, and fosters innovation in our rapidly evolving health care environment.

V. Corporate Integrity Agreements (RFI Section III.H)

1. *How CIAs Are Used by Industry*

As OIG notes in the RFI, published Corporate Integrity Agreements ("CIAs") represent a key source of intelligence for organizations seeking to ensure their compliance programs are up-to-date, relevant, and consistent with OIG's expectations. Many compliance officers religiously review new CIAs as they are posted on the OIG's website for new ideas and guidance when it comes to strengthening an organization's compliance program. However, we understand from our clients that when OIG releases new CIAs containing unique or first-in-time provisions, it is often difficult for the public to discern: (i) what the rationale was for imposing those provisions; and (ii) whether the new requirements were designed to address specific factors in the underlying case or, instead, are perceived by OIG to be the new "gold standard" for an effective compliance program.

This is particularly true given that the covered conduct descriptions in Department of Justice ("DOJ") and OIG press releases are typically short, high-level, and lack detail about how the defendant's practices allegedly ran afoul of the law. As new provisions are incorporated into CIAs, it would be helpful for OIG to provide a brief explanation of its objectives and thought process behind the new provisions. If companies had context for why OIG chose to impose certain new or novel

obligations, such information would help organizations better apply the lessons learned from CIAs to improve their compliance infrastructure and mitigate similar risks.

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In closing, we sincerely appreciate the opportunity to provide feedback in response to the RFI and are hopeful this represents only the beginning of a coordinated, concerted effort to engage with the health care industry on meaningful changes to the OIG's guidance mechanisms and other resources. Should you have any questions or wish to discuss any aspect of this submission, please do not hesitate to contact Brian Bewley by phone at (202) 624-3334 or by e-mail at BBewley@manatt.com, or Katie Dunn by phone at (617) 646-1414 or by e-mail at K.Dunn@manatt.com.