○ Reformat/separate Statutory Funding Preference data from Special Consideration data.

• Table #2 has:

○ ''Students'' reworded to ''participants/trainees;''

○ One column labeled, ''Budget Year,'' to identify the project budget year;

○ One column to create a space for entering the sum for each row;

○ Rows to more clearly indicate the budget year for up to 5 years; and,

○ One final row to create a space for entering the total for each column.

• Frequency of data collection: Data is collected (through the two tables) once during the application period for each funding announcement.

• Information determines:

○ If applicants meet the funding preference or special consideration for funding, and

○ Projected target and baseline numbers of trainees/participants to be supported throughout the project period.

Likely Respondents: Likely respondents will be current ANE Programs awardees and new applicants to the ANE Programs.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name (includes the ANE program specific tables and attachments)	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
ANEW	236	1	236	7	1,652
NAT	115	1	115	7	805
ANE–NPR	101	1	101	7	707
ANE–NPRIP	15	1	15	7	105
ANE–SANE	54	1	54	7	378
Total	521	....	521	....	3,647

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Maria G. Button,
Director, Executive Secretariat.
[FR Doc. 2021–20653 Filed 9–23–21; 8:45 am]
BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

OIG Modernization Initiative To Improve Its Publicly Available Resources—Request for Information

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Request for information.

SUMMARY: This request for information seeks input from the public on OIG resources and how OIG could enhance the usefulness and timeliness of such resources and improve their accessibility and usability.

DATES: Please submit comments electronically at *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions and refer to file code OIG–0922–N. Comments must be received no later than January 31, 2022, to ensure consideration. In light of the broad scope of the RFI and to provide adequate opportunity for input from a wide range of stakeholders, we are providing an extended comment period for this RFI. Thank you in advance for your valued input. For information on viewing public comments, please see the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Susan Edwards, (202) 619–0335.

SUPPLEMENTARY INFORMATION: Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that website to view public comments.

I. Introduction

The Department of Health and Human Services (HHS) Office of Inspector General (OIG) is working to modernize the accessibility and usability of our publicly available resources, including guidance, program integrity resources, publicly available data, and advisory opinions (collectively, resources). Given the significant passage of time since many of our resources launched and corresponding advancements in technology, we are looking holistically at where we can make improvements to delivering publicly available resources effectively and efficiently. We want to continue producing useful and timely resources that, among other things, advance the health care industry's voluntary compliance and help prevent fraud, waste, and abuse. Further, we are mindful that stakeholders increasingly use new technologies to ingest, manage, and operationalize data and information, and we are interested in delivering data and information in ways that are compatible with the technologies used by stakeholders. To modernize our publicly available resources, we anticipate a multistep, multiyear process that prioritizes high-value changes. Input collected from this RFI will help inform decisions about which areas to address first. By tailoring our resources in response to stakeholder

input, and making it easier to use OIG's resources, we hope to spur improved compliance and innovative approaches within the health care industry.

Through this Request for Information (RFI), OIG seeks input from the health care industry and the public, including:

• Health care providers and suppliers, pharmaceutical and medical device manufacturers, compliance professionals, attorneys, boards of directors, payors, health technology companies and professionals, companies and individuals providing health care-related services (such as social services or case management), industry associations, and health care compliance software vendors;

• State officials who administer or oversee Medicaid and other State health care programs;

• Tribal officials and providers and suppliers serving American Indian and Alaska Native communities;

• health care consumers and their advocates; and

• health care researchers and policy analysts.

While our focus is generally on resources related to health care, we also offer resources related to HHS's human services programs, including programs administered through grants and contracts, and would welcome input from stakeholders about resources related to those programs. Any changes we make will continue to ensure that our content and information remain 508 compliant.

We want to know whether and how you currently use the OIG resources listed below, and how we could enhance the value and timeliness of such resources and improve their accessibility and usability. We also are interested in input on additional types of OIG resources that would be useful, or additional subject areas for OIG resources. Specifically, we seek feedback on:

• Advisory opinions;

• fraud alerts (including special fraud alerts);

• special advisory bulletins;

• compliance program guidance;

• frequently asked questions (FAQs), including COVID–19 FAQs;

• other compliance guidance and resources;

• corporate integrity agreements (CIAs);

• the list of excluded individuals/ entities (LEIE); and

• audits and evaluations.

II. RFI Objectives

For 45 years, OIG has provided objective, independent information to the public to foster an improved understanding of program integrity risks in HHS programs, enhance compliance practices by industry stakeholders participating in HHS programs, and protect against fraud and abuse. OIG issues audit and evaluation reports that contain findings and recommendations; conducts investigations; and provides compliance guidance, fraud alerts, and other information to promote program integrity and compliance. Through this RFI, we seek feedback from respondents about how they use OIG's resources (and the related benefits and challenges of such uses) to improve the value and timeliness of, access to, and the usability of, such resources.

This feedback will inform our efforts to modernize our publicly available resources. Our goals are to: (i) Continue producing useful and timely resources, (ii) deliver data and information to the public using modern technology, and (iii) spur improved compliance and innovative approaches that adapt to changes in the health care system and keep pace with technological change.

The health care industry will continue to face many changes. More specifically, the health care delivery system is undergoing structural changes resulting from, for example, the COVID– 19 public health emergency; the entrance of new health care stakeholders, such as digital health technology companies; the development and continuing proliferation of innovative treatments; and the evolution and increasing complexity of financial relationships within the health care industry. Ensuring that OIG's publicly available resources continue to meet stakeholders' needs as these and other changes unfold is important. Modernizing OIG's publicly available resources will further OIG's mission to promote the economy, efficiency, effectiveness, and integrity of HHS programs, as well as the health and welfare of the people they serve.

This RFI is an opportunity for a range of stakeholders to suggest ways to improve the usefulness, timeliness, accessibility, and usability of OIG's resources by: (i) Providing insights into how they use OIG resources, (ii) identifying the successes and challenges organizations have had using OIG resources, and (iii) identifying other potential opportunities for OIG to provide information to the public and other stakeholders. We recognize that many of the issues raised by this RFI may cross different professional disciplines or functions, and we encourage respondents to incorporate a broad perspective, as applicable.

Through this RFI, we intend to elicit a more complete and nuanced understanding of how OIG resources are used by different stakeholders and how we may best improve upon them and their accessibility. We hope that respondents provide candid feedback, including examples of challenges related to any category of OIG resource listed in this RFI, as well as new opportunities for OIG to provide information and data more effectively. Feedback that we receive will inform OIG's consideration and prioritization of potential updates to existing resources, modifications of processes for developing resources, changes in how data and information are provided to the public, and development of new materials or data sets, as appropriate.

Notably, this RFI is just one action we are taking to gather input. We intend to conduct roundtables and are considering other ways to collect feedback, such as performing user surveys regarding targeted aspects of our data. We also are launching a new page on our website to provide information regarding this initiative.

After reviewing comments submitted in response to this RFI and feedback received through any other mechanisms, OIG will consider what changes, if any, should be made to our resources and how to prioritize and implement those changes. Certain changes to the advisory opinion process may require amendments to OIG regulations that would be implemented via notice-and-comment rulemaking. Updated resources, new materials, or modified processes would be introduced incrementally and not according to any specific timeline. We anticipate that this initiative could be a multiyear undertaking. We will prioritize the highest value actions.

III. Request for Information

Historically, OIG has provided extensive publicly available resources across a range of compliance and program integrity topics and information types. For example, some resources provide guidance to the health care industry related to the Federal anti-kickback statute,[1] OIG's administrative enforcement authorities, such as the civil monetary penalty (CMP) provision prohibiting inducements to beneficiaries (the Beneficiary Inducements CMP),[2] and other compliance and program integrity considerations. In addition, the purpose and goals of OIG's resources vary: Some address trends in the health care industry that pose a fraud and abuse risk (*e.g.,* fraud alerts), others

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[1] Section 1128B(b) of the Social Security Act (the Act).

[2] Section 1128A(a)(5) of the Act.

provide information to encourage compliance best practices (*e.g.,* compliance program guidance documents (CPGs) and compliance-focused toolkits), and others are intended to explain OIG's legal interpretations of the Federal anti-kickback statute and the agency's administrative enforcement authorities or to describe our enforcement priorities (*e.g.,* policy statements). Some resources, such as the LEIE, provide data that industry stakeholders use for their own operations or compliance programs. Other resources, such as audit and evaluation reports, provide both findings and recommendations specific to a Federal agency, grantee, health care provider, or other entity, alongside broader takeaways that other stakeholders may use to improve their own operations.

We recognize that the variety of purposes and goals of OIG's resources mean that stakeholders access and use this information in a variety of ways. Respondents interested in providing information broadly across the categories should read the general questions in section III.A. Those questions solicit information on OIG's general approach for providing publicly available resources and issues that may improve the usefulness, timeliness, usability, and accessibility of OIG's resources. In addition, to ensure that we receive specific feedback relevant to each category of OIG resources described here, sections III.B through III.J each have two parts. First, we summarize each category of OIG resources to establish a common understanding. Second, we pose specific questions relevant to each category. For some categories, the RFI asks questions to assess how stakeholders access and use OIG's resources, as well as questions to assess whether new or updated resources are needed. For other categories, such as OIG audit and evaluation reports, we ask questions only about the format of such information but do not request ideas for specific products (*e.g.,* audits or evaluations).

Respondents are urged to address those questions most relevant to them and do not need to respond to every question.

To aid OIG's review of responses, it would be helpful if respondents structured their responses using the same lettering and numbering system we use here.

A. OIG Resources: General Questions

The following questions seek input about OIG's general approach to providing publicly available resources

that may improve the usefulness, timeliness, usability, and accessibility of OIG's resources across categories. Questions 1 through 8 relate to OIG's current resources and web page. Questions 9 through 11 relate to how technology or modern approaches to data analysis could enhance the usability and accessibility of OIG's public data and information. Subsequent sections of this RFI seek information about particular OIG resources, as described in each section.

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?

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?

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?

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?

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

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

7. OIG currently uses its website, email newsletter, and social media platforms to make the public aware of new resources. Are there any other methods of communication OIG should consider to inform the public regarding new or updated resources?

8. Does your organization currently, or plan to, integrate OIG's publicly available data and information related to compliance with other functional areas of your organization, such as organizational financial information? If so, please describe how OIG's publicly available data and information is or

could be most useful for such integration.

9. How is your organization using application programming interfaces (APIs) to automate functions that may relate to compliance or similar issues? For example, have you automated pre-authorization functions using APIs with payors? Would those functions benefit from automated functions related to use of OIG's public data and information?

10. Are there other types of technology that your organization is considering using to improve its compliance program or other related functions, such as using machine learning or artificial intelligence to automate assessment of claims for error before submission? Do these efforts use OIG's public data and information, or would they benefit from such data if made more useable and accessible?

B. OIG Advisory Opinions

Pursuant to section 1128D of the 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. More specifically, OIG, in consultation with the Department of Justice (DOJ), issues written advisory opinions to requesting parties with regard to: (i) What constitutes prohibited remuneration under the Federal anti-kickback statute; (ii) whether an arrangement or proposed arrangement satisfies the criteria in section 1128B(b)(3) of the Act, or established by regulation (*i.e.,* safe harbors), for activities that do not result in prohibited remuneration; (iii) what constitutes an inducement to reduce or limit services to Medicare or Medicaid program beneficiaries under section 1128A(b) of the Act; and (iv) whether an activity or proposed activity constitutes grounds for the imposition of sanctions under sections 1128, 1128A, or 1128B of the Act.

To implement and interpret section 1128D of the Act, OIG issued an interim final rule with comment period in 1997.[3] We revised and clarified our regulations in a final rule issued in 1998.[4] In 2008, we revised certain procedural requirements for submitting payments for advisory opinion costs.[5]

Since OIG implemented the advisory opinion process in 1997, OIG has issued nearly 400 advisory opinions, modified 21 advisory opinions, terminated 4

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[3] 62 FR 7350 (Feb. 19, 1997).

[4] 63 FR 38311 (July 16, 1998).

[5] 73 FR 15937 (Mar. 26, 2008); 73 FR 40982 (July 17, 2008).

opinions, and rescinded 1 opinion. During this time, OIG has received far more advisory opinion requests than these numbers may suggest, over 1,200 requests. For various reasons, including a requestor's withdrawal of a request or OIG's rejection of a request pursuant to its regulatory authority, not all requests submitted ultimately result in a published advisory opinion.

The procedures governing the submission of advisory opinion requests by an individual or entity in accordance with section 1128D of the Act are set forth in part 1008 of title 42 of the Code of Federal Regulations. These regulations impose content-oriented requirements for advisory opinion requests. For example, requests must contain certain information, such as ''[a] complete and specific description of all relevant information bearing on the arrangement,'' and specific certifications.[6] The regulations also describe topics that are not appropriate for an advisory opinion and circumstances in which OIG will not accept a request or will not issue an opinion, such as when the same or substantially the same course of action is under investigation or is or has been the subject of a proceeding involving HHS or another governmental agency.[7]

Section 1128D(b) of the Act provides that advisory opinions will be issued no later than 60 days after the request is received.[8] Notably, however, the regulations governing this process establish triggering events that toll the time period for issuing an advisory opinion.[9] The length of time that it takes for OIG to issue an opinion varies based on a number of factors, including the complexity of the arrangement, the completeness of the request submission, and the promptness of requesting parties in responding to requests for additional information.

As described above, not every request we receive results in an advisory opinion issued by OIG. For example, a requesting party may withdraw a request at any time before OIG issues an advisory opinion.[10] If a request is not withdrawn or rejected, OIG prepares an advisory opinion in consultation with its Government partners, including DOJ. After issuing an opinion to the requesting party, OIG posts a redacted version of the opinion to its website,[11] removing identifying information, such as the names of the parties. After an

opinion is published, OIG has the right to reconsider the questions involved in the advisory opinion, and where the public interest requires, to rescind, terminate, or modify the advisory opinion.[12]

1. Please describe your or your organization's experience, if any, with the current advisory opinion process. What has worked well, and what suggestions do you have for improving the process?

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?

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?

4. Are there types of arrangements or other circumstances in which an FAQ process, similar to the COVID–19 FAQ process, would be a preferable alternative to the advisory opinion process? From your perspective, what types of arrangements or what other circumstances would be amenable to an FAQ process as opposed to the existing advisory opinion process? If OIG implemented an FAQ process that functioned as an alternative to the advisory opinion process, should OIG

charge for that process, and if so, how should OIG determine such charges?

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.

6. OIG is considering modifying its advisory opinion fee structure. Revisions could include, for example, a tiered-cost structure, such as set fee amounts for requests of low, medium, or high complexity; requesting a retainer or other initial payment upon submission of a request; and waiving fees for requests withdrawn before a certain point in the process. Please share any feedback or other ideas on how OIG might structure and apply fees for advisory opinions in the future.

7. OIG is considering whether to set ''expiration dates'' for advisory opinions, at which point the advisory opinion would no longer be in effect. Alternatively, OIG could require requesting parties to recertify that the facts presented in an advisory opinion are still true and correct and constitute a complete description of the facts regarding the arrangement for which an advisory opinion was sought, where the failure to submit a recertification would result in the advisory opinion being terminated. Please share your thoughts on the relative benefits or drawbacks of either approach as well as considerations in setting timeframes for expiration or recertification of advisory opinions.

C. Fraud Alerts (Including Special Fraud Alerts)

With respect to special fraud alerts, pursuant to section 1128D(c) of the 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.'' OIG may elect to issue special fraud alerts in response to such requests, or otherwise, at OIG's discretion. For the most part, special fraud alerts have focused on national

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[6] 42 CFR 1008.36.
[7] 42 CFR 1008.15(c).
[8] Section 1128D(b)(5)(B)(1) of the Act.
[9] 42 CFR 1008.33, 1008.39, 1008.41, 1008.43.
[10] 42 CFR 1008.40.
[11] *See* 42 CFR 1008.47(a).

[12] 42 CFR 1008.45.

fraud and abuse trends in health care and address potential violations of the Federal anti-kickback statute and Beneficiary Inducements CMP. In developing these special fraud alerts, we rely on a number of sources, such as studies or management and program evaluations conducted by OIG's Office of Evaluation and Inspections (OEI). In addition, we may consult with experts in the subject field, including those within OIG, other HHS agencies, other Federal and State agencies, and others in the health care industry. Most recently, OIG released an alert in 2020 highlighting the fraud and abuse risks associated with the offer, payment, solicitation, or receipt of remuneration relating to speaker programs by pharmaceutical and medical device companies.[13]

In addition to the foregoing, section 1128D(a) of the Act requires HHS to develop and publish an annual notification in the **Federal Register**, which it does through OIG, formally soliciting proposals for the development of new special fraud alerts or adding to or modifying existing safe harbors to the Federal anti-kickback statute.

OIG also issues a variety of other fraud alerts, including alerts that warn the public about fraud schemes OIG has identified (*e.g.,* COVID–19 scams).[14]

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

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

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. Examples include a 2014 notice, issued concurrently with a related report by OEI, regarding pharmaceutical manufacturers' offer of copayment

coupons to insured patients [15] and a bulletin in 2013 describing the effect of exclusion from participation in Federal health care programs.[16]

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

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

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?

E. Compliance Program Guidance

As a general matter, 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. Beginning in 1998, OIG developed a series of CPGs directed at a number of different segments of the health care industry, including, for example, nursing facilities, hospitals, and pharmaceutical manufacturers.[17] As stated in each CPG, the suggestions included in the CPGs are not mandatory, and the CPGs are not intended to be an exhaustive discussion of beneficial compliance practices or relevant risk areas.

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

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?

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?

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?

F. Frequently Asked Questions, Including COVID–19 Frequently Asked Questions

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.[18] Through this FAQ process, OIG has received and reviewed questions submitted by a variety of health care stakeholders, and where OIG has determined that it would be appropriate and beneficial, we have provided informal feedback, time limited to the duration of the COVID–19 public health emergency,[19] explaining OIG's assessment of whether a particular arrangement poses a sufficiently low risk of fraud and abuse under the Federal anti-kickback statute, the Beneficiary Inducements CMP, or both. OIG developed this FAQ process consistent with the agency's mission to promote economy, efficiency, and effectiveness in HHS programs and to further OIG's commitment to protecting patients by ensuring that health care providers and others have the regulatory flexibility necessary to adequately respond to COVID–19 concerns. Recognizing the importance of expeditious feedback in the context of a public health emergency, when OIG has

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[13] OIG, Special Fraud Alert: Speaker Programs (Nov. 16, 2020), *available at https://oig.hhs.gov/ fraud/docs/alertsandbulletins/2020/SpecialFraud AlertSpeakerPrograms.pdf.*

[14] OIG, Fraud Alert: COVID–19 Scams (last updated on Aug. 16, 2021), *available at https:// oig.hhs.gov/fraud/consumer-alerts/fraud-alert- covid-19-scams/.*

[15] OIG, Special Advisory Bulletin: Pharmaceutical Manufacturer Copayment Coupons (Sept. 2014), *available at https://oig.hhs.gov/fraud/docs/ alertsandbulletins/2014/SAB_Copayment_ Coupons.pdf.*

[16] OIG, Updated Special Advisory Bulletin on the Effect of Exclusion from Participation in Federal Health Care Programs (May 8, 2013), *available at https://oig.hhs.gov/exclusions/files/sab- 05092013.pdf.*

[17] *E.g.,* OIG Supplemental Compliance Program Guidance for Nursing Facilities, 73 FR 56832 (Sept. 30, 2008); OIG Supplemental Compliance Program Guidance for Hospitals, 70 FR 4848 (Jan. 31, 2005); OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 FR 23731 (May 5, 2003).

[18] OIG, FAQs—Application of OIG's Administrative Enforcement Authorities to Arrangements Directly Connected to the Coronavirus Disease 2019 (COVID–19) Public Health Emergency, *available at https://oig.hhs.gov/ coronavirus/authorities-faq.asp.*

[19] The Secretary of HHS determined, through a January 31, 2020, determination, pursuant to section 319 of the Public Health Service Act, that a public health emergency exists and has existed since January 27, 2020. *See* U.S. Department of Health and Human Services, Determination that a Public Health Emergency Exists (Jan. 31, 2020), *available at https://www.phe.gov/emergency/news/ healthactions/phe/Pages/2019-nCoV.aspx* (COVID– 19 Declaration). The Secretary has issued subsequent 90-day renewals of that original determination. The duration of the COVID–19 public health emergency is tied to these determinations.

responded to questions, it has aimed to do so quickly.

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?

2. Would you or your organization find it valuable if OIG established an FAQ process modeled after the COVID–19 FAQ process that would continue after the COVID–19 public health emergency ends? What suggestions, if any, do you have for the structure of any FAQs, the process for submitting questions, or the topics such process would address?

3. What could OIG do differently to make an FAQ process for public health emergencies or other inquiries more meaningful, useful, or timely in the future?

G. Other Compliance Guidance and Resources

OIG has published numerous other compliance-related documents that target various segments of the health care industry. For example, OIG published ''A Roadmap for New Physicians: Avoiding Medicare and Medicaid Fraud and Abuse'' [20] to help new physicians understand the application of certain Federal fraud and abuse laws, including OIG's administrative enforcement authorities and how they protect Federal health care programs and their beneficiaries from fraud and abuse. We also have developed guidance documents specific to health care boards, including resources jointly published by OIG and professional associations.[21] Although most of OIG's resources are written materials, we also have published video trainings developed as part of the Health Care Fraud Prevention and Enforcement Action Team Provider Compliance Training initiative [22] and podcasts on various compliance topics.[23]

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.

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

H. Corporate Integrity Agreements

OIG negotiates 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. Individuals and entities agree to the obligations set forth in the CIAs, and in exchange, OIG agrees not to seek their exclusion from participation in Medicare, Medicaid, or other Federal health care programs under section 1128(b)(7) of the Act. OIG negotiates each CIA with the specific party or parties to the CIA, and each CIA is binding only on the party or parties to the CIA. However, OIG recognizes that industry stakeholders may review CIAs in the development or refinement of a compliance program and to facilitate an understanding of compliance best practices. In addition, OIG's website includes various materials related to CIAs. For example, OIG posts all open CIAs and maintains a list of closed CIAs.[24] In addition, OIG has issued CIA-specific FAQs and has published guidance on the independence and objectivity requirements relating to independent review organizations retained under CIAs.[25] OIG publishes CIA documents on our website so that industry stakeholders can use them as a resource in developing the essential elements of a compliance program. As noted above, each CIA is negotiated as part of an individual civil settlement and is binding only on the parties to the CIA.

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

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

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 LEIE. Anyone who hires an individual or entity on the LEIE may be subject to CMPs. To avoid CMP liability, health care entities need to routinely check the LEIE to ensure that new hires and current employees are not on the excluded list.

The LEIE website receives approximately 26 million visits annually. Users can check the LEIE through two primary means: downloading a spreadsheet or using web queries for up to five providers at a time. We believe that the number of annual visits combined with the mostly manual interaction with the LEIE means there is considerable opportunity to reduce burden and lower costs associated with checking the LEIE. Additionally, modern data sharing practices, such as APIs and better structured data, provide options to improve how users can access and use the LEIE data.

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?

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?

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.

J. OIG 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. OIG's audits and evaluations provide detailed findings and often include recommendations to Federal and State agencies, health care providers, HHS grantees, contractors, and other entities. In addition, OIG's reports can provide information, data, or methodologies that health care providers and other entities

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[20] OIG, A Roadmap for New Physicians: Avoiding Medicare and Medicaid Fraud and Abuse, *available at https://oig.hhs.gov/compliance/physician-education/roadmap_web_version.pdf.*

[21] *E.g.,* HCCA-OIG Compliance Effectiveness Roundtable, Measuring Compliance Program Effectiveness—A Resource Guide (Mar. 27, 2017), *available at https://oig.hhs.gov/compliance/compliance-resource-portal/files/HCCA-OIG-Resource-Guide.pdf.*

[22] OIG, HEAT Provider Compliance Training Videos, *available at https://oig.hhs.gov/newsroom/video/2011/heat_modules.asp.*

[23] *E.g.,* OIG, Podcasts, What Role Does Data Play in Fighting Healthcare Fraud, Waste, and Abuse?

(June 7, 2016), *available at https://oig.hhs.gov/newsroom/oig-podcasts/what-role-does-data-play-fighting-healthcare-fraud-waste-and-abuse.*

[24] OIG, Corporate Integrity Agreement Documents, *available at https://oig.hhs.gov/compliance/corporate-integrity-agreements/cia-documents.asp.*

[25] *E.g.,* OIG, Corporate Integrity Agreement FAQ, *available at https://oig.hhs.gov/faqs/corporate-integrity-agreements-faq.asp.*

can use to support their own internal audit and evaluation programs. Most of OIG's reports are made available publicly on OIG's website.

For some reports, OIG makes certain downloadable resources and applications available to the public, and OIG has published supplemental information to enable stakeholders to adapt the audit or evaluation methodology for their own use or to provide access to key data related to our findings. For example, OIG issued toolkits that provide detailed steps and programming code for using prescription drug claims data to analyze patients' opioid levels to identify certain patients at risk of opioid misuse or overdose.[26] In another example, OIG provided an interactive map online that enables users to see, by county, data on the need for opioid treatment services overlaid with data on the availability of buprenorphine services (medication-assisted treatment).[27]

OIG audit and evaluation reports are available on our website and can be downloaded as PDFs. In recent years, OIG has refreshed the format and layout of our reports with the goal of making them more user friendly; for example, most reports start with a ''Report in Brief'' that provides the key findings, recommendations, and context on the first page. We have also used different formats for certain types of reports, such as a ''data brief''[28] and a ''data snapshot,''[29] among others, with the intent of making the key results and takeaways clearer and more readily understood.

OIG also publishes other information and resources describing forthcoming reports or summarizing published reports. For example, OIG publishes a Work Plan on our website, which is a searchable repository of our ongoing audits and evaluations, updated monthly, with archived information on completed work plan items that link to their resulting products.[30] OIG also

publishes the agency's Semiannual Report to Congress.[31] Finally, OIG is developing a new tracking system for our recommendations. We intend to make available on our website a searchable repository of OIG recommendations from our audits and evaluations, including information about the status of their implementation.

1. How could OIG facilitate better utilization of data and data analysis through its toolkits or other resources?

2. How could OIG use its toolkits or other resources to help providers and others identify compliance risks or improve upon their compliance programs?

3. To facilitate the monitoring and automation of compliance best practices, would it be helpful to share the data methodology or programming codes employed by OIG in certain of its audit or evaluation reports, similar to OIG's Toolkits for Calculating Opioid Levels and Identifying Patients at Risk of Misuse or Overdose?[32]

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?

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?

6. Please tell us about your experiences, if any, in using supplemental products such as OIG Toolkits or Interactive Maps that sometimes accompany audit or evaluation reports. What have you found most valuable, if anything, about these supplemental products? What could we improve to make these products more valuable to you? Please also share any ideas for other types of supplemental products for OIG to

consider developing that would be useful to you.

7. Please share feedback on your experiences, if any, in accessing and using the OIG Work Plan. For example, how well can you find the information that you are looking for? How, if at all, do you or your organization use the information in our Work Plan?

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?

Please note: This is a request for information only. This RFI is issued solely for information and planning purposes; it does not constitute a request for proposal, application, proposal abstract, or quotation. This RFI does not commit the U.S. Government to contract for any supplies or services or make a grant award. Further, OIG is not seeking proposals through this RFI and will not accept unsolicited proposals. Respondents are advised that the U.S. Government will not pay for any information or administrative costs incurred in response to this RFI; all costs associated with responding to this RFI will be solely at the interested party's expense. Not responding to this RFI does not preclude participation in any future procurement, if conducted. It is the responsibility of the potential responders to monitor this RFI announcement for additional information pertaining to this request. Please note that OIG will not respond to questions about the policy issues raised in this RFI. Contractor support personnel may be used to review RFI responses.

Responses to this RFI are not offers and cannot be accepted by the U.S. Government to form a binding contract or issue a grant. Information obtained as a result of this RFI may be used by the U.S. Government for program planning on a nonattribution basis. Respondents should not include any information that might be considered proprietary or confidential. This RFI should not be construed as a commitment or authorization to incur costs for which reimbursement would be required or sought. All submissions become U.S. Government property and will not be returned. OIG may publicly post the comments received or a summary thereof.

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[26] HHS OIG Toolkits for Calculating Opioid Levels and Identifying Patients at Risk of Misuse or Overdose, *available at https://oig.hhs.gov/oei/reports/oei-02-17-00560.asp.*

[27] OIG, *Geographic Disparities Affect Access to Buprenorphine Services for Opioid Use Disorder* (OEI–12–17–00240) (Jan. 2020), *available at https://oig.hhs.gov/oei/reports/oei-12-17-00240.asp.*

[28] *E.g.,* OIG, Concerns Persist About Opioid Overdoses and Medicare Beneficiaries' Access to Treatment and Overdose-Reversal Drugs (OEI–02–20–00401) (Aug. 2021), *available at https://oig.hhs.gov/oei/reports/OEI-02-20-00401.asp.*

[29] *E.g.,* OIG, National Review of Opioid Prescribing in Medicaid Is Not Yet Possible (OEI–05–18–00480) (Aug. 2019), *available at https://oig.hhs.gov/oei/reports/oei-05-18-00480.asp.*

[30] OIG Work Plan, *available at https://oig.hhs.gov/reports-and-publications/workplan/index.asp.*

[31] OIG Semiannual Report to Congress, *available at https://oig.hhs.gov/reports-and-publications/semiannual/index.asp.*

[32] HHS OIG Toolkits for Calculating Opioid Levels and Identifying Patients at Risk of Misuse or Overdose, *available at https://oig.hhs.gov/oei/reports/oei-02-17-00560.asp.*

IV. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping, or third-party disclosure requirements under the Paperwork Reduction Act of 1995 (PRA). However, section III of this document does contain a general solicitation of comments in the form of a request for information. In accordance with the implementing regulations of the PRA, specifically 5 CFR 1320.3(h)(4), this general solicitation is exempt from the PRA. Facts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the agency's full consideration, are not generally considered information collections and therefore not subject to the PRA. Consequently, there is no need for review by the Office of Management and Budget under the authority of the PRA.

V. Response to Comments

Because of the large number of public comments we normally receive in response to **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, if we proceed with a subsequent document, we may respond to the comments in the preamble to that document. Publication of this RFI does not commit OIG to the promulgation of new regulations or issuance of new guidance.

Christi A. Grimm,
Principal Deputy, Inspector General.
[FR Doc. 2021–20558 Filed 9–23–21; 8:45 am]
BILLING CODE 4152–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice of Diabetes Mellitus Interagency Coordinating Committee Meeting

AGENCY: National Institutes of Health, HHS.
ACTION: Notice.

SUMMARY: The Diabetes Mellitus Interagency Coordinating Committee (DMICC) will hold a meeting on November 8, 2021. The topic for this meeting will be "Evolving Concepts in the Assessment and Management of Hypoglycemia." The meeting is open to the public.

DATES: The meeting will be held on November 8, 2021 from 12:00 p.m. to 3:00 p.m. EDT.

ADDRESSES: The meeting will be held via the Zoom online video conferencing platform. For details, and to register, please contact *dmicc@mail.nih.gov.*

FOR FURTHER INFORMATION CONTACT: For further information concerning this meeting, including a draft agenda, which will be posted when available, see the DMICC website, *www.diabetescommittee.gov,* or contact Dr. William Cefalu, Executive Secretary of the Diabetes Mellitus Interagency Coordinating Committee, National Institute of Diabetes and Digestive and Kidney Diseases, 6707 Democracy Boulevard, Democracy 2, Room 6037, Bethesda, MD 20892, telephone: 301–435–1011; email: *dmicc@mail.nih.gov.*

SUPPLEMENTARY INFORMATION: In accordance with 42 U.S. Code § 285c–3, the DMICC, chaired by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) comprising members of the Department of Health and Human Services and other federal agencies that support diabetes-related activities, facilitates cooperation, communication, and collaboration on diabetes among government entities. DMICC meetings, held several times a year, provide an opportunity for Committee members to learn about and discuss current and future diabetes programs in DMICC member organizations and to identify opportunities for collaboration. The November 8, 2021 DMICC meeting will focus on "Evolving Concepts in the Assessment and Management of Hypoglycemia."

Any member of the public interested in presenting oral comments to the Committee should notify the contact person listed on this notice at least 5 days in advance of the meeting. Interested individuals and representatives or organizations should submit a letter of intent, a brief description of the organization represented, and a written copy of their oral presentation in advance of the meeting. Only one representative of an organization will be allowed to present; oral comments and presentations will be limited to a maximum of 5 minutes. Printed and electronic copies are requested for the record. In addition, any interested person may file written comments with the Committee by forwarding their statement to the contact person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person. Because of time constraints for the meeting, oral comments will be allowed on a first-come, first-serve basis.

Members of the public who would like to receive email notification about future DMICC meetings should register for the listserv available on the DMICC website, *www.diabetescommittee.gov.*

Dated: September 21, 2021.
Bruce Tibor Roberts,
Health Science Policy Analyst, Office of Scientific Program and Policy Analysis, National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health.
[FR Doc. 2021–20802 Filed 9–23–21; 8:45 am]
BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Mental Health Initial Review Group; Mental Health Services Study Section.
Date: October 21–22, 2021.
Time: October 21, 2021, 12:00 p.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).
Time: October 22, 2021, 11:00 a.m. to 4:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).
Contact Person: Aileen Schulte, Ph.D., Scientific Review Officer, Division of