Comment: Some commenters made suggestions related to hospice payment requirements, CMS manuals, and statutory requirements that are not within the scope of our proposal to revise the hospice CoPs or within our regulatory authority.

Response: We have shared these out of scope comments with the appropriate CMS stakeholders.

In accordance with public comments, we are finalizing the change at § 418.106(b)(1) as proposed.

J. Advisory Opinions on the Application of the Physician Self-Referral Law

1. Statutory and Regulatory Background

Section 4314 of the Balanced Budget Act of 1997 (Pub. L. 105–33, enacted August 5, 1997), added section 1877(g)(6) to the Act. Section 1877(g)(6) of the Act requires the Secretary to issue written advisory opinions concerning whether a referral relating to designated health services (other than clinical laboratory services) is prohibited under section 1877 of the Act. On January 9, 1998, the Secretary issued a final rule with comment period in the **Federal Register** to implement and interpret section 1877(g)(6) of the Act (the 1998 advisory opinion rule). (See Medicare Program; Physicians' Referrals; Issuance of Advisory Opinions (63 FR 1646).) The regulations are codified in §§ 411.370 through 411.389 (the physician self-referral advisory opinion regulations).

Section 1877(g)(6)(A) of the Act states that each advisory opinion issued by the Secretary shall be binding as to the Secretary and the party or parties requesting the opinion. Section 1877(g)(6)(B) of the Act requires the Secretary, in issuing advisory opinions regarding the physician self-referral law, to apply the rules in paragraphs (b)(3) and (4) of section 1128D of the Act, to the extent practicable. This paragraph also requires the Secretary to take into account the regulations promulgated under paragraph (b)(5) of section 1128D of the Act.

Section 1128D of the Act was added to the statute by section 205 of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub. L. 104–191, effective August 21, 1996). Among other things, section 1128D of the Act requires the Secretary, in consultation with the Attorney General, to issue written advisory opinions as to specified matters related to the anti-kickback statute in section 1128B(b) of the Act, the safe harbor provisions in § 1001.952, and other provisions of the Act under the authority of the Office of Inspector General (OIG). To implement and interpret section 1128D of the Act, OIG issued an interim final rule with comment period in the February 19, 1997 **Federal Register** entitled Medicare and State Health Care Programs: Fraud and Abuse; Issuance of Advisory Opinions by the OIG (62 FR 7350), revised and clarified its regulations in the July 16, 1998 **Federal Register** (68 FR 38311), and updated its regulations in a final rule published in the July 17, 2008 **Federal Register** that solely revised certain procedural requirements for submitting payments for advisory opinion costs (73 FR 40982) (collectively, the OIG advisory opinion rule). The regulations are codified in part 1008 of this title of the Code of Federal Regulations (the OIG advisory opinion regulations).

Section 1128D(b)(3) of the Act prohibits the Secretary from addressing in an advisory opinion whether: (1) Fair market value shall be or was paid or received for any goods, services, or property; or (2) an individual is a *bona fide* employee within the requirements of section 3121(d)(2) of the Internal Revenue Code of 1986. In the 1998 advisory opinion rule, we incorporated these provisions into the physician self-referral law regulations (63 FR 1646). Section 1128D(b)(4)(A) of the Act states that an advisory opinion related to OIG authorities is binding as to the Secretary and the party or parties requesting the opinion. This section is redundant of the provision in section 1877(g)(6)(A) of the Act, and therefore, not incorporated into the physician self-referral law advisory opinion regulations. Section 1128D(b)(4)(B) of the Act provides that the failure of a party to seek an advisory opinion may not be introduced into evidence to prove that the party intended to violate the provisions of sections 1128, 1128A, or 1128B of the Act. We incorporated section 1128D(b)(4)(B) of the Act in the physician self-referral regulations at § 411.388.

As discussed previously, section 1877(g)(6)(B) of the Act requires the Secretary, to the extent practicable, to take into account the regulations issued under the authority of section 1128D(b)(5) of the Act (that is, the OIG advisory opinion regulations). Section 1128D(b)(5)(A) of the Act requires that the OIG advisory opinion regulations must provide for: (1) The procedure to be followed by a party applying for an advisory opinion; (2) the procedure to be followed by the Secretary in responding to a request for an advisory opinion; (3) the interval in which the Secretary will respond; (4) the reasonable fee to be charged to the party requesting an advisory opinion; and (5) the manner in which advisory opinions will be made available to the public. We interpret the Congress' directive to take into account the OIG regulations to mean that we should use the OIG regulations as our model, but that we are not bound to follow them (63 FR 1647). Nonetheless, in the 1998 advisory opinion rule, we largely adopted OIG's approach to issuing advisory opinions, stating that we intend for physician self-referral law advisory opinions to provide the public with meaningful advice regarding whether, based on specific facts, a physician's referral for a designated health service (other than a clinical laboratory service) is prohibited under section 1877 of the Act (63 FR 1648).

2. Revisions to the 1998 Advisory Opinion Process and Regulations

In the June 25, 2018 **Federal Register**, we published a Request for Information Regarding the Physician Self-Referral Law (83 FR 29524) (June 2018 CMS RFI) that sought recommendations from the public on how to address any undue impact and burden of the physician self-referral statute and regulations. Although we did not specifically request comments on the physician self-referral advisory opinion regulations, we received a number of comments urging that CMS reconsider its approach to advisory opinions and transform the process such that the regulated industry may obtain expeditious guidance on whether a physician's referrals to an entity with which he or she has a financial relationship would be prohibited under section 1877 of the Act. These commenters stated their belief that the current advisory opinion process could be improved. Some commenters also stated that the process is too restrictive, noting that CMS has placed what the commenters see as unreasonable limits on the types of questions that qualify for an advisory opinion (for example, CMS will not issue an advisory opinion where the arrangement at issue is hypothetical and does not issue advisory opinions on general questions of interpretation), and that physician self-referral law advisory opinions apply only to the specific circumstances of the requestor. These commenters asserted that the OIG's advisory opinion process, upon which the physician self-referral law advisory opinion process is modeled, is inappropriate as applied to a payment statute, noting that OIG opines on matters related to a felony criminal statute, whereas the physician self-referral law, by contrast, is a payment rule without a *mens rea* requirement.

Some commenters highlighted the complexity of the physician self-referral regulations, the strict liability nature of the physician self-referral law, and the need for certainty before arrangements are initiated and claims submitted as reasons why an advisory opinion process related to a felony criminal statute is inappropriate for the physician self-referral law. Other commenters asserted that the process is arduous and inefficient. These commenters noted that the advisory opinion process can extend beyond the 90-day timeframe provided for at § 411.380 and asserted that it lags behind the OIG process in terms of efficiency.

In designing its advisory opinion process, OIG stated that it carefully balanced stakeholders' desire for an accessible process and meaningful and informed opinions with its need to closely scrutinize arrangements to insure that requesting parties are not inappropriately granted protection from sanctions. (63 FR 38312 through 38313). We appreciate that there are important differences between the physician self-referral law, a strict liability statute designed to prevent payment for services where referrals are affected by inherent financial conflicts of interest, and the anti-kickback statute, which is a criminal law designed to prosecute intentional acts of fraud and abuse.

More than 20 years have passed since the 1998 advisory opinion regulations were issued. In those 20 years, we issued 31 advisory opinions,[109] 15 of which addressed the 18-month moratorium on physician self-referrals to specialty hospitals in which they have an ownership or investment interest. In light of the comments received on the RFI, we undertook a fresh review of the 1998 advisory opinion process. We agree that it is important to have an accessible process that produces meaningful opinions on the applicability of section 1877 of the Act, especially in light of the perceived complexity of the physician self-referral regulations, including the requirements of the various exceptions and the key terminology applicable to many of the exceptions. We recognize that our current advisory opinion process has not been widely utilized by stakeholders and has resulted in few opinions being issued to date. Accordingly, we reviewed our advisory opinion regulations in an effort to identify limitations and restrictions that may be unnecessarily serving as an obstacle to a more robust advisory opinion process.

Failure to satisfy the requirements of an exception to the physician self-referral law carries significant consequences, regardless of a party's intent.[110] The safe harbors under the anti-kickback statute are voluntary, and the failure of an arrangement to fit squarely within a safe harbor does not *automatically* mean that the arrangement violates the anti-kickback statute. By contrast, the physician self-referral law prohibits a physician's referral if there is a financial relationship that does not satisfy the requirements of one of the enumerated exceptions. In other words, the physician self-referral law is a strict liability law, and parties that act in good faith may nonetheless face significant financial exposure if they misunderstand or misapply the law's exceptions.

Regulated parties' desire for certainty must be balanced with CMS' interest in maintaining the integrity of the advisory opinion process, and ensuring that it is not used to inappropriately shield improper financial arrangements. We believe that the risk of such misuse is acceptably low in this context because the advisory opinion authority at section 1877(g) of the Act is narrowly tailored. CMS can only issue favorable advisory opinions for arrangements that do not violate section 1877 of the Act, for example, because there is no referral for designated health services, there is no financial relationship, or the arrangement satisfies the requirements of an applicable exception. In contrast, OIG has issued favorable advisory opinions for arrangements that do not fit within a safe harbor where it has concluded, based on a totality of the facts and circumstances, that the arrangement poses a sufficiently low risk of fraud and abuse under the anti-kickback statute. CMS cannot similarly extend protection beyond the exceptions, so there is a structural limit on the scope of CMS' authority. Furthermore, a favorable advisory opinion from CMS does not immunize parties from liability under the anti-kickback statute.

We proposed changes that would both clarify the process and remove limitations and restrictions that might be unnecessarily serving as obstacles to a more robust advisory opinion process.

a. General

Comment: Commenters overwhelmingly supported the proposed modifications to the advisory opinion regulations, and many stated that the modifications, if finalized, would facilitate better understanding of how to comply with the law and help parties to nonabusive arrangements avoid the strict penalties that result from noncompliance. Some commenters stated that the proposed modifications to the advisory opinion process, if finalized, would assist in advancing innovation in care delivery by encouraging greater participation in value-based care and alternative payment arrangements. Several commenters agreed that the advisory opinion process for the physician self-referral law, a strict liability law, should not be identical to the advisory opinion process for the anti-kickback statute, a criminal law. Commenters expressed their hope that CMS would publish more advisory opinions in the future.

Response: We appreciate the commenters' support for our efforts to reform the advisory opinion process. We agree that a well-functioning advisory opinion process could aid in advancing two of the Department's top priorities—reducing regulatory burden on providers and encouraging adoption of alternative payment models and coordinated care arrangements. A faster and more robust advisory opinion process facilitates the shift to value-based care arrangements by providing more guidance for parties trying to understand how the physician self-referral law applies in an evolving and innovative marketplace. This will help to reduce provider burden by providing insight into what does and does not comply with the law, which encourages innovation.

Comment: Several commenters who were generally supportive of the proposed modifications to the advisory opinion process also stated that changes to the 1998 advisory opinion rule should not further develop or create additional abusive self-referring arrangements.

Response: This final rule does not change the number or scope of exceptions from the physician self-referral prohibition. This final rule merely updates the process for issuing advisory opinions on whether certain fact patterns would result in a prohibited referral. Under the advisory opinion process, requestors must provide, among other information, sufficient detail about the arrangement

[109] These advisory opinions are available on CMS' website, at *https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/advisoryopinions.html.* This number does not include advisory opinion requests that were withdrawn.

[110] The CMS Voluntary Self-Referral Disclosure Protocol (SRDP) allows providers of services and suppliers to self-disclose actual or potential violations of the physician self-referral statute. Under the SRDP, CMS may reduce the amount due and owing for violations of section 1877 of the Act. Information about the SRDP can be found at *https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/CMS-Voluntary-Self-Referral-Disclosure-Protocol.pdf.*

and the named parties to the arrangement in its submission. The advisory opinion process involves communication with the requestor to ensure CMS has a clear understanding of the arrangement under review and the parties involved. We believe that the regulations governing the advisory opinion process contain sufficient guardrails to limit the risk of improper use of the advisory opinion process.

b. Matters Subject to Advisory Opinions (§ 411.370)

Section 1877(g)(6) of the Act requires the Secretary to issue advisory opinions concerning ''whether a referral relating to designated health services (other than clinical laboratory services) is prohibited under this section.'' In accordance with section 1877(g)(6)(B) of the Act, CMS adopted in regulation rules mirroring the requirements in paragraphs (b)(3) and (4) of section 1128D of the Act, which prohibit OIG from opining on whether an arrangement is fair market value and whether an individual is a *bona fide* employee within the requirements of section 3121(d)(2) of the Internal Revenue Code. In addition to these restrictions on matters that are not subject to advisory opinions, our current regulation at § 411.370(b)(1) states that CMS does not consider, for purposes of an advisory opinion, requests that present a general question of interpretation, pose a hypothetical situation, or involve the activities of third parties. When explaining this regulation, we stated that we interpret section 1877(g)(6) of the Act to allow for opinions on specific referrals involving physicians in specific situations (63 FR 1649). We also noted our reasons for avoiding opinions on generalized arrangements, stating that it would not be possible for an advisory opinion to reliably identify all the possible hypothetical factors that might lead to different results.

(i) Requests That Present a General Question of Interpretation or Pose a Hypothetical Situation

Under our current regulations, we accept requests for advisory opinions that involve existing arrangements, as well as requests that involve arrangements into which the requestor plans to enter. While we did not propose an expansion of the scope of advisory opinion requests, we solicited comments on whether we should do so in the future. We proposed clarifications to § 411.370(b) regarding matters that qualify for advisory opinions and the parties that may request them. Specifically, we proposed to clarify that the request for an advisory opinion must ''relate to'' (rather than ''involve'') an existing arrangement or one into which the requestor, in good faith, specifically plans to enter. Requestors continue to be obligated to disclose all facts relevant to the arrangement for which an advisory opinion is sought. We also proposed revisions to the regulation text for grammatical purposes.

The following is a summary of the comments we received on the above proposals and our responses.

Comment: Commenters generally supported the clarification that an advisory opinion request must ''relate to,'' rather than ''involve,'' an arrangement that is existing or into which the requestor plans to enter, although at least one commenter suggested that CMS not finalize this proposed clarification, based on the perception that it will not serve to decrease the volume of information that requestors will need to provide to CMS.

Response: We are finalizing the proposal to consider questions that ''relate to'' existing or planned arrangements. The modification is intended to provide further clarity on existing physician self-referral law advisory opinion policy. It is not intended to lessen the volume of information submitted, nor expand the scope of the advisory opinion process, but rather, to more precisely capture the appropriate scope of advisory opinion requests. As discussed further below, we will consider all complete requests that relate to either an existing or planned arrangement (that is, requests that describe a specific arrangement with sufficient detail).

Comment: A number of commenters urged CMS to further expand the matters subject to advisory opinions to include requests that present a general question of interpretation or pose a hypothetical situation. These commenters suggested that this would provide needed clarification for providers, would help reduce confusion around compliance with the physician self-referral law, and would help reduce the administrative burden of compliance, especially for small and rural providers. Several of these commenters wanted the flexibility to request an advisory opinion before spending the significant time and resources required to draft and formalize proposed arrangements. Others cited concerns that if they wait to seek an advisory opinion until after an arrangement is in place, they risk being found to be out of compliance and could face penalties.

Many commenters also acknowledged CMS' concern that expanding advisory opinions to cover hypothetical arrangements or general questions of interpretation could significantly increase the volume of advisory opinion requests. However, these commenters suggested that CMS could institute guardrails to ensure only legitimate and complete requests are entering into the process, such as imposing additional fee requirements, or using improved technology and intake processes for requests.

One commenter stated that CMS should not reject an advisory opinion request on the grounds that it poses only a ''general question of interpretation,'' especially since the requestor has no opportunity to rebut CMS' determination. This commenter stated that the distinction between planned arrangements and general matters of interpretation is abstract and favors form over substance, and urged that the ''general question of interpretation'' restriction be deleted. This commenter also stated that the proposed rule's requirement for requestors to describe arrangements in a sufficient level of detail would provide a meaningful safeguard against misuse of the advisory opinion process.

Response: We continue to believe that the Secretary's obligation under section 1877(g)(6) of the Act to issue advisory opinions concerning whether a referral relating to designated health services is prohibited under this section limits the subject of advisory opinions to questions about a specific referral made by a physician in a specific financial relationship under specific facts and circumstances. It remains our position that requests regarding hypothetical facts or general questions of interpretation are not appropriate for an advisory opinion. Further, although we proposed a number of changes to improve the advisory opinion process for stakeholders, we believe that expanding the process to include such questions could overwhelm the agency. As such, we are not expanding the scope of the advisory opinion process to include hypothetical arrangements or general questions of interpretation.

However, based on comments received, we have reviewed the regulation's current terminology of a request ''present[ing] a general question of interpretation'' or ''pos[ing] a hypothetical situation,'' and acknowledge that these terms may lack sufficient clarity. Based on the comments received, there appears to be some confusion over how CMS distinguishes a planned arrangement—that is, a specific arrangement that does not yet exist but the requestor in good faith plans to enter—from a hypothetical

fact pattern or question of general interpretation. Therefore, we are removing this terminology at 11.370(b)(1).

We accept and issue advisory opinions that relate to existing arrangements or arrangements into which the requestor intends to enter if it receives a favorable advisory opinion. To issue an advisory opinion, the requestor must provide, among other information, sufficient detail about the arrangement and the parties to the arrangement, including identifying information about one or both of the parties to the arrangement. Thus, the universe of acceptable advisory opinions would not include requests for guidance that interprets the physician self-referral law generally, such as whether generic noncompete provisions take into account the volume or value of a physician's referrals. Nor would the universe include a request to opine, in the abstract, whether a variety of compensation methodologies take into account the volume or value of referrals. Although we do not consider an arrangement to be a per se hypothetical matter simply because the parties have not yet entered into the arrangement, there are some matters that would be inappropriate for advisory opinions. These include requests for an advisory opinion regarding whether a physician's referral is prohibited under section 1877 of the Act where the underlying financial arrangement between the physician and the entity to which he or she refers designated health services is otherwise illegal or impermissible. For example, we would not accept a request for an advisory opinion regarding whether a referral is permissible if the claim for the designated health services could not be billed to the Medicare program for some reason unrelated to the physician self-referral law. We have made modifications to § 411.370(e) to reflect this view.

We also appreciate the compliance burden on physicians and DHS entities subject to the physician self-referral law, as well as the significant consequences of noncompliance, and we acknowledge the desire for more timely guidance. Therefore, we are considering available means to provide general guidance and compliance advice outside of the advisory opinion process. Several commenters suggested that CMS issue more subregulatory guidance to provide greater clarity around the physician self-referral law and regulations. While subregulatory guidance must always be carefully constructed so as not to impose new obligations on regulated parties, CMS will explore opportunities to provide additional, appropriate guidance through subregulatory means. As we noted in the proposed rule, we respond to questions pertaining to the physician self-referral law through the CMS Physician Self-Referral Call Center email inbox, and frequently assists parties with identifying relevant guidance. The CMS Physician Self-Referral Call Center resource is free to the public, and inquiries may be sent to *1877CallCenter@cms.hhs.gov.* For additional information, *see https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Call-Center.html.* We also respond to frequently asked questions (FAQs) regarding the physician self-referral law from time to time. FAQs issued to date are available on our website at *https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/FAQs.html.*

For these reasons, we are finalizing our proposed changes to § 411.370(b), with the modifications as described above. In response to commenters' desire for greater clarity around the types of requests that CMS will reject, we are also adding a new paragraph § 411.370(e)(1)(v) to clarify that CMS would decline to accept an advisory opinion request that involves a course of conduct that is not legally permissible for reasons other than section 1877 of the Act.

(ii) Acceptance of Requests

Current § 411.370(e) states that CMS does not accept an advisory opinion request or issue an advisory opinion if: (1) The request is not related to a named individual or entity; (2) CMS is aware that 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; or (3) CMS believes that it cannot make an informed opinion or could only make an informed opinion after extensive investigation, clinical study, testing, or collateral inquiry. We proposed changes to this regulation. First, we proposed to add to the reasons that CMS will not accept an advisory opinion request or issue an advisory opinion. Specifically, we proposed that CMS will not accept an advisory opinion request or not issue an advisory opinion with respect to a request that does not describe the arrangement at issue with a level of detail sufficient for CMS to issue an opinion, and the requestor does not timely respond to CMS requests for additional information. We believe that this is important to the agency's ability to focus its resources on complete requests.

Second, we proposed to amend current § 411.370(e)(2), which states that CMS will not issue an advisory opinion if it is aware that 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 other government entities. Although CMS consults with other HHS components and governmental agencies, including OIG and DOJ, on pending advisory opinion requests, we believe the current regulation is too restrictive, and unnecessarily limits CMS' flexibility to issue timely guidance to requestors engaged in or considering legitimate business arrangements. Therefore, we proposed to modify § 411.370(e)(2) to allow CMS more discretion to determine, in consultation with OIG and DOJ, whether acceptance of the advisory opinion request or issuance of the advisory opinion is appropriate. Specifically, we proposed at § 411.370(e)(2) that CMS may elect not to accept an advisory opinion request or issue an advisory opinion if, after consultation with OIG and DOJ, it determines that the course of action described in the request is substantially similar to conduct that is under investigation or the subject of a proceeding involving the Department or other law enforcement agencies, and that issuing an advisory opinion could interfere with the investigation or proceeding. We proposed to retain at renumbered § 411.370(e)(1)(iii) the restriction on accepting requests if CMS is aware that the same course of action is under investigation or is, or has been the subject of a proceeding involving the Department or another governmental agency. We also proposed to clarify that CMS would consult with OIG and DOJ regarding investigations or proceedings involving the same course of conduct described in an advisory opinion request.

We received public comments on these proposals. The following is a summary of the comments we received on the above proposals and our responses.

Comment: Commenters were generally supportive of the requirement that requests must contain a level of detail sufficient to permit CMS to issue an informed opinion, and that it would be appropriate to reject a request if the requestor did not timely respond to CMS' request for additional information. Several commenters opined that this safeguard will protect against inappropriate use of the advisory opinion process.

Response: We agree that this safeguard is necessary to protect the integrity of the advisory opinion process

and to ensure that CMS is focusing its resources on requests that provide sufficient detail to allow CMS to make an informed decision.

Comment: Several commenters agreed with CMS' current policy of rejecting advisory opinion requests where the same course of action described in the request is the subject of an investigation or proceeding.

Response: We are maintaining this current policy set forth at § 411.370(e)(1)(iii).

Comment: Commenters supported the proposed modifications to § 411.370(e) that would give CMS more flexibility with respect to requests involving conduct that is substantially similar to conduct that is under investigation or is the subject of a law enforcement proceeding. Several commenters stated that the current restriction at § 411.370(e)(2) unnecessarily limits CMS' ability to issue timely guidance to requestors engaged in or planning to enter into legitimate business arrangements. Several commenters urged CMS to reject such requests only where the issuance of an advisory opinion could have a direct effect on an investigation or proceeding. Several other commenters, however, suggested that CMS remove the restriction in its entirety, arguing that enforcement actions often involve lengthy investigations and litigation, and parties with substantially similar arrangements could be locked out of the advisory opinion process for long periods of time while these proceedings are ongoing. One commenter considered whether by maintaining the discretion to reject requests involving substantially similar conduct, CMS was unlikely to issue more advisory opinions than it currently issues.

Response: We believe it is important for CMS to retain discretion to reject an advisory opinion request where we determine, after consultation with OIG and DOJ, that issuance of an opinion would interfere with a pending investigation or proceeding. However, we recognize that the exercise of this discretion could result in parties to legitimate arrangements being locked out of the advisory opinion process for lengthy periods of time, and having to make business decisions without the certainty that an advisory opinion can provide. While we will strive to be judicious in our exercise of discretion, we may not be in a position to respond to every request in a timeframe that suits the requestor. In those instances, it is up to regulated parties to decide whether to pursue a particular course of conduct in the absence of an advisory opinion.

For the reasons stated above, we are finalizing our proposed changes to § 411.370(e), and, as described above in section b.(i), adding a new paragraph (e)(1)(v) to clarify that CMS would decline to accept an advisory opinion that involves a course of conduct that is not legally permissible for reasons other than section 1877 of the Act.

c. Timeline for Issuing an Advisory Opinion (§ 411.380)

Section 1877(g)(6) of the Act does not impose any deadlines by which the agency must respond to a physician self-referral law advisory opinion request, but it does require the Secretary to take into account OIG advisory opinion regulations under subsection (b)(5) of section 1128D of the Act. Section 1128D(b)(5)(B)(i) of the Act provides that the Secretary shall be required to issue an advisory opinion no later than 60 days after the request is received. In the 1998 CMS advisory opinions rule, we adopted a 90-day timeframe for most requests. In addition, for requests that we determined, in our discretion, involve complex legal issues or highly complicated fact patterns, we reserved the right to issue an advisory opinion within a reasonable timeframe. We created this timeframe based upon our estimates of the volume and complexity of expected requests, and based upon our then-current staffing situation.

We proposed to modify this time period and establish a 60-day timeframe for issuing advisory opinions. This period would begin on the date that CMS formally accepts a request for an advisory opinion. The 60 days would be tolled during any time periods in which the request is being revised or additional information compiled and presented by the requestor. We are adopting a 60-working day timeframe, and clarifying that day refers to a ''working day,'' where ''working days'' is defined as days excluding Saturdays, Sundays, and legal holidays.[111]

We also considered whether CMS should provide requestors with the option to request expedited review. We believe that a more efficient and expeditious process could give stakeholders more certainty and encourage innovative care delivery arrangements. We solicited comment on the changes to the timeframe, whether CMS in the final rule should include a provision on expedited review and, if so, the parameters for expedited review.

The following is a summary of the comments we received on these proposals and our responses.

Comment: Commenters supported shortening the current 90-day timeframe to 60 days, although many commenters expressed skepticism that CMS would be able to meet such a deadline absent investment of additional resources or other process changes. One commenter requested more clarity as to when CMS ''formally accepts'' a request for an advisory opinion, thereby triggering the beginning of the 60-day timeframe.

Response: We are finalizing a 60-working day timeframe for issuance of advisory opinions, which will begin on the date that CMS formally accepts a request for review. We will formally accept a request once the agency determines that (a) the request and any supplemental submissions describe the arrangement at issue with a level of detail sufficient for CMS to issue the opinion, and (b) the grounds for rejection of a request listed at § 411.370(e) do not apply. We believe that the collection of user fees, a policy we proposed and are finalizing in this rule, will enable CMS to process advisory opinion requests in a timely fashion.

Under our current regulation, we reserve the ability to extend this default time period for requests that present complex legal issues of first impression, or highly complicated fact patterns, and to suspend the time period in the circumstances listed at § 411.380(c)(3). While we are maintaining this reservation of discretion, we appreciate commenters' views that requestors want some degree of assurance that their investment of time in the advisory opinion process will result in the timely issuance of an opinion.

Current regulations provide for a 15-working day review period that begins on the date CMS receives a request for an advisory opinion. Under the new timeframe, CMS will maintain this 15-working day review period. During this time, we will review the submission to make a preliminary[112] determination as to whether the submission describes the arrangement at issue with a level of detail sufficient for CMS to issue an opinion. For submissions clearly lacking in sufficient detail, we will notify the requestors of the deficiencies and request additional information. Once CMS makes a determination that the submission contains the necessary level

[111] ''Legal holidays'' include the days set aside by statute for observing New Year's Day, Martin Luther King Jr.'s Birthday, Washington's Birthday, Memorial Day, Independence Day, Labor Day, Columbus Day, Veterans' Day, Thanksgiving Day, and Christmas Day; and any day declared a holiday by the President or Congress.

[112] CMS may or may not later need to request additional information during the 60-working day review timeframe.

of detail, we will consult with DOJ and OIG to determine whether grounds exist to reject the request. If CMS determines that it can accept the request for review, we will notify requestors that their submission is formally accepted.

Comment: Commenters supported the establishment of an expedited pathway for advisory opinion requests, and several noted that an expedited option would be particularly helpful with respect to transactions with an impending deadline. However, many of these same commenters also noted that the expedited pathway would only be meaningful if CMS had the resources to adhere to it.

Several commenters suggested that CMS establish a process for expedited review for relatively more straightforward requests that lend themselves to a ''yes'' or ''no'' answer, such as requests for CMS' opinion on whether an arrangement is ''indistinguishable in all material aspects'' from another arrangement upon which CMS has issued a favorable advisory opinion.

Response: We agree with commenters that an expedited review process would be appropriate for requests that seek a determination as to whether an arrangement is ''indistinguishable in all material aspects'' from another arrangement that has been reviewed and found to comply with the physician self-referral law. Based on these comments, we are finalizing modifications to § 411.380 to provide for expedited review for these types of requests only. Requestors would indicate in their advisory opinion requests that they are seeking expedited review. We will promptly make a determination on eligibility for expedited review, and communicate our decision to a requestor when notifying the requestor that CMS has formally accepted the request. The expedited review period of 30 working days would begin when CMS formally accepts the submission for review. We believe that the collection of user fees, a policy we proposed and are finalizing in this rule, will enable CMS to process advisory opinion requests in a timely fashion.

Comment: Several commenters suggested that in instances where CMS does not issue an advisory opinion within the relevant timeframe, the requestor should be deemed to have received a favorable advisory opinion and should be protected from any sanctions until such time as CMS formally issues an opinion.

Response: The physician self-referral law is a payment rule, and CMS is statutorily prohibited from making payment for DHS furnished pursuant to a prohibited referral where a financial arrangement exists and no exception applies. Therefore, we do not have the authority to ''deem'' an individual or entity in compliance with the physician self-referral law if such deeming would effectively override the statutory payment prohibition.

Comment: One commenter requested that CMS clarify the criteria it uses to determine whether a request involves ''complex legal issues or fact patterns.''

Response: We appreciate this comment and will consider providing guidance in the future as the agency gains more experience with the modified process.

As a result of the comments, we are finalizing our proposal to issue advisory opinions within 60 working days of the submission being formally accepted. We are also finalizing a 30-working day expedited review pathway for requests that only seek a determination that an arrangement is indistinguishable in all material respects to an arrangement that is the subject of a favorable advisory opinion.

d. Certification Requirement (§ 411.373)

In the 1998 CMS advisory opinions rule, we adopted a requirement identical to OIG's requirement that a requestor must certify to the truthfulness of its submissions, including its good faith intent to enter into proposed arrangements. CMS finalized regulations that require a requestor to make two certifications as part of its request for an advisory opinion. Under current § 411.373(a), the requestor must certify that, to the best of the requestor's knowledge, all of the information provided as part of the request is true and correct and constitutes a complete description of the facts regarding which an advisory opinion is being sought. If the request relates to a proposed arrangement, current § 411.373(b) states that the request must also include a certification that the requestor intends in good faith to enter into the arrangement described in the request. A requestor may make this certification contingent upon receiving a favorable advisory opinion from CMS or from both CMS and OIG. Under current § 411.372(b)(8), if the requestor is an individual, the individual must sign the certification; if the requestor is a corporation, the certification must be signed by the Chief Executive Officer, or a comparable officer; if the requestor is a partnership, the certification must be signed by a managing partner; and, if the requestor is a limited liability company, the certification must be signed by a managing member. We proposed to revise § 411.372(b)(8) to clarify that the certification must be signed by an officer that is authorized to act on behalf of the requestor, but that the signing officer need not be the Chief Executive Officer. We also considered whether it would be appropriate to eliminate the certification requirement in our regulations, given that section 1001 of Title 18 of the United States Code prohibits material false statements in matters within the jurisdiction of a federal agency. We solicited comment on whether the existing certification requirement creates undue burden for requestors, and whether the requirement is necessary given section 1001.

The following is a summary of the comments we received on our proposals and our response.

Comment: Commenters supported the modifications to § 411.372(b)(8) that would allow for any authorized officer of a corporation, in addition to the Chief Executive Officer of a corporation, to sign the certification statement. Most commenters thought the certification requirement was appropriate and not overly burdensome.

Response: Given these comments, we are finalizing the proposed changes in § 411.372(b)(8), and will maintain the certification requirement.

e. Fees for the Cost of Advisory Opinions (§ 411.375)

In the 1998 CMS advisory opinions rule, we established a fee that is charged to requestors to cover the actual costs incurred by CMS in responding to a request for an advisory opinion. Under current § 411.375, there is an initial fee of $250, and parties are responsible for any additional costs incurred that exceed the initial $250 payment. A requestor may designate a triggering dollar amount, and CMS will notify the requestor if CMS estimates that the costs of processing the request have reached or are likely to exceed the designated triggering amount. This fee structure was modeled after the OIG regulations that were in effect at that time.

Since CMS issued the 1998 CMS advisory opinions rule, OIG has updated its regulations to eliminate the initial fee, and instead charges requesting parties a consolidated final payment based on costs associated with preparing an opinion (73 FR 15936). In the proposed rule, we stated that we believe it is appropriate to adopt an hourly fee of $220 for the preparation of an advisory opinion. We said that we believe this amount reflects the costs incurred by the agency in processing an advisory opinion request. We also said that we were considering establishing an expedited pathway for requestors

that seek an advisory opinion within 30 days of the request, and charging $440 an hour to process the request, reflecting the extra resources necessary to produce an advisory opinion within the abbreviated timeframe. We requested comments on this approach. To ensure that obtaining an advisory opinion is affordable, and to prevent unfair surprises to requestors at the end of the process, we considered promulgating a cap on the amount of fees charged for an advisory opinion. We solicited comments on the amount of the cap. We also requested comments on whether CMS should eliminate the initial $250 fee.

The following is a summary of the comments we received on our proposals and our responses.

Comment: Many commenters were supportive of a user fee structure to enable the agency to handle a greater volume of advisory opinion requests and issue opinions in a shorter timeframe. Several commenters thought that the $220 hourly fee was reasonable, and one commenter noted that the $220 rate would ensure that only legitimate requestors are using the advisory opinion process.

Other commenters recommended alternatives to the proposed $220 hourly fee. For instance, commenters recommended adopting an hourly fee of $175 to align with OIG's charges, or adopting a flat ''filing fee.'' One commenter said that physicians should not pay more than the costs CMS incurs in responding to a request for an opinion, and that if CMS is going to adopt an hourly rate of $220, the agency should justify that amount.

One commenter stated that it would support user fees only to the extent those fees would enable the agency to issue advisory opinions on hypothetical facts, and cut the time the agency takes to issue advisory opinions. Another commenter stated that requestors should not be charged an hourly fee for work done by CMS after the expiration of the relevant time period.

Response: We agree with commenters that moving to an hourly rate structure will enable CMS to more efficiently and timely process requests for advisory opinions. Furthermore, the proposed rate of $220 is a reasonable rate given the experience and seniority of the staff and attorneys responding to advisory opinion requests. *See,* for example, USAO ATTORNEY'S FEES MATRIX—2015–2019, *available at https://www.justice.gov/usao-dc/file/796471/download* (reasonable hourly fee for an attorney with less than 2 years of experience practicing law exceeds $220 per hour for the 2018–2019 time period).

Comment: Commenters largely supported the establishment of a higher hourly rate for expedited review.

Response: Because we are finalizing an expedited review pathway only for certain types of requests that we expect to be more straightforward than other requests (that is, those that seek an opinion on whether an arrangement is ''indistinguishable in all material respects'' to another arrangement that is the subject of a favorable advisory opinion), we are not finalizing a $440 hourly rate at this time.

Comment: Several commenters suggested that the agency provide potential requestors with a cost estimate prior to the requestor incurring any costs. Many commenters supported the adoption of a cap, and several commenters recommended that CMS make special accommodations for small and solo practitioners such that they can afford to request advisory opinions. For example, several commenters that supported the imposition of hourly fees urged CMS to consider waiving fees for small groups of up to 15 clinicians, to ensure that smaller practices have access to the advisory opinion process. However, no commenter offered any suggestions on what an appropriate cap might be.

Response: We agree with commenters that in order for the advisory opinion process to be accessible, especially for rural providers and small and solo practitioners, the costs must be predictable and affordable. As we work on operationalizing these reforms to the advisory opinion process, we will consider whether it is feasible to provide requestors with a cost estimate for the review and issuance of an advisory opinion. We will also consider discounting, on a case-by-case basis, the $220 hourly rate for requestors with demonstrated limited financial resources, such as certain rural providers or small or solo practitioners, or, alternatively, capping the total charges for an advisory opinion.

Comment: Several commenters said they supported the elimination of the initial $250 fee, and that the elimination of the fee is appropriate if CMS were to finalize its hourly user fee structure.

Response: We agree and will modify § 411.375(a) to eliminate the initial $250 fee. Accordingly, we are also removing § 411.372(b)(9), which requires each advisory opinion request to include the initial $250 fee.

Comment: Several commenters suggested that we allow requestors to establish a triggering dollar amount, similar to the process used under OIG advisory opinion regulations.

Response: Our current regulations at § 411.375(c)(2) allow for requestors to designate a triggering dollar amount as a means of controlling the cost associated with the advisory opinion process. We are maintaining this provision, which will be redesignated as § 411.375(b)(2).

As a result of the comments, we are finalizing, with modification, our proposal on the timeline for issuance of an advisory opinion request, as well as certain modifications to clarify the process for formal acceptance of a submission.

f. Reliance on an Advisory Opinion (§ 411.387)

As we considered improvements to the advisory opinion process, we also considered regulatory changes to clarify current CMS policies and practices, and make our advisory opinions more useful compliance tools for stakeholders. Specifically, we solicited comment on proposals, described in more detail below, to remove some of the regulatory provisions limiting the universe of individuals and entities that can rely on an advisory opinion, and to add language expressing what we believe are permissible uses of an advisory opinion.

Section 1877(g)(6)(A) of the Act states that an advisory opinion shall be binding on the Secretary and on the party or parties requesting an opinion. Consistent with the policy adopted by OIG, CMS took the view that an advisory opinion may legally be relied upon only by the requestors. While section 1877 of the Act is silent on how third parties may use an advisory opinion, in regulation, CMS has precluded legal reliance on the opinion by non-requestor third parties. At the time, we stated that advisory opinions are capable of being misused by persons not a party to the transaction in question in order to inappropriately escape liability (63 FR 1648). While such a preclusion may be appropriate for purposes of an OIG advisory opinion on the application of a criminal statute, we stated in the proposed rule that we believed it may be unduly restrictive in the context of a strict liability payment rule that applies regardless of a party's intent.

We recognize that in practice, parties to an arrangement that is the subject of a favorable advisory opinion will rely on the opinion, even if the parties did not join in the request. If, for instance, CMS determines that an arrangement does not constitute a financial relationship because it satisfies all requirements of an applicable

exceptions to the physician self-referral law, that determination would necessarily apply equally to any individuals and entities that are parties to the specific arrangement, for example, the referring physician and the entity to which he or she refers patients for designated health services. Thus, even if the physician party to the arrangement was not a requestor of the advisory opinion, the physician party is entitled to rely on that advisory opinion. We proposed changes to § 411.387 to reflect this view. Specifically, we proposed at § 411.387(a) that an advisory opinion would be binding on the Secretary and that a favorable advisory opinion would preclude the imposition of sanctions under section 1877(g) of the Act with respect to the party or parties requesting the opinion and any individuals or entities that are parties to the specific arrangement with respect to which the advisory opinion is issued.

We proposed at § 411.387(b) that the Secretary will not pursue sanctions under section 1877(g) of the Act against any individuals or entities that are parties to an arrangement that CMS determines is indistinguishable in all material aspects from an arrangement that was the subject of the advisory opinion. All facts relied on and influencing a legal conclusion in an issued favorable advisory opinion are material; deviation from that set of facts would result in a party not being able to claim the protection proposed in § 411.387(b). A favorable advisory opinion with respect to one arrangement would not legally preclude CMS from pursuing violations against parties to a different arrangement. In practice, the Secretary will not use CMS enforcement resources for purposes of imposing sanctions under section 1877(g) of the Act to investigate the actions of parties to an arrangement that CMS believes is materially indistinguishable from an arrangement that has received a favorable advisory opinion. As discussed above, such a determination would not preclude a finding by DOJ or OIG that the arrangement violates a law other than the physician self-referral law, including but not limited to the anti-kickback statute. If parties to an arrangement are uncertain as to whether CMS would view it as materially indistinguishable from an arrangement that has received a favorable advisory opinion, then those parties can submit an advisory opinion request. We solicited comment on this approach.

Finally, we also proposed at § 411.387(c) to recognize that individuals and entities may reasonably rely on an advisory opinion as non-binding guidance that illustrates the application of the physician self-referral law and regulations to specific facts and circumstances. We acknowledge that stakeholders already look to advisory opinions issued by CMS to inform their decision-making, and these changes will make clear that CMS acknowledges that such reliance is permissible and reasonable. We requested comments on all aspects of these proposals.

The following is a summary of the comments we received on our proposals and our responses.

Comment: Commenters were supportive of our proposals to remove the restrictions on the individuals and entities that can rely on an advisory opinion. These commenters stated that these modifications will help reduce confusion about compliance with the physician self-referral law, enhance utilization of the advisory opinion process, and maximize the ability of health care entities to innovate and form beneficial business arrangements.

Response: We appreciate the support for these proposals, which we agree will remove unnecessary restrictions on how regulated individuals and entities can use advisory opinions to guide their decisions and aid in compliance activities.

Comment: Several commenters encouraged CMS to continue publishing advisory opinions on its website, with identifiers and any privileged, confidential or proprietary information redacted. At least one commenter suggested that CMS publish an annual reporting summarizing the number of advisory opinions issued and statistics such as the number of advisory opinion requests submitted, the number withdrawn, and information on compliance with regulatory timelines.

Response: We will continue to publish advisory opinions on our website as well as redact information that identifies the requestors and other specific parties. We encourage potential requestors to review the Department's regulations at 45 CFR part 5, which explain how to identify and protect confidential commercial information. We appreciate the suggestion regarding annual statistics on the number of advisory opinion requests received each year, and the disposition of those requests. We are not making any regulatory changes to address this comment, but we will consider publishing such statistics for the next calendar year.

Comment: A few commenters pointed out that accountable care organization (ACO) arrangements can take on a variety of forms, so any single ACO arrangement may be substantially similar, but not identical to, another ACO arrangement that has been the subject of a favorable advisory opinion. These commenters urged CMS to consider how we might adopt a more flexible approach to enable parties to an ACO to rely on an advisory opinion issued to a substantially similar ACO.

Response: Under the regulations we are adopting in this final rule, at § 411.387(c), ACO participants could rely on an advisory opinion as non-binding guidance, even if their ACO arrangement is substantially similar to but not the same as the arrangement that is the subject of the advisory opinion. If the ACO's participants wanted more certainty as to whether CMS would view the factual differences as material, the ACO participants—subject to the physician self-referral law—could request their own advisory opinion through the expedited pathway. If we determined that the arrangement was materially distinct from others that have been the subject of favorable advisory opinions, the requestors would have the option of requesting a new advisory opinion through the normal process.

Comment: Several commenters suggested that CMS should make clear in its regulations that reasonable reliance on an advisory opinion is sufficient to defeat a claim under the False Claims Act that a physician or entity knowingly submitted a false claim as a result of a violation of the physician self-referral law.

Response: We are not authorized to and do not enforce the False Claims Act, and our authority to issue regulations governing the advisory opinion process does not give us the authority to issue regulations interpreting elements of the False Claims Act. We note that a favorable advisory opinion means that CMS has determined that specific referrals for designated health services referrals under the arrangement in question are not prohibited under section 1877 of the Act (as limited to the individuals or entities requesting the opinion and any individuals or entities that are parties to the specific arrangement with respect to which the favorable advisory opinion is issued so long as the specific arrangement as implemented does not deviate from the material facts upon which the advisory opinion is based).

Comment: A few commenters requested that individuals who join arrangements that are the subject of issued advisory opinions have those advisory opinions apply to them retrospectively.

Response: We appreciate this suggestion, however the applicability of an advisory opinion to an individual

joining the arrangement that is the subject of the issued advisory opinion would be a fact-specific determination.

As a result of the comments, we are finalizing the proposed modifications to § 411.387.

g. Rescission (§ 411.382)

Under current § 411.382, CMS may rescind or revoke an advisory opinion after it is issued if CMS determines that it is in the public interest to do so. To date, CMS has not rescinded an advisory opinion. At the time we finalized this regulation, which is modeled on OIG's rescission authority regulation, we sought comment on whether this approach reasonably balanced the government's need to ensure that advisory opinions are legally correct and the requestor's interest in finality (63 FR 1653). We again requested comment on this issue. Specifically, we solicited comments on whether CMS should retain a more limited right to rescind an advisory opinion; that is, CMS could rescind an advisory opinion only when there is a material regulatory change that impacts the conclusions reached, or when a party has received a negative advisory opinion and wishes to have the agency reconsider the request in light of new facts or law.

The following is a summary of the comments we received and our responses.

Comment: Commenters generally supported limiting the grounds upon which CMS would rescind an advisory opinion. Specifically, most commenters agreed that rescission would be appropriate when there is a material regulatory change that affects the conclusions reached in an issued advisory opinion, or when a party that has received a negative advisory opinion wishes to have the agency reconsider the request in light of new facts or law.

Response: We appreciate the feedback on the advisory opinion rescission policy, and agree that the proposed regulatory modification is warranted to provide regulated individuals and entities with greater clarity regarding when CMS believes a rescission may be appropriate. We are therefore modifying § 411.382(a) to provide that CMS may rescind an advisory opinion if it determines that there is good cause to rescind the opinion. In addition, we are modifying § 411.382(a) to provide that ''good cause'' exists when (i) there is a material change in the law that affects the conclusions reached in an opinion; or (ii) a party that has received a negative advisory opinion seeks reconsideration based on new facts or law.

Comment: Many commenters encouraged CMS to provide adequate notice to affected parties and provide adequate time for parties to wind down existing arrangements. Several commenters suggested that CMS allow for a wind-down period. These commenters differed on the appropriate length of a wind-down period. Suggestions included 90 days, 120–180 days, and 3–5 years. Several commenters also suggested that CMS provide for a reasonable period of public notice of no less than 30 days, given the expectation that non-requesting parties will rely on issued advisory opinions. Commenters also requested assurance that CMS would not apply an advisory opinion rescission or revocation in a retrospective manner.

Response: Our current regulations at § 411.382 already provide flexibility for CMS to allow for a reasonable ''wind down'' period to discontinue activities that are the subject of a rescinded advisory opinion. Because every arrangement is unique, and because the allowance of a wind down period amounts to an exercise of agency enforcement discretion, we do not believe it is appropriate for us to establish a minimum wind-down period in regulations. In the event that CMS does, in the future, rescind an advisory opinion, we will work with affected parties to determine a reasonable and appropriate wind down period.

We appreciate commenters' suggestions regarding public notice of a potential rescission. We agree that providing public notice is appropriate given our expectation that non-requesting parties may be relying on an issued advisory opinion to guide their decisions and conduct. We are therefore finalizing an amendment to § 411.382 that provides for advance notice to both the requestor and the public.

As a result of the comments, we are finalizing changes to § 411.382 that will codify the limited instances that a rescission would be appropriate.

h. Other Modifications to Procedural Requirements

We proposed minor modifications to § 411.372 to improve readability and clarity. We also proposed to eliminate the reference to the provision of stock certificates as part of the advisory opinion request submission, as these are typically electronic and may not necessarily list the name of the owner. We requested comments on these and other updates to the procedure for submitting an advisory opinion request that will improve the efficiency of the review process.

Comment: At least one commenter stated that our proposed modifications to the advisory opinion process did not address what they view as a disconnect between the OIG's enforcement of the anti-kickback statute and CMS' enforcement of the physician self-referral law. This commenter stated that the lack of a process to obtain joint agency advisory opinions on specific fact scenarios limits the ability of stakeholders to understand how the two agencies may interpret the two laws differently when reviewing the same factual situation. The commenter said it would be optimal if there were a joint process to obtain both agencies' input on hypothetical arrangements or questions of general applicability. They also said such a joint process would further the Administration's goal of reducing regulatory burden on providers.

Response: We appreciate this comment and recognize that the physician self-referral advisory opinion process, standing alone, cannot give a regulated party certainty that its course of conduct is protected from scrutiny under the anti-kickback statute, even if that party has received a favorable advisory opinion from CMS regarding the arrangement in question. Currently, the timelines for issuing advisory opinions differ under the respective CMS and OIG regulations. Therefore, establishing a joint process is not feasible. However, we will consider how we could achieve greater alignment with the OIG process in the future.

Comment: One commenter suggested that the agency explore whether it has legislative authority to issue opinions that offer protection for arrangements even if they may not squarely fit within an exception, but pose no significant risk of harm.

Response: Due to the nature of the physician self-referral law, we do not have the legislative authority to protect referrals of designated health services that are furnished in violation of the law, even if it is the belief of the parties that the referrals are made pursuant to an arrangement that does not pose a significant risk of harm. Section 1877(g)(1) of the Act states that ''no payment may be made'' for prohibited referrals, and section 1877(g)(6) of the Act limits the scope of our advisory opinion authority to questions of whether or not a referral related to designated health services is prohibited. The commenter's request would require legislative change.