invoice payment submitted by the Contractor under this contract.

(2) (i) Except as provided in paragraph (c) of this clause, the Contractor shall submit invoices using the electronic invoicing program Invoice Processing Platform (IPP), which is a secure web-based service provided by the U.S. Treasury that more efficiently manages government invoicing.

(ii) Under this contract, the following documents are required to be submitted as an attachment to the IPP invoice: *(This is a fill-in for acceptable types of required documentation, such as an SF 1034 and 1035, or an invoice/self-designed form on company letterhead that contains the required information.)*

(iii) The Contractor's Government Business Point of Contact *(as listed in System for Award Management (*SAM*))* will receive enrollment instructions via email from the IPP. The Contractor must register within 3 to 5 days of receipt of such email from IPP.

(iv) Contractor assistance with enrollment can be obtained by contacting the IPP Production Helpdesk via email at *IPPCustomerSupport@fiscal.treasury.gov* or by telephone at (866) 973–3131.

(3) If the Contractor is unable to comply with the requirement to use IPP for submitting invoices for payment, the Contractor shall submit a waiver request in writing to the Contracting Officer. The Contractor may submit an invoice using other than IPP only when—

(i) The Contracting Officer administering the contract for payment has determined, in writing, that electronic submission would be unduly burdensome to the Contractor; and in such cases, the Contracting Officer shall modify the contract to include a copy of the Determination; or

(ii) When the Governmentwide commercial purchase card is used as the method of payment.

(4) The Contractor shall submit any non-electronic payment requests using the method or methods specified in Section G of the contract.

(5) In addition to the requirements of this clause, the Contractor shall meet the requirements of the appropriate payment clauses in this contract when submitting payment requests.

(6) Invoices submitted through IPP will be either rejected, or accepted and paid, in their entirety, and will not be paid on a partial basis.

(b) The Contractor shall prepare its invoice or request for contract financing payment in accordance with FAR 32.905 on the prescribed Government forms, or the Contractor may submit self-designed forms which contain the required information. Standard Form 1034, *Public Voucher for Purchases and Services other than Personal,* is prescribed for used by contractors to show the amount claimed for reimbursement. Standard Form 1035, *Public Voucher for Purchases and Services other than Personal—Continuation Sheet,* is prescribed for use to furnish the necessary supporting detail or additional information required by the Contracting Officer.

* * * * *

(g) * * *

(5) *Voucher Number*—Insert the appropriate serial number of the voucher. A separate series of consecutive numbers, beginning with Number 1, shall be used by the contractor for each new contract. For an adjustment invoice, write ''*[invoice number] #Adj*'' at the voucher number. For a final invoice, put invoice number F. For a completion invoice, put invoice number #C.

* * * * *

Note to paragraph (i)—Any costs requiring advance consent by the Contracting Officer will be considered improper and will be disallowed, if claimed prior to receipt of Contracting Officer consent. Include the total cost claimed for the current and cumulative-to-date periods. After the total amount claimed, provide summary dollar amounts disallowed on the contract as of the date of the invoice. Also include an explanation of the changes in cumulative costs disallowed by addressing each adjustment in terms of: Voucher number, date, dollar amount, source, and reason for the adjustment. Disallowed costs should be identified in unallowable accounts in the contractor's accounting system.

* * * * *

Note to paragraph (j)—Any costs requiring advance consent by the Contracting Officer will be considered improper and will be disallowed, if claimed prior to receipt of Contracting Officer consent. Include the total cost claimed for the current and cumulative-to-date periods. After the total amount claimed, provide summary dollar amounts disallowed on the contract as of the date of the invoice. Also include an explanation of the changes in cumulative costs disallowed by addressing each adjustment in terms of: Voucher number, date, dollar amount, source, and reason for the adjustment. Disallowed costs should be identified in unallowable accounts in the contractor's accounting system.

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[FR Doc. 2018–27478 Filed 12–19–18; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 488

[CMS–3367–NC]

RIN 0938–AT84

Medicare Program: Accrediting Organizations Conflict of Interest and Consulting Services; Request for Information

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Request for information.

SUMMARY: This request for information (RFI) seeks public comment regarding the appropriateness of the practices of some Medicare-approved Accrediting Organizations (AOs) to provide fee-based consultative services for Medicare-participating providers and suppliers as part of their business model. We wish to determine whether AO practices of consulting with the same facilities which they accredit under their CMS approval could create actual or perceived conflicts of interest between the accreditation and consultative entities. We intend to consider information received in response to this RFI to assist in future rulemaking.

DATES:

Comments: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on February 19, 2019.

ADDRESSES: In commenting, refer to file code CMS–3367–NC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this RFI to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3367–NC, P.O. Box 8016, Baltimore, MD 21244–8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the

following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3367–NC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

FOR FURTHER INFORMATION CONTACT: Monda Shaver, 410–786–3410 or Caroline Gallagher, 410–786–8705.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period will be made available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We will 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. Background

To participate in the Medicare program, providers and suppliers of health care services must be in substantial compliance with specified statutory requirements of the Social Security Act (the Act), as well as any additional regulatory requirements related to the health and safety of patients specified by the Secretary of the Department of Health and Human Services (the Secretary). These health and safety requirements are generally called conditions of participation (CoPs) for most providers, requirements for skilled nursing facilities (SNFs), and conditions for coverage or certification (CfCs) for other suppliers. Medicare certified providers and suppliers participate in the Medicare program by entering into an agreement with Medicare in which, among other things, they agree to comply with the CoPs or other applicable health and safety requirements. The providers and suppliers subject to these requirements include hospitals, skilled nursing facilities, home health agencies, hospice programs, rural health clinics, critical access hospitals, comprehensive outpatient rehabilitation facilities, laboratories, clinics, rehabilitation agencies, public health agencies, and ambulatory surgical centers. A Medicare-certified provider or supplier that does not substantially comply with the applicable health and safety requirements risks having its participation in the Medicare program terminated.

In accordance with section 1864 of the Act, state health agencies or other appropriate local agencies, under an agreement with CMS, survey health care providers and suppliers for compliance with the applicable CoPs, CfCs, conditions of certification, or requirements. Based on these State Survey Agency (SA) certifications, CMS determines whether the provider or supplier qualifies, or continues to qualify, for participation in the Medicare program. Additionally, section 1865(a) of the Act allows most health care facilities to demonstrate compliance with Medicare CoPs, requirements, CfCs, or conditions for certification through accreditation by a CMS-approved program of a national accreditation organization (AO), in lieu of being surveyed by SAs for certification. Accreditation by an AO is generally voluntary and is not required for Medicare certification or participation in the Medicare Program. Section 1865(a)(1) of the Act provides that if the Secretary finds that accreditation of a provider entity (which includes a provider of services, supplier, facility, clinic, agency, or laboratory) by a national accreditation body demonstrates that all applicable conditions are met or exceeded, the Secretary may deem those requirements as being met by the provider entity. We are ultimately responsible for the review, approval and subsequent oversight of national AOs' Medicare accreditation programs, and for ensuring providers or suppliers accredited by the AO meet the quality and patient safety standards required by the Medicare CoPs, requirements, CfCs, and conditions for certification. Any national AO seeking approval of an accreditation program in accordance with section 1865(a) of the Act must apply for accreditation program approval in accordance with § 488.5 and may be approved by CMS for a period not to exceed 6 years.

In addition, section 353 of the Public Health Service Act (PHS Act), as amended by the Clinical Laboratory Improvement Amendments of 1988 (CLIA) (Pub. L. 100–578), requires any laboratory that performs testing on human specimens for health purposes to meet the requirements established by CLIA and regulations issued under its authority, and have in effect an applicable CLIA certificate. Pursuant to section 353(e) of the PHS Act, a laboratory covered by CLIA may receive a certificate if, among other things, it is accredited by a laboratory AO approved by CMS under paragraph 353(e)(2) of the PHS Act. Any proposed or future regulation made regarding AOs' practice of providing fee-based consulting services to Medicare-participating providers and suppliers would also apply to AOs that accredit laboratories pursuant to CLIA.

While accreditation by an AO is generally voluntary, suppliers of the technical component of Advanced Diagnostic Imaging (ADI) services (as described at 42 CFR 414.68); Diabetes Self-Management Training (DSMT) services (as described at 42 CFR 410.141); and Durable Medical Equipment (DME) (as described at 42 CFR 424.58) are subject to accreditation required in order to receive reimbursement from Medicare for the services they furnish to Medicare beneficiaries. We also recently finalized regulations, at 42 CFR part 488, subpart L, for the approval and oversight of AOs that accredit Home Infusion Therapy suppliers, because section 1834(u)(5) of the Act requires suppliers of Home Infusion Therapy services (HIT) to be accredited (CY 2019 Home Health Prospective Payment System Rate Update final rule, 83 FR 56406, November 13, 2018).

Pursuant to their respective authorizing statutes, these four supplier types cannot participate in Medicare using a state survey option. One AO provides accreditation for several provider and supplier types, some under accreditation that is required in order for the provider or supplier to receive payment from Medicare for services furnished to Medicare beneficiaries, and some under the voluntary accreditation programs authorized under section 1865 of the Act. Therefore, our RFI also seeks comment on potential conflicts of interest related to this category of AOs that certify the four supplier types subject to accreditation that is required for a provider or supplier to receive payment from Medicare for services furnished to Medicare beneficiaries as well as laboratories accredited by an AO under CLIA.

AOs charge fees to facilities that seek their accreditation and generally offer facilities at least two accreditation options: Accreditation alone, or accreditation under a CMS-approved program for the purpose of participating in Medicare. Accreditation alone may be provided for purposes other than participation in Medicare. Accreditation under a CMS-approved program is provided for the purpose of obtaining and maintaining a Medicare provider agreement. Existing regulations at § 488.4 sets forth the general provisions for CMS-approved accreditation programs for providers and suppliers and § 488.5 outlines the application and re-application procedures for national AOs that seek to obtain CMS approval

of their accreditation programs, often called ''deeming authority.'' Additionally, AO application and re-application procedures are set forth at § 414.68(c) for accreditors of ADI suppliers, § 410.142 for accreditors of DSMT suppliers, and § 424.57(c) for accreditors of DME suppliers. Pursuant to the above regulations CMS has responsibility for oversight and approval of AO accreditation programs used for Medicare participation purposes and for ensuring that providers and suppliers that are accredited under a CMS-approved AO accreditation program meet or exceed the quality and patient safety standards required by the Medicare regulations. A thorough review of each accreditation program voluntarily submitted by an AO seeking CMS approval is conducted by CMS, including a review of the equivalency to the Medicare standards of its accreditation requirements, survey processes and procedures, surveyor training, and oversight and enforcement of provider entities. In addition, we also review the qualifications of the surveyors, staff, and the AO's financial status.

Under the application and re-application requirement procedures in § 488.5 for ''voluntary'' accreditation programs, under § 488.5(a)(10), an AO submitting an application must include a copy of the AO's ''organization's policies and procedures to avoid conflicts of interest, including the appearance of conflicts of interest, involving individuals who conduct surveys or participate in accreditation decisions.'' This provision is implemented by CMS's review of submitted documentation to determine that no conflicts of interest exist.

Section 488.5(e) requires that we publish a notice in the **Federal Register** when we receive a complete application or reapplication from a national AO which is voluntarily seeking approval of its voluntary accreditation program. The notice identifies the organization and the type of providers or suppliers to be covered by the voluntary accreditation program and provides a 30-day public comment period. We have 210 days from the receipt of a complete application to publish notice of approval or denial of the application. Upon approval, any provider or supplier subsequently accredited by the AO's approved program(s) would be deemed by CMS to have met the applicable Medicare conditions and would be referred to as having ''deemed status.'' Similar rules regarding CMS's approval process also apply to the accreditation required to receive payment from Medicare for the services furnished by the provider or supplier to Medicare beneficiaries by ADI, DSMT, DME and HIT suppliers, as discussed above.

In addition to the general accreditation application process, we are also required by statute to submit an annual Report to Congress [1] on our oversight of the national AOs. This report contains information related to the AO activities in a given fiscal year and compares these activities to the previous years. Within this report, we also measure the ''disparity rate'', which is a comparison rate based on AO findings of non-compliance during an AO survey and the SA findings of non-compliance for the same facilities found during a state validation survey. When the state survey agency cites a condition-level deficiency for which the AO has not cited a comparable deficiency, the deficiency is considered by CMS to have been ''missed'' and is factored into the AO's disparity rate for each facility type. The identification of only one missed condition level finding in any survey results in the entire survey being counted as disparate. The number of disparate surveys is divided by the number of validation surveys to determine the AO's disparity rate. According to the most recently published Report to Congress, disparity rates for all CMS-approved AO programs for the following facility types for the most recent year in the report (FY 2017) are: Hospital rates (46 percent); Psychiatric hospitals (57 percent); Critical Access Hospitals (44 percent); Home Health Agencies (18 percent); Hospices (18 percent); Ambulatory Surgery Centers (35 percent).

As part of our ongoing efforts to enhance transparency and oversight of the AOs, in 2018 CMS began a pilot for integrated validation surveys for accredited hospitals. Rather than the SA performing a separate second survey of an accredited facility within 60-days of the AO having completed its survey (of the same facility), state survey teams accompanied the AO survey team to evaluate AO competency and effectiveness during the same survey. CMS plans to refine this process over the next several years in an effort to enhance AO oversight, and to ensure that facilities under deemed status are in compliance with CMS conditions. Additionally, to ensure transparency both in the performance of AOs with CMS-approved accreditation programs and the quality of care provided by those deemed facilities, we are also working to create a *CMS.gov* web page that will provide AO performance data, as well as the latest quality of care findings based on complaint surveys of facilities accredited by these organizations.

As we noted above, section 1865(a)(2) of the Act states that the Secretary shall consider, among other factors with respect to a national accreditation body, its requirements for accreditation, its survey procedures, its ability to provide adequate resources for conducting required surveys and supplying information for use in enforcement activities, its monitoring procedures for provider entities found out of compliance with the conditions or requirements, and its ability to provide the Secretary with necessary data for validation. CMS determines whether accreditation standards and procedures are comparable to those of CMS.

CMS has been aware for some time that some AOs with CMS-approved accreditation programs are also providing fee-based consultative services to Medicare-participating health care facilities. Typical consultative services include, but are not limited to the following:

- Assistance for clinical and non-clinical leaders, including administrators in understanding the AO and CMS standards for compliance;
- Review of facility standards and promised early intervention and action through simulation of a real survey, similar to a mock survey to include comprehensive written reports of findings;
- Review of a facility's processes, policies and functions;
- Identification of and technical assistance for changing and sustaining areas in need of improvement; and,
- Educational consultative services.

These activities are not prohibited by law or regulation, and the training provided by the AOs may be useful for entities to learn to comply with the requirements and identify gaps in compliance.

This RFI is in response to increasing concern about potential conflicts of interest created by the accreditation and consultative activities of the AOs. In September 2017, an article [2] in the Wall Street Journal raised concerns regarding the performance, transparency, and potential conflicts of interest between an AO's accreditation services and its

[1] Report to Congress: *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions.htm.*

[2] The Wall Street Journal, ''Watchdog Awards Hospitals Seal of Approval Even After Problems Emerge'' Stephanie Armour (September 8, 2018) *https://www.wsj.com/articles/watchdog-awards-hospitals-seal-of-approval-even-after-problems-emerge-1504889146.*

consulting services, which brought heightened attention to this issue in the public and the Congress. This article also discussed CMS's oversight of the AOs. Members of Congress subsequently sent letters to CMS [3] regarding the agency's oversight of AOs, which encouraged CMS to consider whether the agency should continue to recognize or approve AOs that seek to provide consultative services to the entities they accredit for CMS participation in light of the potential for actual or perceived conflict of interest.

After consideration of these issues, we are seeking comment to determine whether offering consultative services to the same entities an AO accredits may create actual or perceived conflicts of interest between the AOs accreditation program and its consultative program. We have concerns that this dual function may undermine, or appear to undermine, the integrity of the accreditation programs and could erode the public trust in the safety of CMS-accredited providers and suppliers. We recognize and acknowledge that certain consulting services offered by some of the AOs, such as quality improvement work and training of facility staff, may be beneficial to some facilities and result in improvements in operations or the quality of care furnished and may be provided with the best of intentions. However, it has been brought to our attention that this dual role played by some AOs may create, a minimum, the perception of conflicts of interest or actual conflicts of interest, which are rooted in the intersection of the AO's accreditation program with the AO's consulting services. We are concerned that circumstances could arise where an AO has recommended deemed status through accreditation that a client facility was in compliance with the Medicare regulations, while the consultancy service of the AO was generating revenue assisting the same facility in passing the AO's own accreditation surveys. While the consultancy arm may or may not have used surveyors which were conducting the on-site AO accreditation surveys, the consultants are advertised as experts on compliance standards. Some AOs have indicated that they establish firewalls between the arms of their businesses, but we are concerned that these firewalls may not be sufficient to ensure that no conflicts of interest result from these activities.

We have promulgated regulations and other requirements for other programs to ensure public trust by, for example, taking steps to address potential conflicts of interest in the Quality Improvement Organizations (QIO) (42 CFR 475.102 and 475.103) and External Quality Review Organization (EQRO) (42 CFR 438.354 and 42 CFR 438.358) programs. For example, 42 CFR 475.105(c) prohibits QIOs from subcontracting with a healthcare facilities to perform any case review activities except for the review of the quality of care

Section 1932(c)(2) of the Act and § 438.350 and 438.354, respectively, specifies that EQRO programs must be independent from the State Medicaid agency and the managed care plans it reviews. Under these requirements, EQRO programs may not conduct certain ongoing Medicaid managed care program operations related to oversight of the quality of managed care plan services on the state's behalf. For example, these restrictions preclude an EQRO from reviewing any managed care plan for which it is conducting or has conducted an accreditation review within the previous 3 years, or having a present, or known future, direct or indirect financial relationship with a managed care plan that it will review as an EQRO. We believe that the prohibitions set forth at § 438.354 ensure the independence of the EQROs from the state Medicaid agency and other managed care organizations and provide an example for how to avoid any perceived conflict of interest between their consultative services and work to deliver healthcare services to Medicaid beneficiaries.

Our consideration of this issue and review of how conflicts of interest are handled in similar programs suggested a need to reexamine our current regulations regarding AO conflicts of interest. Prior to initiating the rulemaking process in this area, we are seeking information (for example, evidence, research and trends), including stakeholder and AO feedback, specific to the topics discussed in this request for information. We intend to consider any such comments when we draft proposals for future policy development, to better protect public health and the safety of patients, and ensure our process for approving and ongoing monitoring of AOs is meaningful and maintains the public trust.

II. Potential Alternatives for Addressing Conflicts of Interest

We believe that, similar to QIO and EQRO programs, any AO with a Medicare-approved accreditation program has assumed a position of public trust, and is responsible for acting on behalf of the public, because the AO is performing a function that assists in the federal government's enforcement programs. We also believe that AOs voluntarily take on this position and responsibility when they seek accreditation approval from CMS to accredit providers and suppliers on behalf of CMS for participation in Medicare. Because of the responsibility CMS has related to maintaining public trust and guarding public health, we are compelled to ensure that all entities and programs, including AOs and their accreditation programs, that require CMS approval, be held to the high standards of ethical conduct so that every citizen can have complete confidence in the integrity of the Federal Government. In our view, AO accreditation determinations must be made without regard to any additional services that a Medicare provider or supplier might obtain through the AO or its subsidiaries, in order to ensure and maintain public trust in the Medicare certification program.

While we are seeking public comment under this RFI to gather information which may be used for potential future rulemaking, we also believe that stakeholders may provide insight on other mechanisms to address this potential conflict of interest. These areas for which we are seeking insight from stakeholders are further discussed in Section III, ''Solicitation of Comments''. Section 488.5(a)(10) of our regulations states that the application information from the AO include the organization's policies and procedures to avoid conflicts of interest, including the appearance of conflicts of interest, involving individuals who conduct surveys or participate in accreditation decisions. We implement this by reviewing the AOs policies and procedures regarding conflict of interest to determine that no overt conflicts of interest exist regarding such individuals. AOs typically include provisions in their organization's policies that ban surveyors from conducting surveys in the following situations: If the surveyor has performed any previous consulting services for the facility; if the surveyor (or family member) has any financial interest in the facility; and, if the surveyor was previously employed by a facility.

We are seeking feedback to determine whether we should revise our review process to identify actual, potential or perceived AO conflicts of interest as part of the application and renewal process for all AOs, including the programs that require accreditation in order for the provider or supplier to

[3] *https://energycommerce.house.gov/news/press-release/ec-leaders-request-information-hospital-accreditation-processes/.*

receive payment from Medicare for services furnished to Medicare beneficiaries, as discussed above. We are interested in ways that we could potentially modify § 488.5(a), which lists the required information to be submitted with an application by an AO to CMS for review, to also include a provision which addresses this conflict of interest review process, for which we are seeking public comments. As noted, § 488.5(a)(10) of our regulations requires that the application information include the organization's policies and procedures to avoid conflicts of interest, including the appearance of conflicts of interest, involving individuals who conduct surveys or participate in accreditation decisions. Similarly, for HIT suppliers, under the CY 2019 Home Health final rule (83 FR 56406), at § 488.1010(a)(13), we require AOs for home infusion therapy suppliers to provide documentation of the AO's policies and procedures for avoiding and handling conflicts of interest, including the appearance of conflicts of interest, involving individuals who conduct surveys, audits or participate in accreditation decisions. We believe that potentially expanding § 488.5(a)(10) by adding additional provisions which would require the AOs to disclose information about any consultative services provided by the AO to facilities which the AO accredits would further enhance oversight of AOs with CMS-approved accreditation programs; this would allow CMS to identify consultative relationships that create real, potential and perceived conflicts of interest. We are also considering adding similar provisions to the requirements for accrediting organizations that provide accreditation to providers and suppliers that must be accredited in order to receive payment from Medicare for services they furnish to Medicare beneficiaries, including HIT suppliers, as set out in the CY 2019 Home Health final rule (83 FR 56406) at § 488.1010(a)(13).

III. Solicitation of Comments

This is a request for information only. Respondents are encouraged to provide complete but concise responses to the questions listed in the sections outlined below. Response to this RFI is completely voluntary. This RFI is issued solely for information and planning purposes; it does not constitute a Request for Proposal, applications, proposal abstracts, or quotations. This RFI does not commit the Government to contract for any supplies or services or make a grant award. Further, we are not seeking proposals through this RFI and will not accept unsolicited proposals. Responders are advised that the United States 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. Also, we note that we will not respond to questions about the policy issues raised in this RFI. We may or may not choose to contact individual responders. Such communications would only serve to further clarify written responses. Contractor support personnel may be used to review RFI responses. Responses to this notice are not offers and cannot be accepted by the Government to form a binding contract or issue a grant. Information obtained as a result of this RFI may be used by the Government for program planning on a non-attribution 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 cost for which reimbursement would be required or sought. All submissions become Government property and will not be returned. We may publically post the comments received, or a summary thereof.

While we are soliciting general comments on CMS's oversight of AOs, we are specifically seeking input on the following areas:

A. Public/Stakeholder Feedback

- We are seeking comment on the type of fee-based consultative services provided by AOs to the facilities they accredit. How are these services provided and communicated to the facilities? Are potential conflicts of interest disclosed?
- Training providers and suppliers of services on the applicable requirements for Medicare certification is an important function to improve quality of care. Are there other entities that could provide this training besides the AOs?
- We are seeking public comment related to whether commenters perceive a conflict of interest in AOs providing fee-based consultative services to the facilities they accredit.
- We are seeking public comment related to some stakeholders' perception that the ability of an AO to collect fees for consultation services from entities they accredit could degrade the public trust inherent in an AO's CMS-approved accreditation programs.
- We are seeking public comment on what the appropriate consequences or impacts should be, if a conflict does exist.
- We are seeking public comment on what firewalls may exist within an AO between accreditation and consultation services, or what firewalls would be prudent, to avoid potential and actual conflicts of interest.
- We are soliciting examples of positive and negative effects which may be as a result of a conflict of interest.
- We are seeking public comment from existing AOs on what the potential impact, financially and overall would be if CMS were to finalize rulemaking which would restrict certain activities that might give rise to a real or perceived conflict of interest.
- We are seeking public comment, primarily from stakeholders, by requesting specific information on when and/or under what circumstances it would be appropriate for AOs to provide fee-based consultative services to the facilities which they accredit.
- We are seeking public and stakeholder feedback on whether, and if so, under what specific circumstances CMS should review a potential conflict of interest, and what factors CMS should look at to determine if a conflict of interest exists.
- Specifically, we are seeking comments in a list type format describing under what circumstances the AOs or stakeholders would believe there to be a conflict; and under which circumstances conflict does not exist.
- We seek comment on the type of information which would be considered necessary, useful and/or appropriate in proving or refuting our hypothesis of a connection between the use of consultative services and preferential treatment of accredited providers and suppliers.

We are seeking comment on alternatives for addressing any conflict of interest identified.

B. Financial Impact and Burden

- We are seeking public comment regarding how an AO's revenue and operations may be affected by a prohibition or limitation on AOs' marketing and provision of consultative services.
- We are specifically looking for cost impacts, detailed accounting, and potential business risks for AOs.

C. Adding a New CFR Subpart to Existing Regulation

- We are seeking stakeholder feedback on the most appropriate area

for this potential future rulemaking under the existing regulations for AOs and whether expanding § 488.5(a)(10) to include a provision addressing this matter would be the most sensible placement.

IV. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. However, section II 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 Paperwork Reduction Act of 1995 (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 Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

V. Response to Comments

Because of the large number of public comments we normally receive on **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, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

Dated: November 7, 2018.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2018–27506 Filed 12–18–18; 4:15 pm]

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