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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 488 and 489

[CMS-3367-P]

RIN 0938-AU88

Medicare Program; Strengthening Oversight of Accrediting Organizations (AOs) and Preventing AO Conflict of Interest, and Related Provisions

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would set forth a number of provisions to strengthen the oversight of accrediting organizations (AOs) by addressing conflicts of interest, establishing consistent standards, processes and definitions, and updating the validation and performance standards systems. Additionally, this proposed rule would revise the psychiatric hospital survey process, add a limitation on terminated deemed providers and suppliers when reentering the program, and provides technical corrections for End-Stage Renal Disease facilities and Kidney Transplant Programs. This proposed rule also solicits comments from stakeholders and AOs to refine and revise the AO oversight standards and processes. In addition, this proposed rule includes a request for information on the timeframes and expectations for the submission of AO applications.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE **FEDERAL REGISTER**].

ADDRESSES: In commenting, refer to file code CMS-3367-P.

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 regulation to **https://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-P,

P.O. Box 8010,

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-P,

Mail Stop C4-26-05,

7500 Security Boulevard,

Baltimore, MD 21244-1850.

For information on viewing public comments, see the beginning of the "SUPPLEMENTARY INFORMATION" section.

FOR FURTHER INFORMATION CONTACT:

Caroline Gallaher, (410) 786-8705 or Beth Chalick-Kaplan, (410) 786-6550.

SUPPLEMENTARY INFORMATION:

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

close of the comment period on the following Web site as soon as possible after they have been received: https://www.regulations.gov. Follow the search instructions on that Web site to view public comments. CMS will not post on Regulations.gov public comments that make threats to individuals or institutions or suggest that the commenter will take actions to harm an individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

Plain Language Summary: In accordance with 5 U.S.C. 553(b)(4), a plain language summary of this rule may be found at https://www.regulations.gov/.

Severability of Provisions

To the extent a court may enjoin any part of the rule as finalized, the Department intends that other provisions or parts of provisions should remain in effect. Any provision of the rule as finalized held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

Table of Contents

I. Executive Summary

A. Purpose

B. Summary of the Major Provisions

II. Background

A. Legislative History

B. Regulatory Overview of CMS's Rules Regarding AO Programs

C. Congressional Report on the Oversight of National AOs and CMS Approved Accreditation

Programs

D. CMS Validation Survey Pilot

E. Overview of Transparency and Oversight of Accrediting Organizations

F. Prior Rulemaking - Accrediting Organizations Conflict of Interest Request for Information (RFI)

G. Conflict of Interest – The AO Owner's, Surveyor's and Other Employee's Interest in or Relationship with a Health Care Facility that the AO Accredits

III. Request for Public Comment on Whether it is a Conflict of Interest for AO Board Members or Advisors to Have an Interest in or Relationship with a Health Care Facility that the AO Accredits

IV. Provisions of the Proposed Rule

A. Proposal to add Definition of "Unannounced Surveys" to § 488.1

B. Conflict of Interest

C. Proposal to Require the AOs that Accredit Medicare-Certified Providers and Suppliers to Use the Medicare Conditions; and Strengthened Survey Process Comparability (Proposed § 488.4(a)(1) and (2))

D. Proposal to Revise the AO Crosswalk Requirements at § 488.5(a)(3)

E. Proposal to Strengthen the Comparability of the Survey Process between the AOs and the States

F. Proposal to Revise the AO Application Documentation Requirements Related to the Survey Processes (§ 488.5(a)(4); § 488.5(a)(4)(iii); § 488.5(a)(4)(v); § 488.5(a)(4)(vii); § 488.5(a)(4)(xi); § 488.5(a)(5); § 488.5(a)(6); § 488.5(a)(12); § 488.5(a)(13))

G. Proposal to Require AOs to Provide CMS with Survey Findings (§ 488.5(a)(4)(viii))

H. Proposal to Require that AO Surveyors Must Take the CMS Online Surveyor Basic Training (§ 488.5(a)(8)(ii)

I. Proposal to Establish Criteria for "National in Scope" to § 488.1

J. Proposal to Revise the Definition of "Rate of Disparity" and to Use the Process and Outcome Disparity Rates as Performance Measures (§ 488.1)

K. Proposal to Require AOs to Submit a Publicly Reportable Plan of Correction for Unacceptable Performance Measure Scores (§ 488.8(a)(2))

L. Proposal to Revise the AO Survey Validation Program (§ 489.9)

M. Proposal to Revise the Psychiatric Hospital Survey Process

N. Limitation on Terminated Deemed Providers/Suppliers Seeking Re-entry into Medicare/Medicaid (§ 489.57, § 488.4(b) & § 488.5(a)(21))

O. Proposal for Technical Correction for End-Stage Renal Disease (ESRD) Facilities and Kidney Transplant Programs (§ 488.4(a)(4))

V. Request for Information Regarding Timeframes and Expectation for the Submission of AO Applications

VI. Collection of Information Requirements

A. ICR Related to Conflict of Interest Proposals

B. ICRs Associated with the Requirement that AOs Incorporate the Medicare Conditions

C. ICRs Associated With the Requirement that AOs Use Survey Processes that are Comparable to That Used by CMS and the SAs

D. ICR Related to Requirement that the AO Surveyors Take the CMS Online Surveyor Training

E. ICR Associated with the Establishment of a Definition for "National in Scope"

F. ICR Associated with the Proposed Revision of the AO Performance Measures and to Require a Publically Reportable Plan of Correction

G. ICR Associated with the Revision of the Definition of "Disparity Rate

H. Burden Reduction Associated with the Revision of the AO Validation Program

I. ICR Associated with the Revision of the Psychiatric Hospital Accreditation Process

J. Burden Associated with Limitations to Terminated Deemed Providers Seeking Re-Enrollment and Certification in Medicare/Medicaid Programs

K. Summary of Estimated Burden

VII. Response to Comments

VIII. Regulatory Impact Analysis

A. Statement of Need

B. Overall Impact

C. Detailed Economic Analysis

D. Alternatives Considered

E. Regulatory Flexibility Act (RFA)

F. Unfunded Mandates Reform Act (UMRA)

G. Federalism

Regulations Text

I. Executive Summary

A. *Purpose*

The Centers for Medicare & Medicaid Services (CMS) seeks to protect the health and safety of patients that receive services from Medicare and Medicaid-participating providers that are accredited by CMS-approved accrediting organizations (AOs). We continue to review and revise our health and safety requirements and survey processes to ensure that they are effective in driving quality of care for beneficiaries receiving services from these accredited providers and suppliers.

In 2015, we published a final rule in the **Federal Register** entitled, "Medicare and Medicaid Programs: Revisions to Deeming Authority Survey, Certification, and Enforcement Procedures" (80 FR 29795), hereinafter referred to as the "2015 AO final rule" to clarify and strengthen the oversight of AOs, specifically to provide additional criteria for AOs that apply for, and are granted, recognition and approval of an accreditation program (see section II "Background" of this proposed rule for additional background information). Over the past 5 years, CMS has continued to evaluate the effectiveness of these regulatory changes and the

performance of AOs. This proposed rule proposes multiple provisions to further strengthen our oversight and enforcement capabilities of the AOs. The need for these provisions is based on multiple factors, which include: (1) direct observation and review of the AOs' accreditation programs for those AOs with CMS-approved deeming programs; (2) media reports and complaints against facilities that are deemed; (3) the CMS validation program and analysis of disparity rates between state survey agency (SAs) and the AOs; and (4) our performance evaluations of AOs. The preamble discusses each of the proposed provisions (see section IV "Provisions of the Proposed Rule") in this proposed rule. More specifically, the preamble provides background and analysis of why CMS is proposing additional provisions and revisions to existing requirements. CMS is responsible for the oversight of the national AOs' Medicare accreditation programs, and for ensuring that providers or suppliers under CMS-approved deeming programs by the AOs meet the minimum quality and patient safety standards required by the Medicare conditions (refer to section II of this proposed rule for additional information). Based on several years' experience and data analysis, we are proposing the following provisions as described in the preamble to strengthen our oversight of AOs.

B. *Summary of the Major Provisions*

- We propose at § 488.1 to add the definitions of "geographic regions", "national in scope," "outcome disparity rate," "process disparity rate," and "unannounced survey". In addition, we propose to revise the definition of "national accrediting organization," and remove the definition of "rate of disparity."
- We propose to establish a new requirement at § 488.4(a)(1) that would require the AOs that accredit Medicare-certified providers and suppliers to incorporate the language of the applicable Medicare Conditions of Participation (CoPs), Conditions for Coverage (CfCs), conditions for certification, or requirements (collectively referred to as "Medicare conditions") set forth in the applicable CMS regulations for each provider and supplier type as their minimum accreditation requirements. However, the AOs would be free to

establish additional accreditation requirements that exceed Medicare conditions, as permitted by section 1865(a)(1) of the Social Security Act (the Act).

- We propose to add language at § 488.4(a)(2) regarding use of a comparable survey process approved by CMS, as outlined and contemplated in § 488.5.
- We propose to add a new regulation at § 488.4(b) that would state that if Medicare terminates the participation agreement of a Medicare-certified provider or supplier, then CMS would no longer recognize the facility's AO accreditation for deemed compliance. At proposed § 488.4(b)(2), we would require a terminated provider or supplier to meet all requirements set forth at § 489.57 before their new agreement for participation in the Medicare/Medicaid program can be approved.
- We propose to require AOs to develop a crosswalk between their accreditation standards and the Medicare conditions, at proposed § 488.5(a)(3).
- We propose to revise the existing language at § 488.4(a)(4) to strengthen our process of evaluating the comparability of survey processes of AOs that accredit Medicare-certified providers and suppliers with the SAs' survey processes.
- We propose to strengthen the requirements at § 488.5(a)(4), § 488.5(a)(4)(iii), § 488.5(a)(4)(v), § 488.5(a)(4)(vii), § 488.5(a)(4)(xi), § 488.5(a)(5) and § 488.5(a)(6) related to the comparability of survey processes as mentioned above. We also propose changes under § 488.5(a)(5)(viii) related to survey reports. These strengthened requirements would be applicable to their initial and renewal applications provided to CMS one year after the effective date of the rule.
- We propose at § 488.5(a)(8)(i) through § 488.5(a)(8)(iv) to require AOs that accredit Medicare-certified providers and suppliers have their surveyors complete the CMS online surveyor training.
- We propose to add a requirement at § 488.5(a)(10) that the AOs must provide, as part of their initial and renewal applications, specific policies and procedures that would address

how the AOs prevent and address conflicts of interest. We propose that AOs provide information on a number of specific policies and procedures.

- We propose to also revise requirements under § 488.5(a)(12) related to the AO procedures for investigating and responding to complaints against accredited facilities.
- We propose revisions to § 488.5(a)(13) related to the AO's accreditation status decision-making process, in order to strengthen the comparability of the survey processes.
- We propose to add a new requirement at § 488.5(a)(21) that would require the AOs to submit a statement with its initial or renewal application certifying that, in response to a written notice from CMS notifying the AO that one of its accredited providers or suppliers has been involuntarily terminated from the Medicare/Medicaid program, the AO agrees to terminate or revoke its accreditation of the terminated provider or supplier within 5-business days from receipt of said written notice.
- We propose at § 488.5(a)(22) to require the AOs to submit a declaration from each surveyor disclosing any interests or relationships the surveyor may have in or with another survey agency or health care facility the AO accredits (as defined in § 488.5(a)(10)).
- We propose at § 488.8(a)(2) to expand the types of validation activities included in the performance review.
- We propose at § 488.8(a)(4) to require AOs to submit a plan of correction that would be subject to a public reporting requirement, when the AO's performance on survey activities identify disparity concerns, either through the outcome disparity rates or process disparity rates.
- We propose at new subsection § 488.8(i) to place restrictions on the fee-based consulting services provided by AOs to the health care providers and suppliers they accredit. At § 488.8(i)(1), we propose that an accrediting organization or its associated fee-based consulting division or company may not provide fee-based consulting services to any

health care provider or supplier prior to an initial accreditation survey. At § 488.5(i)(2), we propose to prohibit AOs from providing fee-based consulting services to health care providers and suppliers they accredit within 12 months prior to the next scheduled re-accreditation survey of that provider or supplier. At § 488.5(i)(3), we propose that AOs may not provide fee-based consulting services to a health care provider or supplier in response to a complaint received by the AO regarding that provider or supplier.

- At § 488.8(i)(4), we set forth circumstances in which the restrictions to the provision of AO fee-based consulting services would not apply.
- We propose at § 488.8(i)(5) to require AOs to provide specific information to CMS on a bi-annual basis about the fee-based consulting services they provide.
- We propose at § 488.8(i)(6) to impose penalties on AOs for the provision of prohibited fee-based consulting services.
- We propose at § 488.8(k) that when an AO owner, surveyor, or other employee, currently or within the previous 2 years, has an interest in or relationship with a health care facility that the AO accredits, the AO would be required to take steps to prevent the surveyor from having any involvement with the survey of that facility, having input into the results of the survey and accreditation for that facility; having involvement with the pre and post survey activities for that facility; or having contact with or access to the records for the survey of that health care facility.
- We propose at § 488.9(b) to revise the types of validation programs by adding a new type of validation survey to be conducted by SA or CMS surveyors.
- We propose a new paragraph (z) at § 489.20 to require as a basic commitment of the provider if they are terminated and then seek a new provider agreement, they would follow the terms of proposed new § 489.57(b) noted below.
- We propose to add a new paragraph (b) at § 489.57, to require that Medicare-certified providers or suppliers that have been involuntarily terminated from the Medicare and/or

Medicaid program must meet several requirements before their new agreement for Medicare participation will be approved. Proposed § 489.57(b)(1) would require the terminated provider or supplier to be under the oversight of the SA for a reasonable assurance period for a length of time to be determined by CMS for the purpose of demonstrating compliance with the Medicare conditions. Proposed § 489.57(b)(2) would require the provider or supplier to remain under the exclusive oversight of the SA until the SA has certified and/or CMS has determined its full compliance with all Medicare conditions and the new agreement for participation in the Medicare/Medicaid program has been approved. Proposed § 489.57(b)(3) would require that during the time period in which a provider or supplier is terminated from the Medicare program, is under the oversight of the SA, and during the time the new agreement for Medicare participation is pending, CMS will not accept or recognize deeming accreditation from a CMS-approved accrediting organization.

- We also propose to remove the reference at § 488.4(a)(4) that currently excludes ESRD facilities from the opportunity for accreditation, to reflect a change included in the Bipartisan Budget Act of 2018 (Pub. L. 115-123). Consistent with this same provision, we also propose to remove the reference restricting transplant programs from an accreditation option.
- We are soliciting comments on whether CMS should limit the number of times an AO can submit an incomplete initial application for a new accreditation program. We seek comment on this question because we recently received several incomplete applications which required multiple pass backs due to the applicant's failure to provide information about issues, such as their financial viability, survey processes which appeared not to be operationalized, or similar concerns.

II. Background

A. *Legislative History*

To participate in the Medicare program, providers and suppliers of health care services must, among other things, be in substantial compliance with the applicable statutory requirements of the Social Security Act (the Act), as well as CMS' regulatory requirements related to the health and safety of patients. These health and safety requirements are generally called Conditions of Participation (CoPs) for most providers; Requirements for Participation for skilled nursing facilities (SNFs) and Medicaid Nursing Facilities (NFs) (collectively, long-term care facilities); and Conditions for Coverage or Conditions for Certification (CfCs) for Ambulatory Surgical Centers (ASCs), Rural Health Clinics (RHCs), Federally Qualified Health Centers (FQHCs), dialysis facilities (or End-Stage Renal Disease [ESRD] facilities), and some types of suppliers (collectively referred herein as Medicare conditions). A Medicare-certified provider or supplier that does not comply with the Medicare conditions risks having its Medicare provider or supplier agreement terminated. Medicaid service providers or suppliers that are required by CMS or the State to have Medicare approval would also be affected.

In accordance with section 1864 of the Act, the SAs or other appropriate local agencies, under an agreement with the Secretary of the Department of Health and Human Services (the Secretary), perform surveys of health care providers and suppliers to assess their compliance with the applicable Medicare conditions for the purpose of certification for participation in the Medicare/Medicaid program. There are several types of surveys conducted, including initial certification, recertification, and complaint surveys. The SAs and CMS also perform surveys in certain circumstances for the providers and suppliers that are accredited by an AO and deemed to meet Medicare requirements. For example, the SA performs complaint surveys for health care providers that are accredited by an AO, if the complaint was received by the SA directly. The SA also performs surveys of AO-accredited health care providers that have had their participation in the Medicare program terminated, that wish to be surveyed by the SA instead of an AO, and for the purpose of validation of the results of an AO's surveys. Rules, regulations, and guidance for the certification process performed by the Sas are discussed in the CMS State

Operations Manual (SOM)[1] or communicated via Quality, Safety & Oversight (QSO) policy memorandums.[2.]

Some provider types may only be surveyed by the SA and cannot use AOs while others cannot be surveyed by SAs pursuant to statute but can only be accredited by a CMS-approved AO. We refer readers to section IV, "Provisions of this Proposed Rule" for additional information. Based on the SA's certification of a provider's compliance or noncompliance and recommendation, 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 their compliance with the Medicare conditions through accreditation by a CMS-approved program of an AO, in lieu of being surveyed by SAs for certification. This is referred to as "deeming" accreditation. This is because CMS-approved AOs are recognized by the Secretary as having accreditation programs with accreditation standards that meet or exceed those of Medicare. Therefore, any provider or supplier that is accredited by an AO under a CMS approved accreditation program is deemed by CMS to have also complied with the applicable Medicare conditions or requirements. The AOs perform initial, re-accreditation, follow-up, and certain complaint surveys.

In December, 2020, Division CC, section 407 of the Consolidated Appropriations Act of 2021 (CAA 2021), amended Part A of Title XVIII of Act to add a new section 1822 to the Act, and amended sections 1864(a) and 1865(b) of the Act, establishing new hospice program survey and enforcement requirements. CMS issued implementing regulations for SAs and AOs in the CY 2022 Home Health Prospective Payment System Rate Update (HH PPS) final rule (86 FR 62240). The HH PPS rule finalized changes to increase and improve transparency, oversight, and enforcement for hospice programs under SA and AO oversight. Additionally, the

[1] CMS Internet Only Manual, Pub. 100-07, available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS1201984

[2] https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions

HH PPS final rule in part requires hospice programs to measure and reduce inconsistency in the application of survey results among all surveyors. The HH PPS final rule requires: (1) AOs with CMS-approved hospice programs to use the same survey deficiency reports as the SAs (Form CMS-2567, "Statement of Deficiencies" or a successor form) to report survey findings; (2) comprehensive training and testing of SA and AO hospice program surveyors; and (3) prohibits SA and AO surveyors from surveying hospice programs for which they have worked in the last 2 years from which they would have a perceived or actual conflict of interest.

CMS is responsible for: (1) providing ongoing oversight of the AOs' accreditation programs to ensure that providers or suppliers accredited by the AOs meet the required Medicare conditions; (2) ensuring that the AOs have formalized procedures to determine whether the health care facilities deemed under their accreditation programs meet the AO's accreditation standards (which must meet or exceed the applicable Medicare program requirements); and (3) ensuring that the AO's accreditation standards and practices for surveying providers and suppliers meet or exceed the Medicare conditions and practices for granting approval.

For some provider and supplier types, accreditation is voluntary and seeking deemed status through an accreditation organization is an option, not a requirement for these Medicare-certified providers and suppliers. A provider or supplier has the choice to seek deeming status and accreditation from an AO with a CMS-approved program or certification through the SA survey process. A nationally-recognized AO may have accreditation services which are not specifically related to Medicare-participation or Medicare conditions and an AO may offer accreditation services to a provider or supplier which Medicare does not recognize for deeming status, such as long-term care facilities. The AO may also provide accreditation with a deeming option, which is that their deemed program is recognized and approved by CMS to meet or exceed the Medicare program requirements. We refer readers to section IV.C "Proposal to Require the AOs that Accredit Medicare-Certified Providers and Suppliers to Use Medicare Conditions; and Strengthened Survey Process Comparability" of this proposed rule for additional

context.

AOs typically charge health care facilities a fee for the accreditation services they provide. AOs generally offer at least two accreditation options, which include non-CMS approved accreditation, and accreditation for the purpose of participating in the Medicare program. By "non-CMS approved accreditation" we mean accreditation that is offered by the AOs with an accreditation program that is not approved by Medicare and which is not used for Medicare purposes. Such accreditation could be used for individual State accreditation purposes or additional professional accreditations that a provider or supplier seeks for business purposes, such as the Joint Commission's (TJC's) Nursing Care Center accreditation for skilled nursing facilities, which is not recognized by CMS as an option for deemed status.

This proposed rule would apply only to the AOs with CMS-approved programs that accredit Medicare-certified providers and suppliers and those entities they accredit. The provisions of this proposed rule would not apply to the following parties: (1) health care providers and suppliers that are not accredited by AOs, such as but not limited to, nursing homes and comprehensive outpatient rehabilitation facilities (CORFs); (2) health care providers and suppliers that are certified by the SAs, such as those who elect not to be deemed through an AO; (3) AOs that accredit non-certified suppliers; (4) non-certified suppliers; and (5) AOs that accredit laboratories (under the Clinical Laboratory Improvement Amendments of 1988 (CLIA)).

B. *Regulatory Overview of CMS's Rules Regarding AO Programs*

The current regulations at 42 CFR 488.4 set forth the general provisions for CMS approved accreditation programs for Medicare-certified providers and suppliers. Section 488.5 sets out application and re-application procedures for national AOs that seek to obtain CMS approval of their accreditation programs, often called "deeming authority."

The AO application and re-application procedures set forth at § 488.5 for Medicare-certified providers and suppliers task CMS with the responsibilities of approval and oversight of

the AOs' accreditation programs while ensuring that the accredited providers and suppliers meet or exceed the Medicare conditions.

CMS conducts a thorough review of each accreditation program application that is submitted by an AO for CMS approval. This review establishes the "comparability" of the AOs accreditation standards with Medicare, to determine whether the AO's standards meet or exceed the Medicare conditions. The application review process also includes a review of the AO's survey processes and procedures, the AO's surveyor training, and their policies and procedures for the oversight and enforcement of provider or supplier entities they accredit. The application review team also reviews the qualifications of the AO surveyor staff. In addition, CMS reviews the AO's financial status, to determine their solvency and potential for longevity of operations.

Section 488.5(e)(1) requires that we publish a notice in the **Federal Register** when we receive a complete initial or renewal application from a national AO seeking CMS approval of its accreditation program. The **Federal Register** notice identifies the organization and the type of providers or suppliers to be covered by the accreditation program and provides a 30-day public comment period. CMS has 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 would be deemed by CMS to have met the applicable Medicare conditions and would be referred to as having "deemed status."

C. *Congressional Report on the Oversight of National AOs and CMS Approved Accreditation Programs*

We are required by section 1875(b) of the Act to submit an annual Report to Congress[3] on CMS' oversight of national AOs and their CMS-approved accreditation programs. This report contains information related to the AOs' activities in a fiscal year (FY) and provides a comparison of these activities to the activities of previous years. Within this report, we also

[3] The most recent Report to Congress may be accessed at : https://www.cms.gov/files/document/qso-22-06-ao-clia.pdf

measure the "disparity rate," which is a comparison rate based on AO findings of non-compliance during an accreditation survey and the SA findings of non-compliance for the same facilities found during a look-back validation survey.

There are three levels of adverse findings on a SA survey, which include immediate jeopardy (IJ), condition-level and standard-level deficiencies. Sections 488.1 and 489.3 define immediate jeopardy as a situation in which the provider's or supplier's non-compliance with one or more of Medicare requirements, conditions of participation, conditions of coverage or certification "has caused or is likely to cause, serious injury, harm, impairment, or death to a resident or patient." When investigating a potential immediate jeopardy situation, surveyors must find that there is non-compliance by the provider or supplier, that serious harm has occurred or is likely to occur, and that immediate action needs to be taken by the provider/supplier. (See Appendix Q of the SOM for additional guidance.) A condition-level deficiency means that for that particular Medicare condition of participation, also known as a CoP, the facility's noncompliance is such that it substantially limits the provider or supplier's capacity to furnish adequate care or which adversely affects the health and safety of patients (§ 488.24). There can be noncompliance with a Medicare condition at a regulatory standard level that does not rise to the level of noncompliance with the condition. For example, a hospital may fail to have written policies and procedures regarding the evacuation of patients during an emergency (as required at § 482.15(b)(3)) but complies with the remaining standards set forth at § 482.15 (a) through (f) such as having policies and procedures for alternate source power, provisions, tracking of patients and staff and has a communication plan and training and testing program. In this situation, the hospital generally would not be cited at a condition-level deficiency for the entire Emergency Preparedness Medicare condition (at § 482.15). The manner and degree of the noncompliance is considered to determine whether there is substantial compliance or not. A standard-level deficiency means that the provider may be out of compliance with one or more aspects of a regulatory condition or requirement, but is considered

less severe than a condition-level deficiency. A condition-level deficiency, however, is considered more serious in nature and could lead to a facility being terminated from the Medicare and Medicaid programs for non-compliance. Immediate jeopardy citations are condition-level deficiencies that pose immediate jeopardy to patient health and safety.

On a validation survey, when the SA 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 by the AO and is a factor in determining the AO's "disparity rate" for each facility type. The identification of one missed condition-level deficiency by the AO results in the entire survey being counted toward the disparity rate. The number of disparate surveys is divided by the total number of validation surveys performed with respect to that AO by various States' SAs, in order to determine the AO's disparity rate.

According to the most recent report, the FY 2020 Report to Congress,[4] disparity rates for all CMS approved AO programs for the following facility types for the most recent year in the report (FY 2019) are: Hospitals (42 percent); Psychiatric hospitals (45 percent); Critical Access Hospitals (46 percent); Home Health Agencies (8 percent); Hospices (19 percent) and Ambulatory Surgical Centers (34 percent). From FY 2018 to FY 2019, hospitals, HHAs and ASCs had the only decreases in disparity rates, with a decrease of 5-percentage points, 11-percentage points, and 7-percentage points, respectively. The disparity rates for psychiatric hospitals increased by seven percentage points from FY 2018 to FY 2019. The disparity rates for CAHs and hospices increased by five percentage points and three percentage points respectively from FY 2018 to FY 2019. The findings and other information are consistent with

[4] https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/QSO-19-17-AO-CLIA.pdf.

previous reports, and no notable changes were observed in the FY 2020 RTC covering the FY 2019 period of activities.

D. *CMS Validation Survey Pilot*

As part of our ongoing efforts to enhance transparency and our oversight of the AOs, in 2018, CMS began a pilot for integrated validation surveys for accredited hospitals, known as the Validation Redesign Program (VRP) pilot. In a VRP pilot survey, the SA teams accompany the AO survey teams on a reaccreditation survey for an accredited facility for the purpose of evaluating the AO surveyors' competency at performing surveys and overall effectiveness during the survey process. The initial findings of the VRP pilot will be discussed further later in this preamble at sections IV.J and IV.L.3. CMS plans to continue to refine the validation process over the next several years in an effort to enhance AO oversight, and verify that providers/suppliers under deemed status are in compliance with the Medicare conditions, and focus surveys on key quality concerns while reducing provider burden.

A national AO seeking approval of its accreditation programs in accordance with section 1865(a) of the Act must apply for and be approved by CMS for a period not to exceed 6 years. (See § 488.5(e)(2)(i)). An AO must submit a renewal application seeking re-approval of its accreditation program(s) before the expiration date of its current CMS approval. Review of the AO's renewal application in a timely manner allows CMS to ensure that there would not be a lapse in accreditation for the providers and suppliers accredited by the AO. Requiring the AO to submit a renewal application periodically allows CMS to ensure that the accreditation provided by the AO continues to ensure that the providers or suppliers accredited by that AO meet or exceed the Medicare conditions.

E. *Overview of Transparency and Oversight of Accrediting Organizations*

In September 2017, an article in the Wall Street Journal[5] raised concerns regarding the performance and transparency of AO surveys, and noted potential conflicts of interest between an AO's accreditation services and its consulting services. As a result of this article, CMS initiated an investigation into these allegations.

F. *Prior Rulemaking - Accrediting Organizations Conflict of Interest Request for Information (RFI)*

CMS is aware, from the information submitted with their applications, that some AOs with CMS-approved accreditation programs are also providing fee-based consultative services to Medicare-participating health care facilities. Our understanding is that typical AO fee-based consultative services include, but are not limited to the following:

- Assistance for clinical and non-clinical leaders (including administrators) in understanding the AO and Medicare conditions for compliance;
- Review of facility standards and promised early intervention and action through simulation of a real survey, such as a mock survey with 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.

CMS acknowledges that independent fee-based consulting is a valuable resource that can help providers and suppliers improve the quality and safety of the care they provide. This does not mean that the providers or suppliers who elect not to receive fee-based consulting from an AO that offers it, or that providers or suppliers that are accredited by an AO that does not offer this service would not provide safe, quality care.

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[5] The Wall Street Journal, "Watchdog Awards Hospitals Seal of Approval Even After Problems Emerge" Stephanie Armour (September 8, 2017) https://www.wsj.com/articles/watchdog-awards-hospitals-seal-of-approval-even-after-problems-emerge-1504889146.

There are many third-party consultants that offer fee-based consulting across all provider and supplier types. The availability of third -party fee-based consultants give providers and suppliers access to this educational service, if their AO does not provide fee-based consulting. If a provider's /supplier's AO already offers fee-based consulting, Third-party consultants can offer such providers and suppliers, with an alternative, allowing providers and suppliers to compare the effectiveness and quality of consultants to address their needs within their cost limitations. The provider or supplier may also be able to negotiate a price for educational services provided by a third-party consultant, while this may not be an option with the AOs that offer fee-based consulting. It is important to note there would be no conflict of interest associated with the use of third-party fee-based consultants because these consultants do not also make compliance determinations about the provider or supplier.

Fee-based consulting services are not prohibited by law or regulation. However, CMS is concerned that an AO's provision of such fee-based consulting results in perceived or actual conflicts of interests because of the contractual and financial relationship that exists between the health care provider and the AO, which is a private entity that profits from the performance of the inherently governmental function of regulating health care providers through accreditation.

Because of this, on December 20, 2018, we published a Request for Information (RFI) in the **Federal Register** entitled, "Medicare Program: Accrediting Organizations Conflict of Interest and Consulting Services; Request for Information" (83 FR 65331) hereinafter referred to as "2018 AO Conflict of Interest RFI", in response to increasing concern about potential conflicts of interest created by the accreditation and consultative activities of the AOs. Specifically, we solicited public comments to determine whether offering consultative services to the same entities an AO accredits may create actual or perceived conflicts of interest between an AO's accreditation program and its consultative program. We stated that this dual function may undermine, or appear to undermine, the integrity of the accreditation programs and could erode public trust in the safety of providers and suppliers that have been accredited by CMS-approved

AOs. We further acknowledged 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. We stated that circumstances could arise where an AO has recommended a facility for deemed status through their accreditation service, while the consultancy service of the AO was generating revenue assisting the same facility in passing the AO's own accreditation surveys. Some AOs have indicated that they establish firewalls between the arms of their businesses, but we stated that these firewalls may not be sufficient to ensure that no conflicts of interest result from these activities.

We further stated that, similar to quality improvement organization (QIO) and external quality review organization (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 expressed our view that AOs voluntarily take on this position and responsibility when they seek accreditation approval from CMS to accredit providers and suppliers for participation in Medicare. Because of the responsibility to maintain public trust and public health, we continually ensure that all entities and programs, including AOs and their accreditation programs that require CMS approval, be held to high standards of ethical conduct so that everyone can have complete confidence in the integrity of federal government certification. We stated that the AOs' decisions to accredit facilities must be made without regard to any additional services that a Medicare provider or supplier might obtain through the AO or its subsidiaries. We stated that this policy would ensure and maintain public trust in the Medicare certification program.

In the 2018 AO Conflict of Interest RFI, we solicited public comments to gather information for potential future rulemaking and to obtain insight on mechanisms to address this potential conflict of interest. We were specifically interested in ways to potentially modify

§ 488.5(a), which sets out the required information to be submitted with an AO's application. For example, § 488.5(a)(10) 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 stated that potentially expanding § 488.5(a)(10) by adding provisions that would require the AOs to disclose information about any consultative services they offer to facilities could further enhance our oversight of AOs.

In addition, we solicited comments on the following issues:

- With respect to 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?
- Are there other entities that could provide this training besides the AOs?
- Whether commenters perceive a conflict of interest in AOs providing fee-based consultative services to the facilities they accredit.
- Whether 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.
- What the appropriate consequences or impacts should be, if a conflict does exist.
- 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.
- Examples of positive and negative effects which may be as a result of a conflict of interest.

- 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.
- When and/or under what circumstances it would be appropriate for AOs to provide fee-based consultative services to the facilities which they accredit.
- 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.
- A list describing under what circumstances the AOs or stakeholders would believe there to be a conflict; and under which circumstances conflict does not exist.
- 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. (See 83 FR 65336.)

We received approximately 128 public comments in response to the 2018 AO Conflict of Interest RFI. Approximately half of the commenters, (consisting primarily of AOs and health care facilities that use consulting services) supported the use of AO consulting services and stated that there is no conflict of interest associated with fee-based consulting. The other half of commenters (consisting of individuals, provider associations, medical advocacy groups and one AO) stated that the provision of fee-based consulting by the AOs creates a conflict of interest.

Several commenters stated that the benefits derived from AO fee-based consulting far outweighs any potential or actual conflict of interest that may result. Many commenters believe that AO consulting services allow the facility to seek information and guidance that helps them understand, interpret and comply with the Medicare conditions and regulatory requirements. These commenters stated that use of the AO's fee-based consulting services helped to improve the safety and quality of the care provided by the health care facility.

Many commenters stated that there are already-implemented checks and balances between CMS and the AOs that are sufficient to ensure that no conflicts of interest occur between the AOs and their accredited facilities. These commenters stated that the AOs have robust firewall policies and procedures in place to prevent conflicts of interest related to fee-based consulting. Many commenters also stated that CMS has a specific AO fee-based consulting firewall policy in place and that this policy is adequate to prevent any conflicts of interest. However, CMS does not currently have such a policy. [6]

Several commenters stated that AOs are commissioned to ensure compliance with the Medicare conditions. These commenters stated that a big part of compliance is not only being punitive but informational/educational. One commenter suggested that AOs are in a unique position to provide this education and technical assistance because they understand the complexity of the Medicare conditions. One commenter stated that if AO fee-based consulting services were not provided, facilities could see additional deficiencies cited due to misinterpretation of requirements and multiple rounds of surveys, generating still more cost to the facility.

Several commenters stated that the financial benefit derived by the AOs from providing fee-based education is not significant. Some of these commenters also stated that the AOs gained no benefit from the success or results of accreditation whether they had assisted the provider to deliver better services or not.

One commenter stated that they were are not aware of other organizations who would be capable of educating and advising health care providers in a similar fashion as the AOs' consulting services. Several other commenters expressed concern about having fee-based consulting services provided by an independent third-party. These commenters stated that, while

[6] In section IV.B.6 of this rule, we propose to require any AO that provides fee-based consulting services or its associated fee-based consulting division or company to have written fee-based consulting "firewall" policies and procedures.

there are other entities beside the AOs, such as QIOs that could provide training, the focus would solely be on quality rather than the outcome of an accreditation.

Many commenters stated that the integrity of the accreditation process is of utmost concern for regulators, providers and patients alike and that AOs should position themselves to be above reproach in regard to overseeing patient care and quality of services that health care facilities provide, so as to retain the trust of patients and the public. Several commenters suggested that anything that may undermine the integrity of accreditation programs or the public trust in CMS accredited providers and suppliers be considered and addressed. One commenter stated that the ability of AOs to provide both survey services and consulting services is a conflict of interest, which results in a decreased level of trust among providers, Medicare, and the public.

Many commenters expressed concern about the financial and contractual relationship that exists between AOs and the health care facilities they accredit. These commenters expressed concern that the existence of a financial relationship between AOs and health care providers casts a veil of doubt over the entire CMS hospital accreditation process, eroding the public trust in CMS to maintain the standard of care at our nation's hospitals and to ensure that Medicare patients are receiving safe, therapeutic care. One commenter stated the belief that the business connection between the provider and the AO creates a relationship that the AO could have an incentive to manipulate.

In addition, several commenters expressed concern about the significant financial interest the AOs have in the provision of fee-based consulting. One commenter stated that since AOs are being paid by the health care facilities for both accreditation services as well as consulting services, it is obviously in their financial interest to keep the health care facilities accredited and not to create too much dissatisfaction to incite the organization to seek another AO. Several commenters expressed concern that this financial relationship might provide the incentive for the AOs to ignore or downplay deficiencies during the survey of a consultative client in order to increase the apparent efficacy of its consulting services. Or, perhaps more undetectably, an AO

could exaggerate the deficiencies on surveys in order to increase the apparent value of the consulting services to providers. Because of the above-stated concerns, several commenters suggested that CMS prohibit the AOs from providing fee-based consulting to the health care providers and suppliers they accredit.

G. *Conflict of Interest – The AO Owner's, Surveyor's and Other Employee's Interest in or Relationship with a Health Care Facility that the AO Accredits*

It is typical for an individual health care professional, such as a physician or nurse, to have concurrent employment relationships with more than one health care provider. Many health care professionals, such as physicians, physician assistants, and nurse practitioners have multi-setting practices or are employed at more than one health care facility. For example, a registered nurse (RN) may work on staff at a hospital but also work at other hospitals through a medical staffing agency. In addition, as employees of a health care facility, these health care professionals could possibly gain a financial interest in the health care facility through means such as being a contributor to the construction costs of a new wing of the facility or buying stock in the facility or its parent corporation. Management employees could be awarded stock or stock options for the facility or its parent corporation as part of their compensation and benefits package.

AOs frequently hire surveyors that are also employed at one or more outside health care settings because the professional associations, expertise, knowledge and skills held by these health care practitioners make them an asset as a surveyor. This might include, for example, a RN who is employed by a hospital and also works as a surveyor for an AO. This employment scenario does not generally violate CMS policy or regulations. Furthermore, an AO surveyor having other employment does not, in and of itself, necessarily create a conflict of interest. However, if the AO provides accreditation services to the health care facility that employs the AO surveyor, this would cause a conflict of interest if that surveyor is permitted to have any involvement in the survey process for that health care facility.

CMS has recently encountered two situations in which an AO's surveyor was also employed by the health care facility that was being accredited by the AO. In one of these situations, an AO surveyor was also employed in an administrative position at a rehabilitation facility that was being surveyed by the AO. This situation was not disclosed to CMS by the AO. Currently CMS has no specific regulations that would prohibit a conflict of interest related to an AO surveyor's relationship with a health care facility that the AO accredits, except for home health agencies and hospice programs.

Section 488.5(a)(10) of our regulations requires that an AO provide, with its application seeking CMS approval of its accreditation program, "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." However, § 488.5(a)(10) does not provide requirements for specific types of information or requirements that should be contained in the AO's conflict of interest policy and procedures. This regulation does not specifically prohibit or define conflicts of interest and, based on the comments to the 2018 AO Conflict of Interest RFI, CMS proposes to revise this regulation to more specifically address situations that should be included in the AO's conflict of interest policy.

As noted above, the SAs and AOs perform similar work. Section 4008 of the SOM describes examples of scenarios that would be conflicts of interest for SA surveyors who have an outside relationship with a facility that is surveyed by the SA[7]. Currently, section 4008 of the SOM applies only to the SA surveyors and not AO surveyors.

Scenarios in which an AO surveyor has a relationship with a health care facility that their AO accredits could represent a conflict of interest. As CMS has no specific regulations that would proactively address such conflicts of interest for AOs that accredit healthcare providers other than home health agencies and hospice programs, we propose to establish several requirements to help mitigate such conflicts of interest in section IV.B.7 of this proposed rule.

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[7] https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107c04pdf.pdf

III. Request for Public Comment on Whether it is a Conflict of Interest for AO Board Members or Advisors to Have an Interest in or Relationship with a Health Care Facility that the AO Accredits

As previously stated, it could be a conflict of interest when an AO surveyor is involved with the survey of a facility with which that surveyor has an employment, financial, business or other interest or relationship. We note that in most cases, the AO board members do have interests in or relationships with the health care facilities the AO accredits. In many cases, the board members of the AOs frequently hold upper management positions of a health care facility the AO accredits, such as chief executive officer (CEO), director, or President. In an article published in the Wall Street Journal on September 8, 2017[8], it was stated that "[t]wenty of the Joint Commission's 32 board members are executives at health systems it accredits or else work at parent organizations of such health systems. Some other board members are named by healthcare lobbying groups, such as the American Hospital Association and the American Medical Association. This article compared this situation to "Big Pharma setting up its own accrediting organization" and stated that "if you look beneath the surface, there are conflicts and problems."

We seek public comment as to whether it would be a conflict of interest for an AO board member, AO advisor, or CEO or other executive team members to also have a relationship with a health care organization accredited by such AO. An AO advisor would be an advisory committee member, advisor to the CEO, or an advisor to the board of directors. We refer readers to proposals related to an AO owner's, surveyor's, or other employee's interest in or relationship with a health care facility the AO accredits in section IV.B.7 of this proposed rule.

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[8] S. Armour, Hospital Watchdog Gives Seal of Approval, Even After Problems Emerge, *Wall Street Journal*, September 8, 2017.

IV. Provisions of the Proposed Rule

We establish health and safety standards, known as the Conditions of Participation, Conditions for Coverage, or Requirements for Participation for different types of health care providers and suppliers, and these standards are based on specific statutory authorities for the different provider and supplier types. Pursuant to such authorities, each specific type of Medicare-certified provider and supplier must meet our health and safety standards. As part of the CMS certification process, compliance with these standards is evaluated by SAs under agreement at section 1864 of the Act, through the survey and certification process. However, CMS makes the final Medicare certification determination. In the alternative, we can deem these providers and suppliers to have met those standards if they are accredited by the CMS-approved AOs that are the subject of this proposed rule.

CMS is using the authority established by Congress under section 1865 of the Act to establish certain requirements for AOs in this proposed rule. Section 1865(a)(2) of the Act establishes a process for the Secretary to make a finding with respect to approval of an accrediting organization. In making this finding, the Secretary must consider, among other factors, the AO's 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.

In addition, "Non-certified" suppliers are a statutory category for which CMS does not set health and safety standards, even though they must obtain accreditation in accordance with statute. Because we have not set health and safety standards for these facility types, we are not applying these provisions to non-certified supplier types at this time. These suppliers include (1) Advanced Diagnostic Imaging (ADI) suppliers; (2) home infusion therapy (HIT) suppliers; (3) diabetes self-management training (DSMT) suppliers; and (4) durable medical equipment

prosthetics, orthotics supplies (DMEPOS). We are also not proposing to extend any of the provisions set forth in this proposed rule to AOs that accredit non-certified suppliers.

Non-certified suppliers are those suppliers that are required to be accredited by a CMS-approved AO for Medicare payment, do not enter into a Medicare agreement but are enrolled in the Medicare program, and do not receive a CMS certification number (CCN). These non-certified suppliers are a smaller, discrete group that are not under the jurisdiction of the SAs and do not undergo validation surveys. For example, there are no health and safety regulations for advanced diagnostic imaging (ADI) suppliers and only minimal such standards for DMST suppliers. Also, many ADI suppliers are physician's practices that provide an ADI service, such as computerized tomography (CT) scans in their office. CMS has not yet developed a survey process and health and safety requirements for these supplier types, however we reserve the right to do so in the future. CMS does a review of the applications for AOs that accredit non-certified programs. The provisions proposed in this rule would not align to these programs at this time.

As stated in section I "Executive Summary" and section II "Background" of this proposed rule, since issuing the 2015 AO final rule, there are several provisions related to oversight of AOs that require strengthening. Throughout the last several years, we have worked closely with the AOs, provided guidance and instituted an AO Liaison program in which CMS meets with each AO at least on a quarterly basis. These meetings and discussions have provided an avenue for CMS to also receive feedback on existing Medicare conditions, our interpretive guidelines and allowed for an opportunity for CMS to clarify expectations for the AOs. This experience has helped us to identify areas of our regulations in need of revision to more clearly articulate the requirements for all AOs with a CMS-approved accreditation program. Furthermore, as we have taken actions to exercise more oversight of existing CMS-approved AO programs, we have become aware of the need to clarify, reorganize, and amend our regulations to support a more efficient and effective oversight process.

The below proposal outlines the background behind each proposal and what led to CMS' development of this proposed rule.

A. *Proposal to add Definition of "Unannounced Survey" to § 488.1*

We propose to add a new definition of "unannounced survey" to § 488.1. The definition of "unannounced survey" would be consistent with the definition of "unannounced" contained in the Merriam-Webster dictionary, which is "without previous notice or arrangement and therefore unexpected." Adding this definition of "unannounced survey" would support the existing requirements set out at § 488.5(a)(4)(i) and in our sub-regulatory guidance. This proposal clarifies and codifies existing requirements under § 488.5(a)(4)(i), which requires that surveys must be unannounced, which means that the facility must be unaware of the survey until the time that the survey team arrives, and that the provider or supplier would not receive notice of the survey until the survey team arrives at the facility. Our long standing policy behind the term "unannounced survey" has been within section 2700A, chapter 2 of the SOM, outlining the expectation that all surveys of providers and suppliers (other than clinical laboratories) must be unannounced to the provider or supplier being surveyed. This means that the provider or supplier to be surveyed would not receive notice of the survey until the survey team arrived at the facility for the survey, as is also currently the AO's process for complaint surveys. The proposed definition for "unannounced survey" would also state that unannounced surveys must be scheduled by the AO in a manner so that their timing and occurance will not be predictable to the healthcare facility being surveyed.

One of the primary reasons surveys conducted by either the SA or the AO are required to be unannounced is to prevent the provider or supplier from making unusual preparations for the survey that would not represent the ongoing typical condition of the provider and true nature and quality of care provided. Examples of these activities would include unusual cleaning activities, painting, clearing obstructions from halls and entrances, denying leave to staff during that time or calling staff back to inflate staffing availability, and re-reviewing medical records outside of

what is normally done. If a provider or supplier knows the exact time a surveyor will be onsite, it may temporarily adjust its typical practices such as staffing, which would provide an unrepresentative picture to surveyors of the quality of care typically provided to patients or residents. A notice to facility leadership via organizational websites, emails, or phone calls prior to surveyors arriving onsite is considered a violation with CMS regulations.

In 2009, CMS clarified this expectation in the Survey & Certification Policy Memorandum 09-41[9], to advise that announcing of surveys was in conflict with CMS regulations. In the effort to align AO survey processes with CMS survey processes (which are followed by the SA surveyors), as outlined in section IV.C of this proposed rule, additional clarity regarding this prohibition is needed. Defining the term "unannounced survey" within the regulation as opposed to our SOM (subregulatory guidance) would provide clarity regarding our expectations, and would mirror the processes used by our SAs, who do not announce their surveys (except for clinical laboratories); as noted, any AO practice of announcing surveys could undermine the integrity of the survey process. While we recognize AOs may have provided up to a 60-minute advance notice of the survey team arriving onsite for initial and reaccreditation survey activities, this is inconsistent with the processes followed by our SAs, and is inconsistent with the AOs' own survey processes for complaint surveys (which are always unannounced).

Therefore, in accordance with § 488.5(a)(4)(i), which requires unannounced surveys, as well as our long-standing policy in section 2700A, chapter 2 of the SOM, we propose that all surveys of providers and suppliers (other than clinical laboratories) must be unannounced and any advance notice to facilities would be prohibited. This proposed requirement would apply to AOs as well as SAs and further support our initiative to bring consistency to survey practices as outlined in section IV.C of this proposed rule.

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[9] https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions-Items/CMS1223113.

Furthermore, the definition of "unannounced survey" must ensure that the recertification surveys are unpredictable. AOs generally complete comprehensive re-accreditation surveys of their client providers and suppliers every 32 to 36 months. However, some providers or suppliers have informed us that they know when an AO is scheduled to survey the facility -- the AO may schedule the facility for survey within the same week or month every survey cycle, or has narrowed its schedule via the use of blackout days, or informed the facility close to the time of the survey via administrative contact from the AO, such as payment collection, confirmation or change of address notification or other facility-AO specific information. All of these practices undermine the integrity of the unannounced survey process.

B. *Conflict of Interest*

1. Proposal for Information to be Submitted With the AOs' Conflict of Interest Policies and Procedures (Proposed Revisions to § 488.5(a)(10))

Section 488.5(a)(10) currently requires that the AO submit "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 decisions." This requirement does not require the AO to address any specific areas or issues in their conflict of interest policies and procedures. In addition, the AOs only need to submit this information to CMS with their initial and renewal applications, which is currently every 6 years or less, as established by CMS.

We propose to revise § 488.5(a)(10) by adding a requirement that AOs must provide CMS with more specific conflict of interest policies and procedures. We propose at § 488.5(a)(10)(i) to require the AOs to provide CMS with their policies and procedures for separation of their fee-based consulting services from their accreditation services (that is, fee-based consulting "firewall" policies and procedures). We propose at § 488.5(a)(10)(ii) to require the AOs to provide their policies and procedures for protecting the integrity of the AOs' accreditation program, including the requirements of proposed § 488.8(i) and (j) noted below. Section 488.8(i) pertains to restrictions on certain fee-based consulting services provided by

AOs, and § 488.8(k) pertains to conflicts of interest which arise due to AO owners, surveyors, and other employees having a business, employment, financial or other type of relationship with a health care facility accredited by the AO.

At § 488.5(a)(10)(iii), we propose to require the AOs to provide policies and procedures for the prevention and handling potential or actual conflicts of interest that could arise from situations in which an AO owner, surveyor, or other employee has a business, employment or financial interest in or relationship with another survey agency or health care facility to which the AO provides accreditation services.

Proposed § 488.5(a)(10)(iii) would further state that such interests or relationships would include but not be limited to: (1) being employed as a SA surveyor; (2) being employed in a health care facility that is accredited by the AO; (3) having an ownership, financial or investment interest in a health care facility that is accredited by the AO; (4) serving as a director of or trustee for a health care facility that is accredited by the AO; (5) serving on a utilization review committee of a health care facility that is accredited by the AO; (6) accepting fees or payments from a health facility or group of health facilities that is/are accredited by the AO; (7) accepting fees for personal services, contract services, referral services, or for furnishing supplies to a health care facility that is accredited by the AO; (8) providing consulting services to a health care facility that the AO accredits; (9) having members of their immediate family engaged in any of the stated activities, other than being a non-managerial employee of a health facility that is accredited by the AO; and (10) engaging in any activities during the course of the survey of the facility that would be or cause a conflict of interest.

In proposed § 488.5(a)(10)(iii)(I), we have defined the term “immediate family member” as a husband or wife, birth or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild. This is also

consistent with the definition of "immediate family member" used for the hospice program conflict of interest regulations at § 488.1115.

We further propose at § 488.5(a)(10)(iv) to require AOs to provide policies and procedures for providing notification to CMS when such a conflict of interest is discovered.

We propose at § 488.5(a)(10)(v) to define "conflict of interest" as a situation in which an AO, its owner(s), surveyors, or other employees, or the AO's successors, transferees, or assigns, or the immediate family members of the AO owners(s), surveyors and other employees have an employment, business, financial or other type of interest in or relationship with a health care facility the AO accredits. We would deem a conflict of interest to have occurred if one of the above-stated parties either knowingly or unknowingly exploited their interest in or relationship with that provider or supplier. We remind readers that in the CY 2022 Home Health Prospective Payment System Rate Update (86 FR 62368) that we finalized similar conflict of interest regulations for hospice programs at § 488.1115(b). The proposed requirements of this rule for accrediting organizations are consistent with, and build upon, the current conflict of interest regulation for hospice programs at § 488.1115(b). For additional discussion on the Hospice final rule see 86 FR 62368.

We are proposing changes to § 488.5(a)(10) to require the AO to have policies and procedures for the prevention, handling of and notification of CMS when conflicts of interest arise, because on several occasions, AOs have failed to notify CMS of such conflicts of interest. These changes would broaden our oversight of the AOs' handling and reporting of conflicts of interests. Additionally, by requiring the AOs to provide CMS with more specific information about their conflict-of-interest policies and procedures, CMS would be afforded a more comprehensive look at how the AOs plan to handle specific scenarios that CMS would deem to be conflicts of interest. These proposed requirements would require those AOs that did not have policies and procedures to prevent, address and handle conflicts of interests to develop and use them.

The proposed requirements at § 488.5(a)(10)(iii), for the conflict of interest and information that must be submitted with the AOs' conflict of interest policies and procedures, are more detailed than the requirements currently set forth in section 4008 of the SOM, which provide examples of possible scenarios that could be conflicts of interest for the SA surveyors. Section 4008 of the SOM leaves it to the discretion of the SA management to decide how to identify and address these conflicts of interest.

A more detailed conflict of interest requirement is not necessary for the SA surveyors because SA surveyors, who are state employees, are generally required to report incidences of conflicts of interest to the SA management, who is tasked with taking the appropriate action.

Unlike the SAs, the AOs are more likely to encounter scenarios with conflicts of interest. For example, AO owners, board members, surveyors and other employees might also be employed by health care facilities that are surveyed and accredited by that AO. Therefore, the proposed requirements for AOs must be more detailed and prescriptive than SAs because of the likelihood of them encountering conflicts of interest.

2. Proposal to Require AOs to Obtain and Submit Surveyor Declarations of Any Interest in and Relationships with Health Care Providers the AO Accredits to CMS on an Annual Basis (Proposed § 488.5(a)(22))

A conflict of interest may exist when an AO surveyor has interest(s) in or relationship(s) with a health care facility the AO accredits. Requiring AOs to obtain and submit declarations detailing such interests and relationships would ensure that CMS is notified of potential or actual conflicts of interest AO surveyors might have with the providers and suppliers the AO accredits. Such notice would allow CMS to be aware of the existence of these potential or actual conflicts of interest, some of which would preclude a surveyor from participating in survey activities (see § 488.8(j) discussion at section IV.B.6 of this proposed rule) and some of which would not.

We propose to add a new provision at § 488.5(a)(22) that would require the AO to obtain declarations from all surveyors employed or contracted to the AO regarding any employment,

business, financial or other interests in or relationships they have with the health care facilities the AO accredits. We propose that AOs would initially be required to submit the surveyor declarations with their initial application for CMS approval of their accreditation programs. We further propose to require the AOs to update the surveyor declarations on an annual basis, and that the information from the annual updated surveyor declarations be submitted to CMS no later than December 31st each year. Annual updates would be necessary because a surveyor's interests in and relationships with health care facilities the AO accredits could change over time. This requirement would ensure that the information contained in the surveyor declarations remains up-to-date and accurate. This provision at paragraph (a)(22) would be implemented 1 year after the effective date of the final rule (which would be 60 days after publication of the final rule). We further propose to require the AOs to begin submitting their surveyor declaration information on or before the December 31st that occurs after the implementation date of this requirement.

3. Proposal to Place Restrictions on Fee-Based Consulting Services Provided by AOs to the Medicare-Certified Providers and Suppliers They Accredit (Proposed § 488.8(i))

CMS recognizes the value of fee-based consulting by independent, third-party consultants who provide insight or expertise to assist facilities in achieving or maintaining compliance with AO and/or Medicare's health and safety standards. These interventions are beneficial and often tailored to meet a facility's specific compliance needs. Consulting services also may assist a provider or supplier in identifying quality concerns, whether based on a Medicare requirement or standards of practice, and therefore these services may improve the safety of patient care. AO fee-based consulting activities are not prohibited by federal law and there are no current CMS regulations prohibiting AOs from providing fee-based consulting services.

However, AOs assume a public trust role when voluntarily applying to CMS for deeming authority. This authority, once granted, conveys Medicare certification for those entities

accredited by the AO and it is essential that the integrity of their oversight process be above question. A number of AOs with CMS-approved accreditation programs currently provide AO fee-based consulting services to the Medicare-participating health care facilities they accredit. When an AO provides fee-based consulting services to a provider or supplier it accredits it could create a conflict of interest for several reasons.

First, AOs provide deeming surveys to providers or suppliers on behalf of CMS. AOs are required to use accreditation standards that are comparable to or exceed the Medicare standards and survey processes in the performance of deeming surveys. A potential or actual conflict of interest arises from allowing a CMS-approved AO with deeming authority, the ability to charge a provider or supplier to conduct a deeming survey to identify non-compliance (for Medicare participation), and also charge for providing AO fee-based consulting services to help the provider meet Medicare requirements.

Second, providers and suppliers often choose AO fee-based consulting specifically for the additional resources and assistance provided. Some AOs publicly advertise the ability of their fee-based consulting to simulate what to expect from the actual AO survey. It is possible that Providers and suppliers found to be non-compliant by their AO may assume that the most direct path to compliance is to hire the AO's fee-based consulting services. Such an assumption would provide AOs with fee-based consulting services with an unfair advantage over other, third-party consulting services.

Finally, by charging for accreditation services (for example, deeming surveys) and also for the subsequent fee-based consulting services, for the purpose of remediating deficiencies identified by the same AO, there may be an expectation from providers and suppliers that the AO demonstrate the effectiveness their consulting services on subsequent compliance surveys. In other words, the provider or supplier may expect to receive a favorable survey report because they have paid the AO not only for accreditation but also for fee-based consulting services which are promoted by the AOs to help the provider or supplier do well on their survey. In addition,

this expectation may push AOs to ignore significant deficiencies found during survey of its fee-based consulting clients in order to demonstrate the efficacy of its fee-based consulting and promote these services.

In short, an AO's business model is geared toward retention of its accredited providers and suppliers. AOs that provide both regulatory oversight through Medicare deeming surveys and also fee-based consulting services, which are geared towards assisting clients comply with the requirements required to pass the surveys, invites concerns about the integrity of their final compliance determinations.

CMS issued an AO Conflict of Interest RFI (83 FR 65331) in 2018 to gather feedback related to AO conflict of interest practices. We received 128 public comments in response to the RFI. Many commenters stated that fee-based consulting provided by an AO or its associated consulting division or company to the health care facilities it accredits is a conflict of interest. These commenters stated that this conflict of interest arises from granting the inherently governmental function of monitoring patient safety, by regulating health care providers through accreditation, to a private entity, especially when that private entity profits from those who are regulated.

Several commenters alleged that AOs that provide fee-based consulting may have the incentive to ignore deficiencies detected during the accreditation survey, in order to provide a "good" survey report to demonstrate the apparent efficacy of their AO fee-based consulting services and also to keep the paying customer(s) happy. Many commenters also suggested that if an AO provides poor survey results to a health care facility that has paid a significant fee for accreditation, it is unlikely that the facility would continue to retain that AO as a service provider.

After careful review and analysis of the public comments received in response to the RFI, we agree that a conflict of interest arises from the contractual and financial relationship between the health care provider and the AO, which is a private entity that profits from the performance

of regulating health care providers through accreditation. AOs that provide fee-based consulting services generate additional revenue beyond the fees realized for accreditation services by providing fee-based consulting services to the same facilities they accredit.

We propose at § 488.8(i) several restrictions on fee-based consulting provided by these AOs, their consulting divisions, or separate business entities. By "fee-based consulting division," we mean a separate division within the AO that provides fee-based consulting services. This division of the AO would have a separate manager and staff. By "separate business entity," we mean a business entity, such as a company or corporation, that is separate and apart from the AO and that has been established by the AO, either under a similar or different name, for the purpose of the providing fee-based consulting services.

The proposed regulation at § 488.5(i) would still allow AOs to provide fee-based consulting services to the providers and suppliers they accredit with restrictions that address the conflict of interest issues associated with this service.

We propose at § 488.8(i)(1) that, unless excepted under proposed § 488.8(i)(4), AOs and their associated consulting divisions or companies would be prohibited from providing fee-based consulting services to any health care provider or supplier to which the AO provides accreditation services prior to an initial accreditation survey. However, the health care provider or supplier may seek fee-based consulting services from an entity entirely uninvolved in that provider or supplier's accreditation process. This option allows these providers and suppliers support they may believe necessary to meet Medicare standards and requirements prior to serving patients while eliminating any conflict of interest for their AO.

For purposes of proposed § 488.8(i)(1), the term "initial survey" would mean the first accreditation survey of a health care provider or supplier performed by an AO. The term "prior to the initial accreditation survey" would mean the time period beginning on the day the provider or supplier enters into a contract with the AO to provide accreditation services and continuing until the date that the initial accreditation survey is completed. The survey completion date

would include the completion of any required plans of correction by the provider or supplier. In addition, if a health care provider or supplier was terminated or withdrew from the AO's accreditation and later retained the services of that AO, the first survey of the returning health care provider or supplier performed by the AO would be considered an initial accreditation survey.

The requirement of proposed § 488.8(i)(1), which would prohibit an AO from providing fee-based consulting or coaching to a health care provider or supplier prior to the initial accreditation survey, would provide a more accurate assessment of the provider's or supplier's baseline operating conditions and deficiencies on the initial survey. Such a raw assessment would not be possible if the provider or supplier receives AO fee-based consulting prior to the initial accreditation survey.

In addition, such a baseline assessment of deficiencies would be useful to the AO in assessing areas needing improvement, developing a plan of correction and areas of focus for the fee-based consulting. This proposed restriction would also remove the financial incentive on the part of the AO to ignore deficiencies during the initial survey of providers and suppliers that paid for fee-based consulting prior to an initial survey.

We note that this proposal only restricts an AO with deeming authority and a fee-based consulting practice from providing fee-based consulting services to its accredited providers and suppliers prior to the initial accreditation survey. It does not prohibit providers and suppliers from hiring third-party fee-based consulting services prior to their initial AO survey,– in other words, this proposal does not prohibit other consulting services from being used during this period.

We do not anticipate that this proposal would cause a negative impact on the patient care provided by the provider or supplier for several reasons. First, providers or suppliers would be able to obtain AO fee-based consulting during the first 24 months of the 36-month reaccreditation cycle which occurs after the initial survey. This education could be tailored to

address the deficiencies found during the initial survey. If the AO were to provide fee-based consulting prior to the initial survey, the AO would not know what deficiencies exist and would only be able to provide generalized fee-based education to the provider or supplier. Second, the provider and supplier could always seek fee-based education prior to the initial survey from a third -party consultant. The purpose of our proposal to prohibit AO fee-based consulting prior to the initial survey and during the 12-month period prior to each reaccreditation survey is to reduce or remove any potential or actual conflict of interest. However, if a provider or supplier were to seek fee-based consulting from a third-party consultant, that has no relationship to the AO that accredits that provider or supplier, no conflict of interest would exist.

We also propose at § 488.8(i)(2) to prohibit AOs from providing fee-based consulting services to a health care provider or supplier it accredits within 12 months prior to the next scheduled re-accreditation survey of that provider or supplier. For purposes of proposed § 488.8(i)(2), the term "re-accreditation survey" would mean any subsequent accreditation surveys performed by the AO after the initial survey.

The accreditation cycle for most Medicare-certified providers and suppliers is 36 months (3 years), which means that the AOs perform an accreditation survey of these providers and suppliers no less than every 36 months. The proposed language at § 488.8(i)(2) would allow AOs to provide fee-based consulting during the first 24 months (2 years) of the accreditation cycle, but not during the 12-month (1-year) period preceding the re-accreditation survey. For example, with this proposal, if the initial survey was completed on June 1, 2025, the provider's or supplier's reaccreditation survey would be due by June 2, 2028. The AO could provide fee-based consulting to the provider or supplier from June 2, 2025, to June 2, 2027. The AO would be prohibited from providing AO fee-based consulting to the provider or supplier from June 2, 2027, to June 2, 2028. An accredited provider or supplier would retain the ability to use consultants not affiliated with their AO at any time, including any timeframe prior to or after an accreditation survey for Medicare compliance.

The proposed requirement would provide the accredited provider or supplier ample time to obtain the education they need in order to understand the CMS requirement, the AO's accreditation standards and survey process, and 1-year period, prior to their next accreditation survey, in which to implement the AO's accreditation standards and CMS standards (CoPs) in their facility and rectify any deficiencies found during the initial survey.

The proposed requirement at § 488.8(i)(2) would address the actual or potential conflicts of interest associated with AO fee-based consulting because it creates a 1-year time period prior to the re-accreditation survey in which the AO is prohibited from providing any type of additional teaching or "coaching" that would help the provider or supplier "pass" or obtain better scores on the upcoming accreditation survey.

We further propose at § 488.8(i)(3) that the AOs or their associated consulting divisions or companies be prohibited from providing fee-based consulting services to a health care provider or supplier in response to a complaint received by the AO regarding that provider or supplier. Our rationale for this requirement is that AOs are required by CMS regulation to investigate and resolve complaints received regarding their accredited providers and suppliers (that is, 42 CFR 488.5(a)(4)(ix); 42 CFR 488.5(a)(12)). This regulatory requirement includes investigating the complaint and working with the accredited provider or supplier to help them resolve any deficient practices identified in the complaint. AOs charge a significant fee for their fee-based consulting. AOs should not profit by providing fee-based consulting to a provider and supplier in response to a complaint that they are regulatorily required to investigate and resolve. This proposed regulation would prevent this from occurring.

We propose at § 488.8(i)(4)(i) to (iv) that the restrictions upon AO fee-based consulting would not apply to the following situations: (1) AO fee-based consulting services provided during the 24-month period after the date the initial or re-accreditation survey is performed (proposed § 488.8(i)(4)(i)); (2) AO fee-based consulting services provided to address complaints received and investigated by the SA regarding an AO's accredited provider or supplier in which

one or more condition-level or immediate jeopardy deficiencies are identified, provided however that, the fee-based consulting must occur after the complaint investigation and survey has been completed and must only address those issues identified by the complaint survey (proposed § 488.8(i)(4)(ii)); (3) AO fee-based consulting services provided to health care providers or suppliers to which the AO has never provided accreditation services (proposed § 488.8(i)(4)(iii)); and (4) no-cost consulting or general education provided by the AO about their accreditation program (proposed § 488.8(i)(4)(iv)).

Proposed § 488.8(i)(4)(ii) would allow AOs to provide AO fee-based consulting services in response to complaints received by the SA regarding an AO's accredited provider or supplier. However, this fee-based consulting must be provided by the AO after completion of the SA investigation and complaint survey. We would permit AO fee-based consulting services after a complaint is received by the SA, because the SA, not the AO, would perform an investigational survey. Therefore, the affected provider or supplier should be permitted to seek fee-based consulting from its AO, in accordance with the restrictions stated above, to address the issues identified in the SA complaint and complaint survey, if appropriate.

It is important to note that AO fee-based consulting should only be provided when serious deficiencies have been identified in the SAs complaint investigation report. By serious deficiencies, we mean deficiencies that would be considered condition level by the SA and the AO. However, the AO should first work directly with the provider or supplier, as part of their accreditation services package, to resolve the issues identified in the SAs complaint investigation report and only provide AO fee-based consulting if these issues cannot be resolved successfully, through other methods. It has always been the duty of the AOs to address and resolve complaints received regarding its accredited providers and suppliers, whether said complaint is received by the AO or the SA. An AO receives a significant fee for the accreditation services provided. We believe that the investigation and resolution of complaints falls squarely under these paid accreditation services. We do not believe it appropriate for AOs to offer fee-based

consulting/educational services in response to each and every complaint received regarding one of its accredited providers or suppliers. In other words, the AOs should not realize additional profit from its paying customers, when it has already been paid to perform the task at hand.

More specifically, we would expect that an AO not offer fee-based consulting to an accredited provider or supplier in response to a complaint, unless the deficiency(ies) identified in the complaint are substantiated by the investigation, and found to be systemic, widespread, and ingrained in the culture of the organization. We would also expect to find that the AO first attempted to work with the provider or supplier, as part of the accreditation services provided, to resolve the deficiencies identified in the complaint, before resorting to fee-based consulting. Finally, we would expect to find that if an AO offers fee-based consulting/educational services to the provider or supplier, they do so after trying all non-cost options available, and that the fee-based consulting/education was reasonably expected to resolve the deficiencies identified in the compliant.

Proposed § 488.8(i)(4)(ii) requires that the AO fee-based consulting cannot be provided until after completion of the SA's investigation and complaint survey. By "completion of the SA's investigation", we mean the date upon which the SA has completed all work required to investigate the complaint and has issued its findings. This restriction is necessary because if the affected provider or supplier were to receive fee-based consulting from the AO prior to the completion of the SA's investigation and complaint survey, the affected provider or supplier potentially could alter processes, operations or documentation, all of which could compromise the SAs investigation of the complaint. In such a scenario, the investigation and complaint survey report would not be an accurate reflection of the issues identified in the complaint. While it may seem counter-productive for the affected provider or supplier to obtain AO-fee-based consulting after completion of the SA's investigation and complaint survey, we believe that it would actually be helpful to the affected provider or supplier. After completion of the SA's complaint survey and investigation, the affected provider or supplier will receive a complaint

investigation report, which will allow the AO to tailor the fee-based consulting services or other educational activities to address any deficiencies identified in said report. Also, through AO fee-based consulting services, the AO could work with the affected provider or supplier, at their own pace, to implement long-lasting and sustainable changes that address the deficiencies identified, as opposed to the implementation of quick temporary solutions or corrective action prior to completion of the complaint investigation. A quick temporary solution would be one that the provider or supplier implements on a short-term basis, typically only during the time that the surveyors are present. By contrast, a long-lasting and sustainable solution would be one in which the provider or supplier implements the solution, orients the staff to its requirements, regularly monitors for compliance with the requirements and corrects non-compliance on a continual basis.

Proposed § 488.8(i)(4)(iii) would further allow AOs to provide fee-based consulting services to health care providers or suppliers the AO does not accredit at the time the consulting services are furnished. If the AO has not provided accreditation services to a provider or supplier at the time fee-based consulting services are provided, the AO would not have a preexisting financial relationship with that provider or supplier. Thus, no conflict of interest would exist.

Proposed § 488.8(i)(5) would require AOs to report information about the fee-based consulting provided to the providers and suppliers they accredit to CMS. See section IV.B.4 for information about this proposed rule.

Proposed § 488.8(i)(6) provides for penalties for AOs that provide fee-based consulting in violation of the restrictions set forth on proposed § 488.8(i)(1) to § 488.8(i)(3). See section IV.B.5 of this proposed rule for a discussion of this proposed section.

We propose at § 488.8(i)(7) that the requirements at § 488.8(i) would become applicable 1 year from the effective date of the final rule to allow for an appropriate time of transition. We

believe that this would provide ample time for the AOs to prepare for and implement the proposed requirements at § 488.8(i).

The conflict inherent in AO fee-based consulting on accreditation standards while an AO is also performing surveys to determine compliance with those same standards is what the proposed restrictions on AO fee-based consulting seek to address. An entity that collects fees to remedy findings or prepare for a survey performed by another arm of the same entity creates a perceived conflict of interest that undermines the integrity of the health and safety oversight process. These proposals seek to allow continuance of independent consulting activities while addressing concerns related to fee-based consulting performed by the AOs, themselves.

We note that this proposed restriction on AO fee-based consulting services at §§ 488.8(i)(1), 488.8(i)(2), and § 488.8(i)(3) would not prohibit the AOs from providing no-cost education, such as general education about the AO's accreditation and survey process and mock surveys. The restrictions on AO fee-based consulting would also not prohibit AOs from providing education about the Medicare conditions, AO standards, or survey process, to its accredited health care providers and suppliers, as long as this education is provided completely free of charge. This means that the AO would not be allowed to raise the price of their accreditation services because of the provision of this education, or do anything else that would cause the provider or supplier to incur any additional costs for the education provided by the AO, its consulting division or separate consulting company to the providers or suppliers it has contracted with to provide accreditation services. We believe that it is important that health care providers and suppliers receive education that would assist them in compliance, so long as it is not provided on a fee basis, which would introduce another financial relationship between the AO and the provider or supplier that could cause a conflict of interest.

We also note that other CMS programs have established similar conflict of interest and independence provisions for organizations that have a public trust role in assessing the quality of services provided. For example, in the Medicaid program, CMS has established regulatory

standards with respect to the independent judgment of any External Quality Review Organization that reviews the quality of the Medicaid managed care organization for the state (42 CFR 438.354). These regulations establish, among other requirements, that an External Quality Review Organization may not review any managed care entity for which that organization has also conducted a private accreditation review within the previous 3 years.

Our proposal to place restrictions on the provision of fee-based consulting by AOs to their current accredited providers and suppliers is authorized by section 1865(a)(2) of the Act, which gives CMS the broad power of oversight over the activities of AOs. The provision of AO fee-based consulting is one of the factors in section 1865(a)(2) of the Act that should be considered in determining whether a national accreditation body demonstrates that all of the applicable conditions or requirements of this title are met or exceeded.

4. Proposal to Require AOs to Provide CMS With Information About the Fee-Based Consulting They Provide (Proposed § 488.8(i)(5))

We proposed at § 488.8(i)(1), § 488.8(i)(2), and § 488.8(i)(3) to place restrictions on the fee-based consulting services provided by AOs. In order to enforce our proposals, we propose at § 488.8(i)(5) to require the AOs that provide fee-based consulting services to submit information to CMS, on a calendar year bi-annual basis, about the fee-based consulting services they provide.

We propose to add a requirement at § 488.8(i)(5) that would require the AOs that accredit Medicare-certified providers and suppliers to provide CMS with information regarding the fee-based consulting services no later than 15 days after the end of each calendar year bi-annual (6-month) period.

More specifically, this proposal would require these AOs to submit a document which contains the following information to CMS:

- Whether the AO or an associated consulting division or company established by the AO provides fee-based consulting services.

- The names and CMS Certification Number (CCN) numbers of all health care providers and suppliers to which the AO or its associated consulting division or company has provided fee-based consulting services during the previous calendar year quarter.
- The dates the AO fee-based consulting services were provided to each provider and supplier listed.
- Whether the accrediting organization has, at any time in the past provided, or is currently providing accreditation services to each health care provider or supplier listed in said document, and if so, the date the accreditation services were provided.
- The date of the most recent accreditation survey performed, and the date the next re-accreditation survey is due to be performed for each health care provider and supplier listed in said document.
- A description of the AO fee-based consulting services provided to each health care provider or supplier listed in said document.

We are further proposing that the two bi-annual reporting periods would consist of January 1st to June 30th and July 1st to December 31st each year. The submission deadline for the first period would be July 15th each year. The submission deadline for the second period would be January 15th each year. This would ensure that AOs are not providing fee-based consulting services to providers and suppliers prior to an initial survey, within 12 months prior to a re-accreditation survey, or in response to a complaint received regarding an accredited provider or supplier. In addition, this information would also allow CMS to see the number of providers and suppliers to which the AOs are providing fee-based consulting services.

We propose that these provisions would become applicable 1 year from the effective date of final rule to allow for an appropriate time of transition. We believe that this would provide the AOs with ample time to prepare for and implement this requirement.

5. Proposal for Penalties for AOs Found to be Providing AO Fee-Based Consulting Services to the Health Care Providers or Suppliers They Accredit in Violation of the Restrictions in 42 CFR 488.5(i)(1) through § 488.5(i)(3) (Proposed § 488.8(i)(6))

In section IV.B.3 of this proposed rule, we propose to implement regulations that place restrictions on the fee-based consulting services AOs provide to the health care providers and suppliers that they accredit. In order to enforce these regulations, we propose at § 488.8(i)(6) to implement penalties for the violation of the restrictions on AO fee-based consulting.

We propose at § 488.8(i)(6)(i) that if an AO is found to be in violation of the restrictions set forth in paragraphs § 488.8(i)(1), (2) and (3), CMS may initiate penalties against the AO. These penalties are set forth in proposed § 488.8(i)(6)(i) and § 488.8(i)(6)(ii) and include placing the AO on a program review, and involuntary termination of the CMS-approved AO's accreditation program(s).

Whether or not we impose the penalties provided in § 488.8(i)(6)(i) and (ii) would depend on the severity of the violation and the facts and circumstances surrounding the violation. Such facts might include the number of providers and suppliers that contracted for prohibited AO fee-based consulting services, the number of times the AO violated the restrictions of § 488.8(i).

The purpose of these proposed provisions is to discourage AOs from violating the proposed restrictions on the provision of fee-based consulting to the providers and suppliers they accredit.

We propose that these provisions would become applicable 1 year from the effective date of the final rule. We believe that this would provide ample time for the AOs to prepare for the implementation of the requirements of this rule.

6. Proposal to Require Accrediting Organizations to Have Written Fee-Based Consulting Firewall Policies and Procedures (§ 488.8(j)).

We propose at § 488.8(j) to require any AO that provides fee-based consulting services or its associated fee-based consulting division or company to have written fee-based consulting

"firewall" policies and procedures. We have defined the terms "consulting division" and "associated company" in section IX.B.3 of this proposed rule. We define the term "firewall" as the complete and total separation between the AO's accreditation activities and its fee-based consulting services.

We propose that these firewall policies and procedures must, at a minimum, include the following provisions: at paragraph (j)(1)(i) the AO's fee-based consulting services must be provided by a separate division of the AO or separate business entity (that is company or corporation) from the AO; at paragraph (j)(1)(ii) the AO's fee-based consulting division or separate company must maintain separate staff from that of the AO's accreditation division(s) to ensure that the fee-based consulting division staff do not perform AO's accreditation division functions and that the AO's accreditation division staff do not perform fee-based consulting division functions; and at paragraph (j)(1)(iii), the AO's accreditation staff and surveyors would be prohibited from marketing the AO's fee-based consulting services to the AO's accreditation clients.

The purpose of the provisions of proposed § 488.8(j) is to ensure that the AO maintains a complete division between their fee-based consulting program and their accreditation program. In other words, we seek to require the AOs to prevent any co-mingling of fee-based consulting activities and staff with their accreditation activities and staff. These requirements are necessary because several commenters to our 2018 AO Conflict of Interest RFI, noted concern that while some AOs that provide fee-based consulting have such firewall policies in place, they have been breached. For example, one commenter stated that one AO's accreditation staff aggressively marketed that AO's fee-based consulting services to his health care facility. In addition, during a CMS validation pilot joint survey with an AO, a SA surveyor witnessed the AO's surveyors providing detailed education about the survey process to the healthcare facility staff prior to the start of the survey. This is inappropriate because surveys are to be unannounced to prevent the facility from preparing for the survey. At the beginning of a survey, a brief entrance conference

is held for the purpose of introducing the survey team, providing the survey agenda to the facility staff, and telling the facility what records the surveyors will be reviewing during the survey. However, providing detailed information about the survey process and what areas the AO is going to focus on during the survey gives the facility an advantage and time to prepare for the survey. This negates the purpose of requiring surveys to be unannounced and could allow the facility staff time to clean up and remove deficiencies that would normally be present. In addition, providing such education to a health care facility prior to a survey could assist that facility in getting a better survey report.

We do not currently have any regulations that provide oversight of the fee-based consulting services provided by AOs or their separate divisions or companies. Likewise, we do not currently have any regulations that specifically require AOs that provide fee-based consulting services to have written firewall policies or regulations that provide requirements for such policies. Regulations are needed so that CMS may ensure that an AO's fee-based consulting remains separate from an AO's accreditation activities. This division is necessary to reduce the conflict on interest associated with the provision of AO fee-based consulting services.

7. Proposal to Prohibit AO Owners, Surveyors, and Other Employees From Involvement with the Survey and Accreditation Process for Health Care Facilities With Which They Have an Interest or Relationship (Proposed § 488.8(k))

Surveyors must rely on their professional judgment, in addition to federal rules and guidelines, to determine compliance. An AO surveyor, owner, or other employees' interest in or relationship with a health care facility that the AO accredits could present a conflict of interest that could affect the results of a survey in several ways. For example, an AO owner, surveyor, or other AO employee involved in the survey of a healthcare facility with which the individual has an interest or relationship could have compromised judgment, consciously or unconsciously, regarding that facility. For example, a surveyor with an interest in or relationship with the health care facility being surveyed could be inclined to minimize or ignore deficiencies, possibly

because he or she believes these deficiencies are not representative of the facility. A surveyor who has an interest in or relationship with the facility being surveyed could possibly influence the findings made by other members of the survey team by asking them to give the facility credit for things not observed, since he or she can "vouch" for the facility.

Even if the AO employee with the interest in or relationship with the facility being surveyed is not part of the survey team for the facility, he or she could still potentially influence the members of the survey team prior to or after the survey. For example, attempting to influence the survey decision making process, or the AO's survey follow-up activities by attempting to discuss the facility with the survey team, such as explaining the facility's policies and procedures to the survey team, or even actively advocating on the facility's behalf, potentially influencing their analysis of observed survey results.

An AO surveyor, owner, or other employee that has an interest in or relationship with a health care facility the AO accredits might have additional motivation to improperly give that health care facility notice about the survey ahead of the scheduled survey date. Surveys are required to be unannounced to prevent the facility from preparing for the survey by activities such as unusual cleaning activities, painting, clearing obstructions from halls and entrances, covering up and hiding deficiencies, coaching staff, and otherwise preparing in advance for the survey. If the survey is unannounced, the health care facility is not able to make advance preparations so that the survey team is able to assess the facility in its usual condition and observe the typical standard of care provided.

We propose to add a new requirement at § 488.8(k)(1) to prohibit AOs from allowing AO owners, surveyors, or other employees from participating in the survey and accreditation process for health care facilities with which they have had an interest or relationship within the previous 2 years. At proposed § 488.8(k)(1) we would require that if an AO owner, surveyor or other employee has an interest in or relationship with a health care facility accredited by the AO, they would be prohibited from: (1) participating in the survey of that health care facility (proposed

§ 488.8(k)(1)(i)); (2) having input into the results of the survey and accreditation for that health care facility (proposed § 488.8(k)(1)(ii)); (3) having involvement with the pre- or post-survey activities for that health care facility (proposed § 488.8(k)(1)(iii)); or (4) having contact with or access to the records for the survey and accreditation of that health care facility (proposed § 488.8(k)(iv)). Proposed § 488.5(a)(10)(iii) lists proposed prohibited interests in or relationships with a health care facility accredited by the AO, which would include, but not be limited to, the following situations: (1) being employed as a SA surveyor; (2) being employed in a health care facility that is accredited by the AO; (3) having an ownership interest in a health care facility that is accredited by the AO; (4) serving as a director of or trustee for a health care facility that is accredited by the AO; (5) serving on a utilization review committee of a health care facility that is accredited by the AO; (6) accepting any fees or payments from a health care facility or group of health care facilities that is/are accredited by the AO; (7) accepting fees for personal services, contract services, referral services, or for furnishing supplies to a health care facility that is accredited by the AO; (8) providing consulting services to a health care facility that the AO accredits; (9) having members of an immediate family engaged in any of the above activities; or (10) engaging in any activities during the course of the survey of the facility that would be or cause a conflict of interest.

We propose at § 488.8(k)(2) to define the term "immediate family member" as any person that has a lineal familial or marital relationship with the AO owner, surveyor or other employee. Immediate family members would include a husband or wife, birth or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother–in–law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild. This definition is consistent with the definition used for the home health and hospice conflict of interest requirements. This definition is required for the purposes of § 488.8(k)(1), which states that a conflict of interest can also exist when an AO owner, surveyor or other employee has an interest in or relationship with a health care facility the

AO accredits.

Allowing an AO owner, surveyor or other employee that has an interest in or relationship with a health care facility the AO accredits would not only be inappropriate but could result in inaccurate survey results and/or preferential treatment of the facility.

C. *Proposal to Require the AOs that Accredit Medicare-Certified Providers and Suppliers to Use Medicare Conditions; and Strengthened Survey Process Comparability (Proposed § 488.4(a)(1) and (2))*

Section 1865(a)(1) of the Act requires that if the Secretary finds that the requirements for accreditation from an accreditation organization demonstrates that a provider entity meets or exceeds all applicable conditions, the Secretary must deem such requirements to be met by the provider entity. However, the statutory language of "meets or exceeds" currently allows AOs to develop standards that are more stringent than those of Medicare. When an AO applies for "deeming authority", we determine whether those standards meet or exceed ours. In accordance with § 488.5(e), CMS publishes a proposed rule when CMS receives a complete application from a national accrediting organization seeking CMS's approval of an accreditation program. The proposed notice identifies the organization and the type of providers or suppliers to be covered by the accreditation program and provides 30 calendar days for the public to submit comments to CMS. CMS subsequently publishes a final notice, rendering its decision to either approve or disapprove a national accrediting organization's application, within 210 calendar days from the date CMS determines the AO's application was complete. The final notice outlines a summary of the findings of CMS's review and any corrective action which was required to be taken by the AO in order to be considered to meet or exceed our standards, or comparable survey processes. When CMS approves or reapproves an accrediting organization for deemed status, the approval may not exceed 6 years.

We are concerned that the current application review processes under § 488.5 does not go far enough. Some of our concerns with the efficacy of the AO application review process are based on the results of the initial and renewal applications and the SA findings, as noted below:

- *AO Application Reviews*: Between 2017 to September 2021, we received a total of 22 AO applications for review. After review of these applications, we returned all 22 applications to the AOs because we found that the AOs' standards were not comparable to ours. AO most common standards requiring revisions to meet or exceed Medicare conditions included: governing body, physical environment, emergency preparedness patient rights, medical/clinical records and care planning. Additionally, AO standards regarding coordination of services; skilled professional services; infection control; staff responsibilities and quality improvement assessment programs (QAPI) all required revisions by the AOs.

- *SA Findings*: In FY 2019, CMS conducted 119 hospital surveys (including psychiatric hospitals) and 196 non-hospital surveys totaling 315 validation surveys. In FY 2019, the SAs found serious "condition-level" instances of non-compliance 60 times in accredited hospitals (including psychiatric hospitals), and 51 instances in which the AO missed the deficiencies. In these instances, even though the AOs did not find comparable levels of non-compliance, this non-compliance was sufficient to start enforcement proceedings against the subject hospitals. These results demonstrated that the AOs may have failed to ensure their facilities were meeting Medicare's minimum standards. In total, between FY 2017 and FY 2019, CMS conducted 363 hospital (including psychiatric hospitals) validation surveys, with SAs identifying condition-level non-compliance a total of 185 times and 158 instances in which the AOs missed comparable deficiencies. Between FY 2017 and FY 2019, CMS also conducted a total of 369 validation surveys for HHAs and Hospices, with SAs identifying condition-level non-compliance a total of 57 times and 50 instances in which the AOs missed comparable

deficiencies.[10] This data has amplified CMS' concerns related to the comparability of survey processes as well as the need for increased AO oversight.

Therefore, under the statutory authority granted to us under section 1865(a)(1) of the Act, we propose revisions at § 488.4(a)(1) to require that the AOs that accredit Medicare-certified providers and suppliers use the applicable Medicare conditions as their minimum accreditation standards. This means that the AOs must incorporate the Medicare conditions identical to our regulations within their accreditation standards for their deeming programs. However, AOs would be allowed to use additional accreditation standards that exceed the Medicare conditions, as permitted under section 1865(a)(1) of the Act. We would, however, require the AOs' to clearly delineate their additional accreditation standards that exceed the Medicare conditions when seeking CMS approval for deeming authority.

The requirement that the AOs identify the Medicare conditions as their accreditation standards would also allow providers and suppliers to know what the minimum Medicare deeming standards are and where the AO standards exceed these standards through its accreditation program, as permitted under section 1865(a)(1) of the Act. Facilities are expected to comply with regulatory requirements of CMS and the accreditation standards of the AO, however we have found that in certain circumstances, the facilities were more familiar with AO standards and did not fully understand the AO standards are more stringent than the Medicare conditions. There were several instances in which our comparability review of AO standards under § 488.5 resulted in the need for AOs to correct deficiencies in their survey standards and processes, because we determined that the minimum Medicare conditions would have not been adhered to. Despite these frequent reviews, the regulations only require AO standards to be comparable, not exact to the Medicare conditions, therefore increasing the likelihood of gaps in interpretation.

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[10] FY 2020 Report to Congress (RTC): Review of Medicare's Program Oversight of Accrediting Organizations (AOs) and the Clinical Laboratory Improvement Amendments of 1988 (CLIA) Validation Program https://www.cms.gov/files/document/qso-22-06-ao-clia.pdf

This proposed requirement would increase the likelihood that AO standards and processes would meet or exceed our regulatory requirements and transparency for providers to understand when the AO has more stringent standards, further explained in sections IV.D of this proposed rule.

We also propose to strengthen our process for comparability review of the AOs survey processes at proposed § 488.4(a)(2), further explained in sections IV.E and IV.F of this proposed rule. More specifically, we propose to re-designate existing paragraph (a)(1) as (a)(3) and re-designate existing paragraph (a)(2) as (a)(4) with revisions, and add a new requirement at § 488.4(a)(1). This provision would require the AOs that accredit Medicare-certified providers and suppliers to use the exact text of the applicable Medicare conditions set forth in the applicable CMS regulations for each provider and supplier type as their minimum accreditation requirements. However, the AOs would be free to establish additional accreditation requirements that exceed Medicare conditions as permitted by section 1865(a)(1) of the Act. We propose to add language at § 488.4(a)(2) that AOs use a survey process comparable to the processes set out for SAs in the SOM and approved by CMS, as outlined throughout § 488.5(a)(4). We also propose that these requirements and changes at paragraphs (a)(1) and (2) would be applicable beginning 1 year from the effective date of the final rule.

These proposed changes to § 488.4(a)(1) and § 488.4 (a)(2) would align national health and safety standards across all AOs and strengthen the survey processes used by the AOs. We further believe that our proposal would ensure uniformity and transparency of the surveys performed by the AOs for deeming purposes and improve CMS' ability to accurately evaluate an AO's performance.

We propose to re-designate the current § 488.4(a)(1) and (a)(2) to § 488.4(a)(3) and (a)(4). We also propose to add requirements at paragraphs (a)(1) and (a)(2) that AOs incorporate the Medicare conditions and use survey processes comparable to those of the SA. We also refer readers to additional proposed changes made to § 488.4(a)(4) in section VI.O of this proposed

rule.

The proposal to require AOs to incorporate the Medicare conditions (as defined in § 488.1) as their minimum accreditation standards would become applicable 1 year after the effective date of the final rule.

D. *Proposal to Revise the Crosswalk Requirements at § 488.5(a)(3)*

As a result of our proposal at § 488.4(a)(1) to require the AOs to incorporate the Medicare conditions (as defined in § 488.1) into their accreditation standards for their deeming programs, we would also modify the regulations at § 488.5 that would be affected by this requirement. Section 488.5(a)(3) requires the AOs to submit with their initial and renewal application, "[a] detailed crosswalk (in table format) that identifies, for each of the applicable Medicare conditions or requirements, the exact language of the organization's comparable accreditation requirements and standards." Because section 1865(a) of the Act allows AOs to have accreditation standards for their deeming programs that meet or exceed the Medicare conditions, the content, format, and wording of AOs' accreditation standards frequently differ significantly from that of the Medicare conditions. Therefore, we require the AOs to provide a crosswalk which identifies the applicable Medicare conditions that corresponds to each of the AO's accreditation standards. The purpose of this crosswalk is to help us determine to which Medicare condition each AO accreditation standard corresponds.

Since we proposed at § 488.4(a)(1) to require the AOs to incorporate the Medicare conditions into their accreditation standards, it would no longer be necessary to require the AOs to submit a crosswalk that provides "comparable" standards. Instead, we propose that AOs would need to provide a crosswalk which demonstrates that the AO has incorporated the language of the Medicare conditions, as well as provide the AO standards which exceed the Medicare conditions (see Table 2 in section VI.B.I of this proposed rule for an example). Similar to the existing process for submission of the AO's crosswalk during an application, we propose to revise § 488.5(a)(3) to require a crosswalk that demonstrates the AO's use of CMS's

requirements and standards. AOs would provide additional or exceeding standards under their use of the required exact language and annotate the exceeding standards. This would further allow providers and suppliers to know what the minimum Medicare deeming standards are and where the AO standards exceed these standards through its accreditation program.

We propose to revise § 488.5(a)(3) to first remove the requirement that the AO provide a "comparable" standard for each of the applicable Medicare conditions or requirements and replace it with the " incorporation of the CMS requirements in the AO accreditation standards for any deeming program." Second, in the application that is submitted to CMS for review, the AO would have to submit a detailed crosswalk. We would not expect the AOs to use the same survey tags (a letter/number identifier, for example, A-0001) as used by SA surveyors. For example, CMS' regulatory requirement at § 482.11(c) requires hospitals to "assure that personnel are licensed or meet other applicable standards that are required by State or local laws." In this example and aligned with our proposed provisions, the AO would be required to have an accreditation standard for its hospital deeming program which would state "The hospital must assure that personnel are licensed or meet other applicable standards that are required by State or local laws," with the AOs applicable standard number. Using Table 2 in section VI.B.1 of this proposed rule for this example, the crosswalk would appear as follows:

CFR Citation	Medicare conditions Language	AO Standard Number	AO Standards Language
§ 482.11(c)	The hospital must assure that personnel are licensed or meet other applicable standards that are required by State or local laws.	XX.000	For hospitals under CMS deeming authority: The hospital must assure that personnel are licensed or meet other applicable standards that are required by state or local laws.

As seen in this example, the AO standard number identification may vary from CMS' CFR regulatory citation. Additionally, as previously described, CMS is not restricting AOs from exceeding the Medicare conditions. Therefore, if an AO believes that additional accreditation

standards would need to apply to their deemed facilities, an AO would submit the exceeding requirements under the particular standard. Using the same example, the AO would submit a crosswalk similar to the example below. As seen, AO Standard Number XX.001 would be exceeding the Medicare conditions.

CFR Citation	Medicare conditions Language	AO Standard Number	AO Standards Language
§ 482.11(c)	The hospital must assure that personnel are licensed or meet other applicable standards that are required by State or local laws.	XX.000	For hospitals under CMS deeming authority: The hospital must assure that personnel are licensed or meet other applicable standards that are required by state or local laws.
		XX.001	Hospitals must verify credentials of all providers including all contracted staff or individuals under arrangement. The verification must be completed prior to the official hiring of the staff

Establishing a consistent standard across all AOs would bring transparency to the accreditation process. This would allow providers and suppliers to know what the minimum Medicare deeming conditions are and where the AO standards exceed these Medicare conditions through its accreditation program. It would also provide greater uniformity between an AO certification survey at a facility and a state survey that may be subsequently performed at that same facility, which could include a complaint survey or a validation survey.

Additionally, from CMS' oversight perspective of the AO applications for deeming authority and review of the crosswalks over the last several years, we have also identified that AOs have inadvertently omitted certain standards in their crosswalk submissions. Therefore, while the impression that requiring a crosswalk for AOs may seem unnecessary as we would be requiring AOs to incorporate the Medicare conditions into their accreditation standards, it is imperative that CMS be able to ensure the AO has standards for each Medicare condition. The review of the exceeding standards is also critical for CMS to ensure that any additional

requirements established under accreditation for deemed providers or suppliers do not conflict with the Medicare conditions.

We propose that the proposed provision would be applicable 1 year after the effective date of the final rule.

E. *Proposal to Strengthen the Comparability of the Survey Process Between the AOs and the States*

An AO must demonstrate to CMS that it has the ability to effectively evaluate a health care facility's compliance with the Medicare conditions using survey processes that are comparable to those survey methods, procedures, and forms required by CMS and as implemented by the SAs. A general description of SAs' survey processes are set out at § 488.26 and specified in the SOM.

As part of the application process as set out at § 488.5, CMS is required to complete a survey processes review as part of the AO application review process. The purpose of the survey processes review is to determine whether the AO's survey processes are comparable to the CMS survey processes. The survey process comparability review is done by reviewing information in the application, such as, the AO's survey activity guides, organizational procedures for surveyors, surveyor training materials and AO survey requirements. CMS also conducts an in-person observation of an AO survey (carried out by a CMS survey observation team) as part of CMS' review of an AO's application. The purpose of the survey observation is to ensure that the AO surveyors follow the processes set out in the application and to ensure that the AO surveyors evaluate all Medicare requirements.

Sections 1865(a)(1) and 1865(a)(2) of the Act require us, when making this finding, to consider a national AO's "survey procedures" and ". . . 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. . . ." Our longstanding requirements at § 488.4(a)(3) implemented this statutory

provision by requiring AOs to provide us with detailed information on their survey processes, and our regulations at § 488.5 and § 488.8 set out the procedures for comparability review. We further discussed AO survey procedures' comparability to our SA survey processes and the SOM in the May 22, 2015 final rule published in the **Federal Register**, entitled "Medicare and Medicaid Programs: Revisions to Deeming Authority Survey, Certification, and Enforcement Procedures" (80 FR 29795) (hereinafter referred to as the "2015 AO final rule"). We assess comparability by reviewing the information in the AO's application in light of the SOM survey process requirements for SAs, which implements the survey process requirements found in parts 488 and 489 of our regulations. The role of the SOM is to provide explicit guidance on the process to assess providers' and suppliers' compliance with our regulatory requirements. We do however note, that the AOs are already required to submit the documentation and that most AOs provide this within their applications, therefore we do not believe this imposes any additional burden on the AOs, as this has been a long-standing expectation as described in the preamble of this proposed rule and the 2015 AO final rule (80 FR 29795) which stated that while the explicit reference to the SOM was removed, "this will not change our practice of assessing comparability in light of the SOM survey process requirements for SAs, which implement survey process requirements found in parts 488 and 489 of our regulations governing certification and provider agreements.

As previously noted, CMS received 22 AO applications between January 2017 and August 2021. Of those 22 applications, 14 were returned to the AO for revisions to the AO's survey processes and policies, distinct from the finding that all 22 AO's standards were not initially comparable with the Medicare conditions. These required survey process revisions included ensuring all surveys were unannounced in accordance with § 488.5(a)(1)(i), which we discuss in section IV.A of this proposed rule. Other applications were returned for inconsistencies with our patient or representative complaint processing guidance set out in chapter 5 of the SOM. Additionally, among these 22 applications, we identified concerns within

the AO survey processes during the on-site survey observations, as authorized under § 488.8(h). The following concerns were noted during the survey observations for these 22 applications:

- The survey citations and rationales for citing or not citing "Governing Body" Medicare condition violations (for example, 42 CFR 482.12) were inconsistent with CMS' SA survey methodologies;
- The AO's failure to enforce the deadlines by which facilities must come into compliance after receiving adverse survey results;
- Conflicting timeframe(s), such as the required number of days required to conduct follow-up activities, including follow-up surveys, for facilities that have previously demonstrated non-compliance at the condition-level; and
- Incorrect number of medical records reviews during a survey. (CMS requires that AO surveyors review a specific number of medical records, based on the facilities' patient volume, to ensure the surveyor have an accurate picture of patient care services provided within the facility).

CMS' concerns about the failures of AOs to conduct in-depth investigations; the lack of consistency and comparability exhibited by our having to return all received AO applications for corrections in survey standards and processes; the excessive frequency of disparate findings between AOs and SAs, as further explained in section IV.I of this proposed rule; and the failure to review medical records, as required by SA procedures, all strengthen our resolve to ensure consistency in AO performance. Our initial and renewal application reviews are the foundation for our oversight of AOs to determine the AO's ability to ensure facilities adhere to minimum Medicare conditions.

Because of these disparities, we propose to strengthen our requirements under § 488.5. We refer readers to our discussion of these proposals found in section IV.F of this proposed rule, that would require AOs that accredit Medicare-certified providers and suppliers to use a survey process that is comparable to the survey processes and procedures used by CMS and the SA. We

note that this has been the expectation under the existing requirements, as a condition of obtaining and retaining deeming authority. We propose to increase the specificity of our application and reapplication requirements for national AOs to improve documentation that would demonstrate this comparability.

F. *Proposal to Revise the AO Application Documentation Requirements Related to the Survey Processes* (§ 488.5(a)(4); § 488.5(a)(4)(iii); § 488.5(a)(4)(v); § 488.5(a)(4)(vii); § 488.5(a)(4)(xi); § 488.5(a)(5); § 488.5(a)(6); § 488.5(a)(12); § 488.5(a)(13))

To achieve our goal to require the AOs to use a survey process that is comparable to that used by CMS and the SAs (and in alignment with our proposal at § 488.4(a)(2) regarding comparable survey processes), we propose the following revisions and additions to the existing AO application regulation requirements.

1. Proposed Revisions to § 488.5(a)(4)(Description of Survey Process)

At § 488.5(a)(4), we propose to add language which includes what we believe to be the core fundamental activities of the survey process, such as pre survey preparation; offsite preparation; entrance interview and activities; information gathering and investigation, analysis of information; exit conference; post-survey activities; and statement of deficiencies-related activities. These are processes used by the SA which are needed to ensure that a Medicare-participating provider or supplier receives an unbiased, independent survey.

We have observed, both in our on-site observation of AOs during the existing process set out at § 488.8(h), as well as during the VRP pilot conducted 2018 through 2019, that AOs often provided daily briefings to and had frequent discussions with the management of the surveyed facility whose purpose was not clearly described in the AO's applications. We noted that these "meetings" with facility management impeded or did not allow for sufficient time for the survey team to complete survey activities, such as direct observations or interviews.

Therefore, the proposal to add the core activities, as well as the revisions outlined below, would further strengthen comparability between SAs and AOs, while continuing to allow for

flexibilities in the survey processes used by AOs. These requirements, as revised, shall become applicable beginning [date 1 year after the effective date of the final rule].

2. Proposed Revisions to § 488.5(a)(4)(iii) (Documentation of Surveyor Forms and Guidance)

Section 488.5(a)(4)(iii) currently requires that AOs applying for deeming authority provide, among other documentation, copies of the organizations survey forms, guidelines and instructions to surveyors. We propose to be more specific about the level of detail we require from the survey instructions and guidance the AO provides to us when seeking our approval. Specifically, we propose to require detailed information regarding how the AO surveys for facility compliance with the following core activities or standards within the Medicare Conditions, such as: Governing Body; Patient Rights; Emergency Preparedness; Quality Assessment and Performance Improvement; Medical Staff; Nursing Services; Medical Records Services; and Infection Control. These core activities and standards are part of every state survey and based on Medicare Conditions. With respect to each of these survey subject areas, we would require the applying AO to provide documentation on the instructions it provides for surveying these Medicare conditions, including survey probes, interview questions, and methods for their own review of facility documentation pertaining to these Medicare conditions.

It has become evident through our validation and comparability reviews of AOs that the documentation we currently request from them no longer suffices to adequately determine whether the AO surveyors are investigating these Medicare conditions sufficiently to ensure the health and safety of Medicare beneficiaries and other patients. AOs have failed to survey adequately for facility compliance with their respective documentation requirements, including specific standards or survey processes. We also propose that AOs submit their patient and staff interview questions. By having access to these questionnaires, we would be able to determine whether there are gaps in the survey processes which are leading to the disparity findings, as we have seen in our validation surveys.

3. Proposed Revisions to § 488.5(a)(4)(v) (Survey Review Process)

At § 488.5(a)(4)(v), we propose to add additional areas clarifying and strengthening the requirement that AOs provide a description of their document review processes in their approval applications. We propose to add that AOs must describe processes and surveyor procedures related to the review of medical records, medical staff credentialing procedures; personnel files (including staff competency); and the number of patient observations, patient interviews and staff and facility interviews.

We have noticed that many AOs fail to review adequate numbers of records for the provider/supplier type involved. In the review of the 22 AO applications received between 2017 and September 2021, a total of nine AOs were identified to have not reviewed the adequate number or records. Additionally, we have observed that some AO survey practices, such as interviewing patients in non-confidential settings, and deficient complaint investigations, undermine the integrity and accuracy of AO surveys. We are concerned that staff or patients may not be honest and candid if another facility staff member or supervisor is present during interviews. The expectations are that interviews are conducted privately with staff. For example, in Appendix A of the SOM, we explicitly require surveyors to "Explain that all interviews will be conducted privately with patients, staff, and visitors, unless requested otherwise by the interviewee." Privacy in interviews with staff is important and encourages the likelihood of honest feedback about an organization. Additionally, we also identified a few (three of 22 applications) during our survey observations of AOs onsite, instances in which the AO did not observe actual performance of medication administration, wound care or other services provided by the accredited facility, and most observations within the hospital setting were surgical time-outs (part of the Universal Protocol and performed in the operating room, immediately before the planned procedure is initiated). In one instance, the AO failed to ask the facility for any patient/representative complaint information, which indicates that the AO failed to conduct any investigation as to how the facility manages complaints and grievances. These specific examples raise concern in that the AO survey process does not sufficiently ensure safe

practices for patients.

Furthermore, as noted in our discussion of proposed § 488.5(a)(4)(iii), we have also identified multiple instances in which the AOs have conducted limited review of facilities' staff credentialing and competency testing activities. For instance, in one survey observation, we observed that the AO reviewed the personnel files of only one licensed practical nurse (LPN) and one phlebotomist, and did not review any personnel files for RNs, pharmacists, or dietitians, as outlined in Appendix A of the SOM, which we consider to be critical staff for this provider setting. In another survey, the AO determined that nursing staff were not documenting chains of custody of narcotic medications, but failed to review the facility's pharmaceutical policies and procedures, and conducted no interviews of pharmacy staff. In such circumstances where a category of documentation was missing from the facility's record, we would mandate that the AO or SA conduct further investigations to determine the reason for the lapse.

4. Proposed Revision to § 488.5(a)(4)(vii) (Correction of Identified Non-Compliance)

At § 488.5(a)(4)(vii), we propose to add additional language to the existing requirement that the AO must provide us with descriptions of their procedures and timelines for monitoring the provider's or supplier's correction of identified non-compliance with the accreditation program's standards. We believe this requirement is not specific enough for enforcement; we have regularly had to request revisions of documents submitted by AOs during our review of applications and re-applications over the years. We propose to clarify this language by adding the requirement that AOs must also include documentation related to dates established by the AO and how those accreditation dates are determined by the AO when deficiencies may be found during initial and reaccreditation surveys, as well as the AOs process for accreditation decisions based on survey findings. We also propose to require the AOs to provide as part of this standard, their investigative and organizational process which the AO uses to make determinations on accreditation or the removal of accreditation and recommendation to the Survey Operations Group (based out of the various CMS Survey and Enforcement Division Locations) to remove

deemed status of the non-compliant facility. We have also proposed additional changes at § 488.5(a)(4)(viii) and refer readers to section IV.G "Proposal to Require AOs to Provide CMS with Survey Findings", of this proposed rule.

5. Proposed Revisions to § 488.5(a)(4)(xi) (AO Training and Education Programs)

At § 488.5(a)(4)(xi), we propose to add a new requirement to require AOs to provide CMS with documentation summarizing their staff training programs, whether web-based or via methods such as Power Point presentations or hard-copy materials, which would provide an overview of how they train surveyors to follow their survey processes, and, where applicable, highlight differences from CMS survey processes. Currently, CMS receives limited training materials the AO provides to its surveyors; therefore, when conducting survey observations as under our authority at § 488.8(h), it is often challenging to understand differences in survey processes. We may receive an AO's printed materials for training and/or downloaded versions of electronic surveyor training platforms; however, these materials vary. These materials indicate that some AOs collect employees' oral evidence for a survey, as opposed to a more document-focused review done by the SAs. AOs' applications do not always provide us with the entire scope of surveyor education the AO provides to its surveyors, therefore challenging our review of comparability. The current regulation at § 488.5(a)(8) only requires the AO to give us "[a] description of the content and frequency of the organization's in-service training it provides to survey personnel." CMS frequently asks AOs to submit additional training and education materials during the application review processes. Requesting the AOs' staff training programs and documentation as outlined in the proposal will provide CMS with greater enforcement capabilities and allow CMS to assess the AOs' consistency in training against those of required by the SAs. Additionally, because we review AO applications for comparability to CMS survey processes, this additional information would be invaluable to CMS' better understanding of the AOs' survey processes prior to conducting a survey or during the validation or proposed direct observation process, as discussed in sections II.D and IV.K.3 of this proposed rule.

6. Proposed Revisions to § 488.5(a)(5) (Composition of Survey Team)

At § 488.5(a)(5), we propose to add requirements which describe the AOs' minimum criteria for determining the size and composition of survey teams for the facilities they accredit. We propose to require the AO to provide us with documentation describing the criteria or process by which the AOs determines the makeup of their survey teams, based on: (1) the size of the facility to be surveyed, based on average daily census; (2) the complexity of services offered, including outpatient services; (3) the type of survey to be conducted; (4) Whether the facility has special care units or off-site clinics or locations; (5) Whether the facility has a historical pattern of serious deficiencies or complaints; and, (6) Whether new surveyors are to accompany a team as part of their training.

Our on-site survey observation of AO surveyors has found some concerning practices. For example, we understand some AOs use time limits on the length of their investigations, which can limit the depth and accuracy of the investigation. One AO also only permitted a 2-day period in which to conduct a survey of a critical access hospital (CAH), whereas the policy of the SA is based on the scope of services provided by the provider, type of survey to be conducted, complexity of services offered and whether the facility has off-site locations. The AO's policies did not allow for flexibility to have the survey exceed 2 days, which would likely not allow for all departments to be surveyed, or in the event of an immediate jeopardy or condition-level non-compliance finding, for an investigation to be conducted. While fortunately no condition-level no-compliance was identified, the strict AO policy on timeframe of survey conflicts with the intent to complete the investigative process and did not allow for flexibility in survey length. It appears based on this example that at least one AO may not be giving considerations to the size and number of outpatient departments or provider-based locations per facility and the need to investigate immediate jeopardy or condition-level non-compliance when deciding on time limits for surveys. Additionally, some AOs have not always ensured surveys are conducted on all off-site locations that are still certified under the main campus or facility CCN as is required for SAs

in accordance with Appendix A of the SOM - Survey Protocol, Regulations and Interpretive Guidelines for Hospitals, Survey Protocol, Task 3 (“Information Gathering/Investigation”). This proposed provision would be effective one year following the publication of the final rule.

Clarifying these minimum expectations would help AOs meet Medicare conditions and create more consistency between the approaches used by AOs and the SAs.

7. Proposed Revisions to § 488.5(a)(6) (Adequate Number of Surveyors for Size of Facility)

At § 488.5(a)(6), we propose to add language to the existing requirement that requires the AO to provide documentation demonstrating the overall adequacy of the number of the organization's surveyors, including how the organization will increase the size of the overall survey staff to match growth in the number of accredited facilities while maintaining regular re-accreditation intervals for existing accredited facilities. We propose to add language demonstrating that the AO has enough surveyors to ensure that a sufficient amount of time can be allotted to its clients to complete all survey activities.

Through our direct observations as part of the application process, we identified several instances in which the scope of document reviews was limited and the content of medical records was not thoroughly reviewed, because it seems the AO surveyors did not have enough time to review records. This may be a systemic issue across AOs. This proposed provision would be effective 1 year following the publication of the final rule.

8. Proposed Revisions to § 488.5(a)(12) (Complaint Survey Documentation Requirements)

At § 488.5(a)(12), we propose to add additional elements critical to the AOs’ effective investigation of complaints about their client facilities. Specifically, we propose that the AO in its application documents for CMS approval of its deeming authority would also have to include: (1) a description of its process for triaging and categorizing complaints about the surveyed facility; (2) timeframes for responding to complaints and a method to track and trend complaints (for example, frequency of similar complaints, complaint type, etc.) received with respect to the AOs accredited facilities; (3) procedures and persons responsible for the review of plans of

corrections; and procedures for follow up if the plans of corrections are not adequate; (4) AO requirements for plans of corrections for standard level deficiencies; (5) follow up survey procedures and monitoring of condition-level findings; (6) procedures for addressing immediate jeopardy deficiencies; and (7) sharing of previous deficiency findings or complaints with survey teams. The existing regulatory requirement for the AO to provide procedures for responding to, and investigating, complaints against accredited facilities, including policies and procedures regarding referrals is insufficient. Of our 19 AO initial and renewal applications received in the past years, CMS has requested additional AO documentation for this particular standard in order to adequately assess the comparability of survey processes. Strengthening the language will bring greater clarity as to the expectations for documents to the AO submitting an initial or renewal application.

9. Proposed Revisions to Accreditation Decision-Making Policies and Reporting § 488.5(a)(13)

At § 488.5(a)(13), we propose to re-designate existing paragraph (ii) to (iii) and add two new paragraphs at (ii) and (iv). The section currently requires an AO applying or re-applying for deeming authority to provide CMS with a description of its processes for accreditation status decision making. The proposed revision would require the AO to document its specific policies and procedures for reporting accreditation decisions to CMS, including timeframes for notification. Additionally, we propose to require the AO to submit specific documentation describing how it will inform us when one of the facilities they accredit withdraws from accreditation. This communication is necessary since it alerts us that such facility will need to be surveyed by the SA next time. By requesting this additional information related to accreditation decisions made by the AOs, as well as reviewing documentation on how the AO notifies their facilities and CMS and our SAs of a facility withdrawing from the AO, CMS will strengthen the existing requirements and would create a more consistent, uniform review of the AO survey process for comparability. We also believe by requiring this information, we will be able to review the AOs' processes for reporting. Additionally, we will also be able to identify under

what circumstances an AO maintains accreditation of a facility versus the potential CMS decision to drop deeming authority. We have found in several instances that even in light of serious health and safety deficiencies and CMS's removal of deeming authority, a facility can still remain accredited, which may provide an untrustworthy perception to the public that the facility has no health and safety concerns. When CMS provides deeming authority to an AO, the expectation is that its standards meet or exceed Medicare conditions and that surveys are comparable to those of the SAs, which is not the case for accreditation versus deeming. Facilities may voluntarily end their deeming and accreditation from an AO or be involuntarily removed from deeming authority. When this occurs under the deeming process, the facility is placed under the SA's jurisdiction, meaning the SA will survey and monitor the facility for compliance with federal requirements. However, in situations where the facility's deemed status is removed involuntarily for non-compliance, yet the AO continues to accredit the provider, CMS believes the public perception is that these facilities are still meeting or exceeding the requirements for Medicare, which may not be true.

Through the establishment of a more rigorous and comprehensive survey process review during the required application and renewal process, our concerns regarding insufficient compliance would be addressed. The proposed additional and revised requirements would ensure a more uniform assessment and improve our evaluation of AO performance to ensure that surveys conducted by AOs are comprehensive and fully examine all Medicare conditions. We also believe that codifying these detailed documentation requirements in regulation would establish a consistent standard across all AOs and would bring uniformity and transparency to the accreditation process.

We propose that the provisions clarifying the existing requirements to require AOs that accredit Medicare-certified providers and suppliers to provide us with more detailed descriptions of their survey processes and procedures would become applicable 1 year from the effective date of final rule.

G. *Proposal to Require AOs to Provide CMS with Survey Findings (§ 488.5(a)(4)(viii))*

General AO survey findings are entered into a CMS database known as the Accrediting Organization System for Storing User Recorded Experiences (ASSURE). This database collects general information about the accreditation survey, such as, date, survey findings and severity of problems indicated by the findings. It generally does not include actual survey reports. Currently AOs provide a limited set of data for surveys within the ASSURE database. We use this information in addressing administrative program elements, and in assessing AO performance. While we have the authority to request this information from the AO, we generally do so only when we determine that it is necessary for follow-up. To date, we have not consistently required the AOs to submit copies of their survey reports and related information.

We propose to modify § 488.5(a)(4)(viii) to require that AOs provide all survey reports to CMS, which would not be disclosed except as permissible by statute, pursuant to subsection 1865(b) of the Act. AOs would be required to submit a statement that organization agrees to provide with a copy of all survey reports, including but not limited to, initial, re-survey, and complaint survey reports, and/or any other information related to survey activities as CMS may require (including corrective action plans) as part of its initial and renewal applications, or upon CMS request. The proposed revision to § 488.5(a)(4)(viii) would expand the requirement from the current requirement that AOs provide survey reports from applicants seeking initial participation in Medicare (with other surveys only upon request). Under our proposal, we would have access to any survey reports, including initial, reaccreditation, complaint surveys, and corrective action plans that CMS may require. These reports, like those of survey agencies, would assist CMS in program analysis of tracking citations issued to accredited facilities to determine whether there is a concern with an AO's performance. Similarly, these reports would assist in reviewing disparate findings in which the SA may have cited a deficiency within an accredited facility that the AO failed to recognize.

Current §§ 488.5(a)(4)(viii) and 488.5(a)(11)(ii) allow CMS to receive copies of the

AOs' survey reports. However, CMS is prohibited by section 1865(b) of the Act as well as § 488.7(b) from disclosing these surveys to the public, with the exception that CMS may disclose such a survey and related information to the extent that they are from home health agencies, or hospice programs, or pertain to an enforcement action taken by CMS. Furthermore, the stem statement of § 488.7 requires that a Medicare participating provider or supplier, in accordance with § 488.4, must authorize its respective AO to release to CMS a copy of its most current accreditation survey including corrective action plans and any information related to the survey that CMS may require." Section 488.7(b) further provides that CMS may publicly disclose an accreditation survey and information related to the survey, upon written request, but only to the extent that the accreditation survey and survey information are related to an enforcement action taken by CMS.

CMS has the authority under section 1875(b) of the Act as well as regulations at § 488.8(a)(1) to evaluate the performance of the AOs through review of the organizations' survey activity. Through consistent access to AO survey findings CMS would enhance our ability to analyze survey findings and process, identify emerging quality of care issues and patterns in AO survey findings, and, ultimately, improve care for our beneficiaries.

As the proposal for revision to § 488.5(a)(4)(viii) is being made in connection with our proposal to require the AOs that accredit Medicare-certified providers and suppliers to use the proposed revised comparable survey processes and procedures, we propose that the revisions to § 488.5(a)(4)(viii) become applicable 1 year from the effective date of the final rule.

H. *Proposal to Require that AO Surveyors Must Take the CMS Online Surveyor Basic Training*

Prior to 2006, CMS offered basic surveyor training courses in a traditional in-person classroom setting. Over time, we began providing online basic surveyor training courses for each provider and supplier type (ambulatory surgical centers (ASCs), hospitals, home health agencies (HHAs), etc.), as well as training specific to writing skills for surveyor documentation.

Basic training online courses are designed to provide surveyors with the basic knowledge and skills needed to survey the respective provider or supplier type for compliance with the Medicare conditions. The online courses also help develop and refine surveying skills, foster an understanding of the survey process, and enhance surveyors' overall ability to conduct and document surveys. Courses are self-paced web-based training. Users may access the online courses at any time and have ongoing access to the course. This affords surveyors the opportunity to refresh knowledge regarding Medicare conditions and processes whenever necessary. The numbers of learners trained in online courses have been steadily increasing since their inception.

Currently, the trainings are publicly available through the CMS Quality, Safety & Education Portal (QSEP) website at https://qsep.cms.gov. These trainings are free of charge for AO surveyors and the public at large.

SA surveyors are required to take CMS program-specific trainings along with SA-led orientation, field survey observations, and mentoring as part of a comprehensive training and education program to assure an adequately trained, effective surveyor workforce.

SAs perform validation surveys on a sample of providers and suppliers (such as hospitals, CAHs, ASCs, and HHAs) accredited by the AOs. Validation surveys compare the survey findings of the AO to those of the SA to see if there are any disparities. The disparities found between an AO's surveys and an SA's surveys is used in a performance measure called the "disparity rate" and is tracked by CMS as an indication of the quality of the surveys performed by the AO as described earlier in this proposed rule.

The disparity findings between AO surveyors and SA surveyors may, in part, be attributed to differences in surveyor training and education, which varies from AO to AO, and may be inconsistent with the CMS-provided SA surveyor training discussed earlier in this proposed rule[11]. We further believe that uniform surveyor training would increase the

[11] https://qsep.cms.gov.

consistency between the results of the surveys performed by SAs and AOs, and have a positive impact on the historically high disparity rates. The Fiscal Year 2020 "Report to Congress: Review of Medicare's Program Oversight of Accrediting Organizations (AOs) and the Clinical Laboratory Improvement Amendments of 1988 (CLIA) Validation Program[12]," showed variation in overall disparity rates, by provider type, as well as by the AO. For example, the disparity rate from FY 2018 to FY 2019, hospitals, HHAs and ASCs had the only decreases in disparity rates of all the program types, with a 5-percentage point, 11-percentage point and 7-percentage point decrease respectively. The disparity rates for psychiatric hospitals increased by 7-percentage points from FYs 2018 to 2019. The disparity rates for CAHs and hospices increased by 5-percentage points and 3-percentage points respectively from FY 2018 to FY 2019. On November 4, 2021, we published a final rule in the **Federal Register**, entitled, "Medicare and Medicaid Programs; CY 2022 Home Health Prospective Payment System Rate Update" (86 FR 62240). In that final rule, we finalized implementing regulations to require AO surveyors to have successfully completed the relevant CMS–sponsored basic hospice surveyor training prior to conducting any hospice program surveys in accordance with Division CC, section 407 of the Consolidated Appropriations Act of 2021 (CAA 2021) .

In addition to the recent hospice program surveyor training requirements, we propose to amend the provision at § 488.5(a)(8) by adding new paragraphs (a)(8)(i) to (a)(8)(iv), which would impose a new training requirement on those surveyors working for AOs that accredit Medicare-certified provider and suppliers. We note that we had previously made a similar proposal in the calendar year (CY) 2019 Home Health Prospective Payment System Rate Update proposed rule (83 FR 32470, July 12, 2018). However, we did not finalize this proposal, due to

[12] The most recent Report to Congress may be accessed at : https://www.cms.gov/files/document/qso-22-06-ao-clia.pdf

commenters' concerns with course enrollment access and the amount of time we estimated it would require for an AO surveyor to complete the course.

CMS believes the concerns raised by interested parties during the previous proposed rule comment period have been addressed by narrowing the scope of the required training and providing additional details regarding implementation. Therefore, we are again making this proposal to address the consistency of surveyor knowledge and interpretation, since we propose to require the AOs to use Medicare conditions and survey processes. We describe the courses required as well as the estimated time for each in section VI of this proposed rule. We propose at § 488.5(a)(8) a description of the content and frequency of the organization's in-service training it provides to survey personnel and we would also require AOs to submit their training materials to CMS as part of the application process. We additionally propose at § 488.5(a)(8)(i) to require that all AO surveyors complete two CMS mandatory courses which instruct surveyors, for all facility types, how to document their findings in the standardized survey materials. We would also require AO surveyors to complete all relevant CMS online program-specific basic surveyor training, which we have already established for state and federal surveyors. For example, AO hospital surveyors would be required to take the following CMS online courses: (1) Principles of Documentation for Non-Long-Term Care; (2) Basic Writing Skills for Surveyor Staff; (3) and, Hospital Basic Training. A hospice surveyor would take the Principles of Documentation for Non-Long-Term Care; Basic Writing Skills for Surveyor Staff; and Hospice Basic Training courses. If an AO surveyor participates in both hospital and hospice surveys they would take the two documentation courses and the two basic training courses. These courses would be the minimum mandatory requirements for AO surveyors. In addition, we would also require that all AO surveyors would be required to take any updates to the CMS online surveyor courses when necessary. Any training above and beyond the minimum CMS online surveyor courses would be at the AO's discretion.

We propose at § 488.5(a)(8)(ii), that AO surveyors hired after the date of implementation

of this provision would be required to complete the required CMS online surveyor training courses prior to serving on a survey team (except as a trainee). A time requirement is necessary to ensure that the AO surveyors take the CMS online surveyor training in a timely manner and is consistent with the existing hospice program surveyor training requirements at 42 CFR 488.1115(a).

We propose at § 488.5(a)(8)(iii) that AOs would also be required to document that the CMS online surveyor training courses were completed and the date of completion in the surveyor's staff personnel records. The purpose of this requirement would be to allow the AO and CMS to have records that document that the requirements had been met by each surveyor. We would review these training records during our onsite visit to the AO's office that is performed as part of the initial and renewal application process. We further propose at § 488.5(a)(8)(iii) to require that the AOs maintain this documentation of course completion by each surveyor for no less than one accreditation cycle, so we can verify that AO surveyors had completed the online courses as part of the AO's next renewal application process. One accreditation cycle would be defined as the period of time during which the AOs' CMS approval is in effect, starting from the date of application approval and continuing until the date of approval of the next renewal application.

This proposed requirement aligns with and expands upon recent regulations that require hospice program AO surveyors to successfully complete the CMS online Basic Hospice Surveyor Training prior to performing any hospice program surveys.

In addition, we propose at § 488.5(a)(8)(iv) that the provisions proposed at §§ 488.5(a)(8)(i) through (a)(8)(iv) would be applicable beginning 1 year after the effective date of the final rule.

I. *Proposal to Establish Criteria for "National in Scope" (§ 488.1)*

On April 5, 2013, we published a proposed rule in the **Federal Register** entitled, "Medicare and Medicaid Programs; Survey, Certification, and Enforcement Procedures"

(78 FR 20564), hereinafter referred to as "2013 AO oversight proposed rule", which proposed modifications to the CMS AO oversight regulations. In the 2013 AO oversight proposed rule, we stated that the demonstration of "national in scope" by an AO must be specific to each accrediting program for which new or renewed CMS approval is sought. We also proposed to define "national accreditation organization" in § 488.1 to specify that CMS requires an AO program seeking initial approval to "already be fully implemented and operational nationally" (78 FR 20566). However, in the 2015 AO final rule (80 FR 29796), we finalized the policy that we would not require an AO to reach facility minimums or meet specific geographic distribution requirements to be deemed "national in scope" (80 FR 29802). We did this because we believed AOs should be able to demonstrate the ability to scale over time.

Currently, we require that an AO's accreditation program be national in scope in order to receive CMS approval. However, we have never specified objective criteria for "national in scope" in regulations. Therefore, as the number of AOs (and the number of applications from AOs) grow, it is in the best interest of CMS and the AOs to establish specific criteria to define "national in scope." Establishing a specific definition and criteria for what CMS would consider to constitute widely located geographically across the United States (U.S.) would ensure that CMS is objective and consistent during the AO application review process when making a determination as to whether an AO's accreditation program is, in fact, national in scope. This would further ensure that new AOs, submitting applications for deeming authority, are represented across the nation and not clustered within one area of the country. Furthermore, this also provides an opportunity for facilities to choose any AO with a CMS-recognized accreditation program for its provider/supplier type, versus only having one AO to choose.

Therefore, we propose to add a definition for "National in scope," to the CMS regulations at § 488.1 to establish criteria for determining when an AO's accreditation program meets the requirement. We propose that the definition, "National in scope" would mean that the providers and suppliers accredited by an AO under a specific accreditation program, must be widely

located geographically across the U.S. The proposed requirement for "national in scope" would have two components. First, the AO would be required to have accredited at least five providers or suppliers under the accreditation program in question. Second, the five providers or suppliers accredited by the AO under that accreditation program would have to be geographically located in at least five out of the six geographic regions.

The addition of the proposed definition of "National in scope", requires that we also define the term "geographic regions of the U.S.", because this is a component of the definition of "National in scope." Therefore, we propose to add a definition for "Geographic regions" at § 488.1.

The proposed six geographic regions consist of six groups of states that cover the northeast, southeast, mid-west, central, south, and western areas of the United States which provide six possible areas in which an AO could accredit a provider or supplier to meet the second part of the "national in scope" test. In contrast, the use of a simple north, south, east and west geographical division of the U.S. would only provide four possible regions in which an AO have accredited providers and suppliers.

We believe that use of these six geographic regions as the geographical test for "national in scope" would provide a standard by which CMS could measure whether an AO has accredited the required number of health care providers or suppliers in varying geographical areas of the U.S. We further believe the requirement that an AO have one provider or supplier in at least five of the six geographic regions would demonstrate the AO's ability to scale up and develop a national presence over time and align with CMS' current consortiums or regions[13]. AOs would need to be able to demonstrate this standard in their initial applications for deeming authority, as well as continue to meet this definition, which would be evaluated within their renewal applications.

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[13] CMS Organizational Chart, Page 17, Survey Operations Group https://www.cms.gov/About-CMS/Agency-Information/CMSLeadership/Downloads/CMS_Organizational_Chart.pdf

We also believe that this proposed definition of "Geographic regions" would ensure that we are impartial and consistent during the application review process. We also believe that this proposed definition would provide the AOs with objective criteria for the definition of "national in scope" that they can strive to meet prior to submitting an application, especially for possible new accrediting programs.

We note that § 488.1 currently defines "national accrediting organization" as "an organization that accredits provider entities (as that term is defined in section 1865(a)(4) of the Act) under a specific program and whose accredited providers and suppliers are widely located geographically across the U.S." Because we proposed to add a specific definition for "National in scope" to § 488.1, that requires a two-part test, it is also necessary to update the definition of "National accrediting organization" to add the requirement that the AO must be national in scope.

This would ensure that new AOs submitting applications for Medicare approval of their accreditation programs, would be required to show that they have the ability to provide accreditation services to providers and suppliers across the nation and not just those clustered within one area of the country. Making it a requirement that AOs be capable of providing accreditation services throughout the U.S. provides the opportunity to health care providers and suppliers in all regions of the U.S. to obtain deeming accreditation from the AO of their choice.

Therefore, we propose to revise the existing definition of "National accrediting organization" at § 488.1. The proposed new definition of "National accrediting organization" would read as follows "*National accrediting organization* means an accrediting organization that is national in scope and accredits provider or suppliers, under a specific accreditation program."

We propose to add the new definition for "National accrediting organization" so that we can include the phrase "is national in scope" within the said definition. The purpose for revising the definition of "National accrediting organization" is to enforce national in scope requirement for AOs.

J. *Proposal to Revise the Definition of "Rate of Disparity" and to Use the Process and Outcome Disparity Rates and Performance Measures (§ 488.1)*

In section IV.L of this proposed rule, we propose to revise the validation program by using two different types of validation surveys, which are: (1) the 60-day "look-back" validation survey and, (2) and a direct survey observation approach, to evaluate the performance of the AOs. Validation surveys are full surveys performed for a representative sample of accredited facilities. Look-back validation surveys are completed by the SA within 60 days of an AO's full accreditation survey for the same facility. In some cases, representative sample "mid-cycle validation surveys" may be conducted whether or not there has been a preceding AO survey.

The analysis of the validation survey findings are reported as a "disparity rate." As previously discussed in section II.C of this proposed rule, this rate of disparity is currently defined at § 488.1 as the percentage of all sample validation surveys for which a SA finds noncompliance with one or more Medicare conditions and where no comparable condition-level deficiency was cited by the AO and it is reasonable to conclude that the deficiencies were present at the time of the AO's most recent survey of that provider or supplier. The goal of the validation process is to determine whether the findings of the two surveys are comparable.

In calculating the current rate of disparity, the numerator is the number of surveys in which the AO missed at least one condition-level deficiency found by the SA and the denominator is the number of surveys in the validation sample. The result is the percentage of validation surveys where the AO missed finding a significant deficiency identified by the SA. If the AO missed at least one serious deficiency in a third of the validation surveys, the disparity rate would be 33 percent. A lower disparity rate indicates better AO performance.

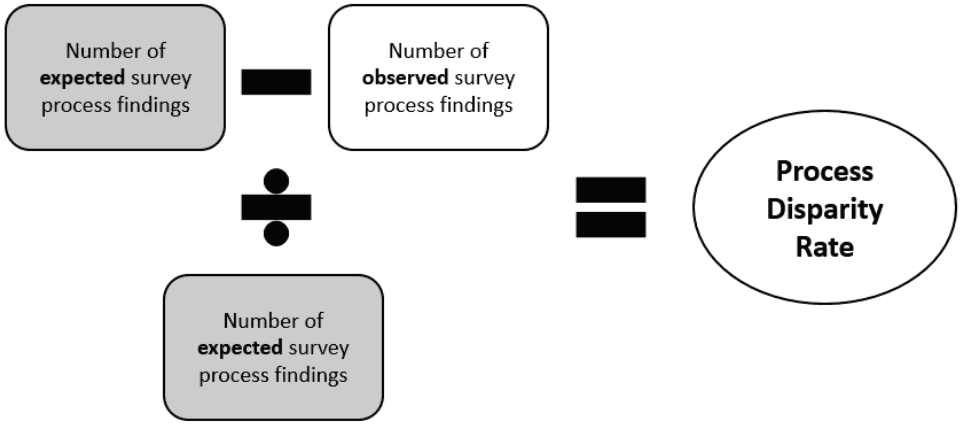
The existing definition of "rate of disparity" is not applicable to the direct observation validation survey because it focuses on the survey process as opposed to outcome of the survey. Therefore, we propose to revise the current definition of "rate of disparity" located at § 488.1 and

replace this definition with two new definitions, which are "outcome disparity rate" and "process disparity rate."

The outcome disparity rate would be applicable to the look-back validation survey, which is the current method of validation. We propose that the new definition of "outcome disparity rate" would generally remain as the existing definition of "rate of disparity" at § 488.1, but would be revised and retitled as "outcome disparity rate" to distinguish it from the "process disparity rate."

When calculating the process disparity rate, the numerator for one provider or supplier for which the direct observation validation survey is done would be the number of observed survey process findings and the denominator would be the number of expected survey process findings for all direct observation validation surveys. The observed survey process findings are the actual number of Medicare conditions that were observed being surveyed for by the AO. The expected survey process findings are the total number of Medicare conditions that the AO should have surveyed for during the survey observation. The result would be reported as a percentage. A high percentage indicates greater disparity between the expected AO performance on direct observation validation survey and the actual AO performance on the direct observation validation survey. For example, a direct observation validation survey with 75 observed process findings out of 100 expected process findings would yield a process disparity rate of 25 percent [((100-75) ÷ 100) * 100], indicating a 25 percent difference between what is observed and what is expected (See Figure 1).

Figure 1:



The proposed process disparity rate would be applicable to the direct observation validation survey and would be defined as the difference between the observed survey process findings and the expected survey process findings.

The overall process disparity rate for a particular AO would be calculated by taking the average of the process disparity rate for each direct observation validation survey performed for an accreditation program of an AO. Preliminary results obtained from the VRP pilot during the period of June 2018 to July 2019 are shown in Figure 2. While we will analyze and explain the pilot data when more is available, we share preliminary data here as a sample of how the process disparity rate would be calculated if this proposed rule is finalized as proposed.

Figure 2:

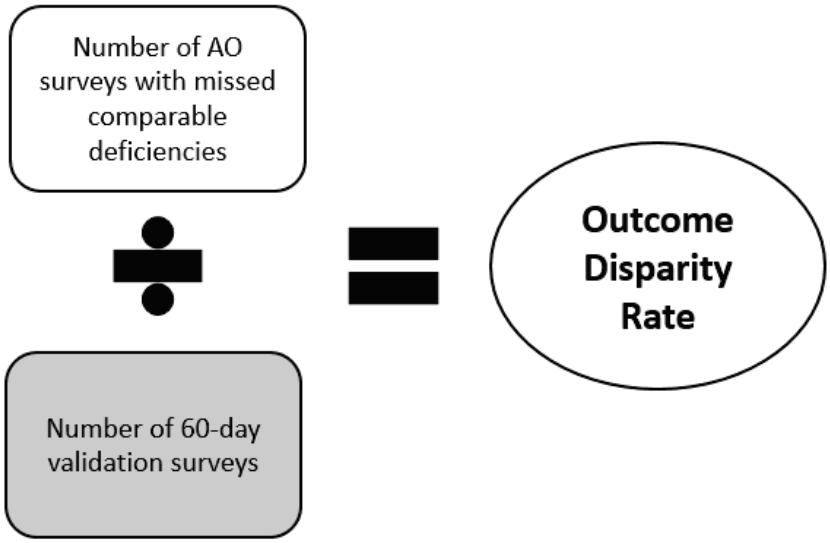
Provider Type	Number of Direct Observation Validation Surveys	Average Process Disparity Rate
Ambulatory Surgery Center	8	19%
Home Health Agency	3	1%
Hospital	11	10%
Psych Hospital	3	7%
Hospice	1	N/A

NOTE: Caution should be used in drawing broader inferences from the data in Figure 2 of this proposed rule because the sample size is very small.

The outcome disparity rate measure would also be a component of evaluating AO performance. We have been measuring the outcome disparity rate as a performance measure for

years and have historical data to share. This measure would comprise any look-back validation survey condition level findings made by the SA that had not been identified by the AO during their reaccreditation survey, where it is reasonable to conclude that these deficiencies were present when the AO performed the survey (see Figure 3).

Figure 3:



In addition to reporting the overall disparity between the outcomes found by both the AO and SA, the differences between the observed and expected survey processes would also be reported as the process disparity rate.

In FY 2019, we found that 42 percent of the state validation look-back validation surveys performed for hospitals, the AO did not cite a comparable deficiency to those cited by the SA. The proposed definition of new process disparity rate would showcase the average percent difference between the observed survey process findings and the expected survey process findings, by provider type.

Figure 4 provides the FY 2020 outcome disparity rate for Medicare provider types as reported in the January 2021 Report to Congress.

Figure 4:

HOSPITAL	FY 2019
60-Day Validation Sample Surveys	99
SA Surveys with Condition Level Deficiencies	48
AO Surveys with Missed Comparable Deficiencies	42
Disparity Rate	42%
PSYCHIATRIC HOSPITAL	**FY 2019**
60-Day Validation Sample Surveys	20
SA Surveys with Condition Level Deficiencies	12
AO Surveys with Missed Comparable Deficiencies	9
Disparity Rate	45%
CRITICAL ACCESS HOSPITAL	**FY 2019**
60-Day Validation Sample Surveys	13
SA Surveys with Condition Level Deficiencies	7
AO Surveys with Missed Comparable Deficiencies	6
Disparity Rate	46%
HOME HEALTH AGENCY	**FY 2019**
60-Day Validation Sample Surveys	84
SA Surveys with Condition Level Deficiencies	8
AO Surveys with Missed Comparable Deficiencies	7
Disparity Rate	8%
HOSPICE	**FY 2019**
60-Day Validation Sample Surveys	32
SA Surveys with Condition Level Deficiencies	6
AO Surveys with Missed Comparable Deficiencies	6
Disparity Rate	19%
AMBULATORY SURGERY CENTER	**FY 2019**
60-Day Validation Sample Surveys	67
SA Surveys with Condition Level Deficiencies	26
AO Surveys with Missed Comparable Deficiencies	23
Disparity Rate	34%

We note that the average disparity rate across all Medicare provider types is 32 percent, based on the most recent data, with the largest disparity rate being CAHs' accreditation surveys, at 46 percent. By continuing to monitor outcome disparities, and further investment in our methodologies for measuring process disparities would help to bring AOs up to the standards of SAs.

K. *Proposal to Require AOs to Submit a Publicly Reportable Plan of Correction for Unacceptable Performance Measure Scores (§ 488.8(a)(2))*

In section IV.J of this proposed rule, we proposed to revise the definition of "disparity rate" to include a process and outcome disparity rates. We noted that the proposed definition of outcome disparity rate generally remains the same as the currently defined definition of disparity rate. We further noted that we have been measuring the outcome disparity rate as a performance measure for years. We would note that we would use the new process disparity rate as a performance measure.

To monitor an AO's ongoing performance as provided by section 1875(b) of the Act and § 488.8, we propose in paragraph (a)(2) to expand the types of validation activities included in the performance review. We also propose in paragraph (a)(4) to require AOs to submit a plan of correction that would be publicly reported, when the AO's performance on survey activities identify disparity concerns either through the outcome disparity rates or process disparity rates.

We propose to revise § 488.8(a)(2) to broaden activities that CMS would evaluate in our ongoing review of AOs. Specifically, we would monitor the results of our outcome disparity rate, the look-back validation surveys, complaint surveys and the process disparity rate as determined by the direct observation survey.

We propose to revise § 488.8(a)(4) to require that when an AO's outcome disparity or process disparity performance measure scores, as determined from look-back and direct observation validation surveys, reveal that the AO's accreditation survey activities do not meet an acceptable performance threshold established by CMS, the AO would be required to submit

an acceptable plan of correction to CMS which identified corrective action the AO proposed to take to correct their performance.

We propose at § 488.8(a)(4)(i), to require that the plan of correction be submitted to CMS for review within 10 business days the AO being notified by CMS of not meeting the acceptable performance threshold. We also propose that in order to be acceptable, the AO's plan of correction would have to: (1) document specific actions being taken by the AO to address improving performance (proposed § 488.8(a)(4)(i)(A); (2) document the timeframe for implementation of the plan (proposed § 488.8(a)(4)(i)(B)); (3) plan for ongoing monitoring of the plan of correction toward achieving an acceptable level of performance (proposed § 488.8(a)(4)(i)(C); and, (4) identify the individual responsible for implementation and monitoring of the acceptable plan of correction (§ 488.8(a)(4)(i)(D)).

CMS would subsequently communicate with the AO on the acceptability of the plan of correction and would provide oversight of implementation. We propose at § 488.8(a)(4)(ii) that upon review and approval of the submitted plan of correction, CMS would provide ongoing evaluation of the progress of plan implementation.

Finally, we propose at § 488.8(a)(4)(iii) that the AO's plan of correction be made subject to public reporting by CMS. Once approved, the plan of correction would be publicly available for review. This means that the acceptable plan of correction would be displayed publicly by CMS once approved. This plan of correction would be utilized to increase an AO's accountability for maintaining performance standards.

The purpose of this oversight is to improve AO survey activity outcome and processes with the presumption that improvements toward acceptable performance would improve the health and safety of patients receiving services in Medicare-participating facilities. This is an effort to strengthen AO oversight by requiring AOs to address issues and take corrective action to improve to an acceptable level of performance. Previously, this was handled verbally or through written correspondence between the AO and CMS staff without a specific plan of

correction.

The proposed publicly reportable plan of correction would be based on both an analysis of data to identify the outcome and process disparity performance measure(s) for which the AO did not meet acceptable performance as well as significant instances of disparity. An analysis matrix would outline both outcome performance and process performance areas of successful achievement and those areas for which achievement was less than acceptable as demonstrated by the outcome and process disparity rate data. An example of what a plan of correction matrix might look like is indicated in Figure 5.

Figure 5:

Overall Condition Citation Performance

OUTCOME + PROCESS +	OUTCOME + PROCESS -
• QAPI • Nursing Services ** • Discharge Planning • Patient's Rights • Infection Control • Medical record requirement for psychiatric hospitals *	• ASC – Patient's Rights • ASC – Governing Body and Management* • Physical Environment • ASC - Environment * • ASC - Infection Control** • Medical record services *
OUTCOME - PROCESS +	**OUTCOME - PROCESS -**
• Organ, tissue and eye procurement • Emergency Services** • Medical Staff** • Emergency Preparedness** • Radiologic Services** • Utilization Review**	• ASC – Pharmaceutical Services * • ASC – Emergency Preparedness** • ASC- QAPI * • Food and Dietetic Services ** • Respiratory Care Services **

* Includes condition citations matched from validation surveys only.
** Includes condition-level citations matched from complaint surveys only.

The matrix in Figure 5 is representative of FY 2018 data collected during the direct observation validation surveys, look-back validation surveys, and complaint surveys (which investigates specific allegations) conducted by the SA at AO facilities. If deficiencies were cited first by the AO and validated by the SA during a look-back or complaint survey this is considered an outcomes match. If the AO survey process under direct observation by the SA did not raise concerns, this indicates a positive outcome and positive process, which are represented in the top left box. The top right and bottom left boxes indicate where improvements need to be

made in either the process or outcome of the respective Medicare condition, also known as CoP, while the bottom right box shows where improvements in both measures should be made.

The AO would be able to use this matrix to identify if the less than acceptable performance is either outcome-focused, process-focused, or both. The proposed plan of correction would be required to be submitted to CMS within 10-business days following CMS' notification to the AO of less than acceptable performance, and would have to address the areas of improvement and the specific actions to be taken by the AO to improve those areas on a sustainable basis.

L. *Proposal to Revise the AO Survey Validation Program (§ 488.9)*

Prior to discussing our proposed changes below, the following provides (1) background on validation surveys, (2) background on look-back validation surveys, and (3) background on additional approaches to conduct validation surveys, before (4) introducing CMS' proposed changes.

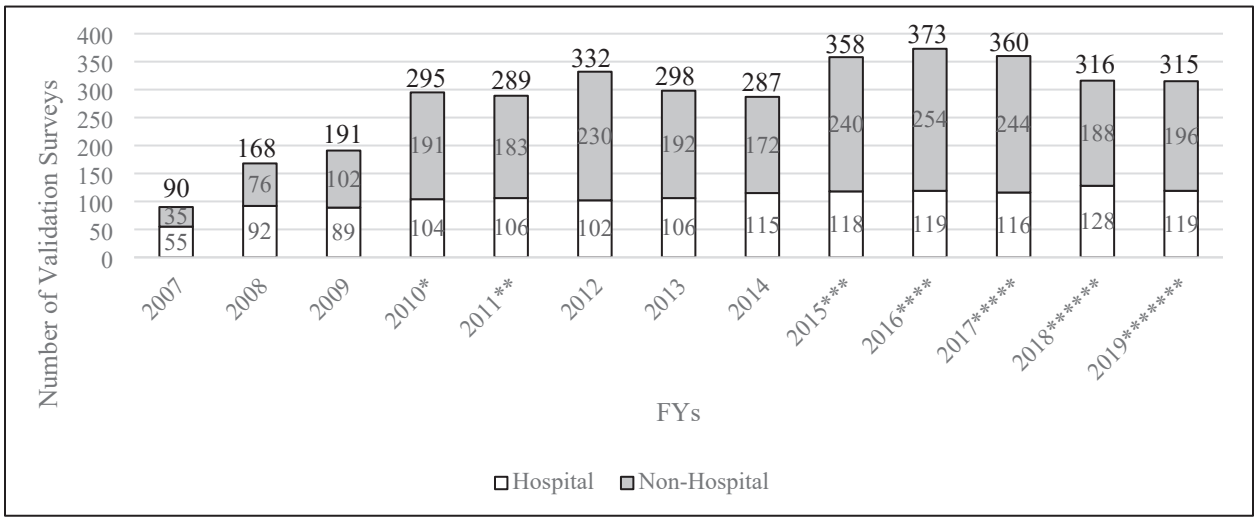
1. Background on Validation Surveys

Section 1864(c) of the Act permits the SAs to perform validation surveys of provider and supplier types deemed for Medicare participation under section 1865(a) of the Act as a means of validating the AOs' accreditation processes. The accreditation validation program is one component of CMS' oversight of AOs with approved Medicare accreditation programs, and consists of two types of validation surveys:

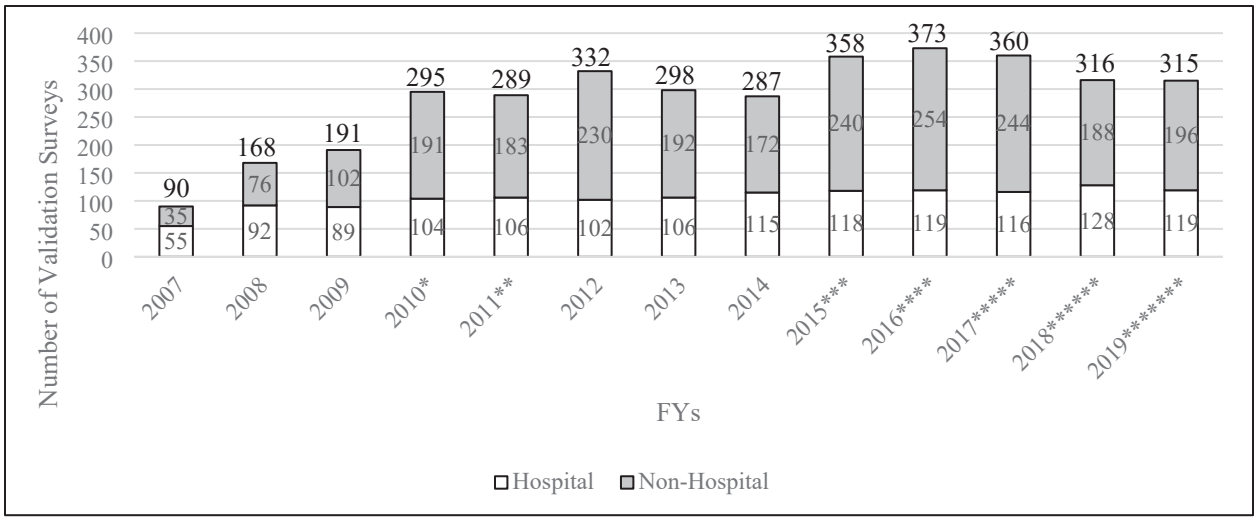
- Complaint surveys – focused surveys based on complaints, which, if substantiated, could indicate serious non-compliance with one or more Medicare conditions; and
- Validation surveys – full surveys, which are routinely performed for a representative sample of deemed facilities as part of the annual CMS-AO representative sample validation survey program. These surveys are completed by the SA within 60 days of an AO full accreditation survey for the same facility.

Prior to 2007, section 1875 of the Act required CMS to report to Congress annually only on the Joint Commission's (TJC's) hospital accreditation program.[14] In FY 2007, we expanded this oversight and began conducting 60-day representative sample validation surveys for selected non-hospital facility types (CAHs, HHAs and ASCs), in addition to those already being performed for deemed status hospitals. In FY 2010, hospice look-back validation surveys were added, and in FY 2011, psychiatric hospital 60-day validation surveys were added. In FY 2019, we conducted a total of 315 representative sample look-back validation surveys for six facility types across AOs.[15] This total comprised of 119 hospital surveys (including 20 psychiatric hospitals) and 196 non-hospital validation surveys. (See Graph 1.)

Graph 1: Number of Sample Validation Surveys for Hospital and Non-Hospital Providers Performed from FY2007 to 2019



[14] Section 125(b)(4) of Pub. L. 110-275 (2008), which was subsequently revised to apply to all AOs.
[15] Outpatient physical therapy and rural health clinics were not part of the validation sample.



*In FY 2010: The non-hospital total of 191 includes 72 mid-cycle ASC validation surveys.
**In FY 2011: The hospital total of 106 includes 33 mid-cycle LTCH validation surveys.
***In FY 2015: The hospital total of 118 includes 16 psychiatric hospital validation surveys.
****In FY 2016: The hospital total of 119 includes 21 psychiatric hospital validation surveys.
*****In FY 2017: The hospital total of 116 includes 21 psychiatric hospital validation surveys.
******In FY 2018: The hospital total of 128 includes 21 psychiatric hospital validation surveys.
*******In FY 2019: The hospital total of 119 includes 20 psychiatric hospital validation surveys.

Since 2007, CMS has worked to strengthen its oversight of AOs and increase the number of validation surveys. The recent history of validation survey samples is as follows:

2015: 118 hospital and 240 non-hospital surveys totaling 358 surveys.

2016: 119 hospital and 254 non-hospital surveys totaling 373 surveys.

2017: 116 hospital and 244 non-hospital surveys totaling 360 surveys.

2018: 128 hospital and 188 non-hospital surveys totaling 316 surveys.

2019: 119 hospital and 196 non-hospital surveys totaling 315 surveys.

These numbers represent a 250 percent increase in the overall number of validation surveys conducted, from 90 in FY 2007 to 315 in FY 2019. During the same time period, the number of non-hospital validation surveys conducted increased by 460 percent, from 35 surveys in FY 2007 to 196 surveys in FY 2019. The number of hospital validation surveys conducted increased by 116 percent, from 55 surveys in FY 2007 to 119 surveys in FY 2019.

2. Background on Look-Back Validation Surveys

The purpose of look-back validation surveys of deemed providers or suppliers is to assess the AO's ability to ensure compliance with Medicare conditions. These surveys are on-site full surveys completed by SA surveyors no later than 60 days after the end date of an AO's Medicare

accreditation program full survey. The SA performs these surveys without any knowledge of the findings of the AO's accreditation survey. CMS determines the number of look-back validation surveys to perform for each AO based on its total number of facilities, as well as the overall budgeted validation survey targets, by state and facility type.

The proportion of look-back surveys completed for deemed facilities is calculated by dividing the number of look-back validation surveys conducted by the total number of deemed facilities. The proportion of deemed facilities that received a look-back validation survey in FY 2019 is as follows:

- **Hospitals:** Three percent of deemed hospitals received a validation survey in FY 2019 (99 validation surveys conducted out of 3,332 deemed facilities).
- **Psychiatric Hospitals:** Four percent of deemed psychiatric hospitals received a validation survey in FY 2019 (20 validation surveys conducted out of 466 deemed facilities).
- **CAHs:** Three percent of deemed CAHs received a validation survey in FY 2019 (13 validation surveys conducted out of 449 deemed facilities).
- **HHAs:** Two percent of deemed HHAs received a validation survey in FY 2019 (84 validation surveys conducted out of 4,034 deemed facilities).
- **Hospices:** One percent of deemed hospices received a validation survey in FY 2019 (32 validation surveys conducted out of 2,458 deemed facilities).
- **ASCs:** Four percent of deemed ASCs received a validation survey in FY 2019 (67 validation surveys conducted out of 1,803 deemed facilities).

3. Background on Additional Approaches to Conducting Validation Surveys

Over the years, we have looked for ways to improve the validation survey process and the disparity rate methodology. As discussed earlier in this proposed rule, the disparity rate for various provider types ranged between 8 percent for HHAs and 46 percent for CAHs.

To address concerns about high disparity rates, CMS has been testing a VRP pilot since

2018. In the VRP pilot, instead of the separate look-back validation survey, a direct observation of the AOs survey by is performed. During the direct observation validation survey, the SA surveyors are present when the AO surveyors perform an accreditation survey, so that they can directly observe and evaluate the ability to the AO surveyors to assess compliance with the Medicare conditions. The purpose of this direct observation is to evaluate, in real time, the AO performance on the survey process. The real time observation of the survey allows the SA surveyors to make suggested improvements and address any concerns with AOs immediately.

From June 2018 through August 2019, CMS conducted a total of 30 VRP pilot surveys in 17 states in the acute care hospital program (11), ASC program (10), psychiatric hospital program (3), HHA program (5) and hospice program (1). This proposed direct observation validation process has yielded additional information about the extent to which the AO's process meets or exceeds the survey process used by the SA surveyors. Our preliminary findings from our VRP pilot surveys include the following:

- Certain AOs have rigid survey schedules that prove to be burdensome to the SA observers while onsite.
- AOs have strict timeframes for each section of the survey to which they adhere, regardless of the findings or need to further investigate an issue within a facility.
- Not all AOs survey offsite locations consistently for all portions of the survey.
- Certain AO survey methodology favored a "yes/no," "have/don't have" format versus a more in-depth investigative approach.
- Verbal assertion was considered adequate evidence of compliance without verification via observations and/or document review.

4. Proposal to Revise the Existing AO Survey Validation Program (Proposed revisions to § 488.9)

We propose to revise the validation program by using two different types of validation surveys, which are: (1) the look-back validation survey and, (2) and a direct observation

validation survey approach, to evaluate the performance of the AOs. We propose that direct observation surveys can be performed by the SA or CMS surveyors.

We will also be looking at programmatic adjustments to the look-back validation survey to address some of the concerns stakeholders have raised, to focus on key quality concerns, and to reduce provider burden. These programmatic changes do not require a regulatory change and are under development.

Specifically, we propose at § 488.9(b) to revise the types of validations surveys. We will continue using the existing look-back validation survey, through use of a sample of facilities in each program type, which would take place within 60 days following the AO surveys. These 60-day validation surveys are referred to as look-back-validation surveys. As discussed above, we are planning to make additional programmatic adjustments to the existing look-back validation survey process to address the scope of the review and provider burden. Those adjustments would not require a regulatory change and are under development.

We propose at § 488.9(b)(2) to require validation using the direct observation validation survey, which focuses on real-time observation and evaluation of the AOs survey process. At § 488.9(c) we propose the rules for look-back validation surveys. At § 488.9(d) we propose the rules for selection for look-back validation surveys. More specifically, proposed § 488.9(d)(1) would provide that "a provider or supplier selected for a look-back validation survey must cooperate with the SA that performs the look-back validation survey." We propose at § 488.9(d)(2) that "if a provider or supplier selected for a look-back validation survey fails to cooperate with the SA, it will no longer be deemed to meet the Medicare conditions or requirements, will be subject to a review in accordance with paragraph (a) of this section, and may be subject to termination of its provider agreement under § 489.53 of this chapter."

At § 488.9(e), we propose the rules for the direct observation validation surveys. These rules would include the following: (1) All direct observation validation surveys will be unannounced to the AO and the facility being surveyed (proposed § 488.9(e)(1)); (2) The SA or

CMS surveyors will generally be assigned to the AO surveyors on a 1:1 basis, matching the experience of the accreditation surveyor where possible, and using the CMS approved standards and processes to determine compliance with the Medicare conditions (proposed § 488.9(e)(2)); (3) the SA surveyors will observe the AO survey in accordance with CMS established policies and procedures and will report the findings directly to CMS (proposed § 488.9(e)(3)); and, (4) where the SA or CMS surveyors disagree with the findings of the AO surveyors, and these differences cannot be reconciled, CMS will render a final decision (proposed § 488.9(e)(4)). This finding would not be appealable pursuant to 42 CFR 498.3(d)(1), which provides that administrative actions that are not initial determination (and therefore not subject to appeal under this part) are not appealable. Specifically, the findings that a provider or supplier determined to be in compliance with the conditions or requirements for participation or for coverage has deficiencies is such a non-appealable administrative action.

At proposed § 488.9(f), we propose circumstances in which an accredited provider or supplier would be deemed to have not met the applicable Medicare conditions or requirements, such as if: (1) the provider or supplier refuses to authorize its AO to release a copy of their current accreditation survey to CMS (proposed § 488.9(f)(1)); (2) the provider or supplier refuses to allow a validation survey (for either look-back or direct observation validation surveys) (proposed § 488.9(f)(2)); or (3) CMS finds that the provider or supplier does not meet the applicable Medicare condition (also known as CoP, CfC, conditions of certification, or requirements) (proposed § 488.9(f)(3)).

At § 488.9(g), we propose the consequences for non-compliance. At § 488.9(g)(1), we propose that if a CMS validation look-back or direct observation validation survey results in a finding that the provider or supplier is out of compliance with one or more Medicare conditions, deemed status may be removed by CMS and the provider or supplier will be subject to ongoing review by the SA or CMS (in accordance with § 488.10(d)) until the provider or supplier demonstrates compliance. At proposed § 488.9(g)(2), we propose that CMS may take actions for

the deficiencies identified in the in accordance with § 488.24, or may first direct the SA or CMS surveyors to conduct another survey of the provider's or supplier's compliance with specified Medicare conditions or requirements before taking the enforcement actions provided for at § 488.24. At proposed § 488.9(g)(3), we propose that if CMS determines that a provider or supplier is not in compliance with applicable Medicare conditions or requirements, the provider may be subject to termination of the provider agreement and any other applicable intermediate sanctions and remedies.

At proposed § 488.9(h), we propose the re-instatement of the deemed status of a provider or supplier. An accredited provider or supplier would be deemed to meet the applicable Medicare conditions or requirements in accordance with this section if any of the requirements are met, as applicable:

- It withdraws any prior refusal to authorize its AO to release a copy of the provider's or supplier's current accreditation survey (proposed § 488.9(h)(1)).
- It withdraws any prior refusal to allow a look-back or direct observation validation survey, if applicable (proposed § 488.9(h)(2)).
- CMS finds that the provider or supplier meets all applicable Medicare CoP, CfC, conditions of certification, or requirements (proposed § 488.9(h)(3)).

At proposed § 488.9(i), we propose that the existence of any performance review, comparability review, deemed status review, probationary period, or any other action by CMS, does not affect or limit CMS in conducting any subsequent validation survey.

By providing a flexible approach to the validation process, this could reduce provider burden by reducing the frequency with which CMS would perform validation using the look-back validation survey method in which CMS performs a look-back validation survey within 60 days of the end date of the AOs accreditation survey. This would reduce the number of times that health care providers would have to undergo two full surveys within a 60-day period. We further believe this approach broadens the validation program activities and would be welcomed

by both the AOs and the providers and suppliers.

We propose that our proposals to revise the validation process by adding direct observation validation surveys and our proposed revisions to § 488.9 would be applicable 60 days after the effective date of the final rule.

We also propose that the direct observation surveys may be performed by not only the SA but also by CMS surveyors. This allows for flexibility and expediency in the performance of these validation surveys.

The proposal to revise the validation process by adding look-back and direct observation validation surveys and our proposed revisions to § 488.9 would not apply to laboratories, as they are subject to the provisions under part 493.

M. Proposal to Revise the Psychiatric Hospital Survey Process

Under section 1861(f) of the Act, psychiatric hospitals are a defined provider type. This statutory provision requires psychiatric hospitals to comply with most hospital Medicare conditions, known as CoPs, but includes a few provisions applicable exclusively to them. In 1986, special Medicare conditions for psychiatric hospitals were published and included, as part of the hospital Medicare conditions, as provisions of 42 CFR Part 482. At that time, psychiatric hospital surveys were performed by either SA personnel or Health Care Financing Administration[16] (HCFA) mental health surveyors (board-certified psychiatrists, masters prepared psychiatric nurses, masters prepared psychiatric social workers, doctorally prepared clinical psychologists, and doctorally prepared clinical psychopharmacologists) who were under contract with HCFA. This extensive experience requirement was beyond what is required for other types of hospital services. This requirement limited the numbers of SAs with qualified surveyors. Therefore, a CMS contractor with specially-trained and/or experienced psychiatric surveyors assisted the SAs in performing such surveys. This has resulted in a bifurcated survey

[16] Health Care Financing Administration was the former name for CMS, which was changed on June 14, 2001.

process, as most psychiatric hospitals were subjected to two survey teams for each accreditation survey: the hospital survey team and the psychiatric component survey team.

However, in the FY 2014 QSOG Mission and Priority Document, the restrictive requirement for extensive education and/or experience for psychiatric surveyors was removed. CMS developed online psychiatric surveyor training, provided on-site psychiatric surveyor training through contractors and offered partnership training for surveyors who did not have extensive psychiatric education or experience. This training became the standard and expectation for qualification to survey to the psychiatric Medicare conditions.

The special Medicare conditions applying to psychiatric hospitals are set forth in § 482.60 through § 482.62. The special provisions at § 482.60 require the following: (a) that the hospital be primarily engaged in providing, by or under the supervision of a doctor of medicine or osteopathy, psychiatric services for the diagnosis and treatment of mentally ill persons; (b) meet the conditions of participation specified in §§ 482.1 through 482.23 and §§ 482.25 through 482.57; (c) maintain clinical records on all patients, including records sufficient to permit CMS to determine the degree and intensity of treatment furnished to Medicare beneficiaries, as specified in § 482.61; and (d) meet the staffing requirements specified in § 482.62. As noted earlier, participating psychiatric hospitals must also meet the Medicare conditions for acute-care hospitals.

In March 2020, we eliminated the contract for separate psychiatric hospital surveyors and provided comprehensive online training for all SAs. This training focused on the specific psychiatric hospital Medicare conditions so that the SA surveyors would be fully trained to conduct all aspects of a complete psychiatric hospital inspection. At this time, we also combined the interpretive guidance at Appendix AA for psychiatric hospital surveys into the Appendix A for hospital surveys to provide a single location for all of the Medicare conditions during a full psychiatric survey.

At this time, TJC and DNV are the only AOs that have CMS-approved psychiatric

hospital accreditation programs. They conduct one complete survey of the entire psychiatric hospital, to include inspection of the regular hospital Medicare conditions and the psychiatric hospital Medicare conditions. Any AO is eligible to submit an application for consideration for accreditation to survey psychiatric hospitals.

We propose to integrate the acute care hospital and psychiatric hospital survey processes for SAs to ensure that there is a systematic, and integrated look at psychiatric hospital quality. Therefore, AOs that currently survey only hospitals would need to expand their hospital accreditation programs to include Medicare conditions to survey for psychiatric hospitals as well.

We believe that consolidating psychiatric and acute-care hospital Medicare condition oversight will improve the overall quality of the care by ensuring that systemic issues are more easily identified. With a single survey team conducting the survey for the entire facility, inconsistencies, trends, and subtle discrepancies can be connected more easily and provide a more comprehensive overview of underlying systemic issues. We believe that this comprehensive approach to survey both the psychiatric and acute-care hospital will enhance patient health and safety by ensuring the system as a whole is evaluated to meet the applicable Medicare requirements. Moreover, a single survey team decreases the team's physical imprint on the facility which minimizes any facility disruption resulting from the survey. When revisits are required related to deficiencies in the psychiatric Medicare conditions, only one survey team will return for re-inspection, which will reduce coordination time and resources as well as impact on individual facilities. Finally, we have determined that combining the survey process for psychiatric hospital Medicare conditions into the hospital program would improve the cost efficiency of CMS's survey and certification activities and simplify the survey process for SAs and AOs alike.

For SAs, we would consolidate the deficiency report from psychiatric hospital survey activity into one Form CMS-2567, reporting on compliance with both the hospital Medicare conditions as well as the psychiatric services Medicare conditions. The survey process for

inpatient psychiatric units located in acute care hospitals would not change, and this change would not require any revisions to our regulations.

To ensure that surveys of psychiatric hospitals and units located in hospitals are performed properly by the SA surveyors, they have been provided online training on the psychiatric hospital Medicare conditions. CMS developed this online training and released it in March 2020. It is now available to all SA and AO surveyors at https://qsep.cms.gov/.

We would expand the acute care hospital accreditation program for AOs to include current psychiatric hospital accreditation standards. As per § 488.8(b), CMS assesses the equivalency of the AOs programs to the CMS-approved program requirements, and, as such, this proposal to combine acute care and psychiatric hospital surveys necessarily required that we also propose to revise the hospital accreditation program application process for AOs that have an approved hospital program, so as to include psychiatric hospital accreditation in their hospital programs. Those AOs who currently have an approved hospital program would be required to resubmit their standards, survey process and surveyor training (which may include as part of CMS' training) to include review of the psychiatric Medicare conditions for psychiatric hospitals for CMS approval. This means that an AO that is seeking approval of a hospital accreditation program would be required to file one application that includes how they will assess for the two special Medicare conditions for psychiatric hospitals within their hospital accreditation program, whether or not they are currently accrediting psychiatric hospitals or have plans do to so in the future.

As part of this proposal, we would also require that the AOs that already have an existing CMS-approved hospital program expand their existing hospital programs to include survey activities of psychiatric services in psychiatric hospitals. Those AOs who currently have an approved hospital program would be required to resubmit their standards, survey process and surveyor training for CMS approval in accordance with § 488.8(b) by no later than 30-calendar days from CMS notice to the hospital AOs using the existing process described in

§ 488.5(a)(19)(i). That process also permits CMS to give due consideration to a request for extension.

We hope that this would encourage additional AOs to participate in deeming psychiatric hospitals. Overall, the intent of these proposals is to ensure that psychiatric services are evaluated in the context of the larger hospital program evaluation so that systemic quality issues are not missed. A single, comprehensive and focused survey team will be able to identify and connect individual issues and trends which may be occurring under two separate programs. Combining the two programs provides a more global view of the facility's potential deficiencies and is more likely to ensure the overall safety and quality of care delivered. For example, if there were significant issues with staff supervision of patients, one team of surveyors would be investigating areas which now cross the two sets of requirements and survey teams including patient-specific care planning, staff training, patient rights, and potentially governing body. Integrating the survey activities for hospital and psychiatric standards would also provide an avenue for additional AOs to participate in deeming psychiatric hospitals, which would produce more competition and provide facilities with more options for surveying authorities.

N. *Limitation on Terminated Deemed Providers/Suppliers Seeking Re-entry into Medicare/Medicaid (§ 489.57, § 488.4(b) & § 488.5(a)(21))*

Involuntary termination of the Medicare provider agreement is the ultimate sanction for non-compliance with Medicare's basic health and safety requirements. On average, less than ten involuntary terminations occur each year. From January 2015 through September 2023, a total of fifty-eight accredited providers and suppliers, including ASCs, ESRD facilities, HHAs, Hospices, Hospitals, RHCs, and OPTs, were involuntarily terminated from the Medicare program for unresolved health and safety concerns. These providers currently have the option of seeking re-approval to participate in Medicare/Medicaid through an AO with a CMS-approved program. We remain concerned that providers who have been involuntarily terminated from the Medicare program may continue to remain accredited by an AO, and hold their continued

accreditation out to the public as a marker of high-quality care. Most consumers, due to branding and advertising by the accredited community, associate quality of care with accreditation, rather than CMS certification. Therefore, involuntarily terminated providers who retain their AO accreditation status convey that they continue to meet high quality of care standards, despite their termination from Medicare. This situation could weaken public trust in accreditation as a marker of patient quality and safety. Since AO standards are required to meet or exceed those of Medicare, we are proposing at § 488.5(a)(21)) that termination by Medicare represents a prima facie case that the facility similarly fails to meet accreditation standards.

These concerns were highlighted in media reports that noted psychiatric hospitals whose provider agreements under Medicare were terminated for harm to patients. These psychiatric hospitals nonetheless retained their accreditation despite serious health and safety concerns.[17,18] An article published in the Wall Street Journal (WSJ) on September 8, 2017[19] discussed patient-safety problems at a hospital accredited by one of the AOs that provides fee-based consulting. These safety issues were so severe that Medicare considered terminating the hospital's Medicare participation agreement. The AO that accredited the hospital made no changes in the hospital's accreditation status and allowed it to continue promoting itself as fully accredited, despite being out of compliance with the Medicare safety requirements.

The WSJ article reinforced concerns CMS had previously identified regarding the very small number of facilities which we terminated for failing to meet our basic health and safety regulations, but which nonetheless retained their AO accreditation. Continued accreditation of these outlier facilities which receive the ultimate sanction CMS may impose based on their ongoing failure to meet basic health and safety requirements raises serious concerns about the survey integrity and public trust attached to AO accreditation. Therefore, we would propose to

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[17] S. Armour, Psychiatric Hospitals With Safety Violations Still Get Accreditation, *Wall Street Journal*, December 26, 2018.

[18] D. Gilbert Behind Joint Commission's 'Gold Seal of Approval,' a history of missed safety violations at psychiatric hospitals, *Seattle Times*, October 9, 2019.

[19] S. Armour, Hospital Watchdog Gives Seal of Approval, Even After Problems Emerge, *Wall Street Journal*, September 8, 2017.

explicitly prohibit AOs from allowing terminated facilities to retain their accreditation, in order to reduce confusion for patients and families about the continued health and safety of terminated entities.

To address the issue of terminated providers or suppliers remaining accredited by an AO, we propose to add a new regulatory requirement at § 488.4(b) (currently reserved). More specifically, proposed § 488.4(b)(1) would provide that if CMS terminates the participation agreement of a Medicare-certified provider or supplier, under our authority at section 1865(c) of the Act, we would no longer recognize the accreditation provided by an AO as evidence that Medicare standards had been met or exceeded for that terminated provider or supplier.

In support of the proposed requirements at § 488.4(b), we also propose to add a new requirement at § 488.5(a)(21) that would require AOs to provide, with their initial and subsequent renewal applications, a statement certifying that, in response to a written notice from CMS notifying the AO that one of its accredited providers or suppliers has been terminated from the Medicare/Medicaid program, the AO agrees to terminate or revoke its accreditation of the terminated provider or supplier within 5-business days from receipt of said written notice.

The Medicare-approved deeming accreditation provided to Medicare-certified providers and suppliers by AOs permits Medicare participation in lieu of certification by the SA. Therefore, if a Medicare-certified provider or supplier chooses to obtain deeming accreditation from an AO, and then their Medicare participation is involuntarily terminated after failing to meet the Medicare conditions, we would no longer recognize the validity of the AO's accreditation with respect to that provider/supplier under our oversight authority at section 1865 of the Act. We do not believe that it is appropriate for a terminated provider or supplier's AO deeming accreditation to remain effective for CMS purposes after we have terminated this provider or supplier for significant deficiencies that the AO may not have cited, discovered, or fully recognized. A terminated provider or supplier may attempt to use the AO's accreditation as

a quality marker, when in fact their practices are severely deficient, unsafe and non-compliant with the CMS conditions.

Under section 1865 of the Act, we may involuntarily terminate CMS approval of an AO's overall deeming authority if they miss egregious deficiencies in one of their accredited providers or suppliers' practices. However, we would prefer to withdraw our recognition of the individual provider's or supplier's deeming accreditation instead, and separately work with the AO to determine why such deficiencies went undiscovered.

Proposed § 488.4(b)(2) would provide that if CMS terminates the participation agreement of a Medicare certified provider or supplier, that terminated provider or supplier would be required to meet the requirements set forth at § 489.57 before a new agreement for Medicare participation will be approved. We also propose a new paragraph at § 489.20(z) that reinstatement of a terminated provider or certified supplier agreement is subject to the proposed revision to § 489.57.

The introductory text to § 489.57 states that when CMS has terminated a provider agreement under § 489.53, or by the OIG under § 489.54, a new agreement with that provider will not be accepted unless CMS or the OIG, as appropriate, finds that said provider or supplier meets the requirements set forth in sections § 489.57(a) and (b). We propose to redesignate § 489.57(a) and (b) as § 489.57(a)(1) and § 489.57(a)(2) without any change to the text. Redesignated § 489.57(a)(1) requires a provider or supplier that has been terminated from the Medicare program to demonstrate that the reason for termination of the previous Medicare provider agreement has been removed and provide reasonable assurance that it will not recur. Redesignated § 489.57(a)(2) requires the terminated provider or supplier to fulfill, or make satisfactory arrangements to fulfill, all of the statutory and regulatory responsibilities of its previous agreement.

We also propose to add a new paragraph (b) at § 489.57. Proposed § 489.57(b) would provide that before a new agreement for Medicare participation of the terminated provider or

supplier is approved, such terminated provider or supplier would have to meet the requirements of proposed § 489.57(b)(1) through (b)(3).

Proposed § 489.57(b)(1) would require that the terminated provider or supplier be under the exclusive oversight of the SA for the purposes of the initial certification survey, initial certification and demonstration of compliance with the Medicare conditions. Proposed § 489.57(b)(2) would require that the terminated provider or supplier remain under the exclusive oversight of the SA until the SA had certified the provider's/supplier's full compliance with all applicable Medicare conditions and their application for participation in the Medicare/Medicaid program had been approved. Finally, proposed § 489.57(b)(3) would provide that CMS would not recognize accreditation from a CMS-approved accrediting organization for deeming purposes while the terminated provider or supplier was under the oversight of the SA and its new agreement for Medicare participation was pending.

Our intent for proposing the new requirements at § 489.57(b) is to ensure that the SA would have the initial survey and certification oversight authority over terminated providers and suppliers seeking re-entry into the program about which we had significant health and safety concerns. The terminated provider or supplier would remain under the oversight of the SA for a reasonable assurance (RA) period of a duration to be determined by CMS. During the RA period, the terminated provider or supplier would be required to provide reasonable assurance to the SA and CMS that the deficiencies that caused the termination have been rectified and that they are not likely to recur. This means that a terminated provider or supplier would have to use the SA, as opposed to an accrediting organization, to perform their initial participation survey and assessment of compliance before a new agreement for Medicare participation is approved. If, after completion of the reasonable assurance period, the SA found that the provider or supplier met all of the applicable Medicare conditions, it would certify said provider or supplier's compliance and notify CMS of its findings. CMS would consider the SA's survey findings (certification) in deciding whether to approve or deny the provider's or supplier's new

initial certification request for participation in the Medicare program. However, if the SA were to find deficiencies and determine that the provider or supplier did not meet the CMS conditions, the SA could take several courses of action, depending on the severity of the deficiencies. The SA could require the provider or supplier to submit a plan of correction and give the provider or supplier time to correct the deficiencies. The SA would then perform a subsequent survey to see if the deficiencies have been removed and compliance with all requirements has been achieved. If the deficiencies found during the initial SA survey were significant or egregious, the SA may not approve a plan of correction, notify CMS of its findings and recommendation, and CMS may deny the provider's or supplier's request for new participation in the Medicare program.

The SA cannot recommend certification of a previously terminated provider or supplier that has significant condition or immediate jeopardy level deficiencies, unless these deficiencies are properly and promptly addressed and removed by the provider or supplier. Therefore, the proposed new requirements at § 489.57(b) would help to provide reasonable assurance to CMS that the significant health and safety concerns that warranted termination of the provider or supplier's Medicare agreement have been corrected and compliance with all applicable requirements and conditions have been achieved before a new agreement for participation in the Medicare program is approved. We believe that SA oversight during a reasonable assurance period of a length to be determined by CMS, and survey and certification that the terminated provider or supplier now meets the Medicare conditions is a safer alternative to accepting AO deeming of that terminated provider or supplier. This is because in the majority of cases of terminated providers and suppliers, the SA discovered the egregious deficiencies that caused terminations during a validation or complaint survey that took place within 60 days of an AO reaccreditation survey. The AOs that accredited the terminated providers and suppliers had not detected or cited these deficiencies during their surveys.

Section1865(b) of the Act prohibits public disclosure of surveys performed by AOs (with the exception of HHAs, hospice programs, and surveys that relate to an enforcement action taken

by the Secretary). However, the proposed new requirements at § 489.57(b) will allow the findings from the compliance surveys performed by the SA to be made publicly available under our authority at subpart B, 42 CFR 401.133(a) and section 1864(a) of the Act states: "within 90 days following the completion of each survey of any health care facility, ambulatory surgical center, rural health clinic, comprehensive outpatient rehabilitation facility, laboratory, clinic, agency, or organization by the appropriate State or local agency described in the first sentence of this subsection, the Secretary shall make public in readily available form and place, and require (in the case of skilled nursing facilities) the posting in a place readily accessible to patients (and patients' representatives), the pertinent findings of each such survey relating to the compliance of each such health care facility, ambulatory surgical center, rural health clinic, comprehensive outpatient rehabilitation facility, laboratory, clinic, agency, or organization with (1) the statutory conditions of participation imposed under this title and (2) the major additional conditions which the Secretary finds necessary in the interest of health and safety of individuals who are furnished care or services by any such health care facility, ambulatory surgical center, rural health clinic, comprehensive outpatient rehabilitation facility, laboratory, clinic, agency, or organization."

Thus, the proposed new requirements at § 489.57(b) would allow for greater transparency regarding the current compliance of terminated health care providers and suppliers seeking re-entry into the program.

O. *Proposal for Technical Correction for End-Stage Renal Disease (ESRD) Facilities and Kidney Transplant Programs (§ 488.4(a)(4))*

Section 1865(a)(1) of the Act had historically excluded dialysis facilities from participating in Medicare via a CMS-approved accreditation program; however, section 50403 of the Bipartisan Budget Act of 2018 amended section 1865(a) of the Act to include renal dialysis facilities as provider entities allowed to participate in Medicare through a CMS-approved accreditation program. In addition, the Bipartisan Budget Act of 2018 also amended section 1865(a) of the Act to remove a reference to section 1881(b) of the Act, which had prevented

kidney transplant programs from being accredited via CMS-approved accreditation programs. CMS' existing regulations at § 488.4(a)(4), requires that when a national AO has applied for and has received CMS-approval of a provider or supplier accreditation program, then when a provider or supplier demonstrates full compliance with all of the accreditation program requirements of the accrediting organization's CMS-approved accreditation program, the accrediting organization may recommend that CMS grant deemed status to the provider or supplier. Further, the regulation at § 488.4(a)(4) states that " CMS may deem the provider or supplier, excluding kidney transplant centers within a hospital and ESRD facilities, to be in compliance with the applicable Medicare conditions or requirements." The CMS regulatory language of "excluding kidney transplant" programs is therefore in direct conflict with the Bipartisan Budget Act of 2018 amendment. We therefore propose to remove the exclusion specifically in our accreditation regulations under § 488.4(a)(4) to align with the statutory changes implemented the Bipartisan Budget Act of 2018.

V. Request for Information Regarding Timeframes and Expectation for the Submission of AO Applications

We are requesting public comments on the timeframes and expectation for the submission of applications submitted by AOs, because our existing AO oversight regulations do not restrict how many times an AO may submit an initial application to CMS for review. Based on our initial review of an application for completeness, which verifies the AO has submitted all required elements under § 488.5, we often find the application to be incomplete and must return it to the AO for additional clarifications, missing items or revisions. CMS also receives applications, which require multiple pass backs due to the applicant's failure to provide information about issues, such as their financial viability, survey processes which appeared not to be operationalized, or similar concerns. However, our existing regulations do not limit the number of times an AO may submit an application for review by CMS. Therefore, it is possible that incomplete application could be submitted an unlimited number of times.

Therefore, we are soliciting public comments on the following possible future limitations to the submission of applications by the AOs that accredit Medicare-certified providers and suppliers:

- An AO may only re-submit an application for CMS re-review two additional times after CMS initially deems the application to be "incomplete".
- If the AO's application is found by CMS to be incomplete after the third submission, the AO must wait a minimum of 2 years before resubmitting the entire application for CMS consideration.

VI. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including the use of automated collection techniques.

We are soliciting public comment on each of these issues stated in sections III and IV of this proposed rule.

If you comment on these information collections, that is, reporting, recordkeeping or third-party disclosure requirements, please submit your comments electronically as specified in the "ADDRESSES" section of this proposed rule.

Comments must be received on [INSERT DATE 60 DAYS AFTER THE DATE OF PUBLICATION IN THE **FEDERAL REGISTER**].

Wage Data

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2021 National Occupational Employment and Wage Estimates for all salary estimates (http://www.bls.gov/oes/current/oes_nat.htm). In this regard, Table 1 presents the mean hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent of salary), and the adjusted hourly wage.

TABLE 1: U.S. Bureau of Labor Statistics 2021 Wages Rates

BLS Occupation Title	BLS Occupation Code	Mean Hourly Wage	Fringe Benefits and Overhead	Adjusted Hourly Wages
Registered Nurse*	29-1141	$39.78	$39.78	$79.56
Medical or Health Services Manager**	11-9111	$57.61	$57.61	$115.22
Medical Secretaries***	43-6013	$19.11	$19.11	$38.22
General and Operations Managers****	11-1021	$60.45	$60.45	$120.90
Physicians*****	29-1228	$105.22	$105.22	$210.44
Radiologic Technologists******	29-2034	$31.97	$31.97	$63.94
Medical Records and Health Information Technicians*******	29-2071	$23.21	$23.21	$46.42
Chief Executive Officer********	11-1011	$102.41	$102.41	$204.82
Health care Support Occupations*********	31-0000	$16.02	$16.02	$32.04

* https://www.bls.gov/oes/current/oes291141.htm
** https://www.bls.gov/oes/current/oes119111.htm
*** https://www.bls.gov/oes/current/oes436013.htm
**** https://www.bls.gov/oes/current/oes111021.htm
***** https://www.bls.gov/oes/current/oes291228.htm
****** https://www.bls.gov/oes/current/oes292034.htm

******* https://www.bls.gov/oes/current/oes292071.htm
******** https://www.bls.gov/oes/current/oes111011.htm
********* https://www.bls.gov/oes/current/oes310000.htm

A. *ICRs Related to Conflict of Interest Proposals*

In this proposed rule, we made several proposals related to AO and AO surveyor conflicts of interest. We will address the cost and time burden associated with each of these proposals separately below.

1. ICR Related to Proposed Conflict of Interest Policies & Procedures AOs Must Submit to CMS (§ 488.5(a)(10))

We proposed to modify § 488.5(a)(10) to add a requirement that the AOs must provide specific information with their conflict of interest policies and procedures with the application they submit to CMS. Specifically, the AO must submit the following policies and procedures: (1) the AO's policies and procedures for separation of its fee-based consulting services from its accreditation services; (2) policies and procedures for protecting the integrity of the AO's accreditation program, including the requirements of § 488.8(k)(3) policies and procedures for the prevention and handling potential or actual conflicts of interest that could arise from situations in which an AO owner, surveyor, or other employee has a direct interest in or relationship with another survey agency or health care facility to which the AO provides accreditation services, including being employed as a SA surveyor or having an ownership interest in a health care facility, etc., and (4) policies and procedures for notification of CMS when a conflict of interest is discovered.

The AO would need to modify their current conflict of interest policy and procedures to include the above-stated information required under the proposed revisions to § 488.5(a)(10). We estimate that this task would be performed by a team of at least two AO staff members. The AO staff that would most likely perform this task would be a person whose background is a RN or a health or medical services manager. According to the U.S Bureau of Labor statistics, the mean hourly wages for an RN is $39.78. This wage adjusted for the employer's fringe benefits

and overhead would be $79.56. According to the U.S Bureau of Labor statistics, the mean hourly wages for a medical or health services manager is $57.61. This wage adjusted for the employer's fringe benefits and overhead would be $115.22.

We estimate that it would that at least two persons working in a full-time basis for 3 days for the AO staff to revise their conflict of interest policies and procedures to add the required information. Therefore, we estimate that the total time required for the two team members to perform this task would be 48 hours (8 hours x 3 days = 24 hours per each person) +(24 hours per person x 2 persons = 48 hours).

As of February 4, 2020, there are 11 AOs, that accredit Medicare-certified providers and suppliers. We estimate that the total time burden across these 11 AOs would be 528 hours (48 hours x 11 AOs).

We estimate that the cost burden related to the work performed by the RNs on the team would be $1,909.44 (24 hours x $79.56)**.** We estimate that the cost burden related to the work performed by the medical or health services manager on the team would be $2,765.28 (24 hours x $115.22). Finally, we estimate that the total burden costs related to the requirements for proposed § 488.8(i)(1) would be $4,674.72 per AO ($1,909.44 + $2,765.28). The total cost across the 11 AOs that accredit Medicare-certified providers and suppliers is $51,421.92 (11 AOs x $4,674.72).

We believe that the stated burden would be incurred by the AO once prior to the time that they submit their first application after this requirement becomes effective. However, we believe that after the AOs have made required modifications to their conflict of interest policies, they will not have to revise them again, but will submit the same revised conflict of interest policies every 6 years with their renewal applications, so this burden would not be incurred again. We do not count the burden related to the submission of the application because the AO would be required to submit the application every 6 years to renew the CMS approval for their accreditation programs.

2. ICR Related to Requirement that the AOs Submit Surveyor Declarations to CMS on an Annual Basis (§ 488.5(a)(22))

We propose to add a new paragraph (22) to § 488.5(a), which would require that the AO submit a declaration by each surveyor of any outside interests or relationships with the health care facilities that the AO accredits. This section would also require that the surveyor declarations must be updated on an annual basis and submitted to CMS no later than December 31st each year.

There would be a time and cost burden to the AO for having to collect declarations from each of their surveyors annually. There would also be a time and cost burden to the AO for the submission of the surveyor declarations to CMS.

We estimate that it would take at least two persons working on a full-time basis for 3 days (8 hours per day) to prepare the surveyor declarations, get each AO surveyor to complete a declaration and submit them to CMS. This would equate to 24 hours per person or 48 hours across both staff performing this task.

We believe that the AO staff that would be performing these tasks would be an RN and a management staff person, whose job duties meets the description of the U.S. Bureau of Labor Statistics job of category of health and medical services manager. As stated previously, the adjusted mean hourly wage for an RN is $79.56. The adjusted mean hourly wage for a medical and health services manager is $115.22.

We estimate that the time burden for this task per each AO would be 48 hours (24 hours x 2 staff persons). We further estimate that the total time burden across all 11 AOs that accredit Medicare-certified providers and supplier would be 528 hours (48 hours x 11 AOs).

We estimate that the cost burden related to the work performed by the RN would be $1,909.44 (24 hours x $79.56). We estimate that the cost burden related to the work performed by the medical or health services manager would be $2,765.28 (24 hours x $115.22).

Finally, we estimate that the cost burden associated with the requirements for proposed § 488.5(a)(22) per each AO would be $4,674.72 ($1,909.44 + $2,765.28. The total annual cost burden across the 11 AOs that accredit Medicare-certified providers and supplier is estimated to be $51,421.92 (11 AOs X $4,674.72).

3. ICRs Related to Proposal to Place Restrictions on AO Fee-Based Consulting Services Provided by AOs to the Medicare-Certified Providers and Suppliers They Accredit (Proposed § 488.8(i)(1) through (3))

In section IV.B.3 of this proposed rule, we propose restrictions on AO fee-based consulting provided by accrediting organizations or their associated consulting divisions or companies. We believe the proposed regulations at § 488.5(i) would still allow AOs to provide fee-based consulting services to the providers and suppliers they accredit with restrictions that address the conflict of interest issues associated with this service.

This proposal would require the AOs that provide fee-based consulting to modify their fee-based consulting to revise their fee-based consulting business documents, such as their business charter, business documents, employee training information, informational documents that are distributed to prospective clients, and their as policies and procedures.

We believe that the AO staff that would be performing these tasks would be an RN and a management staff person that has a job that meets the U.S. Bureau of Labor Statistics job of category of health and medical services manager. The adjusted mean hourly wage for an RN is $79.56. The adjusted mean hourly wage for a medical and health services manager is $115.22.

We estimate that this proposal would require the above-stated two AO staff member to work on a full-time basis for 1 week (that is, 40 hours per person) to complete the required revisions to the AO's fee-based consulting business documents. Therefore, we estimate that the time burden per each AO for the two AO staff members to perform the required tasks would be 80 hours (2 team members x 40 hours).

At this time, there are only four AOs that provide fee-based consulting. Therefore, the

total annual time burden would be 320 hours (80 hours x 4 AOs).

The cost burden related to the work performed by the RN on this task would be $3,182.40 (40 hours x $79.56). The cost burden related to the work performed by the medical or health services manager on this task would be $4,608.80 (40 hours x $115.22).

Finally, we estimate that the annual cost burden per each AO related to the requirements for proposed § 488.8(i)(1) would be $7,791.20 ($3,182.40 + $4,608.80). We estimate that the total annual cost burden to the four AOs that provide fee-based consulting would be $31,164.80 ($7,791.20 x 4 AOs).

4. ICR Related to Proposed Requirement for Submission of Information About AO Fee-Based Consulting Services Provided (§ 488(i)(5))

We propose to add a requirement at § 488.8(i)(5) that would require the AOs to provide CMS with the following information about the fee-based consulting services they provide to CMS on a bi-annual basis: (1) whether the AO or its fee-based consulting division or separate business entity (such as a company or corporation, that provides fee-based consulting) provides fee-based consulting services; (2) the names and CCN numbers of all health care providers and suppliers to which the accrediting organization or its associated consulting division or company has provided fee-based consulting services during the previous 6-month period; (3) the dates the AO fee-based consulting services were provided to each provider and supplier; (4) whether the accrediting organization has, at any time in the past. provided, or is currently providing accreditation services to each health care provider or supplier listed in said document; (5) for each health care provider and supplier listed in said document, the date of the most recent accreditation survey performed, and the date the next re-accreditation survey is due to be performed; and, (6) a description of the AO fee-based consulting services provided to each health care provider or supplier listed in said document.

This proposed regulation further requires that statement containing the information require by § 488.8(i)(5)(i) through (i)(5)(iv) must be submitted to CMS every 6 months. We

proposed that the document containing this information must be submitted to CMS by no later than 15 days after the end of each calendar bi-annual period which consist of January 1st to June 30th and July 1st (period #1) through December 31st (period #2) each year. This means that the submission deadline for period #1 would be July 15th and the submission deadline for period #2 would be January 15th each year.

We estimate that the burden associated with this proposed requirement would include the time and costs associated with the gathering of the information necessary to prepare the required document, the time required to prepare the document and the time required to send the document to CMS. This burden would occur on a continuing bi-annual basis.

We believe that the burden would be greater for the preparation of the first report. Thereafter, the AOs would have already prepared and formatted this report and would simply have to update the information every 6 months.

We estimate that it would that at least two persons working on a full-time basis for 3 days to prepare and submit the first required statement to be submitted CMS. We further estimate that this team would consist of one RN and one Medical or Health Service Manager. Therefore, we estimate that the total hourly time burden for each team member would be 24 hours (3 days x 8 hours per).

We estimate that the time burden per each AO per for the work performed by the two AO staff members to prepare each report would be 48 hours (2 team members x 8 hours x 3 days). The total annual time burden per each AO would be 96 hours (2 reports x 48 hours).

There are four AOs that provide fee-based consulting. However, we propose that this provision would apply to all 11 AOs that accredit Medicare-certified providers and suppliers because it would require each AO to, at a minimum, respond to question #1 which asks whether the AO or an associated consulting division or company established by the AO provides fee-based consulting services. Those AOs that do not provide fee-based consulting would simply respond in the negative to this question and would not have to provide any further information.

The time and cost burden to the AOs that do not provide fee-based consulting would be negligible because they would send this notice to CMS via email. This task would take an AO staff member less than a minute to complete every 6 months. Therefore, as this task is so minimal, we have not assessed burden for this task for the AOs that do not provide fee-based consulting.

The estimated total annual time burden across all AOs that do provide fee-based consulting would be 384 hours (96 hours per 2 reports annually x 4 AOs). The estimated total time burden across these 11 AOs would be 384 hours (96 hours x 4 AOs).

The cost burden related to the work performed by RNs on the team would be $1,909.44 (24 hours x $79.56 per hour). The cost burden for the work performed by the medical or health services manager would be $2,765.28 per each AO (24 hours x $115.22). The total estimated cost burden per each AO would be $4,674.72. ($1,909.44 + $2,765.28) The total estimated cost burden across the 4 AOs that provide fee-based consulting services would be $18,698.88 ($4,674.72 x 4 AOs).

We believe that the above stated time and cost burdens would be incurred by the AOs that provide fee-based consulting only the first time that they prepare the required document and send it to CMS. We believe that after the AO has prepared their first report, they would have this report in an electronic format on their computers. Therefore, for the second and all subsequent report, we estimate that the related to the preparation and submission of this report would be reduced by at least two-thirds. This means that it would take only one RN a period of 8 hours to prepare the required statement and submit it to CMS. We estimate that the total time burden across the four AOs that provide fee-based consulting, would be 32 hours (8 hours x 4 AOs).

We estimate that the cost burden per each AO related to the work performed by an RN to prepare the second or subsequent report would be $636.48 (8 hours x $79.56). The total cost

burden across the four AOs that provide fee-based consulting would be $2,545.92 ($636.48 x 4 AOs).

We are requesting comments from the public on our estimated burden for this activity and whether the frequency of bi-annual (every six months) is appropriate.

5. ICR Related to Proposed Requirement that Accrediting Organization Establish Fee-Based Consulting Firewall Policies and Procedures (Proposed § 488.8(j))

We propose at § 488.8(j) to require any AO that provides fee-based consulting services or its associated fee-based consulting division or company to have robust, written AO fee-based consulting firewall policies and procedures. These firewall polices and procedure must, at a minimum, include the following provisions: (1) the AO's fee-based consulting services must be provided by a separate division or company from the AO's accreditation division; (2) the AO's fee-based consulting division or separate company must maintain separate staff from that of the AO's accreditation divisions to ensure that the fee-based consulting division staff do not perform AO's accreditation division functions and that the AO's accreditation division staff do not perform fee-based consulting division functions; and, (3) the AO's accreditation staff and surveyors are prohibited from marketing the AO's fee-based consulting services to the AO's accreditation clients.

This proposed requirement would only apply to the AOs that provide fee-based consulting and would require these AOs that establish new fee-based consulting firewall policies or revise their policies and procedures to meet the proposed requirements. It is our understanding, from review of the comments received on the submitted by the AOs in response to the AO Conflict of Interest RFI, that these AOs already have such fee-based consulting firewall policies in place. If this is the case, then the time and cost burden associated with revising these policies and procedures would not be extensive.

In section VI.A.5 of this proposed rule, we estimated that it would take each AOs that provide fee-based consulting services 80 hours to revise their fee-based consulting business

documents, such as their business charter, business documents, employee training information, informational documents that are distributed to prospective clients, and their as policies and procedures.

We have included the burden associated with the revision of AO fee-based consulting firewall policies and procedures. We believe that the burden associated with the revision of the AO's fee-based consulting policies and procedures would fall under the time and cost burden estimated in section VI.A.5 of this proposed rule. As such, we will not assess a separate burden here.

6. ICR Related to Proposed Regulation to Prevent Conflicts of Interest Caused by AO Owners, Surveyors or Other Employees Interest in or Relationship with A Health Care Facility Accredited by the AO (Proposed § 488.8(k))

We propose to avoid conflicts of interest related to employment relationships between AO surveyors and health care facilities that are accredited by the AO, the AO's shall do the following: (1) AOs shall not allow its surveyors to participate in the survey of facilities with which they have a relationship; (2) AOs shall not allow its surveyors to have any input into or influence the outcome of any survey performed for facilities with which they have a relationship; (3) AOs shall not allow its surveyors to have any involvement with the pre or post survey activities for the health care facilities with which they have a relationship; and, (4) AOs shall not allow its surveyors to have any contact with the records from the surveys for any health care facilities with which they have a relationship.

We believe that this in exempt from the PRA in accordance with 5 CFR 1320.3(b)(2). We believe that this should already be a usual and customary practice of the AOs.

B. *ICRs Associated with the Requirement that AOs Incorporate the Medicare Conditions*

1. ICRs Associated with the Requirement that the AOs Provide Detailed Crosswalks Identifying Incorporation of the CMS Standards

As proposed under § 488.5(a)(3), we would require AOs to incorporate the language of the CMS' Medicare conditions and provide CMS with a detailed crosswalk. While AOs are required to provide a similar crosswalk under the existing process, CMS previously only required a "comparable" standard, therefore through this proposal, AOs would need to recreate their AO standards to incorporate the Medicare condition language into their accreditation standards for their deemed programs. We also note that this proposal would require a one-time overhaul of AO standards and burden would be imposed for the first year following the effective date of this rule and not be a reoccurring annual burden. Burden costs subsequent to changes would remain as current practice with updates required to be reviewed and approved as outlined in existing § 488.5.

We would expect that the AOs use the existing CFR language they are required to crosswalk currently and assign an AO standard number or realign their existing AO standards in a manner which would allow for a one-to-one comparison to ensure their accreditation standards incorporate the CFR language. Aforementioned, CMS is not restricting the AOs from exceeding the Medicare conditions, however if exceeded the AO would need to provide additional language or clearly delineate the exceeding language. For example, we would only anticipate that the format used be similar to the one seen in Table 2.

TABLE 2: Example of Proposed Crosswalk

CFR Citation	Medicare conditions Language	AO Standard Number	AO Standards Language
§482.13(h)	Patient visitation rights. A hospital must have written policies and procedures regarding the visitation rights of patients, including those setting forth any clinically necessary or reasonable restriction or limitation that the hospital may need to place on such rights and the reasons for the clinical restriction or limitation.	XX.000	Same as CMS. Patient visitation rights. A hospital must have written policies and procedures regarding the visitation rights of patients, including those setting forth any clinically necessary or reasonable restriction or limitation that the hospital may need to place on such rights and the reasons for the clinical restriction or limitation.
		XX.0001	Exceeds: The hospital must update these written policies on an annual basis with Governing body approval.

We anticipate that the AOs for each program type (that is,hospice, home health, outpatient physical therapy, hospitals, ESRD facilities, RHC, CAH, ASCs, psychiatric hospitals) for which the AO has deeming authority would be required to review and revise their existing crosswalk and standards into the required format. We further anticipate that the review and updating of AO standards crosswalk would be done by AO staff consisting of at least one RNs and a medical secretary.

We estimate that the RN would spend 2 hours performing this task. We further estimate that a medical secretary would spend 198 hours performing this task. Therefore, the total time burden per each AO for this task would be 200 hours. (2 hours per 1 RN + 198 hours per 1 medical secretary).

This requirement applies only to those AOs that accredit Medicare-certified providers and suppliers. There are 11 AOs that accredit Medicare-certified providers and suppliers. Therefore, the total time burden for this task would be 2,200 hours (200 hours x 11 AOs).

The adjusted mean hourly wage for an RN is $79.56. We estimate that the cost for the work performed by the RN to perform the work on this task would be $159.12 (2 hours x $79.56 per hour).

The adjusted mean hourly wage for a medical secretary is $38.22. We estimate that the cost burden for the work performed by the medical secretary on this task would be $7,567.56 (198 hours x $38.22 per hour). The total estimated cost burden for all work performed on this task would be $7,726.68 ($159.12 + $7,567.56).

There are currently 11 AOs that accredit Medicare-certified providers and suppliers. Therefore the annual burden cost for all 11 AOs for one program only would be $84,993.48 ($7,726.68 x 11 AOs).

However, the majority of our AOs have multiple accreditation programs, therefore this cost would increase based on the number of programs. For example, one of the AOs has

deeming authority for six program types, therefore this AO would be subject to a burden cost of $46,360.08 ($7,726.68 x 6 programs).

CMS has 24 approved accreditation programs across 11 AOs (as of February 15, 2022) which are accredited, and so the total cost across all AOs and their programs would be $185,440.32 ($7,726.68 x 24).

2. ICRs Related to AO Providing Their New Accreditation Standards to Their Accredited Providers and Suppliers.

In addition to changing the survey standards as proposed under § 488.5(a)(3), the AOs would be required to provide the newly revised AO standards to the facilities they accredit. There are approximately 14,904 accredited facilities across the program types. We anticipate that a Medical Secretary (see Table 1 in section VI of this proposed rule for wage estimates) would provide all accredited facilities a copy of the revised standards for accreditation. We believe that the majority of AOs have a website portal which standards are available to their facilities, therefore we anticipate the estimated time to upload and notify facilities of the revisions to take 2 hours per program type. Between the 11 AOs we have 24 programs which are accredited.

As noted above, we estimate that this task would take approximately 2 hours to complete per each program. We also estimate that the total burden hours for this task would be 48 hours (2 hours x 24 programs).

We estimate that the cost burden per each program would be $76.22 ($38.22 x 2 hours). We further estimate that the total cost associated with uploading the AOs revised standards across the 24 accreditation programs would be $1,829.28 ($76.22 x 24 AO programs).

In addition, we believe the AOs would also notify their individual facilities impacted. We believe this would be done by an AO staff person with a job that falls under the U.S. Bureau of Labor Statistics job category of medical secretary. The adjusted mean hourly wage for a medical secretary is $38.22.

We estimate this task would take 15 minutes per each facility notified. There are 14,904 facilities that must be notified. Therefore, the total time required to notify all of these facilities would be 3,726 hours (.25 hours x 14,904 facilities).

We estimate that the annual cost burden per each AO for notifying the facility would be $9.55 per each facility (60 minutes divided by 15 minutes = 4) and ($38.22 divided by 4 = $9.55). We estimate that the total annual cost across all of these facilities would be $142,333.20 ($9.55 x 14, 904 facilities).

3. ICRs Related to Education to Providers and Suppliers Regarding New Standards

We believe the AOs would be required to provide education to their deemed facilities related to the new standards (standards incorporating the CMS Medicare condition language). As part of this education, the AOs would provide an overview of the changes in the AOs accreditation standards to the healthcare facilities accredited by the AO. We further believe that the regulations to persons from the health care facility that would take this training would be staff such as a regulatory compliance specialist (general manager) at the health care facilities the AO accredits. We further believe the AO would generally send an education specialist or RN to provide this overview of the revised standards, or have an online platform of training for the facilities to use.

The adjusted mean hourly wage for a general and operations manager is $60.45. This wage adjusted for the employer's fringe benefits and overhead would be $120.90 (see Table 1). According to the U.S Bureau of Labor Statistics, the mean hourly wage for a RN is $39.78. This wage adjusted for the employer's fringe benefits and overhead would be $79.56 (see Table 1).

We anticipate that the training to be provided by the AOs about the new regulations would take approximately 1 hour to complete. We believe that each facility would send at least two persons to this training. We believe that the persons that would be likely to attend this training would be a general or services operation manager at the facility and an RN, who is a regulatory compliance manager.

There are approximately 14,904 deemed facilities. Therefore, we estimate that the total time burden to each health care facility for the completion of the AO training would be 2 hours. The total estimated time burden for the accredited facilities would be 29,808 hours (2 hours x 14,904 facilities).

We estimate that the cost burden for the time spent for the RN to attend the training would be $79.56. RN (1 hour x $79.56 per hour). We further estimate that the cost burden for the general or services manager from the facility to attend the training would be $120.90 (1 hour x $120.90 per hour). We estimate that the total cost burden per each accredited facility for the completion of this training by the two facility staff persons would be $200.46 ($79.56 per RN + $120.90 per general or services manager). We further estimate that the total annual cost burden across all 14,904 accredited facilities would be $2,987,655.84 ($200.46 x 14,904 facilities).

The burden associated with these requirements will be submitted to OMB under OMB control number (0938-NEW).

C. *ICRs Associated With the Requirement that AOs Use Survey Processes that are Comparable to That Used by CMS and the SAs*

Our proposal to § 488.5(a)(4) through (13), would require the AOs to submit revised initial and renewal application information supporting comparability in the survey processes and guidance established by CMS and used by the SA. However, we note that while additional regulatory language changes are being made under § 488.5(a)(4) through (13), AOs are already required to submit this type of documentation. Our intent is to clarify in regulation the minimum standards and required documentation that AOs show comparability to CMS survey process, forms, guidelines and instructions to surveyors.

1. ICR Related to Revised Documentation Submission Requirements Imposed by Requirements that AOs Use Comparable Survey Process at § 488.5(a)(4), § 488.5(a)(4)(iii), § 488.5(a)(4)(v), and § 488.5(a)(4)(vii)

The requirements under(§ 488.5(a)(4), § 488.5(a)(4)(iii), § 488.5(a)(4)(v), and § 488.5(a)(4)(vii)) would require AOs to ensure that with the submission for an initial or renewal application for deeming authority, in addition to what is required in the existing regulations, that the AO includes: (1) core principals of the survey process; (2) comparable survey guidance and instructions, including specific processes for certain survey activities; and, (3) description of the organizations survey review process, including the accreditation decisions and investigative and organizational processes used to make determinations of non-compliance. We do however note, that the AOs are already required to submit the documentation and that most AOs provide this within their applications, therefore we do not believe this imposes any additional burden on the AOs, as this has been a long-standing expectation as described in the preamble of this proposed rule and the 2015 AO Final Rule, (80 FR 29795, May 22, 2015), which stated that while the explicit reference to the SOM was removed, "this will not change our practice of assessing comparability in light of the SOM survey process requirements for Sas, which implement survey process requirements found in parts 488 and 489 of our regulations governing certification and provider agreements. Therefore, we believe no additional burden is imposed through these proposed provisions.

2. ICR Related to Revised Documentation Submission Requirements Imposed by Requirements that AOs Use Comparable Survey Process at § 488.5(a)(5), § 488.5(a)(6), and § 488.5(a)(12)).

As described above related to the clarified and strengthened proposed requirements under § 488.5(a)(4), § 488.5(a)(4)(iii), § 488.5(a)(4)(v), and § 488.5(a)(4)(vii), we further propose to require additional information under § 488.5(a)(5), § 488.5(a)(6), and § 488.5(a)(12). As also mentioned above, we believe that the AOs currently submit this information with their initial and renewal applications, however by codifying the requirements within regulation, we are clarifying the requirements which are instrumental to maintaining the integrity of the survey process, whether conducted by the SA or the AO. Therefore, we do not believe these clarifications to

what our expectations are within regard to the survey process documentation would impose any additional burden on the AOs.

3. ICR Related to Revised Documentation Submission Requirements Imposed by Requirements that AOs Use Comparable Survey Process at § 488.5(a)(13)

The proposed requirements under § 488.5(a)(13) would require AOs to submit specific information on the AOs' notification procedures, including timeframes for notification, to CMS in regards to a facility which the AO accredits if the facility fails to meet accreditation standards or its accreditation status is affected, as part of the documentation currently required under § 488.5(a)(13). Furthermore, the existing requirements currently require the AOs to have: (1) procedures for responding and investigating complaints; and (2) a process for decision-making as it relates to accrediting status. In addition to the above added proposed requirement, we also propose to add that AOs must submit documentation regarding the AO's process for facilities that withdraw from accreditation, including notification procedures.

We believe this review and revision would be conducted by a one RN, one general health care support member, one medical secretary and the CEO to develop these procedures, review and approve all changes. The adjusted mean hourly wage for an RN is $79.56. The adjusted mean hourly wage for a health care support staff person is $32.04. The adjusted mean hourly wage for a medical secretary is $38.22. The adjusted mean hourly wage for a CEO is $204.82.

We anticipate it would take approximately 5 hours for the AO staff to review the new requirements set forth in the final rule and to determine what changes need to be made to their standards, policies and procedures. We also estimate that it would take an additional 5 hours for the AO staff to make the revisions required to align their accreditation standards and policies and procedures with our proposed revisions. Therefore, the total estimated time burden per each AO would be 10 hours.

This requirement applies to the 11 AOs (as of February 15, 2022) that accredit Medicare-certified providers and suppliers. Therefore, the total time burden across these 11 AOs would be 110 hours (10 hours x 11 AOs).

As stated above, we believe that the AO staff that would perform this task would consist of an RN, a health care support staff person, a medical secretary and the AO's CEO to review and approve all changes. We estimated that the cost burden for the work performed by the RN would be $198.90 (2.5 hours x $79.56 per hour). We estimate that the cost burden for the work performed by the health care support staff person would be $80.10 (2.5 hours x $32.04). We estimate that the cost burden for the work performed by the medical secretary would be $95.55 (2.5 hours x $38.22). We estimate that the cost burden for the work performed by the CEO would be $512.05 (2.5 hours x $204.82).

We estimate that the total cost burden per each AO for this task would be $886.60 ($198.90 + $80.10 + $95.55 +$512.05). The burden across the 11 AOs that accredit Medicare-certified providers and suppliers would be $9,752.60 ($886.60 x 11 AOs).

4. ICR Associated with the Requirement that the AOs Prepare a Training for CMS About its Revised Survey Process (Proposed § 488.5(a)(4)(xi))

The proposed requirement at § 488.5(a)(4)(xi) would require the AOs to submit a presentation or web-based training materials to CMS, in a format to be chosen at the discretion of the AO, which would provide CMS with an overview of the AOs survey process and demonstrate how the AO's survey process is comparable to that of CMS. We would require the AOs to provide this presentation to CMS prior to the performance of any direct observation surveys as provided for at § 488.8(h).

As the AOs currently have existing training for its surveyors on the survey process, we believe that the preparation of this presentation would only require the AOs to extrapolate what they believed are the core differences within CMS survey process and that of their organization.

We believe it would take approximately 5 hours for the review of the current AO processes and approximately 25 hours to develop an abbreviated course of their survey processes for their accredited programs. We believe that the persons at the AO who would perform these tasks would be two RNs and a medical secretary. We estimate that each RN would spend approximately 25 hours performing the required work. We further estimate that the medical secretary would spend 5 hours performing work on this task. The adjusted mean hourly wage for an RN is $79.56. The adjusted mean hourly wage for a medical secretary is $38.22.

We estimate that the total time burden per each AO would be 55 hours. This provision would apply to all 11 AOs that accredit Medicare-certified providers and suppliers. Therefore, the estimated total annual time burden for these tasks would be 605 hours (55 hours x 11 AOs)

We estimate that the cost burden to each AO for the work performed by the RNs would be $3,978 ($79.56 x 50 hours). We further estimate that the cost burden to each AO for the work performed by the medical secretary would be $191.10 ($38.22 x 5 hours). The total estimated cost burden per each AO for this task would be $4,169.10 ($3,978 + $191.10).

This requirement would apply to all 11 AOs that accredit Medicare-certified providers and suppliers. Therefore, we estimate that the total cost would be $45,860.10 ($4,169.10 x 11).

Across these 11 AOs there are 24 different types of accreditation programs. We estimate that the burden associated with this task would be $100,058.40 ($4,169.10 x 24 accreditation programs).

5. ICR Related to Requirement for AO to Submit Survey Findings/Reports

As mentioned in section IV.C of this proposed rule, we also propose to require the AOs as part of their application under § 488.5(a)(4)(viii) to acknowledge that it will submit any requested survey findings and reports, to include complaint survey reports to CMS for internal use.

This requirement would not cause the AOs to incur any new additional burden as the submission of this information is already required by this regulation and is therefore a usual and

customary component of initial and renewal applications. AOs are also already required to submit the deficiencies and facility non-compliance in a roll up format. Therefore, this proposed requirement for a full survey report could potentially be seen as a burden reduction as CMS would not require a specific new entry or format and reduce time spent by the AO summarizing the survey activity.

6. ICR Related to Documentation Requirements for Submission to CMS for Approval of the AOs' Revised Accreditation Standards and Survey Process as required by § 488.8(b)

The AOs would be required to resubmit their new survey processes and standards for a comparability review as required by § 488.8(b)(1).

We believe that the AO staff that would work on this task would be a medical secretary We believe that the medical secretary would gather all required documents, complete the compilation of documents and verification. The adjusted mean hourly wage for a medical secretary is $38.22.

We anticipate the total burden hours for each AOs to compile each accrediting program and the revisions as proposed within § 488.4(a)(1) and § 488.4(a)(2) for a resubmission to CMS for review and approval would be 80 hours.

This requirement would apply to the 11 AOs that accredit Medicare-certified providers and suppliers. Therefore, we estimate that the total annual would be 880 hours (80 hours x 11 AOs).

The total estimated cost burden for each AO is $3,057.60 (80 hours x $38.22). The total annual cost burden s is $33,633.60 ($3,057.60 x 11 AOs).

There are 24 accreditation programs across the 11 AOs that accredit Medicare-certified providers and suppliers. We estimate that the total annual cost burden across all 24 accreditation programs would be $73,382.40 ($3,057.60 x 24 accredited programs).

As mentioned in section IV.C of this proposed rule, the proposed changes would not implement a reoccuring annual burden, but rather have a one-time burden on the AOs until the

survey processes and activities are aligned with our proposed changes. CMS would resume the current process for approval and re-approval of AOs and their accrediting programs as outlined within the revised proposed § 488.5.

We note, there is no direct burden associated with these changes to the deemed provider or supplier, and there is no cost burden or reporting burden associated with the proposed addition of the definition of unannounced under § 488.1.

D. *ICR Related to Requirement that the AO Surveyors Take the CMS Online Surveyor Training*

We proposed at § 488.5(a)(8), to add a new requirement that would require AOs to state in their application for CMS approval, that all AO surveyors have completed or will complete two CMS mandatory documentation courses and the relevant program specific CMS online trainings established for SA surveyors, initially, and thereafter.

There are a total of 163 online training programs that are available to SA surveyors on the CMS QSEP website. These courses are self-paced and the person taking the course can take the courses over a period of time. The amount of time required to complete each of these training course varies depending on the pace at which the surveyor completes the training. The basic surveyor training courses for specific programs range in time from 16-82 hours for completion. We estimate the average time it takes for completion of one of the basic surveyor courses is 27 hours. This could be more or less depending upon the specific program that AO surveyors need to take.

We propose that each AO surveyor take the two mandatory documentation courses (that is "Principles of Documentation for Non-Long-Term Care" and "Basic Writing Skills for Surveyor Staff") and the basic surveyor course for the care setting for which they perform surveys. We further estimate that it would take approximately 4 hours to complete each of the documentation courses, however, these courses are self-paced and could take less or longer. Therefore, an AO surveyor would incur a time burden of approximately 35 hours for the completion of these CMS surveyor training courses (27 hours for the basic surveyor course +

4 hours for “Principles of Documentation for Non-Long-Term Care” course + 4 hours for “Basic Writing Skills for Surveyor Staff” course).

Each AO had different numbers of surveyors, depending on its size and the number of accreditation programs it has. Therefore, for the purposes of this burden estimate, we will estimate that each AO has an average of 75 surveyors. This would equate to an estimated time burden to each AO associated with this requirement would be 2,625 hours. (35 hours x 75 surveyors).

As of February 15, 2022, there are 11 AOs that accredit Medicare-certified providers and suppliers. We estimate that the time burden across all of these AOs associated with the requirement that their surveyors take the CMS online surveyor training would be 28,875 hours (2,625 hours x 11 AOs).

The adjusted mean hourly wage for an RN is $79.56. We estimate that each AO would incur wages in the amount of $2,784.60 per each surveyor that completes the CMS online surveyor training (35 hours x $79.56). Each AO would incur a total cost burden in the amount of $208.845 for all 75 surveyors that take the CMS online surveyor training (75 surveyors x $2,784.60)

The estimated cost burden across all AOs (that accredits Medicare-certified providers and supplies) associated with this requirement would be $2,297,295. ($208.845 x 11 AOs). The burden associated with this requirement will be submitted to OMB under OMB control number 0938-NEW.

E. *ICR Associated with the Establishment of a Definition for “National in Scope”*

As proposed at § 488.1, we would require the AO to provide documentation for meeting the definition of “national in scope” within their initial and reapplication process. As currently required by § 488.1, the AO must provide documentation that demonstrates the organization meets the definition of a “national accrediting organization” as it relates to the accreditation

program. Therefore, we estimate the burden on AOs to be minimal as they are already required to provide documentation to this effect. Therefore, we estimate the following:

1. ICR Related to Documentation Requirements for "National in Scope"

We anticipate that a CEO of an AO would compile and verify that the AO meets the proposed definition of "national in scope".

Since CMS is not requiring a specific format for this documentation, but suggests the AO provide a list which identifies the accredited facilities meeting the definition, we anticipate the compiling of this information would take approximately 40 minutes (0.66 hour) per each AO. For existing CMS approved AOs, the general re-application cycle is not to exceed 6 years. Therefore, we anticipate this burden to be applicable every 4 to 6 years. Therefore, we estimate that the total time burden across all 11 AOs would be 7.33 hours (or 7 hours & 20 minutes) every 4 to 6 years.

The average hourly wage of the AOs CEO is $204.82. Therefore, we estimate that the total cost burden for this task per each AO would be is $136.52 ($204.82 divided by 60 minutes = $3.413 per min.) and ($3.413 x 40 min. = $136.52 per 40 min.)). We further estimate that the total cost burden across the 11 AOs that accredit Medicare-certified providers and suppliers would be $1,501.72 ($136.52 x 11 AOs).

2. ICR Related to Incorporation of the "National in Scope" Requirements into the AO's Application

We anticipate that a medical secretary would finalize and package/send the application for CMS approval.

We believe this additional document of meeting "national in scope" would take approximately 5 minutes (0.083 hours) per each AO to be included in the package which is already required under § 488.5. This requirement would apply only to the 11 AOs that accredit Medicare-certified providers and suppliers. We estimate that the total time burden associated

with this task across these 11 AOs would be 55 minutes (0.91 hour) (5 minutes per each AO x 11 AOs).

The adjusted mean hourly wage for a medical secretary is $38.22. Therefore, we estimate that the cost burden per each AO for this task would be $3.18 (5 minutes (0.083 hour) x $38.22). We further estimate that the total cost burden would be $35.03 ($38.22 / 60 min. per hour = $0.637 per min.) and ($0.637 per min. x 55 min. = $35.03 per 55 min.) or ($3.185 x 11 AOs = $35.03).

We would anticipate that this burden would be imposed to ensure AOs submit verification of meeting the new definition. However, this burden would only be incurred by the AOs during the submission of their initial or renewal applications which would only take place every 4 to 6 years. The burden associated with these requirements will be submitted to OMB under OMB control number 0938-NEW.

We do note, there is no direct burden associated with these changes to the deemed provider or supplier.

F. *ICR Associated with the Proposed Revision of the AO Performance Measures and to Require a Publically Reportable Plan of Correction*

SAs perform validation surveys on a sample of providers and suppliers (such as hospitals, CAHs, ASCs, and HHAs) accredited by the AOs. Validation surveys compare the survey findings of the AO to those of the SA to see if there are any disparities. The disparities found between an AO's surveys and an SA's surveys is used in a performance measure called the "disparity rate" and is tracked by CMS as an indication of the quality of the surveys performed by the AO as described earlier in this proposed rule.

We proposed to revise the validation process for Medicare-certified providers and suppliers by adding a new type of validation survey know as direct observation validation survey. As a result of the revisions made to the validation process, we have necessarily been

required to propose a new two-part definition for "disparity rate" to revise the definition of disparity rate.

At § 488.8(a)(4), we propose that the AO submit a publicly reportable plan of correction for performance that is less than an acceptable threshold for established performance measures.

This is a new requirement and therefore would be a new burden for AOs to complete. The plan of correction will be completed and submitted to CMS within 10-business days following the notification of the AO of their less than acceptable performance. It will address the areas of improvement and the specific actions to be taken to improve those areas on a sustainable basis, the process for ongoing monitoring of progress of the toward acceptable performance, as well as the individuals responsible for overseeing the plan of correction and the anticipated implementation dates of the proposed actions.

We believe that this task would be performed by the AO's CEO. We also anticipate that each AO would prepare approximately 123 plans of correction per year. We further estimate that it would take 80 hours of time by the AO's CEO to prepare each plan of correction. This is using the overall average disparity rate of 33 percent. There are approximately 374 annual validation surveys performed across all provider types (374 x 0.33 total plans of correction). We further estimarte that the total annual time burden per each AO for the completion of POCs would be 9,840 hours (80 hours x 123). We further estimate that the total annual time burden for the completion of all POCs across all 11 AOs that accredit Medicare-certified providers and suppliers would be 108,240 hours (9,840 hours x 11 AOs).

We estimate that the cost burden to each AO for the completion of each POC would be $16,385.60 (80 hours x $204.82) We further estimate that the annual cost burden per each AO for the completion of the estimated 123 POCs per year would be $2,015,428.80 (9,840 hours x $204.82). We further estimate that the total annual cost burden across all 11 AOs that accredit Medicare-certified providers and suppliers for the completion of all POCs annually would be $22,169,716.80 ($2,015,428.80 x 11 AOs.

G. *ICR Associated with the Revision of the Definition of "Disparity Rate"*

In the proposal for the definition of disparity rate as dicussed in section IV.I of this proposed rule, there is no associated burden as look-back validation surveys are a usual and customary part of the existing validations program. Direct observation validation surveys are already being performed under current regulatory authority § 488.8(a)(2) and are a usual and customary part of the VRP. AO will continue to perform survey activities as required, the revised and expanded definition of disparity would impact data collection by CMS, but no additional burden to the AO or provider.

H. *Burden Reduction Associated with the Revision of the AO Validation Program*

At § 488.9, we propose to revise the AO validation program to include the additional component of a direct observation of the AO's survey process by SA or CMS surveyors. This would be called a direct observation validation survey. There is no associated burden to the AO or SA. Currently, CMS funds validation surveys. We do not anticipate additional costs.

However, there are associated burden reductions to the provider community since half of the traditional validation survey will be replaced by direct observation validation surveys. To determine the amount of burden reduction on the provider community, it would be assumed that providers undergoing a traditoinal validation survey assign facility liaison staff to accompany and assist SA surveyors during their on-site validation survey. We believe that this task would be performed by RNs and other medical administrative staff. We estimate that the time burden for this task would be 8 hours per day for an average of 3 days. Therefore, we estimate that the time burden per each direct observation surveys would be 24 hours.

We anticipate a burden reduction based on our proposed changes because the implementation of the direct observation validation surveys would decrease the number of look-back validation validation surveys to be performed by at least 50 percent.

The anticipated annual burden reduction calcualtions are based on our FY 2019 look-back validation survey data collection. In FY 2019, we conducted approximately 315 surveys.

We estimate that at least a 50 percent reduction in the look-back validation surveys would reduce the provider and supplier burden by 144 hours per survey (3 days x 8 hours x 6 liaison staff) for a total of 25,920 hours (144 hours x 180 look-back validation surveys) across all programs that receive validation surveys. This figure assumes on average a look-back validation on-site survey of 3 days with three SA surveyors and a total of six provider facility staff as provider liaisons. Total annual burden reduction to providers and supplier nationwide would be -$2,062,195.20 (25,920 hours X $79.56).

I. *ICR Associated with the Revision of the Psychiatric Hospital Accreditation Process*

As discussed in section IV.L of this proposed rule, we propose to require AOs which have a CMS-approved hospital accreditation program to expand their programs to include the three special conditions for psychiatric hospitals and provide CMS with a detailed crosswalk which identifies the inclusion of the psychiatric standards that meet or exceed CMS psychiatric Medicare conditions. While these AOs already have approved hospital programs, we note that this proposal would require a one-time overhaul of the AO's hospital program standards to be expanded to include the psychiatric standards and burden would be imposed for the first year following the effective date of this rule and not be a reoccurring annual burden. Burden costs subsequent to changes would remain as current practice with updates required to be reviewed and approved as outlined in existing § 488.5. As proposed in multiple sections of this proposed rule, we propose to require the AOs to use Medicare conditions, more comparable survey processes through clarifications of what CMS considers "core survey processes" with the ability to delineate where they exceed and take the CMS online surveyor training courses. Therefore, we believe burden would be minimal and most of the burden would be in areas in which the AO would "exceed" Medicare requirements.

As of December 7, 2022, there are four CMS-approved AOs which have established hospital accreditation programs. Two of these four AOs already have an established CMS approved psychiatric accreditation program.

We anticipate that this requirement would be of moderate burden for AOs, however we anticipate the burden to be a one-time burden for two of four hospital AOs, because two of these AOs already have a CMS-approved psychiatric accreditation program and, therefore, would not be required to submit a new application to CMS. This requirement would be part of the initial and renewal application process as defined in § 488.5, therefore would not impose annual reoccurring burden to any AOs initially applying or reapplying. We would expect that the AOs use the existing CFR language they are required to crosswalk currently in the regular hospital program and expand it to assign an AO standard number to the psychiatric standards with language which meets or exceeds the Medicare conditions.

1. ICR Associated With the Requirement That AOs Develop a Psychiatric Hospital Accreditation Program

We anticipate that the AOs would be required to review and revise their existing hospital program crosswalk and standards to include the psychiatric standards. We believe this review and revision would be conducted by a cadre of AO professionals consisting of two RNs, one physician, one medical secretary and the CEO to review and approve all changes.

We believe the two RNs would develop the initial psychiatric standards incorporated under the AOs hospital program. We estimate that this task would take approximately 150 hours to complete. The adjusted mean hourly wage for an RN is $79.56.

We believe the AO's CEO would review and approve the revised standards and that this task would take approximately 45 hours. The adjusted mean hourly wage for a CEO is $204.82.

We believe the medical secretary would process the AO's revised application and send it to CMS. We estimate that this task would take 5 hours. The adjusted mean hourly wage for a medical secretary is $38.22.

We estimate that the time burden for each AO would be 200 hours (150 hours for the two RNs + 45 hours by the CEO and 5 hours by the medical secretary).

There are currently three AOs that would need to revise their hospital programs to

incorporate the three psychiatric special standards. We estimate that the total time burden across these three AOs would be 600 hours (200 hours x 3 AOs).

We estimate that the cost burden for the work performed by the RNs would be $11,934 ($79.56 x 150 hours), the CEO would be $9,216.90 ($204.82 x 45 hours), the medical secretary would be $191.10 ($38.22 x 5 hours). Therefore, the total estimated cost burden per AO for these tasks would be $21,342 ($11,934 + $9,216.90 + $191.10).

We further estimate that the total cost burden across the three AOs which would need to revise their hospital programs to incorporate the three psychiatric special standards into their hospital accreditation programs would be $64,026 ($21,342 x 3 AOs).

2. ICR Associated With Accrediting Facilities under the Revised Psychiatric Hospital Accreditation Program

As aforementioned, there are four existing AOs which have a CMS approved hospital accreditation program; however, two of four AOs would need to resubmit their applications for CMS-approval based on the proposed provisions for the psychiatric standards as well as meeting the definition and criteria of national in scope. The scope of the CMS approved hospital programs would not change with this proposed expansion of the program to include the psychiatric special conditions. Once the hospital program is approved as national in scope, the addition of the three special conditions does not change the overall scope of the entire program. Therefore, there would be no additional burden associated with this requirement.

J. *Burden Associated with Limitations to Terminated Providers Seeking Re-Enrollment and Certification in Medicare/Medicaid Programs*

We propose to add a new policy at § 488.4(b) which would withdraw CMS recognition of the "deeming authority" accreditation of any Medicare certified provider or supplier that is involuntarily terminated from the Medicare/Medicaid program, if such provider/supplier subsequently applies to re-enter the Medicare program. We also propose adding a new requirement at § 488.4(b)(2) that would require a terminated provider or supplier to have to meet

all of the requirements of § 489.57 before a new agreement with that provider or supplier into the Medicare program will be approved.

In support of proposed § 488.4(b), we also propose to add a new requirement at § 488.5(a)(21) that would require AOs to provide, with their initial and subsequent renewal applications, a statement certifying that, in response to a written notice from CMS notifying the AO that one of its accredited providers or suppliers has been terminated from the Medicare/Medicaid program, the AO agrees to terminate or revoke its accreditation of the terminated provider or supplier within 5-business days from receipt of said written notice.

We have also made revisions and added proposed new requirements at § 489.57(b) that would require a terminated provider or supplier to meet the requirements set forth at §§ 489.57(b)(1) to (b)(3) before their new agreement for Medicare participation will be approved.

Proposed new § 489.57(b)(1) would require that a terminated provider or supplier must be under the exclusive oversight of the SA for the purpose of the initial survey, certification and demonstration of compliance with the Medicare conditions before their new agreement for Medicare participation can be approved. Proposed new § 489.57(b)(2) would require that the previously terminated provider or supplier must remain under the exclusive oversight of the SA until the SA or the applicable CMS Location (formerly called CMS Regional Office) has performed a reasonable assurance survey, determined that the terminated provider or supplier has corrected the deficiencies that caused the termination and that they are unlikely to recur and has certified its full compliance with all applicable Medicare conditions. The previously terminated provider's or supplier's new agreement for participation in the Medicare/Medicaid program may not be approved until such certification has been provided by the SA or CMS Location. Finally, our proposal at new § 489.57(b)(3) would require that during the time period in which the terminated provider or supplier is under the exclusive oversight of the SA and while the new agreement for Medicare participation is pending, CMS will not accept or recognize accreditation

from a CMS-approved accrediting organization.

We believe that there would be no additional cost or time burden associated these proposed requirements for several reasons. First, the terminated providers and suppliers would have to undergo periodic, unannounced surveys performed by the SA or CMS. We believe that this is exempt from the PRA in accordance with 5 CFR 1320.3(b)(2) because these surveys are a usual and customary practice of accreditation. Therefore, the terminated provider or supplier would incur no additional time or cost burden related to the SA survey process.

Also, considering that as a result of the above-stated proposals, CMS would not recognize deeming accreditation from an AO while a provider or supplier is terminated from the Medicare program, the AOs would be required to terminate or revoke accreditation for terminated providers and suppliers; and that during the time that a new agreement for Medicare participation is pending, would be under the exclusive oversight of the SA, they would not incur any fees for SA's services. If they remained accredited by the AO, they would pay fees for this accreditation.

In addition, all prospective providers and suppliers, including those that were terminated and seeking re-entry into the Medicare/Medicaid program are already required to submit an initial Form CMS-855 provider enrollment application to CMS. The provider or supplier would therefore not incur any new time or cost burden related to the submission of this application. The burden associated with all requirements stated above will be submitted to OMB for approval under OMB control number (0938-NEW).

K. *Summary of Estimated Burden*

The Table 3 provides a summary of the estimated burden related to the proposals being made in this proposed rule.

TABLE 3: Summary of Cost Burden

Time & Cost Burden Summary Table		
Name of Proposal	**Time Burden**	**Cost Burden**
A. Conflict of Interest Proposals		
1. Requirement that the AOs provide information about the fee-based consulting services they provide. (§ 488.5(a)(10))	• 48 hours per each AO • 528 hours across 11 AOs	• $4,674.72 per each AO for 1st report • $51,421.92 across all 11 AOs
2. Requirement that AO surveyors submit conflict of interest declarations to CMS on an annual basis (§ 488.5(a)(22))	• 48 hours per each AO • 528 hours across 11 AOs	• $4,674.72 per each AO • $51,421.92 across all 11 AOs
3. Restrictions on AO fee-based consulting services (§ 488.8(i))	• 80 hours per each AO • 320 hours across 4 AOs that provide fee-based consulting	• $7,791.20 per each AO • $31,164.80 across the 4 AOs that provide fee-based consulting.
4. Submission about information about the fee-based consulting provided by the AO	• 96 hours per each of the 4 AOs that provide fee-based consulting for the 1st year of annual reports • 384 hours across the 4 AOs that provide fee-based consulting for 1st set of annual reports • 48 hours per each AO for 2nd yearly reports & all subsequent yearly reports • 192 hours per each AO for 2nd year & all subsequent yearly reports	• $4,674.72 per each AO for 1st report • $18,698.88 across the all 4 AOs that provide fee-based consulting for 1st report • $636.48 per AO for the 2nd yearly reports & all subsequent yearly reports • $2,545.92 across the all 4 AOs that provide fee-based consulting for the 2nd yearly reports & all subsequent yearly reports
5. Requirement that Accrediting Organization Establish Fee-Based Consulting Firewall Policies and Procedures (Proposed § 488.8(j))	• 0 hours (The time burden associated with this requirement is included with burden calculation for proposed 488.8(i) above)	• $0 (The cost burden associated with this requirement is included with burden calculation for proposed 488.8(i) above)
6. Requirement to Prevent Conflicts of Interest Caused By AO Surveyor Relationship with A Health Care Facility Accredited by the AO (Proposed § 488.8(k))	• 0 hours	• $0 – because this should be a usual and customary practice of the AOs.
B. Requirement that the AO Incorporate the CMS standards to ensure improved evaluation of AO performance 1. Requirement that the AOs provide a detailed crosswalk identifying equivalent standards	• 200 hours per each AO • 2,200 hours across the 11 AO that accredit Medicare-certified providers & suppliers	• $7,726.68 per each AO • $84,993.48 • across the 11 AOs that accredit Medicare-certified providers & suppliers$185,440.32 across 24 accreditation programs
2. Burden related to AO providing copies of their revised accreditation standards to their accredited providers and suppliers	• 1-hour training per each health care facility personnel • 2 hours per each accreditation program type • 48 hours across all 24 program types	• $76.22 per each accreditation program • $1,829.28 across all 24 accreditation programs

Time & Cost Burden Summary Table		
Name of Proposal	**Time Burden**	**Cost Burden**
3. Burden to AO related to providing notice to the accredited providers and suppliers impacted	• 0.25 hour per each facility • 3,726 hours across all 14,904 facilities	• $9.55 per each facility • $142,333.20 across all 14,904 facilities
4. Burden to providers and suppliers related to taking education about the AOs revised accreditation standards	• 2 hours across each facility • 29,808 hours across all 14,904 facilities	• $200.46 per facility • $2,987,655.84 across all 14,904 facilities
C. <u>Burden Related to Requirement that AOs Must Use Comparable Survey Processes to That Used by CMS and the SAs</u> 1. Burden associated with requirement that AOs must submit documentation about their survey processes as required by § 488.5(a)(4), § 488.5(a)(4)(iii), § 488.5(a)(4)(v), and § 488.5(a)(4)(vii).	• 0 hours	• $0 – because the AOs are already required to submit this information
2. Burden associated with new documentation requirements created by requirement that AOs must use a comparable survey process (§ 488.5(a)(5), § 488.5(a)(6), and § 488.5(a)(12))	• 0 hours	• $0 – because the AOs are already required to submit this information
3. Burden Related to Documentation Requirements Imposed By Requirement that AOs Use Comparable Survey Process (§ 488.5(a)(13) ICR Related to Requirement for AO to Submit Survey Findings/Reports)	• 10 hours per each AO • 110 hours across the 11 AOs that accredit Medicare-certified providers & suppliers	• $886.60 per each AO • $9,752.60 across 11 AOs
4. Burden associated with the preparation of a presentation that AOs must prepare and provide to CMS to demonstrate how their survey processes are comparable to that of CMS	• 55 hours per each AO • 605 hours across the 11 AOs that accredit Medicare-certified providers & suppliers	• $4,169.10 per each AO • $45,860.10 across 11 AOs • $100,058 across all 24 accreditation program types
5. ICR Related to Requirement for AO to Submit Survey Findings/Reports	• 0 hours	• $0 – because the AOs are already required to do this.
6. Burden Related to Submission of Revised Accreditation Standards and Survey Processes for review and approval by CMS as required by § 488.8(b)	• 80 hours per each accreditation program type • 880 hours across the 11 AOs that accredit Medicare-certified providers and suppliers • 1,920 hours across the 24 accreditation program types	• $3,057.60 per each accreditation program type • $33,633.60 across the 11 AOs that accredit Medicare-certified providers and suppliers • $73,382.40 across all 24 accreditation program types
7. Burden Related to Addition of the Definition of "Unannounced Surveys"	• 0 hours	• $0

Time & Cost Burden Summary Table		
Name of Proposal	**Time Burden**	**Cost Burden**
D. Proposal to Require AO Surveyors to Take CMS Online Surveyor Training	• 35 hours per each surveyor • 2,625 hours per 75 surveyors per each AO • 28,875 hours (per 75 surveyors per each AO) across the 11 AOs that accredit Medicare-certified providers & suppliers	• $2,784.60 per each surveyor that takes the training • $208.845 per AO per 75 surveyors • $2,297,295 across the 11 AOs that accredit Medicare-certified providers & suppliers
E. Burden Related to Documentation Requirements for "National in Scope" 1. Documentation requirement for "National in Scope"	• 0.66 hour every 4-6 years • 7.33 hours across the 11 AOs that accredit Medicare-certified providers & suppliers	• $136.52 per each AO • $1,501.72 across the 11 AOs that accredit Medicare-certified providers & suppliers.
2. ICR related to incorporation of the "National in Scope" requirements into the AO's application	• 0.083 hour per each AO • 0.91 hour across the 11 AOs that accredit Medicare-certified providers & suppliers	• $3,185 per each AO • $35.03 across the 11 AOs that accredit Medicare-certified providers & suppliers
F. Burden Related to AO Performance Measures, and Plans of Correction	• 80 hours per each POC • 9,840 hours per each AO annually for completion of 123 POCs per year • 108,240 hours annually across all 11 AOs that accredit Medicare-certified providers and suppliers,	• $16,385.60 per each POC • $2,015,428.80 per each AO for completion of 123 POCs per year. • $22,169,716.80 across all 11 AOs that accredit Medicare-certified providers and suppliers,
G. Burden Related to Revision of the Definition of "Disparity Rate"	• 0 hours	• $0
H. Burden Reduction Associated with the Revised AO Validation Survey Program	• -144 hours per each validation survey • -25,920 hours (144 hours x 180 look-back validation surveys) across all programs that receive validation surveys	• -$2,062,195.20
I. Accreditation of Psychiatric Hospitals 1. ICR Associated With the Requirement That The AOs Develop a Psychiatric Hospital Accreditation Program	• 200 hours per each AO • 600 hours across the 3 AOs that would need to modify their accreditation programs	\ • $21,342 per AO • $64,026 across the 3 affected AOs
2. ICR Associated With Accrediting Facilities under the Revised Psychiatric Hospital Accreditation Program	• 0 hours	• $0
J. Limitation on Deeming Option for Terminated Providers	• 0 hours	• $0

Time & Cost Burden Summary Table		
Name of Proposal	**Time Burden**	**Cost Burden**
Total Estimated Time Burden	• **67,334** total burden across all AOs/program types /or accreditation programs	
Total Cost Burden Across All AO		$24,859,522
Total Cost Burden Calculated Across All Facility Types		$3,129,989
Total Cost Burden Calculated Across All Accreditation Program Types		$1,829
TOTAL ESTIMATED **GROSS** BURDEN		$27,991,340
TOTAL COST SAVINGS		-$2,062,195
TOTAL NET COST BURDEN		**$25,929,145**

VII. 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.

VIII. Regulatory Impact Analysis

A. *Statement of Need*

We seek to strengthen the public trust in CMS-approved AOs' findings and to protect the health and safety of patients that seek services from Medicare and Medicaid-participating providers that are accredited by CMS-approved AOs. We believe that AOs that voluntarily seek approval for "deeming purposes" are taking on a critical quality assurance role for the American people. Patients need to be able to rely on the strength of that accreditation to be assured that their health care services will be safe and of high quality. Where there are gaps in that accreditation process, or where quality issues are not fully identified or investigated by the AO, it

means that current and future patients may experience unnecessary harm or quality issues. Therefore, we are seeking to strengthen our oversight of AOs by revising existing regulations or implementing new regulations that would address the following issues: (1) place limitations on the fee-based consulting services AOs offer to the providers and suppliers they accredit; (2) implement penalties for violation of the prohibition against AO fee-based consulting; (3) require AOs to report information to CMS on a bi-annual basis about the fee-based consulting services they provide; (4) require AOs to report specific conflict of interest information to CMS with their initial and renewal applications; (5) require AOs to submit surveyor conflict of interest declarations to CMS on an annual basis; (6) prohibit AO owners, surveyors and other employees, that currently or within the previous 2 years have had an interest in or relationship with a health care facility the AO accredits from doing the following: (a) participating in the survey of that health care facility; (b) having input into the results of the survey and accreditation for that health care facility; (c) having involvement with the pre-or post-survey activities for that health care facility, or (d) having contact with or access to the records for the survey and accreditation of that health care facility; (7) require AOs to incorporate the CMS conditions into their accreditation standards for its deeming programs; (8) use a comparable survey processes; (9) revise the validation process, implement new performance measures and the use of plans of correction for unacceptable performance measure scores; (10) revise the hospital application process for AOs that have an approved hospital accreditation program to incorporate surveys of psychiatric hospitals into their hospital programs; (11) add new definitions for the terms "unannounced survey", "national in scope", "geographic regions", "process disparity rate", and "outcome disparity rate"; and (12) place limitations on terminated providers or suppliers seeking re-entry into the Medicare program. In addition, we are soliciting comments from the public on whether CMS should limit the number of times an AO can submit an incomplete initial application for a new accreditation program and soliciting comments regarding other opportunities to improve the public transparency of quality of care findings at facilities surveyed

by AOs; recognizing that under section 1865(b) of the Act, surveys performed by AOs may not be disclosed except for hospices, home health agencies, and surveys related to enforcement activity.

We continue to review and revise our health and safety requirements and survey processes to ensure they are effective in driving quality of care for our accredited providers and suppliers.

B. Overall Impact

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), Executive Order 14094 entitled "Modernizing Regulatory Review" (April 6, 2023), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates reform Act of 1995 (March 22, 1995; Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). The Executive Order 14094 entitled "Modernizing Regulatory Review" (hereinafter, the Modernizing E.O) amends section 3(f)(1) of Executive Order 12866 (Regulatory Planning and Review). The amended section 3(f) of Executive Order 12866 defines a "significant regulatory action" as an action that is likely to result in a rule: (1) having an annual effect on the economy of $200 million or more in any 1 year (adjusted every 3 years by the Administrator of OIRA for changes in gross domestic product), or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or tribal governments or communities; (2) creating a serious inconsistency or

otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise legal or policy issues for which centralized review would meaningfully further the President's priorities or the principles set forth in this Executive Order as specifically authorized in a timely manner by the Administrator of OIRA in each case.

A regulatory impact analysis (RIA) must be prepared for major rules with significant regulatory action/s and/or with significant effects as per section 3(f)(1) of Executive Order 12866 ($200 million or more in any 1 year). Based on our estimates, OMB's Office of Information and Regulatory Affairs has determined that this rulemaking is "significant".

C. *Detailed Economic Analysis*

1. Benefits

In developing this proposed regulation, we carefully considered its potential effects including both costs and benefits. The overall benefit of this rule would be to improve CMS' oversight of the AOs and to improve the overall quality and safety of healthcare. More specifically, the benefits of this rule include the prevention and removal of potential and actual conflicts of interest, the improvement of the validation process and anticipated reductions in the validation disparity rate, the additional performance measure and the implementation of plans of correction that would help AOs that have low performance measure scores to prepare a plan for how to improve their performance. We note that the generation of benefits is contingent upon behavior change, which entails costs; provisions that are discussed, below, as having negligible costs would therefore be anticipated to have minimal benefits.

2. Provision-Specific Costs, Benefits and Transfers.

We have identified the direct costs associated with this proposed rule as the costs associated with reporting, recordkeeping, and other costs. These costs are discussed below.

a. Impact Related to Conflict of Interest Proposals

In this proposed rule, we have made several proposals related to AO and AO surveyor conflicts of interest. In the 2018 AO Conflict of Interest RFI, many commenters stated that AOs tend to ignore deficiencies during surveys in order to promote the efficacy of their consulting services. These commenters also stated the belief that the AOs may ignore deficiencies to avoid giving poor survey results to their clients, who have paid substantial fees for both accreditation and AO fee-based consulting services. These commenters further stated the belief that the financial relationship between the AO and the health care facilities they accredit causes a conflict of interest. We believe that the proposed restrictions on AO fee-based consulting would reduce this conflict of interest and hopefully remove the incentive for AOs to ignore deficiencies during surveys. We further believe that the conflict of interest proposals we have made would prevent potential and new conflicts of interests from occurring. We will address the financial impacts associated with each of these proposals separately below.

(1) Impact Related to Proposed Conflict of Interest Policies & Procedures AOs Must Submit to CMS (Proposed Revisions to § 488.5(a)(10))

We proposed to modify § 488.5(a)(10) to add a requirement that the AOs must provide specific information with their conflict of interest policies and procedures with the application they submit to CMS. Specifically, the AO must submit the following policies and procedures: (1) for separation of its fee-based consulting services from its accreditation services; (2) policies and procedures for protecting the integrity of the AO's accreditation program, including the requirements of § 488.8(j); and, (3) for the prevention and handling potential or actual conflicts of interest that could arise from situations in which an AO owner, surveyor, or other employee has a direct interest in or relationship with another survey agency or health care facility to which the AO provides accreditation services, including a surveyor's outside interest, abuse of influence or disclosures of privileged information, etc.

The AO would need to modify their current conflict of interest policy and procedures to include the above-stated information required under the proposed revisions to § 488.5(a)(10).

We estimate that this task would be performed by a team of at least two AO staff members which would be a RN and a health services manager. We estimate that the total burden costs related to the requirements for proposed § 488.8(i)(1) would be $4,674.72. We estimate that the cost across all AOs would be $51,421.92.

We believe that the above stated burden impact would be incurred by the AO once prior to the time that they submit their first application after this requirement becomes effective. However, we believe that after the AOs have made required modifications to their conflict of interest policies, they will not have to revise them again, but will submit the same revised conflict of interest policies every 6 years with their renewal applications, so this burden would not be incurred again. We do not count the burden related to the submission of the application because the AO would be required to submit the application every 6 years to renew the CMS approval for their accreditation programs.

(2) Impact Related to Requirement that the AOs Submit Surveyor Conflict of Interest Declarations to CMS on an Annual Basis (Proposed § 488.5(a)(22))

We proposed to add a new paragraph (a)(22) to § 488.5, which would require that the AO must submit a declaration by each surveyor of any outside interests or relationships with the health care facilities that the AO accredits. This section would also require that the surveyor declarations must be updated on an annual basis and submitted to CMS by no later than December 31st each year.

We believe that the AOs would incur time and cost burdens for having to collect declarations from each of their surveyors annually. There would also be a time and cost burden to the AO for the submission of the surveyor declarations to CMS.

We estimate that the total burden costs related to the requirements for proposed § 488.8(i)(1) would be $4,674.72. We further estimate that the total cost across the 11 AOs that accredit Medicare-certified providers and supplier, would be $51,421.92.

(3) Impacts Related to Proposed Restrictions on Fee-Based Consulting Provided by AOs to the Health Care Providers and Suppliers They Accredit (§ 488.8(i)(1), § 488.8(i)(2), and § 488.8(i)(4)

In this proposed rule, we propose to modify the AO oversight regulations § 488.8(i) by adding a new provision which would add restrictions on the fee-based consulting services provided by the AOs to the same health care providers and suppliers they accredit for Medicare deeming purposes.

At proposed § 488.8(i)(1), an AO or its associated fee-based consulting division or company would not be permitted to provide fee-based consulting services to any health care provider or supplier prior to an initial accreditation survey. For purposes of this requirement, the term "initial survey" means the first accreditation survey performed of a health care provider or supplier by an accrediting organization. If a health care provider or supplier is terminated or withdraws from the services of an accrediting organization and then, a later time, again retains the services of that accrediting organization, the first survey performed by the accrediting organization of the returning health care provider or supplier would be considered an initial accreditation survey.

At proposed § 488.8(i)(2), an AO or its associated fee-based consulting division or company may not provide fee-based consulting services to a health care provider or supplier the accrediting organization accredits within 12 months prior to the next scheduled re-accreditation survey of that provider or supplier. For purposes of this paragraph, the term "re-accreditation survey" means the any subsequent accreditation surveys performed by the accrediting organization following the initial survey.

At proposed § 488.8(i)(4), an AO or its associated fee-based consulting division or company may not provide fee-based consulting services to a health care provider or supplier, to which the accrediting organization provides accreditation services, in response to a complaint received by the AO regarding that provider or supplier.

At proposed § 488.8(i)(4)(i) through § 488.8(i)(4)(iv) the restriction upon AO fee-based consulting shall not apply to the following situations: AO fee-based consulting services provided during the 24-month period after an initial or re-accreditation survey is performed; AO fee-based consulting services provided to address complaints received and investigated by the SA regarding an accrediting organization's accredited provider or supplier in which one or more condition-level or immediate jeopardy deficiencies are identified, provided however that, the AO fee-based consulting must occur after the complaint investigation and survey has been completed and must only address those issues identified by the complaint survey; AO fee-based consulting services provided to health care providers or suppliers to which the accrediting organization has never provided accreditation services; no-cost consulting or general education provided by the accrediting. Also, as we stated in the preamble, the proposed restriction on AO fee-based consulting services at § 488.8(i)(1) through (3) would not prohibit the AOs from providing fee-based consulting services to health care providers and suppliers the AO is accrediting such as mock surveys, education about the Medicare conditions or the survey process. This proposal would also not prohibit the general education provided by the AO about their accreditation program. This proposal would apply only to the four AOs that provide fee-based accreditation,

We believe that there would be two types of impact related to the proposals for § 488.8(i). First, the AOs would incur time and cost burden to the AOs related to having to make changes to their fee-based consulting program standards and policies. Second, we recognize that there would be a financial impact to the AOs due to the loss of revenue that would have been realized from the fee-based consulting services they currently provide that would now be prohibited. We will address these two burdens separately below.

As a result of our proposals at § 488.8(i)(1) through (3), the AOs will no longer be allowed to provide fee-based consulting services to a health care provider or supplier prior to an initial survey, within 12-months prior to a provider's or supplier's re-accreditation survey or in response to a complaint received in response to an accredited provider or supplier. We believe

that this limitation on the AOs' fee-based consulting model will require the AOs to revise their fee-based consulting business documents, such as their business charter, business documents, employee training information, informational documents that are distributed to prospective clients, and their policies and procedures as well as potentially restructure their staffing.

We estimate that these changes would cause each AO to incur a total time burden of 80 hours and a total cost burden of $7,791.20. We further estimate that the total impact across the four AOs that provide fee-based-consulting would be a time burden of 320 hours and a cost burden of $31,164.80. (See section VI.A.3 of this proposed rule for the details of how these time and cost burdens were calculated.)

We also believe that there will be a financial impact to the four AOs that provide fee-based consulting from the proposed restrictions on of fee-based consulting. Although the 2018 AO Conflict of Interest RFI gathered information about the nature of these relationships, they did not provide enough information for us to accurately calculate the financial impact that the requirements of proposed § 488.8(i)(1) would have on the AO. We do estimate that the AOs would have a decrease in approximately 25 percent of the fee-based consulting business due to the restriction on providing fee-based consulting prior to initial surveys. We say this because AOs perform accreditation on a 3-year cycle, following the initial survey. We estimate that 25 percent of the fee-based consulting performed by an AO on an annual basis would be for new clients prior to their initial survey. We further estimate that the remaining 75 percent of the AOs fee-based consulting business would be provided to providers and suppliers prior to a reaccreditation survey.

According to IRS financial disclosure statements filed by the AO that provides the most fee-based consulting through an associated fee-based consulting, this AO realized gross revenue from fee-based consulting services in the amount of $44,960,143 in 2020 and $55,970,543 in

2021.[20] This equates to an average annual revenue of $50,465,298 from fee-based consulting.

We estimate that new accreditation clients make up approximately 33 percent of an AOs client base and that the remaining 66 percent consist of existing clients that require reaccreditation surveys. We further estimate that, currently, only 25 percent (out of the 33 percent) of an AO's new clients elect to have fee-based consulting prior to the initial survey. Therefore, if the AOs are restricted from performing fee-based consulting prior to the initial survey of new clients, they would lose 25 percent of the revenue they receive from their fee-based consulting business. We estimate that the proposed restrictions on fee-based consulting would cause the AO that provides the most fee-based consulting services to incur lost revenue in the amount of $12,616,324 per year ($50,465,298 divided by 4).

While we do not have any independent information about the amount of profits the other AOs realize from their fee-based consulting services, we presume that these three AOs do not realize as much revenue from the provision of fee-based consulting as this large AO. We say this for several reasons. First, the other AOs are smaller businesses and have a smaller client base than does this large AO. It is our understanding that these AOs provide fee-based consulting on a smaller scale because they have less clients and some that are smaller businesses that may not have the funds to pay for fee-based consulting services. Therefore, we are not able to provide an accurate estimate of how much loss in revenue will result from the restrictions in AO fee-based consulting.

We estimate that the AOs charge between $100,000 and $500,000 for the fee-based consulting they provide to each healthcare provider or supplier. We do not know how many providers or suppliers currently use the fee-based consulting services of their AO prior to their initial survey. Therefore, we are not able to provide an accurate estimate of the total amount of consulting services shifting to new consultants and away from AOs no longer permitted to

[20] See https://www.jcrinc.com/-/media/jcr/jcr-documents/about-jcr/financial-statements/2021-jcr-form-990-redacted-pdc.pdf

provide such services to the providers and suppliers for whom they conduct initial surveys.

(4) Impact Related to Proposed Requirement for Submission of Information About AO Fee-Based Consulting Services Provided (Proposed § 488(i)(5))

We propose to add a requirement at § 488.8(i)(5) that would require the AOs to provide CMS with the following information about the fee-based consulting services they provide to CMS on a bi-annual basis: (1) whether the AO or an associated consulting division or company established by the AO provides fee-based consulting services; (2) a list which contains the names and CCN numbers of *all* health care providers and suppliers to which the AO or its associated consulting division or company has provided fee-based consulting services during the previous 6 months; (3) whether the AO has provided accreditation services to each health care provider or supplier on said list, and if so, the date the accreditation services were provided; and (4) a general description of the AO fee-based consulting services provided to each health care provider or supplier on said list. This proposed regulation further requires that statement containing the above-stated information must be submitted to CMS no later than 15 days after the end of each 6-month period.

We estimate that the impact associated with this proposed requirement would include the time and costs associated with the gathering of the information necessary to prepare the required statement, the time required to prepare the statement and the time required to send the statement to CMS. This impact would occur on a bi-annual basis, although, we believe that the burden would be greater for the preparation of the first report. Thereafter, the AOs would have already prepared and formatted this report and would simply have to update the information on a quarterly basis.

We estimate that the total hourly time burden per each AO for these tasks would be 96 hours and the total estimated cost burden would be $4,674.72. The impact across the four AOs that provide fee-based consulting would be 96 hours and $18,698.88.

We believe that the above stated burden would be incurred only the first time that the AO would be required to prepare the required statement and send it to CMS. We believe that after the AO has prepared their first report, they would have this report in an electronic format on their computers. Therefore, for the second and all subsequent reports, we estimate that the cost related to the preparation and submission of this report would be reduced by at least 25 percent.

We estimate that the financial impact to each AO for preparation of the second or subsequent report would be $636.48 and to all AOs that provide fee-based consulting would be $2,545.92.

(5) Impact Related to Proposed Requirement that Accrediting Organization Establish Fee-Based Consulting Firewall Policies and Procedures (Proposed § 488.8(j))

At § 488.8(j) we proposed to require any AO that provides fee-based consulting services or its associated fee-based consulting division or company to have robust, written fee-based consulting firewall policies and procedures. We would require that these firewall polices and procedure at a minimum, include the following provisions: (1) the AO's fee-based consulting services must be provided by a separate division or company from the AO's accreditation division; (2) the AO's fee-based consulting division or separate company must maintain separate staff from that of the AO's accreditation divisions to ensure that the fee-based consulting division staff do not perform AO's accreditation division functions and that the AO's accreditation division staff do not perform fee-based consulting division functions; and, (3) the AO's accreditation staff and surveyors are prohibited from marketing the AO's fee-based consulting services to the AO's accreditation clients.

This proposed requirement would only apply to the AOs that provide fee-based consulting and would require these AOs that establish new fee-based consulting firewall policies or revise their policies and procedures to meet the proposed requirements.

We believe that the burden associated with the revision of the AO's fee-based consulting policies and procedures would fall under the time and cost burden estimated in section VI.A.5 of

this proposed rule. As such, we will not assess a separate burden here.

(6) Impact Related to Proposed Regulation to Prevent AO Owners, Surveyors or Other Employees that Have an Interest in or Relationship with A Health Care Facility Accredited by the AO from Participating in Survey Activities For That Facility (Proposed § 488.8(k))

We propose to avoid conflicts of interest related to employment relationships between AO surveyors and health care facilities that are accredited by the AO. At proposed § 488.8(k) we would require the AO's to prohibit their owners, surveyors and other employees from doing the following: (1) participating in the survey of facilities with which they have a relationship; (2) having input into or influence the outcome of any survey performed for facilities with which they have a relationship; (3) having any involvement with the pre or post survey activities for the health care facilities with which they have a relationship; or, (4) having any contact with the records from the surveys for any health care facilities with which they have a relationship. We believe that this should already be a usual and customary practice of the AOs and therefore there should be no additional burden to the AOs to comply with the requirements of this section.

b. *Impacts Associated with the Requirement that AOs Incorporate the Medicare Conditions (§ 488.4(a)(1))*

(1) Impacts Associated with the Requirement that the AOs Provide Detailed Crosswalks Identifying the Incorporation of CMS Standards

We propose at § 488.4(a)(1) to require AOs to incorporate the CMS' health and safety standards. Currently, the AOs are required to provide a similar crosswalk under the existing process, CMS previously only required a "comparable" standard. Therefore, we propose to revise § 488.5(a)(3) to require the AOs to submit "A detailed crosswalk (in table format, as specified by CMS) that identifies each of the applicable Medicare conditions (as defined in § 488.1) incorporating the language of CMS requirements and standards."

As a result of this proposal, AOs would need to recreate their AO standards to match CMS'. We also note that this proposal would require a one-time overhaul of AO standards and

burden would be imposed for the first year following the effective date of this rule and not be a reoccurring annual burden. Incremental costs subsequent to changes would be minimal, as our proposal reflect current practice) with updates required to be reviewed and approved as outlined in existing § 488.5).

We anticipate the impact to AOs for the revision of their existing crosswalk and standards into the required format would be $159.12 per AO. We estimate that the total cost impact across the 11 AOs that accredit Medicare-certified providers and suppliers would be $84,993.48 for one accreditation program each.

However, the majority of our AOs have multiple accreditation programs, therefore this cost impact would increase based on the number of programs. CMS has 24 approved accreditation programs across the 11 AOs that accredit Medicare-certified providers and suppliers. We estimate that the total financial impact across all of these accreditation programs would be $185,440.32.

(2) Impacts Related to AO Providing Notice of the Revised Accreditation Standards to Their Accredited Providers and Suppliers Via Their Website

In addition to changing the survey standards as proposed under § 488.4(a)(1), the AOs would be required to provide the newly revised AO standards to the facilities they accredit. There are approximately 14,904 accredited facilities across all program types. We believe that the majority of AOs have a website portal on which they make their standards available to their accredited providers and suppliers.

We estimated that the total impact across the 11 AOs that accredit Medicare-certified providers and suppliers for providing notice of their revised accreditation standards on their website would be $1,829.28.

(3) Impact Related to Providing Notice of the Revised Accreditation Standards to the Accredited Providers and Suppliers via Email

We also believe the AOs would provide notice of their revised accreditation standards to

their accredited providers and suppliers directly via email. We believe this would be a group email that would be sent out via group text to all of the AOs accredited providers and suppliers. We estimate that it would take only 15 minutes to prepare this email and there are approximately 14,904 accredited providers and suppliers across all 11 AOs that accredit Medicare-certified providers and suppliers. Therefore, the total estimated financial impact across all these 11 AOs for providing notice of the AOs revised accreditation standards via email would $142,333.20**.**

(4) Impacts Related to Education of Providers and Suppliers Regarding New Standards

We believe that the AOs that accredit Medicare-certified providers and suppliers would be required to provide education to their accredited providers and suppliers about their new Medicare accreditation standards, which must be revised to be the same as the CMS standards, or more stringent. We believe that this training would most likely be provided by webinar. There are approximately 14,904 deemed facilities. We estimate that the cost impact to each facility would be $200.46 ($79.56 per RN + $120.90 per general or services manager). We further estimate that the total annual cost burden across all 14,904 accredited facilities would be $2,987,655.84.

c. Impacts Associated With the Requirement that AOs Use A Survey Process That is Comparable to That Used by CMS and the SAs

We propose to require the AOs to use the strengthened and revised requirements for initial and renewal applications for deeming authority, which includes revisions specifically to the documentation submitted related to the AO survey processes and guidance and its comparability to those survey processes used by the SA. We also propose to require the AOs to state in their survey reports, to identify the specific Medicare condition that corresponds with each finding of non-compliance.

(1) Impact Related to Documentation Associated with Requirements that AOs Use Comparable Survey Processes (§ 488.5(a)(4), § 488.5(a)(4)(iii), § 488.5(a)(4)(v), and § 488.5(a)(4)(vii))

We believe that impact of the changes to the require specific information related AOs'

survey processes; surveyor guidance and instructions; survey forms and survey review process would vary depending on the AO because there are three out of the eleven AOs that accredit Medicare-certified providers and suppliers that already use survey processes and guidance that are very similar to that used by the SA. Therefore, the impact to these three AOs would be much less than the impact to the remaining AOs, which use a different survey process which are causing more concern related to the comparability of survey activities and the ability to maintain the integrity of the survey process. For the purposes of this impact analysis we have provided our estimates based on an AO that would require the most changes to their existing documentation provided to show AO comparability to CMS survey processes, guidance and documentation.

The requirements under § 488.5(a)(4), § 488.5(a)(4)(iii), § 488.5(a)(4)(v), and § 488.5(a)(4)(vii)) would require AOs to ensure documentation submitted supported the already existing expectations under the regulatory requirements and only added additional clarity within these proposed provisions. Therefore, we estimate that there is no impact on each AO for providing these requirements, as further explained in section VI.C.1 of this proposed rule, that AOs Use Comparable Survey Process (§ 488.5(a)(4), § 488.5(a)(4)(iii), § 488.5(a)(4)(v), and § 488.5(a)(4)(vii)).

(2) Impact Related to Documentation Requirements Imposed by Requirement that AOs Submit a Training for CMS About its Revised Survey Process (§ 488.5(a)(4)(xi))

The proposed requirements under § 488.5(a)(4)(xi) would require the development of a presentation, such as an abbreviated web-based training or related training materials, for CMS about the AOs revised survey processes, specifically highlighting areas which vary from the survey processes and activities used by the SA. We believe while this would require development of new material, the content of such material is already available and would be extrapolated from the AOs training to new surveyors.

We believe that development of the training would be $4,169.10 per AO and $45,860.10

across all 11 AOs. However, we further determined that we would consider the total across all 24 accredited programs to be $100,058.40 as survey processes used by the AO may vary based on the provider or supplier.

(3) Impact Related to Documentation related to Requirements that AOs Use Comparable Survey Process (§ 488.5(a)(5), § 488.5(a)(6), and § 488.5(a)(12))

Aforementioned in the Impact Related to Documentation Imposed by Requirements that AOs Use Comparable Survey Process (§ 488.5(a)(4), § 488.5(a)(4)(iii), § 488.5(a)(4)(v), and § 488.5(a)(4)(vii)), the proposed requirements under § 488.5(a)(5), § 488.5(a)(6), and § 488.5(a)(12) also clarify existing and longstanding standard practices on the survey processes and do not impose additional burden to the AOs. Therefore, we estimate these proposed requirements would have no financial impact on the AOs.

(4) Impact Related to Documentation Requirements Imposed by Requirement that AOs Use Comparable Survey Process (§ 488.5(a)(13))

The requirements at § 488.5(a)(13) currently require the AOs to have: (1) procedures for responding and investigating complaints and, (2) a process for decision-making as it relates to accrediting status. We propose to add two new requirements which would require the AO to provide CMS with its organizational policies and procedures related to the AOs notification procedures, including timeframes for notification, to CMS in regards to a facility which the AO accredits when the facility fails to meet accreditation standards or its accreditation status is affected, as well as its processes and timelines for notification to CMS when one of its accredited facilities withdraws from accreditation. We estimate the total burden to be $886.60 per AO or $9,752.60 across all 11 AOs.

We estimate that the total financial impact for these tasks would be $109,650.20 across all 11 AOs and the 24 programs currently recognized under AO deeming authority.

5. Impact Related to the Requirement for AO to Submit Survey Findings/Reports

As mentioned in the preamble, we also propose to require the AOs as part of their

application under § 488.5(a)(4)(viii) to acknowledge that it will submit any requested survey findings and reports, to include complaint survey reports to CMS for internal use.

This requirement would not cause the AOs to incur any new additional burden as the submission of this information is already required by this regulation and is therefore is a usual and customary part requirement for initial and renewal applications. AOs are also already required to submit the deficiencies and facility non-compliance in a roll up format. Therefore, this proposed requirement for a full survey report would not cause any additional burden as CMS would not require a specific new entry or format and reduce time spent by the AO summarizing the survey activity.

(6) Impact Related to the Requirement that the AOs Submit Their Revised Accreditation Standards and Survey Processes to CMS for Review and Approval

Finally, in addition to the burden estimates above, the AOs would be required to resubmit their new survey processes and standards for CMS review as required under § 488.8(b)(2). We anticipate the total financial impact associated with the requirement at § 488.8(b)(2) that an AO submit any proposed changes in its accreditation requirements or survey process to CMS for review and approval would be $3,057.60 per AO per accrediting program type. We estimate that the financial impact across the 11 AOs would be $33,633.60. Finally, we estimate that the total financial impact across the 24 accredited programs is estimated at $73,382.40**.**

As mentioned within the preamble, the proposed changes would not implement a reoccuring annual burden, but rather have a one-time burden on the AOs until the survey processes and activities are aligned with our proposed changes. CMS would resume the current process for approval and re-approval of AOs and their accrediting programs as outlined within the new proposed § 488.5.

We do note, there is no direct burden associated with these changes to the deemed provider or supplier.

d. Impact Related to the Requirement that the AO Surveyors Take the CMS Online Surveyor

Training

We proposed at § 488.5(a)(8), to add a new requirement that would require AO to state in their application for CMS approval, that AOs that who accredit Medicare-certified providers and suppliers must include a statement acknowledging that all AO surveyors have completed or will complete two CMS mandatory documentation courses and the relevant program specific CMS online trainings established for SA surveyors, initially, and thereafter.

CMS provides a number of online surveyor training modules that are available to the SA surveyors. We proposed to require the AO surveyors to take this training in an attempt to decrease the historically high disparity rate between the AOs survey results and those of the validation surveys performed by the SA surveyors.

There are a total of 163 online training programs that are available the SA surveyors on the CMS Quality, Safety and Education Portal (QSEP) website. This website provides courses that are general in nature such as "Principles of Documentation for Non- Long Term Care" and "Basic Writing Skills for Surveyor Staff", infection control, patient safety, Emergency Preparedness. The CMS QSEP website also offers courses related to specific health care settings such as hospitals, CAHs, ASCs, Laboratories, Community Mental Health Centers, EMTALA, Federally Qualified Health Centers (FQHCs), Home Health Agencies and OASIS, Hospices, Nursing Homes and the MDS, Outpatient Physical Therapy/Outpatient Speech Therapy. These courses are self-paced and the person taking the course can take the courses over a period of time. The amount of time required to complete each of these training course varies depending on the pace at which the trainee completes the training. The basic surveyor training courses for specific programs range in time from 16-82 hours for completion. We estimate the average time it takes to take one of the basic surveyor courses is 27 hours. This could be more or less depending upon the specific program that AO surveyors need to take.

We would require that each AO surveyor takes the 2 mandatory documentation courses (that is "Principles of Documentation for Non-Long-Term Care" and "Basic Writing Skills for

Surveyor Staff") and the basic surveyor course for the care setting for which they perform surveys. We further estimate that it would take approximately 4 hours to complete each of these courses, however, these courses are self-paced and could take less or longer. Therefore, an AO surveyor would incur a time burden of approximately 35 hours for the completion of all of the required CMS surveyor training courses.

Based upon this information we estimate that the financial impact to the AOs that accredit Medicare-certified providers and suppliers would $2,784.60 per each surveyor that completes the CMS online surveyor training.

We are not able to accurately estimate to total time and cost burden to each AO for the wages incurred for the time spent by all surveyors from each AO to take the CMS online surveyor training courses, because we do not know exactly how many surveyors each AO has. However, if we estimate that each AO has 75 surveyors, the estimated financial impact to each AO associated with this requirement would be $208.845.

As of February 4, 2020, there are currently 11 AOs that accredit Medicare-certified providers and suppliers. We estimate that the total estimated financial impact across these 11 AOs would be $2,297,295.

e. Impact Associated with the Establishment of a Definition for "National in Scope"

As proposed under § 488.1, we would require the AO to provide documentation for meeting the definition of "national in scope" within their initial and reapplication process. As currently required under § 488.5(a)(1), the AO must provide documentation that demonstrates the organization meets the definition of a "national accrediting organization" under § 488.1 as it relates to the accreditation program. Therefore, we estimate the burden on AOs to be minimal as they are already required to provide documentation to this effect. Therefore, we estimate the following:

(1) Impact Related to the Documentation Requirements for "National in Scope"

We anticipate that a CEO of an AO would compile and verify that the AO meets the

proposed definition of "national in scope". According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a CEO is $102.41. This wage adjusted for the employer's fringe benefits and overhead would be $204.82. (See Table 1 in section IV "Collection of Information Requirements" of this proposed rule.)

CMS is not requiring to use a specific format for the documentation they submit to show that their accreditation program is national in scope. However, we suggest that the AO provides a list, which lists the accredited facilities and which would show the geographic locations for these accredited facilities. For existing CMS-approved AOs, the general re-application cycle is not to exceed 6 years. Therefore, we anticipate this below burden to apply every 4 to 6 years.

We anticipate the compiling of this information would take approximately 40 minutes (0.66 hours). Currently, there are 11 approved AOs and we anticipate no more than two new AOs per year to apply for deeming authority. We estimate that the total financial impact to each AO for completion of this task would be $136.55 every 6 years ($204.82 per hour x 0.66 hours). We further estimate that the financial impact across the 11 AOs that accredit Medicare-certified providers and suppliers would be $1,501.72.

(2) Impact Related to Incorporation of the "National in Scope" Requirements into the AO's Application

When preparing an initial application of CMS approval of its accreditation programs, an AO must include documentation that their accreditation programs meet the definition of "national in scope." We anticipate that would be performed by a Medical Secretary with an hourly wage of $38.22 and would take 5 minutes (0.083 hour) to complete. We estimate that the financial impact for this requirement would be a $3.18.

There are 11 AOs. We estimate that the total financial impact for this work across all AOs would be $35.03.

We do note, there is no direct burden associated with these changes to the deemed provider or supplier.

f. Impact Associated with the Proposed Revision of the AO Performance Measures

As proposed in this rule, we are requiring that AO submit a publicly reportable plan of correction for performance measure scores that are under an acceptable threshold for established performance.

This is a new requirement and therefore would be a new burden for AOs to complete. The plan of correction must be completed and submitted to CMS within 10-business days follow the notification of the AO of their less than acceptable performance. The plan of correction must address the areas of improvement and the specific actions to be taken to improve those areas on a sustainable basis, the process for ongoing monitoring of progress of the toward acceptable performance, as well as the individuals responsible for overseeing the plan of correction and the anticipated implementation dates of the proposed actions.

We estimate that it would take 80 hours for the AO staff to prepare each plan of correction. We believe that the financial impact to the AO for this task would be $15,395, based on the preparation of 123 plans of correction per year. We estimate the the total annual impact per each AO for the complation of 123 POCs per year would be $2,015,428.80 per each AO for completion of 123 POCs per year. The total financial impact across all 11 AOs that accredit Medicare providers and suppliers would be $22,169,716.80.

g. Impact Associated with the Revision of the Definition of "Disparity Rate"

In the proposed definition of disparity rate there is no associated burden as look-behind validation surveys are a usual and customary part of the existing validations program. Direct observation validation surveys are already being performed under current regulatory authority § 488.8(a)(2) and have become a usual and customary part of the validation program. AO will continue to perform survey activities as required, the revised and expanded definition of disparity will impact data collection by CMS, but no additional burden to the AO or provider.

h. Impact for the Revision of the AO Validation Program

In the proposed revision and expansion of § 488.9, we propose to revise the validation

program to include the additional component of a direct observation of the AO's survey process by the SA or CMS surveyors. There would be no associated impact to the AO or SA as a result of the additional validation method. Currently, CMS funds validation surveys. We do not anticipate additional costs. However, there are associated burden reductions to the provider community since half of the traditional validation survey will be replaced by direct observation validation surveys.

We anticipate a burden reduction based on our proposed changes. The anticipated annual burden reduction to providers and suppliers is based on our FY 2019 look-behind validation survey data collection. In FY 2019, we conducted approximately 315 surveys. The anticipated burden reduction with our new proposed changes are based on the look-behind validation surveys, which allows a reduction by at least 50 percent (180 look-back surveys) through replacing them with the direct observation validation survey. This burden reduction occurs because during direct observation surveys, the SA surveyors observe the AO surveyors during the performance of a reaccreditation survey instead of performing a separate validation survey within 60 days of the AO's reaccreditation survey. As only one survey is performed, the burden to providers and suppliers undergoing validation using the direct observation validation method is reduced by at least 50 percent. We determined that the use of the direct observation validation surveys would reduce the burden related to the look-back validation surveys to providers and supplier by at least 50 percent because with direct observation validation surveys, the SA surveyors observe the AO surveyors during the performance of their survey. This requires only one survey to be performed. Whereas, with 60-day look-back validation surveys, the SA surveyors perform a validation survey within 60 days of the AO's reaccreditation survey. This requires the provider or supplier selected for validation to undergo two surveys within a 60-day period. Half of the validation surveys to be performed with the revised validation program will use the direct observation method. Therefore, we estimate that provider/supplier burden would be reduced by 50 at least percent. We believe this, in turn, would reduce the financial impact of

the validation program to provider and supplier burden or in other words result in a cost savings of $2,062,195.20.

i. Impact Associated with the Revision of the Psychiatric Hospital Accreditation Process

As discussed in this proposed rule, we propose to require AOs which have a CMS-approved hospital accreditation program to expand their programs to include the three special conditions for psychiatric hospitals and provide CMS with a detailed crosswalk which identifies the inclusion of the psychiatric standards which meet or exceed CMS psychiatric Medicare conditions. While these AOs already have approved hospital programs, we note that this proposal would require a one-time overhaul of the hospital program standards to expand the program to include the psychiatric standards and burden would be imposed for the first year following the effective date of this rule and not be a reoccurring annual burden. Burden costs subsequent to changes would remain as current practice with updates required to be reviewed and approved as outlined in existing § 488.5. As proposed in multiple sections of this proposed rule, we propose to require the AOs to use Medicare conditions, more comparable survey processes with the ability to delineate where they exceed and take the CMS online surveyor training courses. Therefore, we believe burden would be minimal and most of the burden would be in areas in which the AO would "exceed" Medicare requirements.

Currently, there are four CMS-approved AOs which have established hospital accreditation programs. One of these four AOs which already has an established CMS-approved psychiatric accreditation program.

We anticipate that this requirement be of moderate burden for AOs, however we anticipate the burden to be a one-time burden for 3 of 4 hospital AOs. Once effective by the date of the final rule, or as specified by CMS, this would be part of the initial and renewal application process as defined in § 488.5, therefore would not imposed annual reoccurring burden to any AOs initially applying or reapplying. We would expect that the AOs use the existing CFR language they are required to crosswalk currently in the regular hospital program and expand it

to assign an AO standard number to the psychiatric standards with language which meets or exceeds the Medicare standards.

(1) Impact Associated With the Requirement That the AOs Develop a Psychiatric Hospital Accreditation Program

We anticipate the burden for AOs to review and revise their existing hospital program crosswalk and standards to include the psychiatric standards would cause a financial impact to each affected AO in the amount of $21,342.

There are currently three AOs which would need to revise their hospital programs to incorporate these standards. We estimate that the total financial impact across these 3 AOs would be $64,026.

(2) Impact Associated With Accrediting Facilities Under the Revised Psychiatric Hospital Accreditation Program

As aforementioned, there are four existing AOs which have a CMS-approved hospital accreditation program, however three of four AOs would need to resubmit their applications for CMS-approval based on the proposed provisions for the psychiatric standards as well as meeting the definition and criteria of national in scope. The scope of the CMS-approved hospital programs would not change with this proposed expansion of the program to include the psychiatric special conditions. Once the hospital program is approved as national in scope, the addition of the three special conditions does not change the overall scope of the entire program. Therefore, we believe this burden would be incorporated into the burden required with the new proposed changes of this rule. Therefore, please see the impact section for comparability to the CMS survey processes as required by § 488.4(a)(2).

j. Impact Associated with Limitations to Terminated Deemed Providers and Suppliers Seeking Re-approval into Medicare/Medicaid

We proposed to add a new policy at § 488.4(b) which would withdraw CMS recognition of the “deeming authority” accreditation of any Medicare certified provider or supplier that is

terminated from the Medicare/Medicaid program, if such terminated provider/supplier subsequently applies to re-enter Medicare and seek initial certification. We also proposed to add new requirement at § 488.4(b)(2) that would require that before a terminated provider or supplier would be eligible for participation in the Medicare program, they would have to meet all of the requirements of § 489.57.

In support of our proposal at § 488.4(b), we also propose to add a new requirement at § 488.5(a)(21) that would require AOs to provide, with their initial and renewal applications, a statement certifying that, in response to a written notice from CMS notifying the AO that one of its accredited providers or suppliers has been terminated from the Medicare/Medicaid program, the AO agrees to terminate or revoke its accreditation of the terminated provider or supplier within 5-business days from receipt of that written notice.

Section 1865(c) of the Act states that if the Secretary finds that a provider or supplier has significant deficiencies, then it is no longer deemed to meet the requirements the entity has been treated as meeting pursuant to subsection (a)(1) for such period as may be prescribed in regulations. As further explained below, our proposed revised regulations at § 489.57 governs the process that terminated providers and suppliers must follow to be allowed to submit a new request for Medicare participation. Specifically, § 489.57, as revised, would require that when a provider agreement has been terminated by CMS or OIG, a new agreement with that provider would not be accepted unless CMS or the OIG finds the following: (1) that the reason for termination of the previous agreement has been removed and there was reasonable assurance that it would not recur; and (2) that the provider has fulfilled, or has made satisfactory arrangements to fulfill, all of the statutory and regulatory responsibilities of its previous agreement. Also, the terminated provider or supplier would have to meet the following requirements before a new agreement with that provider or supplier could be approved: (1) the terminated provider or supplier would have to submit to, and remain under, the exclusive oversight of the state survey agency for a reasonable assurance period of a length of time to be determined by CMS, for the

purposes of the initial survey, certification and demonstration of compliance with the Medicare conditions; (2) the terminated provider or supplier would have to remain under the exclusive oversight of the SA until the SA or CMS certified that the provider or supplier was in compliance with all applicable Medicare conditions, and CMS approved the new agreement for participation in the Medicare/Medicaid program; and (3) during the time period in which a terminated provider or supplier was not certified to participate in the Medicare program, while the prospective provider or supplier was under the oversight of the SA, and while the new agreement for Medicare participation was pending, CMS could not deem the provider to have met CMS standards via accreditation until the SA determined that the applicable Medicare requirements have been met or exceeded, as described in § 488.4.

The intended purpose of these proposed new and revised regulations is to further clarify the existing process for terminated providers and suppliers and also prevent providers and suppliers that have been terminated from the Medicare/Medicaid program from mischaracterizing their continued AO accreditation as proof that they meet the Medicare standards and provide safe and effective care, when in fact they were terminated from the Medicare program for egregious deficiencies that had, in many instances, not been detected by the AO. Currently CMS does not have explicit regulatory authority to withdraw recognition of an AO's deeming accreditation when a provider or supplier has been terminated from the Medicare/Medicaid program. Nor does CMS currently have a regulation requiring AOs to withdraw or revoke their accreditation of providers or suppliers that have been terminated from the Medicare/Medicaid programs. These proposed new and revised regulations will provide this regulatory authority for CMS. We are also proposing additional requirements at § 489.57(b) that would require that if a terminated provider or supplier filed a new application for participation in the Medicare/Medicaid program, said terminated provider or supplier would have to meet the requirements set forth at § 489.57(b)(1) to (b)(3) before their new agreement for Medicare participation could be approved.

Proposed new § 489.57(b)(1) would require that a terminated provider or supplier be under the exclusive oversight of the SA for the purpose of the initial survey, certification and demonstration of compliance with the Medicare conditions. Proposed new § 489.57(b)(2) would require that the terminated provider or supplier seeking re-entry must remain under the exclusive oversight of the SA until the SA has certified its full compliance with all applicable Medicare conditions and the agreement for participation in the Medicare/Medicaid program has been approved. Finally, proposed new § 489.57(b)(3) would require that during the time period in which the terminated provider or supplier was under the oversight of the SA and while the new agreement for Medicare participation was pending, CMS would not accept or recognize accreditation from a CMS-approved accrediting organization.

We believe that there would be no additional cost or time burden associated with these proposed requirements because the terminated providers and suppliers would have to undergo periodic, unannounced surveys performed by the SA. If these providers and suppliers had not been terminated, they would have had to undergo surveys by the AO. Therefore, the provider or supplier would incur no additional time or cost burden related to the SA survey process. Also, there would be no increase in the time required for survey of these terminated providers or suppliers to become newly certified or participate in the Medicare program.

Also, considering that as a result of the above-stated proposals, CMS would not recognize accreditation from an AO while a provider or supplier is terminated from the Medicare program, the AOs would be required to terminate or revoke accreditation for terminated providers and suppliers; and that during the time that a new agreement for Medicare participation is pending, the prospective Medicare provider or supplier would be under the exclusive oversight of the SA, they would not incur any fees for SA's services.

In addition, terminated providers seeking re-entry into the Medicare/Medicaid program would be required to submit an initial enrollment application to CMS. The provider or supplier would not incur any new time or cost burden related to the preparation and submission of the

application because the preparation and submission of this application is a usual and customary requirement for any entity seeking initial certification as a provider or supplier in the Medicare/Medicaid program.

Summary of Financial Impact Caused by the Proposals in this Proposed Rule

Table 4 summarizes the financial impact of the proposals that we are making in this proposed rule.

TABLE 4: Summary of Impact

Summary of Impact	
A. <u>Conflict of Interest Proposals:</u> 1. Restrictions on AO fee-based consulting services (§ 488.8(i))	• $31,164.80 across all 11 AOs
2. Loss of revenue to AOs due to prohibition of fee-based consulting	• $12,616,324 million dollars annually (the AO that provides the most fee-based consulting services) • $100,000 to $500,000 annually for other AOs
3. Requirement that the AOs provide information about the fee-based consulting services they provide (§ 488.5(a)(10))	• $51,421.92 across all 11 AOs for 1st report
4. Requirement that AO surveyors submit conflict of interest declarations to CMS on an annual basis (§ 488.5(a)(10))	• $51,421.92 across all 11 AOs
5. Requirement that Accrediting Organization Establish Fee-Based Consulting Firewall Policies and Procedures ((Proposed § 488.8(j))	• $0 (The cost burden associated with this requirement is included with burden calculation for proposed § 488.8(i) above)
6. Requirement to Prevent Conflicts of Interest Caused By AO Surveyor Relationship with A Health Care Facility Accredited by the AO (Proposed § 488.8(k))	• $0 – because this should be a usual and customary practice of the AOs.
B. <u>Requirement that the AO Incorporate the Medicare standards to ensure improved evaluation of AO performance.</u> 1. Requirement that the AOs provide detailed crosswalks identifying equivalent standards	• $84,993.48 across the 11 AOs that accredit Medicare-certified providers/suppliers.
2. Burden related to AO providing copies of their revised accreditation standards to their accredited providers and suppliers	• $1,829.28 across all 24 accreditation programs.
3. Burden to AO related to providing education to its accredited providers and suppliers about the new accreditation standards	• $142,333.20 for all 14,904 facilities
4. Burden to providers and suppliers related to taking education about the AOs revised accreditation standards	• $2,987,655.84 across all facilities
C. <u>Burden Related to Requirement that AOs Must Use Comparable Survey Processes</u>	

Summary of Impact	
1. Burden associated with requirement that AOs must submit documentation about their survey processes as required by (§ 488.5(a)(4), § 488.5(a)(4)(iii), § 488.5(a)(4)(v), and § 488.5(a)(4)(vii))	• $0 – because the AOs are already required to submit this information
2. Burden associated with new documentation requirements created by requirement that AOs must use a comparable survey process - (§ 488.5(a)(5), § 488.5(a)(6), and § 488.5(a)(12))	• $0 – because the AOs are already required to submit this information
3. Burden Related to Documentation Requirements Imposed By Requirement that AOs Use Comparable Survey Process - § 488.5(a)(13) ICR Related to Requirement for AO to Submit Survey Findings/Reports	• $9,752.60 across 11 AOs
4. Burden associated with the preparation of a presentation that AOs must prepare and provide to CMS to demonstrate how their survey processes are comparable to that of CMS	• $45,860.10 across 11 AOs
5. ICR Related to Requirement for AO to Submit Survey Findings/Reports	• $0 – because the AOs are already required to do this.
6. Burden Related to Submission of Revised Accreditation Standards and Survey Processes for review and approval by CMS as required by § 488.8(b)	• $33,633.60 across the 11 AOs that accredit Medicare-certified providers and suppliers
7. Burden Related to the Addition of the Definition of "Unannounced"	• $0
D. Proposal to Require AO Surveyors to Take CMS Surveyor Training	• $208.845 per each AO per 75 surveyors • $2,297,295 across 11 AOs
E. National in Scope 1. Burden Related to Documentation Requirements for "National in Scope"	• $1,501.72 across 11 AOs
2. Burden Related to Incorporation of the "National in Scope" Requirements into the AO's Application	• $35.03 across 11 AOs
F. Burden Related to AO Performance Measures, and Plans of Correction	• $2,015,428.80 per each AO per 123 POCs anually • $22,169,716.80 across 11 AOs anually
G. Burden Related to Revision of the Definition of "Disparity Rate"	• $0
H. Revised Validation Survey Program	• -$2,062,195.20 (burden reduction to providers/suppliers)
I. Accreditation of Psychiatric Hospitals	• $64,026 across the three affected AOs
J. Limitation on Deeming Option for Terminated Providers	• $0
Total Impact Across All AOs	$24,859,522
Total Impact Across All Facility Types	$3,129,989

Summary of Impact	
Total Impact Across All Accreditation Program Types	$1,829
TOTAL *GROSS* IMPACT	$27,991,340
TOTAL ESTIMATED COST SAVINGS	-$2,062,195
TOTAL ESTIMATED *NET* IMPACT	**$25,929,145**
TOTAL ESTIMATED LOSS OF PROFITS	$12,616,324
TOTAL NET IMPACT	**$38,545,469**

3. Regulatory Review Cost Estimation

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this proposed rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters to the 2018 AO Conflict of Interest Request for Information (December 20, 2018, 83 FR 65331) will be the number of reviewers of this proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed the 2018 AO Conflict of Interest Request for Information in detail, and it is also possible that some reviewers chose not to comment on the published rule. For these reasons we thought that the number of past commenters would be a fair estimate of the number of reviewers of this rule. We welcome any comments on the approach in estimating the number of entities which will review this proposed rule.

We believe that persons reviewing this rule would consist of AO management staff, healthcare association management staff, and health care facility management staff. We believe all of these persons would have positions that fall under the U.S. Bureau of Labor Statistics job category of medical and health services manager. Assuming an average reading speed, we estimate that it would take approximately 2 hours for the staff to review this proposed rule.

Using the wage information from the BLS for Medical and Health Service Managers (Code 11-9111), we estimate that the cost of reviewing this rule is $230.44 ($115.22 per hour x 2 hours).[21]

D. *Alternatives Considered*

1. Proposed Changes to AO Fee-based Consulting

We considered proposing a complete ban on AO fee-based consulting because of the conflict of interest associated with the provisions of this service by the AOs to the health care providers and suppliers they accredit. However, we presume the financial impact to the AOs associated with a complete ban on fee-based consulting would be larger. For example, the AO that provides the most fee-based consulting realized over $50 million dollars annually from providing these services. A complete or almost complete ban on the provision of AO fee-based consulting services would eliminate or severely limit this revenue source.

Therefore, we decided to propose more limited restrictions on AO fee-based consulting services that would address the conflicts of interest.

2. Proposed Changes to the Validation Program

We considered several alternatives for changes to the validation program. First, we considered making no changes to the validations program, which would mean that we would continue performing only look-back surveys. We also considered performing only direct observation surveys. After considering the alternative, we decided to propose performing a combination of both look-back and direct observation surveys because this would result in a cost savings to providers and suppliers. If we were to continue the validation program as is, there would be no change in provider burden. If we modify the validation program by performing only direct observation validation surveys, burden to providers and suppliers would be reduced significantly, however, the workload on the SAs would be increased significantly. The SAs have indicated during the pilot program that they would not be able to handle such an increased workload. Therefore by using the direct observation method for at least 50 percent of the

[21] https://www.bls.gov/oes/current/oes119111.htm

validation surveys performed annually this would provide a significant decrease in provider and supplier burden while placing a manageable and acceptable workload on the SAs.

E. *Regulatory Flexibility Act (RFA)*

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than $8.0 million to $41.5 million in any 1 year. Individuals and states are not included in the definition of a small entity. We are not preparing an analysis for the RFA because we have determined, and the Secretary certifies, that this proposed rule would not have a significant economic impact on a substantial number of small entities. (See the Table 2 in section VI.B.1 of this proposed rule.)

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

F. *Unfunded Mandates Reform Act (UMRA)*

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2023, that threshold is approximately $177 million. This proposed rule would not impose a mandate that will result in the expenditure by State, local, and Tribal Governments, in the aggregate, or by the private sector, of more than $177 million in any 1 year.

G. *Federalism*

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. Since this regulation does not impose any costs on State or local governments, the requirements of Executive Order 13132 are not applicable.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on May 23, 2023.

List of Subjects

42 CFR Part 488

Administrative practice and procedure, Health facilities, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 489

Health facilities, Medicare, and Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare and Medicaid Services proposes to amend 42 CFR chapter IV, as set forth below:

PART 488 SURVEY, CERTIFICATION, AND ENFORCEMENT PROCEDURES

1. The authority citation for part 488 continues to read as follows:

Authority: 42 U.S.C. 1302; and 1395hh.

2. Section 488.1 is amended by —

a. Adding the definition of "Geographic regions";

b. Revising the definition of "National accrediting organization";

c. Adding the definitions of "National in scope", "Outcome disparity rate" and "Process disparity rate";

c. Removing the definition of "Rate of disparity"; and

d. Adding the definition of "Unannounced survey".

The additions and revisions read as follows:

§ 488.1 Definitions.

* * * * *

Geographic regions – CMS uses specified geographic regions of the Unites States to measure whether an accrediting organization's accreditation program meets the definition of "national in scope." For this purpose, the United States is divided into the following five geographic regions:

(1) *Northeast:* Delaware, District of Columbia, Maryland, Pennsylvania, Virginia, West Virginia, New York, New Jersey, Puerto Rico, Virgin Islands, Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont;

(2) *Southeast*: Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, and Tennessee;

(3) *Midwest*: Illinois, Indiana, Michigan, Minnesota, Ohio, Wisconsin;

(4) *Central*: Iowa, Kansas, Missouri, and Nebraska; Colorado, Montana, North Dakota, South Dakota, Utah, Wyoming;

(5) *South*: Arkansas, Louisiana, New Mexico, Oklahoma, and Texas;

(6) *Western*: American Samoa, Arizona, California, Hawaii, Commonwealth of the Northern Mariana Islands, Guam, Alaska, Idaho, Nevada, Oregon, Washington

* * * * *

National accrediting organization means an accrediting organization that is national in scope and accredits provider or suppliers, under a specific accreditation program.

National in scope means that the providers and suppliers accredited by an accrediting organization under a specific accreditation program, are widely located geographically across the United States. The requirement for "national in scope" has two components. First, the accrediting organization must have accredited at least five providers or suppliers under the accreditation program in question. Second, the five providers or suppliers accredited by the accrediting organization under that accreditation program must be geographically located in at least five out of the six geographic regions.

Outcome disparity rate means the percentage of all look-back validation surveys for an accrediting organization's program for which the state survey agency finds noncompliance with one or more Medicare conditions and no comparable condition level deficiency was cited by the accrediting organization, where it is reasonable to conclude that the deficiencies were present at the time of the accrediting organization's most recent survey of that provider or supplier.

Process disparity rate means, for a direct observation validation survey, the difference between the observed survey process findings and the expected survey process findings expressed as a percentage.

* * * * *

Unannounced survey means a survey that is conducted without any prior notice of any type, through any means of communication or forums, to the facility to be surveyed, and therefore, is unexpected to the facility until the arrival onsite by surveyors. This also means that the accrediting organizations must schedule their surveys so that the facility is unable to predict when they will be performed.

* * * * *

3. Revise § 488.4 to read as follows:

§ 488.4 General rules for a CMS approved accreditation program for providers and suppliers.

(a) The following requirements apply when a national accrediting organization has applied for CMS approval of a provider or supplier accreditation program and CMS has found that the program provides reasonable assurance to providers or suppliers accredited under the program:

(1) The accrediting organizations that accredit Medicare-certified providers and suppliers shall incorporate the applicable Medicare conditions language as their minimum accreditation standards, which are applicable beginning [date 1 year after the effective date of the final rule].

(2) The accrediting organizations that accredit Medicare-certified providers and suppliers shall use a survey process comparable to the processes set out in the State Operations Manual, or as issued via policy memorandums, and approved by CMS, as defined in § 488.5, applicable beginning [date 1 year from the effective date of the final rule].

(3) When a provider or supplier demonstrates full compliance with all of the accreditation program requirements of the accrediting organization's CMS-approved accreditation program,

the accrediting organization may recommend that CMS grant deemed status to the provider or supplier.

(4) CMS may deem the provider or supplier to be in compliance with the applicable Medicare conditions or requirements. The deemed status provider or supplier is subject to validation surveys as provided at § 488.9.

(b) The following requirements apply for termination of a provider's or supplier's Medicare participation agreement on CMS recognition of its accreditation provider by an Accrediting Organization:

(1) If CMS terminates the participation agreement of a provider or supplier, CMS will no longer recognize or accept the accreditation provided by an accreditation organization to that provider or supplier as demonstrating that the Medicare requirements have been met by such provider or supplier; and,

(2) If CMS terminates the participation agreement of a provider or supplier, the terminated provider or supplier must meet all requirements set forth at 42 CFR 489.57 before a new agreement with that provider or supplier for Medicare participation will be approved.

4. Section 488.5 is amended by--

a. Revising paragraphs (a)(3), (4), (5), (6), (8), (10), (12) and (13); and

b. Adding paragraphs (a)(21) and (22)

The revisions and additions read as follows:

§ 488.5 Application and re-application procedures for national accrediting organizations.

(a) * * *

(3) A detailed crosswalk (in table format, as specified by CMS) that identifies each of the applicable Medicare conditions (as defined in § 488.1) incorporating the language of the CMS requirements and standards, and those accreditation standards that exceed the CMS conditions. This requirement, as revised, shall become applicable beginning [DATE 1 YEAR AFTER THE EFFECTIVE DATE OF THE FINAL RULE].

(4) A detailed description of the organization's survey process including, but not limited to, the core activities of the survey process such as, but not limited to, documentation supporting Pre Survey Preparation/Offsite Preparation, Entrance Interview/Activities, Information Gathering/Investigation, Analysis of Information, Exit Conference, Post Survey Activities/Statement of Deficiencies activities, to confirm that a provider or supplier meets or exceeds the Medicare program requirements, and maintains the integrity of the survey process, which is intended to be a non-biased evaluation of a facility's ability to provide safe care and protect the health and safety of patients. This description must include all of the following information:

(i) Frequency of surveys performed and an agreement by the organization to re-survey every accredited provider or supplier, through unannounced surveys, no later than 36 months after the prior accreditation effective date, including an explanation of how the accrediting organization will maintain the schedule it proposes. If there is a statutorily mandated survey interval of less than 36 months, the organization must indicate how it will adhere to the statutory schedule.

(ii) Documentation demonstrating the comparability of the organization's survey process and surveyor guidance to those required for state survey agencies conducting federal Medicare surveys for the same provider or supplier type, in accordance with the applicable requirements or conditions of participation or conditions for coverage or certification.

(iii) Copies of the organization's survey forms, guidelines, and instructions to surveyors, including but not limited to specific processes of how surveyors' survey facilities for the core survey activities: Governing Body, Patient Rights, Emergency Preparedness, Quality Assessment and Performance Improvement, Medical Staff, Nursing Services, Medical Records Services, and Infection Control. This would also include interpretive guidelines and survey probes, including patient and staff interview questions, and processes used by surveyors when interviewing facilities for compliance based on each of the specific survey standards, comparable to those

instructions required for state survey agencies.

(iv) Documentation demonstrating that the organization's survey reports identify, for each finding of non-compliance with accreditation standards, the comparable Medicare CoP, CfC, conditions for certification, or requirements.

(v) Description of the organization's accreditation survey review process, to include but not limited to processes for review of medical records, medical staff credentialing procedures based on services provided; staff record review to review for competency and personnel files; adequate number of patient observations; and confidential patient interviews and staff interviews.

(vi) Description of the organization's procedures and timelines for notifying surveyed facilities of non-compliance with the accreditation program's standards.

(vii) Description of the organization's procedures and timelines for monitoring the provider's or supplier's correction of identified non-compliance with the accreditation program's standards, including the deadlines for initial and reaccreditation surveys, accreditation decisions, as well as the investigative and organizational process which the accrediting organization uses to make these determinations.

(viii) A statement acknowledging that, as a condition for CMS approval of a national accrediting organization's accreditation program, the organization agrees to provide CMS with the following information as part of its initial and renewal applications and, upon request from CMS, and as part of the data submissions required under paragraph (a)(11)(ii) of this section:

(A) a copy of all survey reports, including but not limited to, initial, re-survey, and complaint survey reports, and

(B) any other information related to survey activities as CMS may require (including corrective action plans).

(ix) A statement acknowledging that the accrediting organization will provide timely notification to CMS when an accreditation survey or complaint investigation identifies an immediate jeopardy as that term is defined at § 498.3 of this chapter. Using the format specified

by CMS, the accrediting organization must notify CMS within 2-business days from the date the accrediting organization identifies the immediate jeopardy.

(x) For accrediting organizations applying for approval or re-approval of CMS–approved hospice programs, a statement acknowledging that the accrediting organization (AO) will include a statement of deficiencies (that is, the Form CMS–2567 or a successor form) to document findings of the hospice Medicare conditions of participation in accordance with section 1822(a)(2)(A)(ii) of the Act and will submit such in a manner specified by CMS.

(xi) Documentation summarizing the AOs staff training programs, whether web-based electronic or hard-copy materials, on how the AO provides training or education to surveyors on the AOs survey processes, and, where applicable, highlight differences from CMS survey processes.

(xii) The requirements of paragraph (a)(4), shall become applicable beginning [DATE 1 YEAR AFTER THE EFFECTIVE DATE OF THE FINAL RULE].

(5) Beginning [DATE 1 YEAR AFTER THE EFFECTIVE DATE OF THE FINAL RULE], the criteria the accrediting organization uses in determining the size and composition of the organization's survey teams for the type of provider or supplier to be accredited, these criteria at a minimum should address survey team size and composition based on:

(i) The size of the facility to be surveyed, based on average daily census;

(ii) The complexity of services offered, including outpatient services;

(iii) The type of survey to be conducted;

(iv) Whether the facility has special care units or off-site clinics or locations;

(v) Whether the facility has a historical pattern of serious deficiencies or complaints; and

(vi) Whether new surveyors are to accompany a team as part of their training.

(6) Beginning [DATE 1 YEAR AFTER THE EFFECTIVE DATE OF THE FINAL RULE], the overall adequacy of the number of the organization's surveyors to ensure sufficient amount of time is allotted to complete all survey activities, including how the organization will

increase the size of the survey staff to match growth in the number of accredited facilities while maintaining re-accreditation intervals for existing accredited facilities.

* * * * *

(8) A description of the content and frequency of the organization's in-service training it provides to survey personnel, including the training materials provided, and, with respect to CMS training, a statement acknowledging that:

(i) The accrediting organization will ensure all of its surveyors complete two mandatory CMS online documentation courses and the relevant program-specific CMS online basic surveyor training course (established for state survey agency surveyors), initially, and thereafter when updates are necessary;

(ii) The required CMS online surveyor training will be completed by each existing surveyor before serving on a survey team (except as a trainee); and

(iii) The accrediting organization must document in the staff personnel records for each surveyor, that the CMS online surveyor documentation and basic training courses were completed and the date of completion. The statement must acknowledge that the accrediting organization will maintain this documentation for no less than one accreditation cycle.

(iv) These requirements shall become applicable beginning [DATE 1 YEAR AFTER THE EFFECTIVE DATE OF THE FINAL RULE].

* * * * *

(10) The organization's policies and procedures to avoid conflicts of interest, (as defined in paragraph (a)(10)(v) of this section) including the appearance of conflicts of interest, involving individuals who conduct surveys or participate in accreditation decisions. These policies and procedures will include the following:

(i) The accrediting organization’s policies and procedures for separation of its fee-based consulting services from its accreditation services;

(ii) The accrediting organization’s policies and procedures for protecting the integrity of

the accrediting organization's accreditation program, including the requirements of § 488.8(i) and (k),

(iii) The accrediting organization's policies and procedures for the prevention and handling potential or actual conflicts of interest that could arise from situations in which an accrediting organization owner, surveyor, or other employee has an interest in or relationship with another state survey agency or health care facility to which the accrediting organization provides accreditation services. Such interests or relationships include but are not limited to:

(A) Being employed as a state survey agency surveyor;

(B) Being employed in a health care facility that is accredited by the accrediting organization;

(C) Having an ownership, financial or investment interest in a health care facility that is accredited by the accrediting organization;

(D) Serving as a director of or trustee for a health care facility that is accredited by the accrediting organization;

(E) Serving on a utilization review committee of a health care facility that is accredited by the accrediting organization;

(F) Accepting fees or payments from a health facility or group of health facilities that is/are accredited by the accrediting organization;

(G) Accepting fees for personal services, contract services, referral services, or for furnishing supplies to a health care facility that is accredited by the accrediting organization;

(H) Providing consulting services to a health care facility that the accrediting organization accredits;

(I) Having members of their immediate family engaged in any of the above stated activities. The term "immediate family member" is defined as any person with which the accrediting organization owner(s), surveyors or other employees have a lineal or immediate familial or marital relationship, including a husband or wife, birth or adoptive parent, child, or

sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother–in–law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild.

(J) Engaging in any activities during the course of the survey of the facility that would be or cause a conflict of interest.

(iv) The accrediting organization's policies and procedures for notification of CMS when a conflict of interest is discovered.

(v) For the purposes of this section, a conflict of interest exists when an accrediting organization, the accrediting organization's successors, transferees, or assigns, the accrediting organization owner(s), surveyors, or other employees, or the immediate family members of the accrediting organization owners(s), surveyors and other employees have an employment, business, financial or other type of interest in or relationship with a health care facility the accrediting organization accredits.

* * * * *

(12) Beginning [DATE 1 YEAR AFTER THE EFFECTIVE DATE OF THE FINAL RULE], the organization's procedures for responding to, and investigating, complaints against accredited facilities, including policies and procedures regarding referrals to appropriate licensing bodies and ombudsman programs, when applicable. This would also include:

(i) Accrediting organization's process for triaging and categorizing complaints about the surveyed facility;

(ii) Timeframes for responding to complaints and a method to track and trend complaints received with respect to the accrediting organization's accredited facilities;

(iii) Procedures and persons responsible for the review of plans of corrections and procedures for follow up if the plans of corrections are not adequate;

(iv) Accrediting organization requirements for plans of corrections for standard level deficiencies;

(v) Follow up survey procedures and monitoring of condition-level findings;

(vi) Procedures for addressing immediate jeopardy deficiencies and,

(vii) Sharing of previous deficiency findings or complaints with survey teams.

(13) The organization's accreditation status decision-making process, including its policies and procedures for granting, withholding, or removing accreditation status for facilities that fail to meet the accrediting organization's standards or requirements, assignment of less than full accreditation status or other actions taken by the organization in response to non-compliance with its standards and requirements. The organization must furnish the following:

(i) A description of all types and categories of accreditation decisions associated with the program for which approval is sought, including the duration of each.

(ii) The accrediting organization’s general notification procedures to notify CMS, including the timeframes for notification of any decision to revoke, withdraw, or revise the accreditation status of a specific deemed status provider or supplier. Such notification must be made within three business days from the date the organization takes an action.

(iii) A statement acknowledging that the organization agrees to notify CMS (in a manner CMS specifies) of any decision to revoke, withdraw, or revise the accreditation status of a specific deemed status provider or supplier, within three business days from the date the organization takes an action.

(iv) The organizations process for facilities that withdraw from accreditation, to include timeframes for notification to CMS and include the process for surveying facilities which may require an upcoming survey.

(v) These requirements of this paragraph (a)(13) become applicable beginning [DATE 1 YEAR AFTER THE EFFECTIVE DATE OF THE FINAL RULE].

* * * * *

(21) A statement certifying that, in response to a written notice from CMS notifying the organization that one of its accredited providers or suppliers has been terminated from the

Medicare/Medicaid program, the accrediting organization agrees to terminate or revoke its accreditation of the terminated provider or supplier within 5-business days from receipt of said written notice, and not re-accredit the provider until CMS has approved the provider or supplier for participation in Medicare.

(22) A declaration by each surveyor of any employment, business, financial or other interests in or relationships with a State Survey Agency or a health care facility the accrediting organization accredits as described in paragraph (a)(10)(iii) of this section, which must be updated on an annual basis and submitted to CMS no later than December 31st each year. This provision will become applicable beginning [DATE 1 YEAR AFTER THE EFFECTIVE DATE OF THE FINAL RULE].

* * * * *

5. Section 488.8 is amended by –

a. Revising paragraph (a)(2); and

b. Adding new paragraphs (a)(4), (i), (j) and (k).

The revision and additions read as follows:

§ 488.8 Ongoing review of accrediting organizations.

(a) * * *

(2) Analysis of the results of the validation surveys under § 488.8(a)(4), including the outcome disparity rate as determined from look-back validation surveys, surveys from substantial allegations of noncompliance, and the process disparity rate as determined from direct observation validation surveys.

* * * * *

(4) When an accrediting organization's performance measure scores as determined from look-back and direct observation validation surveys, reveal that the accrediting organization's accreditation survey activities do not meet an acceptable performance threshold established by

CMS, the accrediting organization will be required to submit an acceptable plan of correction that meets the requirements set forth below:

(i) The accrediting organization's acceptable plan of correction must be submitted to CMS for review within 10 business days of CMS notification of not meeting acceptable performance. An acceptable plan of correction must:

(A) Document specific actions being taken by the accrediting organization to address improving performance.

(B) Document the timeframe for implementation of this plan.

(C) Plan for ongoing monitoring of the plan of correction toward achieving an acceptable level of performance.

(D) Identify the individual responsible for implementation and monitoring of the acceptable plan of correction.

(ii) Upon review and approval of the plan of correction, CMS will provide ongoing evaluation of the progress of plan implementation.

(iii) The accrediting organization's plan of correction is subject to public reporting by CMS.

* * * * *

(i) *Restrictions on fee-based consulting provided by accrediting organizations or their fee-based consulting divisions or separate fee-based business entities.* (1) Except as provided in paragraph (i)(4) of this section, an accrediting organization or its fee-based consulting division or separate business entity (such as a company or corporation, that provides fee-based consulting), may not provide fee-based consulting services to any new health care provider or supplier before the initial accreditation survey has been completed. For purposes of this paragraph, the term "initial survey" means the first accreditation survey performed of a health care provider or supplier by an accrediting organization that has not previously received accreditation services from that accrediting organization. If a health care provider or supplier is terminated or

withdraws from the services of an accrediting organization and later retains the services of the same or a new accrediting organization, the first survey performed by the same or new accrediting organization of that health care provider or supplier would be considered an initial accreditation survey;

(2) Except as provided in paragraph (i)(4) of this section, an accrediting organization, its fee-based consulting division or separate business entity, such as a company or corporation, that provides fee-based consulting, may not provide fee-based consulting services to a health care provider or supplier the accrediting organization accredits within 12 months prior to the next scheduled re-accreditation survey of that provider or supplier. For purposes of this paragraph, the term "re-accreditation survey" means the any subsequent accreditation surveys performed by the accrediting organization following the initial survey;

(3) Except as provided in paragraph (i)(4), an accrediting organization, its fee-based consulting division, or separate business entity, such as company or corporation that provides fee-based consulting, may not provide fee-based consulting services to a health care provider or supplier, to which the accrediting organization provides accreditation services, in response to a complaint received by the accrediting organization regarding that provider or supplier.

(4) An accrediting organization, its fee-based consulting division, or separate business entity, such as a company or corporation that provides fee-based consulting, may provide fee-based consulting to the health care providers and suppliers it accredits only under the following circumstances:

(i) During the 24-month period after an initial or re-accreditation survey is performed.

(ii) To address complaints received and investigated by the State Survey Agency regarding an accrediting organization's accredited provider or supplier in which one or more condition level or immediate jeopardy deficiencies are identified. Such fee-based consulting by an accrediting organization may occur only after the State Survey Agency complaint

investigation and survey has been completed and must only address those issues identified by the complaint survey.

(iii) Fee-based consulting services provided to health care providers or suppliers the accrediting organization does not accredit at the time the consulting services are furnished.

(iv) Non fee-based consulting or general education provided by the accrediting organization about their accreditation program.

(5) The accrediting organization must provide to CMS, on a biannual basis, a document which contains the following information:

(i) Whether the accrediting organization or an associated consulting division or company established by the accrediting organization provides fee-based consulting services;

(ii) The names and CCN numbers of all health care providers and suppliers to which the accrediting organization or its associated consulting division or company has provided fee-based consulting services during the previous 6-month period;

(iii) The dates the fee-based consulting services were provided to each provider and supplier;

(iv) Whether the accrediting organization has, at any time in the past provided, or is currently providing accreditation services to each health care provider or supplier listed in said document; and

(v) For each health care provider and supplier listed in said document, the date of the most recent accreditation survey performed, and the date the next re-accreditation survey is due to be performed; and

(vi) A description of the fee-based consulting services provided to each health care provider or supplier listed in said document.

(6) If an accrediting organization provides fee-based consulting services to a health care provider or supplier it accredits, in violation of the restrictions set forth in paragraphs (i)(1), (2) and (3) of this section, CMS may take the following actions:

(i) CMS may place the accrediting organization on a CMS approved accreditation program review in accordance with paragraph (c) of this section; or

(ii) CMS may involuntarily terminate the CMS approval for the accreditation programs in accordance with paragraph (g) of this section.

(7) The provisions at paragraph (i) of this section will become applicable beginning [DATE 1 YEAR FROM THE EFFECTIVE DATE OF THE FINAL].

(j) *Accrediting organization fee -based consulting firewall policies and procedures.* (1) An accrediting organization, its fee-based consulting division, or separate business entity, such as a company or corporation that provides fee-based consulting services to the health care providers and suppliers the accrediting organization accredits, must have written fee-based consulting firewall policies and procedures, which, at a minimum, include the following provisions:

(i) The accrediting organization's fee-based consulting services must be provided by a separate division of the accrediting organization or separate business entity, such as a company or corporation, that is separate from the accrediting organization's accreditation division;

(ii) An accrediting organization's fee-based consulting division or separate business entity must maintain separate staff from that of the accrediting organization's accreditation divisions to ensure that the fee-based consulting division staff do not perform accrediting organization's accreditation division functions and that the accrediting organization's accreditation division staff do not perform fee-based consulting division functions; and

(iii) An accrediting organization's accreditation staff and surveyors are prohibited from marketing the accrediting organization's fee-based consulting services to the accrediting organizations accreditation clients.

(2) An accrediting organization that provides fee-based consulting must submit its written fee-based consulting firewall policies and procedures to CMS by a date specified by CMS and with each application submitted seeking renewal of the CMS approval for their accreditation

programs.

(k) *Conflict of interest due to accrediting organization owner, surveyor or other accrediting organization employee relationship with a health care facility accredited by the accrediting organization.* (1) If an accrediting organization owner, surveyor or other employee, currently or within the previous 2 years, has an interest in or relationship (as defined in § 488.5(a)(10)(iii)(B) to 488.5(a)(10)(iii)(J)) with a health care facility, accredited by the accrediting organization, the accrediting organization owner, surveyor or other employee shall not be permitted to:

(i) Participate in the survey of that health care facility,

(ii) Have input into the results of the survey and accreditation for that health care facility,

(iii) Have involvement with the pre-or post-survey activities for that health care facility, or

(iv) Have contact with or access to the records for the survey and accreditation of that health care facility.

(2) For the purposes of this section, "immediate family member" is defined as any person that has a lineal familial or marital relationship with the accrediting organization owner, surveyor or other employee. Immediate family members would include a husband or wife, birth or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in -law, mother-in-law, son-in-law, daughter-in-law, brother–in–law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild.

6. Revise § 488.9 to read as follows:

§ 488.9 Validation surveys.

(a) *Basis for survey*. CMS may require a survey of an accredited provider or supplier to validate the accrediting organization's CMS-approved accreditation process. These surveys are conducted on a representative sample basis, or in response to substantial allegations of non-compliance.

(1) For a representative sample, the survey may be comprehensive and address all Medicare conditions or requirements, or it may be focused on a specific condition(s) as determined by CMS.

(2) For a substantial allegation of noncompliance, the SA surveys for any condition(s) or requirement(s) that CMS determines is related to the allegations.

(b) *Types of validation surveys.* (1) Look-back Validation Surveys are performed by the state survey agency on a sample of health care facilities accredited by CMS approved accrediting organization that are scheduled for survey by the accrediting organization, and are performed within 60 days after the accrediting organization has performed its survey.

(2) Direct observation validation surveys are performed on a sample of the accrediting organization's surveys and are performed concurrently by the accrediting organization and the state survey agency or CMS. The state survey agency or CMS surveyors are present to observe the accrediting organization's survey process.

(c) *Rules for state look-back validation surveys.* (1) All look-back validation surveys will be unannounced to the accrediting organization and the facility being surveyed.

(2) The look-back validation survey may address compliance with all Medicare conditions or requirements, or it may be focused on a specific condition(s) or requirement(s) as determined by CMS.

(3) For a look-back validation survey that addresses a substantial allegation of non-compliance, the state survey agency surveys for any condition(s) or requirement(s) that CMS determines is related to the allegations.

(d) *Selection for look-back validation survey.* (1) A provider or supplier selected for a look-back validation survey must cooperate with the state survey agency that performs the look-back validation survey.

(2) If a provider or supplier selected for a look-back validation survey fails to cooperate with the state survey agency, it will no longer be deemed to meet the Medicare conditions or

requirements, will be subject to a review in accordance with paragraph (a) of this section, and may be subject to termination of its provider agreement under § 489.53 of this chapter.

(e) *Rules for direct observation validation surveys.* (1) All direct observation validation surveys will be unannounced to the accrediting organization and the facility being surveyed.

(2) The state survey agency or CMS surveyors will generally be assigned to the accrediting organization surveyors on a 1:1 basis, matching the experience of the accreditation surveyor where possible, and using the CMS approved standards and processes to determine compliance with the Medicare conditions.

(3) The state survey agency or CMS surveyors will observe the accrediting organization survey in accordance with CMS established policies and procedures and will report the findings directly to CMS.

(4) Where the state survey agency or CMS surveyors disagree with the findings of the accrediting organization surveyors, and these differences cannot be reconciled, CMS will render a final decision. Such decision would not be appealable under part 498 of this chapter.

(f) *Provider or supplier not in compliance.* A provider or supplier will be deemed non-compliant with the validation process, in accordance with this section, if any of the following conditions are present:

(1) The provider or supplier refuses to authorize its accrediting organization to release a copy of their current accreditation survey to CMS;

(2) The provider or supplier refuses to allow a validation survey (for either look-back or direct observation validation surveys); or,

(3) CMS finds that the provider or supplier does not meet the applicable Medicare Conditions of Participation, Conditions for Coverage, conditions of certification, or requirements.

(g) *Consequences for a finding of non-compliance.* (1) If a CMS validation look-back or direct observation validation survey results in a finding that the provider or supplier is out of

compliance with one or more Medicare conditions or requirements, deemed status may be removed by CMS and the provider or supplier will be subject to ongoing review by the state survey agency (in accordance with § 488.10(d)) until the provider or supplier demonstrates compliance.

(2) CMS may take actions for the deficiencies identified in the look-back validation survey or direct observation survey in accordance with § 488.24, or may first direct the state survey agency to, or CMS may, conduct another survey of the provider's or supplier's compliance with specified Medicare conditions or requirements before taking the enforcement actions provided for at § 488.24.

(3) If CMS determines that a provider or supplier is not in compliance with applicable Medicare conditions or requirements, they may be subject to termination of their provider agreement with CMS under § 489.53 of this chapter and any other applicable intermediate sanctions and remedies.

(h) *Re-instating deemed status.* An accredited provider or supplier will be deemed to meet the applicable Medicare conditions or requirements in accordance with this section, if the following requirements are met, as applicable:

(1) It withdraws any prior refusal to authorize its accrediting organization to release a copy of the provider's or supplier's current accreditation survey.

(2) It withdraws any prior refusal to allow a look-back or direct observation validation survey, if applicable.

(3) CMS finds that the provider or supplier meets all applicable Medicare Conditions of Participation, Conditions for Coverage, conditions of certification, or other requirements.

(i) *Impact of adverse actions.* The existence of any performance review, comparability review, deemed status review, probationary period, or any other action by CMS, does not affect or limit conducting any validation survey.

PART 489—PROVIDER AGREEMENTS AND SUPPLIER APPROVAL

7. The authority citation for part 489 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395i-3, 1395x, 1395aa(m), 1395cc, 1395ff, and 1395(hh).

8. Section 489.20 is amended by adding paragraph (z) to read as follows:

§ 489.20 Basic commitments.

* * * * *

(z) In the case of a provider that has been involuntarily terminated by CMS under § 489.53, or by the OIG under § 489.54, reinstatement of the provider agreement is subject to § 489.57(b).

9. Revise § 489.57 to read as follows:

§ 489.57 Reinstatement after termination.

When a provider agreement has been terminated by CMS under § 489.53, or by the OIG under § 489.54, a new agreement with that provider will not be accepted unless:

(a) CMS or the OIG, as appropriate, finds –

(1) That the reason for termination of the previous agreement has been removed and there is reasonable assurance that it will not recur; and

(2) That the provider has fulfilled, or has made satisfactory arrangements to fulfill, all of the statutory and regulatory responsibilities of its previous agreement.

(b) The terminated provider or supplier that had deemed status meets the following requirements before a new agreement with that provider or supplier may be approved:

(1) The terminated provider or supplier must become and remain under the exclusive oversight of the state survey agency for a reasonable assurance period of a length of time to be determined by CMS, for the purposes of the initial survey, certification and demonstration of compliance with the Medicare conditions.

(2) The terminated provider or supplier must remain under the exclusive oversight of the state survey agency until the state survey agency or CMS has certified that the provider or supplier is in compliance with all applicable Medicare conditions and the agreement for

participation in the Medicare/Medicaid program has been approved.

(3) During the time period in which a terminated provider or supplier is not certified to participate in the Medicare program, while the prospective provider or supplier is under the oversight of the state survey agency, and while the new agreement for Medicare participation is pending, CMS will not accept or recognize deeming accreditation from a CMS-approved accrediting organization until the applicable Medicare requirements have been met or exceeded, as described in § 488.4 of this chapter.

Xavier Becerra,
Secretary,
Department of Health and Human Services.
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