Issue Brief

FEDERAL ISSUE BRIEF

Analysis provided for MHA by Larry Goldberg, Goldberg Consulting

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CMS Proposing Strengthening Oversight of Accrediting Organizations (AOs) and Preventing AO Conflict of Interest, and Related Provisions

The Centers for Medicare & Medicaid Services (CMS) have issued a proposed rule that 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.

"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 (is something missing here – deemed what); (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."

A copy of the proposal is at: https://public-inspection.federalregister.gov/2024-02137.pdf. Publication in the ***Federal Register*** is scheduled for February 15. A 60-day comment period is provided.

Comments

It is interesting to continue to see the variations in CMS' rulemaking. Some documents are bare minimum content. Others dwell extensively on past history. Some have no table of contents and others a reasonable table of contents.

This rule has an extensive table of contents. We are detailing most sections below. We, again, are adding page numbers in red.

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Provisions of the Proposed Rule

The material that follows is excerpted from CMS' fact sheet accompanying this proposal

"The changes proposed in the NPRM would strengthen oversight of AOs, reduce conflicts of interest, and strive for enhanced consistency of survey processes, all of which aim to improve patient safety and quality of care. These proposed changes, which align with CMS's National Quality Strategy, are outlined below:

- Holding AOs accountable to the same standards as State Survey Agencies (SAs), that also conduct surveys on behalf of CMS.
- Ensuring that AOs remain independent reviewers by addressing conflicts of interest and placing certain limitations on the fee-based consulting services AOs provide to the health care facilities they accredit.
- Preventing AO conflicts of interest by prohibiting AO owners, surveyors, and other employees, and as well as their immediate family members that have an interest in or relationship with a health care facility accredited by the AO from participating in surveys, having input into the survey results and involvement in pre- or post-survey activities of that facility, or from having access to survey records related to that facility.

- Addressing potential and actual conflicts of interest by requiring AOs to report specific information to CMS about how they will monitor, prevent, and handle conflicts of interest and fee-based consulting services they provide.
- Improving AO performance by requiring AOs with poor performance to submit a publicly reported correction plan to CMS.
- Improving consistency and standardization in surveys nationwide by more closely aligning AO survey activity requirements and staff training with those of SAs."

Affected AOs

"Currently, CMS has approved nine AOs to survey and accredit Medicare-certified facilities. The changes outlined in the NPRM affect all AOs except those that accredit clinical laboratories and noncertified suppliers, which include suppliers of advanced diagnostic imaging (ADI), home infusion therapy (HIT), and diabetes self-management training (DSMT), as well as durable medical equipment (DME) suppliers and suppliers of durable medical equipment prosthetics, orthotics, and supplies (DMEPOS)."

Summary of Major Provisions (Page 7)

- CMS proposes at § 488.1 to add the definitions of "geographic regions", "national in scope," "outcome disparity rate," "process disparity rate," and "unannounced survey". In addition, CMS proposes to revise the definition of "national accrediting organization," and remove the definition of "rate of disparity."
- CMS proposes 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).
- CMS proposes 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.
- CMS proposes 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.
- CMS proposes to require AOs to develop a crosswalk between their accreditation standards and the Medicare conditions, at proposed § 488.5(a)(3).
- CMS proposes 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.
- CMS proposes 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. CMS also proposes 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.
- CMS proposes 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.

- CMS proposes 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. CMS proposes that AOs provide information on a number of specific policies and procedures.
- CMS proposes to also revise requirements under § 488.5(a)(12) related to the AO procedures for investigating and responding to complaints against accredited facilities.

- CMS proposes 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.
- CMS proposes 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.
- CMS proposes 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)).
- CMS proposes at § 488.8(a)(2) to expand the types of validation activities included in the performance review.
- CMS proposes 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.
- CMS proposes 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), CMS proposes 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), CMS proposes 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 reaccreditation survey of that provider or supplier. At § 488.5(i)(3), CMS proposes 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), CMS sets forth circumstances in which the restrictions to the provision of AO fee-based consulting services would not apply.
- CMS proposes 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.
- CMS proposes at § 488.8(i)(6) to impose penalties on AOs for the provision of prohibited fee-based consulting services.
- CMS proposes 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.
- CMS proposes 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.
- CMS proposes 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.
- CMS proposes 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.

- CMS also proposes 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***. Consistent with this same provision, CMS also proposes to remove the reference restricting transplant programs from an accreditation option.
- CMS is soliciting comments on whether CMS should limit the number of times an AO can submit an incomplete initial application for a new accreditation program. CMS seeks comment on this question because it 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.

Collection of Information and Burden (Pages 112 and 143)

CMS spends considerable effort in establishing the costs and burdens of information being required. The following table summarizes such.

Summary of Cost Burdens

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 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
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. Burden Related to Requirement that AOs Must Use Comparable Survey Processes to That Used by CMS and the SAs 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
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

Final Thoughts.

While this proposal is basically aimed at accrediting organizations, providers will be impacted as well. To insure knowledge of the changes being proposed are well understood, there is no alternative to reading the entire rule.

There are areas that we disagree with CMS' findings. For example, CMS says it should take no more than 2 hours to read the document. I needed more than 2 hours. Not sure how others can do such in the 2 hours.

"Assuming an average reading speed, we (CMS) estimate that it would take approximately 2 hours for the staff to review this proposed rule." (Page 177)