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Association**

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July 1, 2013

Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

Re: CMS-3255-P, Medicare and Medicaid Programs; Survey, Certification and Enforcement Procedures; Proposed Rule (Vol. 78, No. 66), April 5, 2013

Dear Ms. Tavenner:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations and our 43,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule to revise the survey, certification and enforcement procedures related to the agency's oversight of national accrediting organizations (AOs). We commend CMS for its efforts to update the regulations related to oversight of CMS-approved AO programs and for its dedication to ensure that patients receive high-quality, safe care.

The proposed rule would revise the regulations that govern the oversight of various types of CMS-approved accreditation programs, including but not limited to, hospital accreditation programs. Among other provisions, CMS proposes to update the application procedures for AOs who wish to submit a program for approval and revise the performance review process for AOs within the context of their CMS-approved programs. We note that AOs may have additional non-CMS approved programs that do not evaluate whether providers meet Medicare program requirements, and those programs fall outside of the parameters of this rule.

In our view, a continuous collaborative partnership between CMS and AOs serves patients best, and we encourage CMS to work with AOs to define what that partnership looks like. However, our overarching concern about this rule is that some of its provisions will substantially change the nature of the relationship between CMS and AOs from a partnership model to a framework in which CMS is overly prescriptive. This, in turn, may alter the relationship between AOs and hospitals.



We are particularly concerned about the proposal to require AOs to demonstrate comparability of their standards and survey processes to those of state survey agencies (SAs). It is unclear what will be required of AOs to meet this obligation, and we believe AOs do a better job of updating their standards than SAs. In addition, we do not believe that AOs should be required to obtain approval for changes to non-Medicare related standards within a CMS-approved accreditation program. That overreaching proposal could cause delays in implementing improved standards. We elaborate on these issues below and identify other provisions within the proposed rule that stray too far from statutory authority, lack clarity or could negatively impact patient care.

BACKGROUND

For more than 50 years, hospitals have relied on the accreditation surveys conducted by AOs, particularly The Joint Commission (TJC), to give them an unbiased and expert review of their operations and to reveal important opportunities for improvement. The work of AOs helps hospitals keep patients safer from harm and deliver higher quality care. We view AOs as key experts in the field of quality improvement.

At the same time, AOs have become important partners with CMS in the agency's administration of the Medicare program. As you know, if the Secretary finds that accreditation of certain provider entities by an AO demonstrates that the applicable conditions or requirements for participation in Medicare are met or exceeded, the law requires her to treat the entities as meeting those conditions or requirements. For example, hospitals are "deemed" to meet the hospital Conditions of Participation (CoPs) when they are accredited by TJC as long as the Secretary finds that TJC's hospital accreditation program standards and procedures meet or exceed the CoPs. This framework relieves CMS of the need to spend time and resources on the task of surveying thousands of hospitals for compliance with the Medicare CoPs.

CMS and the AOs share the same goal of ensuring safe, high-quality patient care, but their approaches to setting standards and conducting surveys differ. In general, TJC has done a better job of updating its standards to reflect new knowledge and changes in practice. In addition, TJC has improved its survey processes, adapting methods of improvement and embracing the role of leadership and culture in the review of hospital care.

COMPARABILITY TO STATE SURVEY STANDARDS AND PROCESSES

Under the proposed rule, a new provision at § 488.5(a)(4)(ii) would require AOs to demonstrate the comparability of their survey processes and surveyor guidance to those required for state SAs conducting federal Medicare surveys for the same provider or supplier type as specified in the State Operations Manual (SOM). However, CMS does not elaborate on what it means by "demonstrating comparability." Since CMS does not clearly identify what would be required of AOs to comply with this provision, we cannot determine how changes might affect accredited providers. We believe CMS has not provided adequate information to justify finalizing its proposal. We are concerned that CMS intends to (1) require AOs to adhere to quality standards included in the SOM guidance and (2) require AOs to alter their current survey processes to conform to those required of the state SAs. The AHA opposes both of these potential actions

because they would constitute a step back from the AOs' more effective standards and survey processes.

Demonstrating Comparability with SOM Standards

TJC accredits most hospitals in the U.S. As one of TJC's partners, the AHA has observed that TJC's quality standards are extremely well-researched in terms of both their impact on patient safety and their feasibility. Proposed changes in TJC standards typically undergo a rigorous process of review by an expert panel as well as a public comment period to ensure the changes will achieve their purpose. The SOM sub-regulatory guidance is not as widely reviewed and specifically lacks a public review period to enable stakeholders to weigh in on a standard's effectiveness or impact. Given the wide variability in the sizes, structures, locations, processes, capacities, technology capabilities and unique attributes (i.e., academic, specialty) of hospitals, as well as differences in patient characteristics, community resources and state laws, it is vitally important to investigate thoroughly the impact of any proposed changes in standards through rigorous review processes that include a public comment period. **It would be a mistake to require AOs to align their guidance standards with those of the SOM, which are not as thoroughly vetted and could prove infeasible or negatively impact patient care.**

Further, TJC, as a private organization of experts in hospital quality, has a better ability to keep standards current with advances in medicine, technology and facility management. The standards included in the SOM guidance are often outdated both in terms of quality standards and regulatory requirements. For example, SOM Appendix W, which is the state surveyor guidance for critical access hospitals, cites older versions of regulations. In some cases, Appendix W references regulations that are up to seven years out of date. Further, CMS regulations themselves are frequently outdated, such as the CoP requirement that hospitals comply with the 2000 edition of the Life Safety Code. The most recent edition is 2012.

Demonstrating Comparability with SOM Survey Processes

In addition to our concerns about whether AOs will need to change their survey standards, it is completely unclear whether or how AOs would need to change their survey processes to demonstrate comparability to SA survey processes. Currently, TJC's core survey process utilizes a tracer methodology that tracks patients throughout their hospital stays to assess compliance with current standards. We cannot gauge whether TJC would need to change any aspect of this methodology or any other aspect of its survey activities. For example, would AOs need to change how they handle complaint surveys? We note that in some parts of the SOM, surveyor processes are very specific to the SAs, such as provisions within Chapter Five that require SAs to obtain approval from a Regional Office before conducting a complaint survey. Further, we are concerned that CMS might require AOs to conduct additional onsite surveys as compared to current practice. Such a requirement could cause hospitals to incur higher expenses without value added. We want to ensure that CMS does not begin to create disincentives for hospitals with financial challenges to remain accredited and thus impact their ability to receive continuous patient safety information.

Given the uncertainty of how AOs would be required to change their survey processes and guidance, as well as what impacts such changes would have on providers, we urge CMS not to finalize this provision of the proposed rule. CMS needs to be more specific about how it

will require providers “to demonstrate comparability” and whether this proposed provision would apply to all or only parts of the SOM. **At the very least, in the final rule, CMS should clarify that “demonstrating comparability” does not mean that AOs must have quality standards and survey processes that are identical to those included in the SOM.**

CMS APPROVAL FOR CHANGES TO AO ACCREDITATION PROGRAM REQUIREMENTS

In two sections of the proposed regulatory language, CMS would codify its expectation to review AO program changes before such changes may be implemented. Proposed language at § 488.5(a)(19) states that AOs must “provide written notification to CMS at least 60 calendar days in advance of the effective date of any proposed changes in the organization’s CMS-approved accreditation program requirements, including an agreement not to implement the changes before receiving CMS approval.”

Similar proposed regulatory language appears at § 488.8(b)(2)(i) and (ii):

- (i) An accrediting organization must provide written notice to CMS at least 60 calendar days before the proposed effective date of any proposed changes in its accreditation requirements or survey process.
- (ii) The accrediting organization must not implement any changes before receiving CMS’s approval.

The AHA has two concerns about these provisions. First, in § 488.8(b)(2)(i), the words “CMS-approved” do not appear before the words “accreditation requirements” as they do in § 488.5(a)(19). Therefore, § 488.8(b)(2)(i) reads more broadly than § 488.5(a)(19). We believe that CMS does not intend to require AOs to submit changes to non-Medicare related programs to CMS for approval. Specifically, in the preamble of the proposed rule, CMS states:

Further, the current provision seems to require the AO to submit information on its accreditation programs that fall outside the parameters of its Medicare accreditation programs. Since we do not approve accreditation programs unrelated to Medicare, we believe that there is no reason to require AOs to submit such information to us, nor for us to have and review this non-relevant information.

We agree that it would be inappropriate for CMS to require AOs to submit changes to their programs that are unrelated to Medicare deeming status, and we urge CMS to add the words “CMS-approved” before the words “accreditation requirements” to § 488.8(b)(2)(i).

Second, CMS should not require AOs to obtain approval for changes to non-Medicare related standards within a CMS-approved accreditation program. For example, within an accreditation program, TJC may include emergency preparedness standards for which a related Medicare requirement does not exist. We understand that currently, TJC does alert CMS when a TJC standard that lacks a related Medicare requirement is substantively updated, and CMS could require such notice. While it is appropriate for AOs to provide that information to CMS, AOs should not be required to *obtain approval* to implement standards within a CMS-approved

accreditation program that lacks a related Medicare requirement. To require such approval could delay needed improvements or updates in patient safety standards and would be exceptionally intrusive upon the activities of a private organization. If CMS has concerns that a non-Medicare related standard could impact Medicare requirements, then CMS would have the opportunity to voice that concern upon an AO's notice of such a change and ultimately, if necessary, initiate an AO program review. **For all of the reasons listed above, we suggest that CMS amend the language at § 488.5(a)(19) and § 488.8(b)(2)(i) to require AOs to “provide written notification to CMS at least 60 calendar days in advance of the effective date of any proposed changes in the organization’s Medicare-related standards within CMS-approved accreditation program requirements, including an agreement not to implement the changes before receiving CMS approval.”**

APPROVAL OF AO ACCREDITATION PROGRAMS IN THEIR ENTIRETY

In the preamble of the proposed rule, CMS states it will add a new provision at § 488.4(b) to make it clear that an AO's CMS-approved accreditation program would need to be approved in its entirety. CMS states: “Under this provision, an AO would not be permitted to make a recommendation to us for deemed status for a provider or supplier unless that provider or supplier satisfied all of the AO's requirements for accreditation. This would include both the AO accreditation program standards that may exceed the Medicare standards, as well as those that meet the Medicare standards.”

However, the regulatory text for proposed § 488.4(b) merely reads, “Reserved,” and it contains no relevant language. We think the intended language may be captured in proposed § 488.4(a)(1). That section reads: “When a provider or supplier demonstrates full compliance with all of the accreditation program requirements of the national accrediting organization's CMS-approved accrediting program, the national accrediting organization may recommend to CMS to grant deemed status to the provider or supplier.”

We believe this provision creates a double standard between accredited and non-accredited hospitals because accredited organizations must then meet higher standards to participate in Medicare. Further, we are concerned about the rare situation in which a hospital may be found by an AO to be fully in compliance with the CoPs and yet not obtain accreditation because it does not meet an AO standard that falls outside of the CoPs. No hospital should be at risk of losing its deemed status and possibly even its Medicare agreement when it is actually in compliance with Medicare requirements. Further, in this scenario it would be a waste of time and resources to require an additional survey by a state agency or another AO to certify CoP compliance. In the context of an AO's larger accreditation program (and without AOs necessarily having a separate CoP certification program), AOs should be able to notify CMS when a hospital meets the CoPs, and CMS should enable hospitals to be deemed compliant with the CoPs with such notification.

Also, we note that although CMS is clarifying that it will approve accreditation programs in their entirety, we do not believe that CMS intends to use the AO application process to assert authority over an AO's non-Medicare related standards. In fact, we do not believe Medicare law provides that authority.

NEW DEFINITION OF “REASONABLE ASSURANCE”

Currently, the term “reasonable assurance” means that an AO has demonstrated to CMS’s satisfaction that its requirements, *taken as a whole*, are at least as stringent as those established by CMS, *taken as a whole*. The proposed new definition of “reasonable assurance” would state that an AO has demonstrated to CMS’s satisfaction that its accreditation program requirements meet or exceed the Medicare program requirements. We are concerned about the deletion of the words “taken as a whole.” AOs may have standards related to Medicare requirements that effectively achieve the protections envisioned by CMS but which lack an exact one-to-one correspondence with a specific CoP. **We urge CMS to modify this proposed definition to clarify that CMS will accept AO requirements that may not be identical to Medicare requirements but that achieve the same patient safety goals.** For example, CMS could add the phrase, “although AO standards and Medicare requirements need not be identical” to the end of the proposed definition.

AO INVOLVEMENT IN THE CREATION OF COPs

Current regulations require the Secretary to consult with TJC and the American Osteopathic Association before creating CoPs that are “higher or more precise” than the AOs’ requirements. CMS would change this language to state that “The Secretary may consult with state agencies and other organizations to develop conditions of participation, conditions for coverage, conditions for certification, and long-term care requirements.” **We believe this language is inconsistent with existing statutory law, which requires the Secretary to consult certain organizations. We urge CMS to review Section 1863 of the *Social Security Act*, which states:**

In carrying out his functions, relating to determination of conditions of participation by providers of services, under subsections (e)(9), (f)(4), (j)(15), (o)(6), (cc)(2)(I), and (dd)(2) of section [1861](#), or by ambulatory surgical centers under section [1832\(a\)\(2\)\(F\)\(i\)](#), the Secretary shall consult with appropriate State agencies and recognized national listing or accrediting bodies, and may consult with appropriate local agencies.

CMS should change the proposed language to conform to the statute and clarify that the Secretary will consult with appropriate state agencies and recognized national listing or accrediting bodies in developing CoPs. We encourage CMS to continue its practice of consulting organizations such as the AHA and TJC in developing CoPs in order to benefit from the knowledge and expertise of organizations that work with all types of hospitals every day to improve patient safety and quality of care.

CONFLICTS OF INTEREST

CMS would strengthen a provision at § 488.5(a)(10) stating that AOs must provide to CMS their “policies and procedures for avoiding potential conflicts of interest by precluding individuals who are professionally or financially affiliated with a provider or supplier from participating in the survey or accreditation decision process with respect to that provider or supplier.” This

language is very similar to the current regulation, but neither the current nor the proposed language mentions any potential conflicts of interest with a surveyor who might have a relationship with someone who works at a *competitor* of the hospital being surveyed. **We encourage CMS to incorporate this potential conflict of interest into the regulations.**

NOTIFICATION TO PROVIDERS

There is confusion in the proposed rule about the time allotted for AOs to notify providers when they voluntarily terminate a CMS-approved accreditation program. At proposed § 488.5(a)(18), the AO would need to give providers/suppliers at least 90 days notice before the effective date of a voluntary termination. At proposed § 488.8(e), an AO must notify providers no later than 30 calendar days after the notice is published in the *Federal Register* when either CMS approval has been withdrawn or when the AO voluntarily terminates its program. These timeframes may be compatible, but it is unclear why there must be two separate standards phrased in different ways. **We encourage CMS to ensure hospitals have as much notice as possible, at least 90 days, and to simplify the notice requirement so that providers know what to expect.**

USE AND DISCLOSURE OF ACCREDITATION SURVEYS

The proposed rule retains language stating that CMS may determine that a provider does not meet Medicare requirements on the basis of its own investigation of the accreditation survey or any other information related to the survey. Given the framework of the AO deeming structure and its checks and balances, we do not agree that CMS should be second-guessing the decisions of the AOs. Should CMS have concerns about a particular survey, the agency should engage the AO in a conversation about its concerns. However, in the context of the robust accreditation program application process and the ongoing performance reviews of AOs, it is unclear why CMS would keep this redundancy rather than trust the AOs to which it has delegated authority. **CMS should remove this provision from the regulations.**

The proposed rule also retains language at § 488.7 that CMS may publicly disclose an accreditation survey and information related to that survey upon written request if they are related to an enforcement action by CMS. When accreditation survey information is supplied to the public, we urge CMS to also supply information about any corrective action that was taken by the provider. Otherwise, the patients are put at a disadvantage because they may not understand that a deficiency at a preferred hospital has been corrected.

ONGOING REVIEW OF ACCREDITING ORGANIZATIONS

At proposed § 488.8, CMS would retain language that allows the agency to conduct onsite observations of AO activities in order to verify the organization's representations and assure the organization's compliance with CMS policies and procedures. We are concerned that the language in this section, which allows CMS to review documents, audit meetings and interview staff, is too broad. While we agree that CMS should be able to conduct onsite observations of AOs, the language is not tailored to CMS-deemed programs only.

CMS should amend its language to clarify that (1) onsite inspections will relate only to CMS-approved deeming programs and (2) onsite inspections will be reasonable in scope and will not disrupt normal business activities.

CONTINUATION OF DEEMED STATUS

Under the proposed rule, if CMS removes approval of an AO accreditation program, the affected providers' deemed status will continue for 180 days as long as the providers submit an application to another AO approved program within 60 calendar days of the *Federal Register* notice. The current requirement is to continue deemed status for 120 days. However, it is unclear why deemed status would not continue until the providers' next scheduled survey. Unless CMS has found serious deficiencies related to an AO's ability to assess providers on quality and patient safety, the affected providers' deemed status should remain the same. **While we appreciate the longer timeframe, we recommend that the provider retain its accreditation status until its next scheduled survey.**

IMMEDIATE JEOPARDY

Current language at § 488.28(a) states that when a provider has deficiencies, it must provide an acceptable plan of correction to achieve compliance in a reasonable amount of time in order to continue participating in Medicare. In the proposed rule, CMS would add language that states, "In the case of an immediate jeopardy situation, the Secretary may require a shorter time period for achieving compliance." The AHA agrees that hospitals must act quickly when a deficiency could pose serious risk to patient health and safety. **We also believe that CMS needs to revise the way immediate jeopardy (IJ) citations are handled.** The decision of whether a citation should be issued at the condition-level or the IJ-level is subjective. As noted previously, our member hospitals have experienced inconsistency in the way IJ citations are processed. For example, some state SAs appear to cite IJs more frequently than others. We surmise that a handful of states may account for a large proportion of IJ citations. In addition, disagreement may exist between the state SA and the regional office as to what constitutes an IJ situation, putting hospitals in the middle.

VALIDATION SURVEYS

At proposed § 488.9, CMS states that the basis for a validation survey may include a substantial allegation of non-compliance. However, the statutory authority for this basis is more specific. Current law at 42 USC 1395aa(c) states that the Secretary may contract with states to conduct surveys when "substantial allegations of the existence of a significant deficiency or deficiencies which would, if found to be present, adversely affect health and safety of patients..." **We urge CMS to amend its proposed regulatory language to align with the statutory language.**

Thank you for the opportunity to comment on this proposed rule. We appreciate the agency's commitment to assuring safe, high-quality care for Medicare beneficiaries and other patients. If you have any questions about our comments, feel free to contact me or Nancy Foster, vice president of quality and patient safety policy, at 202-626-2337 or nfoster@aha.org, or Evelyn Knolle, senior associate director of policy, at (202) 626-2963 or eknolle@aha.org.

Sincerely,

/s/

Rick Pollack
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