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Advancing Health in America

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April 12, 2024

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Room 445-G
Washington, DC 20201

RE: Strengthening Oversight of Accrediting Organizations (AOs) and Preventing AO Conflict of Interest, and Related Provisions, CMS-3367-P, Feb. 15, 2024

Dear Administrator Brooks-LaSure:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, our clinician partners — including more than 270,000 affiliated physicians, 2 million nurses and other caregivers — and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to comment on CMS' proposals to strengthen the agency's oversight of accrediting organizations (AOs).

AOs have a long-established role in allowing hospitals and other providers to demonstrate both their compliance with Medicare's health and safety standards and their commitment to delivering high quality, safe and equitable care. While hospital accreditation is not required, most hospitals and health systems work with AOs because their standards often exceed CMS' and can evolve more nimbly to reflect rapid changes in clinical practice. Given that AOs are entrusted by law with ensuring accredited providers meet Medicare's Conditions of Participation (CoPs) and Conditions for Coverage (CfCs), we agree with CMS' stated goals of ensuring AOs conduct their work in a consistent, rigorous and unbiased manner.

The AHA supports several of CMS' proposed policy changes that would help advance these stated goals, such as requiring AOs to use CoPs and CfCs as their minimum accreditation standards, and to provide an explicit crosswalk of their standards with relevant Medicare regulations. **However, the AHA is concerned that some of CMS' proposed changes are needlessly punitive to hospitals and other providers.**

Furthermore, while we appreciate CMS attempting to foster stronger alignment between AOs' work and the agency's standards, state survey agencies also conduct important — and sometimes overlapping — oversight work on CMS' behalf. **For this reason, we urge CMS to ensure that hospitals and other providers do not face redundant federal standards oversight activity from state surveyors and AOs.**

As described in more detail below, the AHA recommends that CMS:

- Permit AOs to retain a limited number of "black-out" dates for accreditation surveys to protect time for emergency preparedness and other key activities drawing heavily on hospital staff and resources.
- Protect patient and workforce safety by allowing AOs to provide a same-day notification of the pending arrival of onsite surveyors.
- Transition to a direct observation approach for validation surveys to reduce the rework and disruption of look back surveys.
- Modify its overly punitive proposal to remove the deemed status of providers following certain validation surveys.
- Clarify the circumstances under which CMS would make AO survey reports public.
- Eliminate duplicative complaint survey activity conducted by state survey agencies and AOs, which adds unnecessary administrative burden and confusion for hospitals and other providers.

BLACK-OUT DATES AND PRE-ARRIVAL NOTIFICATION

As CMS notes in the proposed rule, some AOs have permitted hospitals and other providers to identify a small number of black-out dates during which they could request that AOs not conduct on-site surveys for full accreditation or reaccreditation. In addition, some AOs have provided hospitals with a pre-arrival notification (usually a same day notification via a web portal) of an accreditation survey. However, in the proposed rule, CMS asserts that all AO surveys must be entirely unannounced to more effectively assess whether organizations are in continual compliance with requirements. As a result, CMS proposes to prohibit the use of black-out dates and pre-arrival notifications. The agency also would require AOs to schedule surveys in ways that would not be predictable to hospitals or other providers.

Black-out Dates. **The AHA urges CMS to permit AOs to retain a limited number of black-out dates to ensure that health care providers can protect time for important emergency preparedness and other activities.** CMS appears to presume in the proposed rule that providers only use black-out dates to guess or guarantee a specific date for an accreditation survey. Yet, hospitals and health systems tell us that they used black-out dates to ensure an onsite survey does not conflict with other important activity that may draw intensely on the time and resources of the organization and its leadership. For example, hospitals have used black-out dates to limit the likelihood of an onsite survey during a local or regional emergency preparedness

exercise. In addition, they have used them to identify times when the hospitals' key leadership may be offsite for board or other major meetings. Some compliance leaders have used them to ensure they can schedule their own planned medical procedures so that they would be available to meet the needs of a survey team. In other words, the black-out dates are not used as a tool to predict when a survey may happen. Rather, they are used to ensure that hospitals have the team available to ensure AOs can fully and fairly evaluate their compliance. The availability of black-out dates is especially important for small and rural hospitals that have far smaller numbers of personnel available to assist surveyors when they are onsite.

Furthermore, as CMS correctly points out, compliance with AO standards is a continual process. The survey approaches used by hospital AOs assess not just whether hospitals are complying at the very moment the surveyor is in front of them. Rather, AOs review the totality of a hospitals policies and procedures — including evidence of when and how hospitals adopt and implement such policies — to ensure that documentation supports what the AO observed in the moment. In short, we do not believe that prohibiting black-out dates is necessary to achieve CMS' goal of rigorous, consistent and unbiased assessment of provider performance by AOs.

Rather than entirely prohibiting the use of black-out dates, we recommend that CMS consider asking AOs to describe their criteria for when hospitals and other providers can request black-out dates and how many black-out dates would be available within a given survey window. If CMS finds that the number of black-out dates would make the survey date too easy to predict, it could then ask the AO to either reduce the number of dates or adopt more stringent criteria for requesting them.

Pre-arrival Notification. **The AHA believes that pre-arrival notifications serve an important safety function for hospitals and the patients they serve. For this reason, we urge CMS to permit AOs to provide pre-arrival notifications within 60 minutes of the arrival of surveyors.** The reason that some AOs adopted pre-arrival notifications is that hospitals and health systems experienced incidents in which individuals purporting to be members of an AO survey team — and wearing sophisticated but fake credentials — presented themselves at hospitals, demanding access to the facility and patient medical records. The pre-arrival notification enabled hospitals to verify the identity of AO surveyors while ensuring that unauthorized individuals did not gain access to the facility or to sensitive patient information.

Furthermore, the current health care environment makes it vital to enable health care providers to take reasonable precautions to protect their workforce and patients from unauthorized entry. Unfortunately, the entire health care field has experienced a sharp increase in incidents of violence and intimidation against health care workers. Bureau of Labor Statistics data show that health care workers are more than five times as likely as other workers to experience physical attacks while on the job. Thankfully, incidents of fraudulent AO surveyors have been rare. However, we believe the patient and workforce safety benefits of AO pre-arrival notifications far outweigh any potential risk

and would not undermine CMS' stated goals of rigorous, consistent and unbiased AO surveys. Indeed, given that AOs design their surveys to assess ongoing compliance with standards, the likelihood that any provider could come into compliance with AO requirements with just 60 minutes of prior notice would seem exceedingly low.

VALIDATION PROCESS CHANGES

Two-pronged Validation Model. Under current policy, CMS conducts validation surveys on a representative sample of hospitals and other providers each year. During validation surveys, state agency staff and sometimes CMS surveyors conduct a full review of the organization approximately 60 days after an organization completes accreditation. The survey is done "cold" — that is, the validation team does not actually see the AO's survey report before it surveys the organization. Ostensibly, the goal of the validation process is to evaluate the performance of the AO. However, hospitals can and sometimes do receive citations directly from CMS during validation surveys.

In 2018, CMS also began piloting a direct observation validation survey model in which state agencies accompanied the AOs on their surveys to observe and evaluate the AO's work and processes. CMS believes there is value to both types of validation surveys in assessing AO performance. As a result, CMS proposes to make a two-pronged validation survey process permanent. That is, CMS would conduct both look-back surveys and direct observation validation surveys.

The AHA believes that the primary purpose of any AO validation process should be to *assess the work of the AO* rather than providers' compliance with regulations. We believe the direct observation model is better aligned with the agency's goals of gaining meaningful, timely and actionable insights on whether AOs are conducting their work appropriately. **For this reason, we recommend that CMS phase out the use of look-back surveys altogether. At the same time, we urge CMS to ensure that direct observation surveys do not result in added burden or confusion for providers and AOs.**

While look-back surveys have long been a staple of CMS' approach to evaluating AOs, we believe the premise of such surveys is somewhat misguided. In conducting a full resurvey of a facility and comparing the results to the AO's survey, CMS is assuming that a facility's state of compliance in those two time periods is identical; that is why CMS believes it can detect a "disparity rate" between the validation survey and the AO survey. Yet, our members have stressed that hospitals and health systems operate in a highly dynamic environment, making it problematic to assume that a finding on a validation survey should have been cited during the AO survey. Furthermore, CMS' proposed changes to require stronger alignment between AO standards and its CoP could significantly lower the likelihood of finding a disparity between an AO survey and a validation survey. This raises questions about whether the look-back survey will be meaningful.

The question of meaningfulness is especially important given how resource and time intensive it is for hospitals to undergo a full resurvey of their compliance with CMS regulations. Because look-back validation surveys occur so soon after a full accreditation survey, they serve to disrupt hospitals' ability to use the findings of their most recent AO survey to plan for their ongoing compliance. Even worse, look-back validation surveys effectively shift the burden and responsibility of any CMS perceived gaps in an AO's oversight activity to hospitals and other providers. Hospitals that work to comply with AO standards with a good faith understanding that doing so also puts them in compliance with relevant Medicare regulations. It seems incongruous and unfair for CMS to then penalize hospitals and other providers because the agency believes the AO failed to do its job.

If CMS' goal is to ensure that AO surveyors "get it right the first time," the direct observation approach would seem like the more effective way of giving AOs timely, direct and usable feedback on whether their survey approach is consistent with CMS standards. At the same time, CMS should ensure that it implements the direct observation model in ways that do not add unnecessary burden or confusion for providers. For example, CMS could instruct state surveyors to perform their work in an "observation mode" that ensures AO surveyors fully lead the survey. In the event a state surveyor interprets a standard or an organization's compliance with a standard differently from an AO, CMS should encourage state surveyors to discuss those interpretations with the AO rather than with the hospital. We believe this would help keep providers from being "in the awkward middle" of a difference of opinion between the AO and state surveyors.

Removal of Deemed Status for One or More Condition-level Citations. CMS proposes that hospitals or providers receiving one or more condition-level citation on either type of validation survey could lose their deemed status. In addition, the provider could be subject to "ongoing review by the state survey agency…until [it] demonstrates compliance." Organizations could regain their deemed status and ability to use an AO to demonstrate compliance with the CoPs once CMS finds the provider meets relevant requirements.

The AHA believes that removal of deemed status is an overly punitive approach that is not necessary to achieve CMS' stated goals of more rigorous, consistent and unbiased surveys. Even more troublingly, the proposal seems inconsistent with the adjudication process already in place for hospitals and other providers to respond to validation survey findings. When hospitals undergo validation surveys, CMS provides them with a survey report and 10 days to provide CMS a plan of correction. The plan of correction also gives hospitals the chance to submit evidence of their compliance that CMS might have missed during the survey. In some cases, state surveyors will revisit the facility to verify the plan of correction. Presuming there are no further issues, CMS considers the validation process closed and the provider compliant. This process is important for ensuring that hospitals and other providers have a fair opportunity to correct issues and demonstrate their compliance.

Yet, under its proposal, hospitals and other providers could lose their deemed status while CMS' adjudication of the validation process takes place. Put colloquially, CMS' proposed approach characterizes providers as "guilty until proven innocent." To be clear, even a short-term loss of deemed status could have devastating impacts to providers and the communities they serve. Indeed, many states and commercial payers require hospitals to maintain their deemed status to participate in contracts. The process of responding to validation survey findings can take months, raising real concerns about the ability for hospitals and other providers to sustain access to care for their communities while CMS completes its adjudication of their compliance.

For the reasons outlined above, we urge CMS not to finalize its proposal to remove providers deemed status for receiving one or more condition-level citation. Indeed, we believe CMS should remove deemed status only in those cases when providers either fail to provide CMS a plan of correction, or when they are still found out of compliance following two or more plans of correction.

AO SURVEY REPORTS

Currently, CMS collects only high-level data from AOs (e.g., date of survey, overall findings, severity of problems, etc.) on their surveys. CMS asserts it has the authority to collect all reports from AOs and believes doing so would help it understand AO performance and identify discrepancies with state agencies. As a result, CMS proposes to require AOs to share all survey reports with CMS. CMS notes the law does not permit it to make AO reports on hospitals and other providers public unless it pertains to an enforcement action, such as terminating a provider agreement.

The AHA believes this proposed policy raises significant concerns about the confidentiality of provider information in a health care facility, and we do not support it in its current form. We urge CMS to provide greater clarity about the scope and intent of the policy and the circumstances under which AO survey reports would be made public. We appreciate that one of CMS' goals with obtaining AO reports is to evaluate the AO's performance. Yet, those reports also contain confidential information about the health care facility. For example, AO reports often indicate the specific patient care locations where surveyors observed noncompliance. This raises the real concern that individual practitioner's — or even an individual patient's — identity may become public if CMS were to disclose the report. This is especially true in small and rural facilities where the number of patient care units, patients and providers is small.

In addition, while CMS has acknowledged that it is constrained by statute from publicly disclosing AO survey reports unless they are related to enforcement actions, the proposed rule does not provide sufficient specificity about what is meant by an "enforcement action" from CMS and at what point along the continuum of enforcement actions CMS would be permitted to disclose an AO's survey report. Throughout 42 CFR

§488 outlining CMS' survey, certification and enforcement procedures, CMS refers to enforcement actions at CFR §488.24. These enforcement actions focus on decertification of providers by state survey agencies, which constitutes effective termination of the providers from the Medicare and Medicaid programs. As a result, if CMS were to finalize this rule, we believe the agency should clarify that it would disclose an AO survey report only when CMS has used it as part of its basis for terminating a provider agreement.

ELIMINATING DUPLICATIVE COMPLAINT SURVEYS

The proposed rule includes several new requirements for AOs to describe their processes for responding to complaint surveys at health care facilities. **While the AHA supports CMS' effort to ensure that complaint surveys are handled in a consistent and robust way across AOs, we believe the agency also should take steps to ensure that AO complaint survey activity is not redundant with state survey agency complaint surveys when they are related to compliance with Medicare regulations.**

Under existing regulations, patients and families have multiple avenues to submit concerns about the care received in health care facilities, including CMS, state agencies and AOs. Complainants also have a right to avail themselves of all three reporting options for the same patient care event. As a general matter, CMS uses both AOs and state survey agencies to conduct complaint investigations. However, we are concerned that CMS may not be sufficiently coordinating the investigative efforts of AOs and state survey agencies.

Indeed, many hospitals and health systems have experienced complaint investigations done under CMS' auspices by AOs and state survey agencies in which they receive multiple visits from AOs and state survey agencies on the same patient care event. At times, the AOs and state agencies have provided hospitals with divergent survey findings. This has left hospitals confused about how to respond to both the AO and the state survey agency in a consistent and compliant manner. Moreover, hospitals are required to pay AOs for complaint surveys. When hospitals receive two surveys from two different parties on the same Medicare regulation, it leads to duplicative and wasteful spending of time and resources to respond. It also raises concerns about whether hospitals have the clarity they need to come into compliance with CMS regulations.

For these reasons, we urge CMS to work with state survey agencies and AOs to de-duplicate complaint survey activity performed under the auspices of CMS, thereby ensuring that hospitals do not respond to two sets of surveyors.

REQUEST FOR INFORMATION — AO BOARDS OF DIRECTORS

A number of the proposed rule's policy changes focus on identifying and mitigating conflicts of interest between AOs and the organizations that they accredit, including potential conflicts of interest between individual surveyors and the organizations where they worked in the past. The proposed rule also asks for feedback on whether it would be 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.

As a general matter, the AHA agrees that AOs should have systematic processes to identify and eliminate any potential conflicts of interest, including with AO executive management and boards. Several of CMS' proposed changes focus on individual surveyors disclosing their relationships with organizations — and not participating in accreditation surveys or decisions in such organizations for at least two years. The AHA supports such changes and believes it would be reasonable to apply these policies to executives and other leaders in AOs.

However, including board members from organizations an AO accredited would not constitute a conflict of interest if an AO's board governance process precluded the board from weighing in on individual accreditation decisions. AO boards also should have conflict of interest disclosures for board members and stated policies for ensuring that board members recuse themselves from discussions when appropriate. The AHA believes that the AOs used by hospitals have such policies in place. Furthermore, boards of directors have a broader fiduciary responsibility to ensure that the organization is executing on its mission, strategy and goals for the organizations they serve. AO boards understand fully that CMS and the public entrusts their organizations with the vitally important task of ensuring the organizations they accredit not only meet health and safety requirements from CMS, but also deliver high quality, safe and equitable care. The expertise of health care leaders and professionals from accredited hospitals can help ensure that the AOs are developing standards and processes with sufficient relevance and rigor to achieve these goals.

The AHA thanks CMS for the opportunity to provide feedback on this proposed rule. Please contact me if you have questions or feel free to have a member of your team contact Akin Demehin, AHA senior director for policy, at ademehin@aha.org.

Sincerely,

/s/

Ashley B. Thompson
Senior Vice President
Public Policy Analysis and Development