MISSOURI HOSPITAL ASSOCIATION

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Andrew M. Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-3295-P
Department of Health and Human Services
Room 445-G Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 20201

Re: Proposed Rule CMS-3295-P (Medicare and Medicaid Programs; Hospital and Critical Access Hospital (CAH) Changes to Promote Innovation, Flexibility, and Improvement in Patient Care)

Dear Mr. Slavitt:

On behalf of its 148 member hospitals, including 36 critical access hospitals, the Missouri Hospital Association offers the following comments regarding the Centers for Medicare & Medicaid Services' proposal to update the hospital and CAH Conditions of Participation (CoPs) for Medicare and Medicaid. MHA appreciates CMS' efforts to continue updating the CoPs to reflect current practice and foster better quality of care and patient outcomes.

MHA supports CMS' proposal to specifically reference current anti-discrimination standards in the CoPs and to provide a process for conveying information to the patient and a "support person" as defined by the rule. Also, revising the term "independent licensed practitioner in §482.13 will reduce some of the confusion and inefficiency created by current regulations. However, the phrase "if not, in a readable hard copy form …" in §482.13(d)(2) is of concern. The added language raises unresolved questions as to whether the hospital is obligated to provide a hard copy in a particular language or rework it to a specified reading level.

MHA has concern that the proposed addition of §482.23 (b)(7)(iii) would give the medical staff the authority to review and approve nurse staffing plans for outpatient departments. It is clear elsewhere in §482.23 that the Director of Nursing or nursing leadership is responsible for ensuring adequate nurse staffing. The nursing service can and should collaborate with the medical staff in advancing the aims of the hospital, but MHA asserts that it would be counterproductive to grant the medical staff authority to approve or deny decisions regarding the administration of the nursing staff and would undermine the language of the current CoPs to promote collaboration among the nursing service and medical staff.

The proposed changes to §482.24, Medical Record Services, add clarity. However, we believe CMS has understated the financial impact of these revisions in terms of time and resources needed for implementation and ongoing compliance. Specifically, §482.24(c)(4)(ii) and §482.24 (c)(4)(viii) are of concern. Hospital medical records allow for one admitting diagnosis. While they also may reflect past diagnoses and co-morbidities, their inclusion will require process and responsibility changes to accurately identify all the required information. The information may not be available at time of entry into the health care system and requires review of previous hospitalizations. There are less cumbersome ways for CMS to obtain data on hospitalized patients for internal use and for hospital staff to obtain data for discharge planning. Furthermore, requiring that outpatient records be completed in a 7-day timeframe seems arbitrary. MHA requests, at a minimum, that hospitals be allowed the time needed to revise their medical records and institutional processes; that requirement for documentation of all diagnoses is clearly defined; and the requirement for closure of outpatient records within 7 days be removed in the final rule.

MHA supports the inclusion of infection prevention language as well as the establishment of an antimicrobial stewardship program. The provisions of the proposed rule would change the current language from "infection control officer" to "infection preventionist(s)/infection control professional(s)" and require appointment by the governing body based on the recommendation of the medical staff leadership and nursing leadership. We understand the purpose is to require involvement of high-level hospital and clinical leadership. The selection of the "infection preventionist(s)/infection control professional(s)" will not necessarily ensure involvement of the governing board beyond the appointment itself, but would instead create administrative tasks with no proven connection to better outcomes. MHA recommends removal of the language calling for "appointment by the governing body based upon the recommendation of medical staff and nursing services." Instead, it suggests reinforcing the language that outlines the roles of the CEO, medical staff and director of nursing services in §482.42 (b). MHA recommends comparable changes regarding antimicrobial stewardship.

MHA also voices concern with CMS' proposal that the infection preventionists/infection control professional and the leader of the antimicrobial stewardship program cannot be the same person. MHA applauds the distinction between infection control and antimicrobial stewardship. It should not be assumed the antimicrobial stewardship is a simple extension of infection control management programs. Even so, while we understand they are different programs, in some hospitals a single individual may be the most qualified individual based upon the size, scope, and complexity of services provided. We see little rationale for a regulatory prohibition of that option.

Regarding proposed changes to CoPs for CAHs, MHA welcomes CMS' proposal to simplify regulations by removing the disclosure language at §485.627 which is redundant to the regulatory language at §420.206. Duplicative language in multiple locations creates confusion and increases the chances of misinterpretation. MHA supports CMS' efforts to allow clinicians to practice to the fullest extent of their credentials. The proposal at §485.635 requiring patient diets be ordered by the practitioner responsible for the patient or a qualified dietitian or qualified

nutrition professional as authorized by the medical staff and in accordance with state law, recognizes the specialized knowledge and training of dietitians and the benefit available to patients.

Complying with the proposed requirements for developing, implementing and sustaining an antibiotic stewardship program may be a challenge for some of MHA's smallest CAHs. While all Missouri hospitals maintain active infection control and prevention programs, the addition of an antibiotic stewardship program will require a level of knowledge and experience that many smaller hospitals may not currently possess. MHA would request that as these proposed rules are implemented, CAHs are given maximum time and flexibility to achieve compliance through whatever means are available. This should include obtaining knowledge and training through telehealth/distance learning mechanisms and the ability to contract for subject matter expertise in stewardship activities. Also, we encourage CMS to recognize that some state governments, including Missouri's, have created their own antibiotic stewardship programs and ask the agency to tailor its regulatory proposals to eliminate contradictory federal and state standards.

Finally, MHA is concerned about the ambiguity regarding the development, implementation and maintenance of a data-driven quality assessment and performance improvement program. MHA acknowledges the importance of an effective, ongoing QAPI program and supports this change in the CoPs. The proposed changes suggest that participation and reporting in the Medicare Beneficiary Quality Improvement Project (MBQIP) is one way a CAH can satisfy the requirements of proposed §485.641. Are there other examples of how a CAH can meet this requirement? Five elements of QAPI program design and scope are specified at §485.641(b). There is no requirement for external reporting within this standard. In fact, there is no specification for reporting in any subsection of §485.641. Language at §485.641(f)(1) states "The program must incorporate quality indicator data … such as data submitted to or received from national quality reporting and quality performance programs …" This language is problematic and will certainly result in conflicting interpretations. If the intent is that CAH quality indicator data is reported externally for comparative benchmarking and performance improvement activities, the standards should be written to specify that reporting is required and the options available to comply with the standard.

Sincerely,

Daniel Landon
Senior Vice President of Governmental Relations

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