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August 15, 2016

Andrew M. Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8010
Baltimore, MD 21244

Re: CMS 3295-P, Medicare and Medicaid Programs; Hospital and Critical Access Hospital Changes to Promote Innovation, Flexibility, and Improvement in Patient Care (Vol. 81, No. 116, June 16, 2016)

Dear Mr. Slavitt:

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 on revisions to the hospital and critical access hospital (CAH) Conditions of Participation (CoPs). This rule addresses important facets of health care quality, especially ensuring equity in the treatment of patients and the appropriate use of antibiotics. **The AHA and its members support these critical goals and pledge to continue our efforts to advance them.**

The vision of the AHA and our members is a society of healthy communities, where all individuals reach their highest potential for health. The elimination of health care disparities is essential to achieving that aim. That is why we joined as a partner in the National Call to Action to Eliminate Health Care Disparities and launched the AHA #123forEquity Pledge to Act Campaign to ensure equitable care for all persons in every community. As part of this effort, hospitals are pledging to analyze quality data by race, ethnicity, language preference or other sociodemographic variables; develop plans to address gaps in care; provide cultural competency training for staff; and explore how their leadership reflects the communities they serve. We believe this [campaign](#) is crucial to the effort to advance diversity and inclusion in health care; we will continue to provide [tools and resources](#) and other support to accelerate progress.

Antibiotic stewardship programs in hospitals are part of an important national effort to reduce the emergence and spread of drug-resistant bacteria. In 2014, the AHA collaborated with the Centers for Disease Control and Prevention (CDC) and six other national organizations to develop an



antimicrobial stewardship [toolkit](#) for hospitals, and many hospitals already have or are implementing programs aimed at appropriate antibiotic prescribing and antimicrobial efficacy.

The AHA supports many of CMS's proposals, including antibiotic stewardship standards. However, we urge CMS to make several revisions to improve clarity and ensure the final standards are practical and effective in meeting desired outcomes. As CMS finalizes the rule, we urge the agency to incorporate these overarching principles:

- Flexibility. The AHA appreciates CMS's emphasis that infection control, antibiotic stewardship, and quality assessment and performance improvement programs must reflect the scope and complexity of the services provided. This flexibility is especially crucial for smaller hospitals and CAHs that may face particular challenges in implementing these provisions. **We urge CMS to provide technical assistance to help CAHs implement these new programs. In addition, we ask that CAHs have at least a year from the date of the final rule to come into compliance with the new requirements.**
- Outpatient Services Vary. Several of CMS's proposed changes seek to improve clarity about how the CoP standards apply to outpatient services. We ask CMS to recognize the wide range of the types and levels of outpatient services. A proposed standard that makes sense for a more complex procedure, such as same-day surgery, could be impractical for simpler services, such as diagnostic tests. CMS should clarify that the proposed regulations would apply only to certain outpatient services or only when the scope of the outpatient service warrants it.
- Compliance Consistency. We urge CMS to carefully review potential overlap of its proposals with other laws, regulations and pending rules to ensure alignment across the numerous requirements imposed on hospitals and their clinicians. We outline below several ways CMS could promote consistency and avoid conflicting standards. In particular, we ask CMS to communicate with the Office of the National Coordinator for Health Information Technology (ONC) to ensure that certified electronic health record technology (CEHRT) requirements support the quality and safety standards adopted by CMS and encompassed in the CoPs.

Below we address specific aspects of the proposed rule.

PATIENTS' RIGHTS (HOSPITALS AND CAHS)

In the proposed rule, CMS articulates patients' rights to care without discrimination on the basis of race, color, religion, national origin, sex (including gender identity), sexual orientation, age or disability. **Hospitals understand these basic human rights and fully support them as fundamental values that must be upheld, particularly by health care providers who have the privilege of working with patients and families when they are at their most vulnerable. Patients and their families should always be treated with dignity and respect.**

Current regulations require that Medicare-participating hospitals comply with civil rights provisions of laws such as Title VI of the Civil Rights Act of 1964, Section 504 of the Rehabilitation Act of 1973, the Age Discrimination Act of 1975, and Section 1557 of the Affordable Care Act. The Department of Health and Human Services (HHS) Office of Civil Rights (OCR) recently undertook a notice-and-comment rulemaking process to implement Section 1557 of the Affordable Care Act and finalized non-discrimination policies with identical intent and similar content to CMS's current proposals. In our experience, similar rules with the same goal, but distinct language and sub-regulatory guidance, can cause confusion if hospitals must struggle to understand how to comply. Thus, we urge CMS to consider simply adopting by reference OCR's regulation as HHS's articulation of the expectations for hospitals as well as other health care providers in providing equitable care. Further, we urge CMS to create sub-regulatory guidance by working with OCR to ensure CMS's guidance is consistent with OCR's interpretations. This will prevent hospitals and patients from being caught in the middle between different agency interpretations. We urge CMS to clearly state that it will ensure that its policies are consistent with those of OCR.

NURSING SERVICES (HOSPITALS)

The AHA asks CMS to make changes to its nursing services proposals to improve clarity and to ensure that policies related to nurse staffing needs are approved by a hospital's nursing leadership.

Current regulations require hospitals to have "supervisory and staff personnel for each department or nursing unit to ensure, when needed, the immediate availability of a registered nurse for *bedside* care of any patient." CMS proposes to remove the word "bedside" to clarify that this provision applies to both inpatient and outpatient services. CMS would allow hospitals to designate which outpatient departments do not need a registered nurse present (such as an MRI facility), and the AHA supports that flexibility.

However, the removal of the word "bedside" could create confusion with regard to certain inpatient departments. The revised standard would read: "There must be supervisory and staff personnel for each department or nursing unit to ensure, when needed, the immediate availability of a registered nurse for the care of any patient." Similar to outpatient settings, registered nurses are not typically present in each inpatient department, such as physical/respiratory therapy and laboratory departments. Although the term "when needed" provides some context to qualify this provision, we believe further clarification is required.

We ask CMS to restate this requirement so that it will apply to direct patient care units where registered nurses need to be present. In lieu of its proposed version of this standard, CMS could adopt the following language: "There must be supervisory and staff personnel to ensure, when needed, the immediate availability of a registered nurse for the care of inpatients and outpatients. The hospital must have policies and procedures that specify which direct patient care departments, clinics, or nursing units must have immediate availability of a registered nurse."

Regardless of how CMS chooses to finalize this provision, the agency should always require that policies and procedures about nurse staffing be developed by the hospital's nursing service and approved by the nursing leadership.

MEDICAL RECORDS SERVICES (HOSPITALS)

Changes to Medical Record Content Requirements. CMS proposes to update and slightly expand several CoP provisions related to the required content of medical records and clarify that the standards apply to both inpatient and outpatient records. **The AHA asks CMS to modify several of its proposals in order to recognize the variation in outpatient services and promote alignment with other standards.**

CMS believes that current regulations related to the content of medical records do not adequately incorporate the documentation needed for outpatient medical records. In the rule, CMS would require the content of medical records to “contain information to justify all admissions and continued hospitalizations, support the diagnoses, describe the patient’s progress and responses to medications and services, and document all inpatient stays and outpatient visits to reflect all services provided to the patient.” In the final rule, we ask CMS to address two aspects of this proposed standard:

- **CMS should clarify that the requirement to “justify all admissions” applies only to inpatients, and the agency should provide flexibility with regard to the justification required for outpatient services.** While it is appropriate to require justification for some procedures, such as outpatient surgery, it would be problematic to require it for all outpatient services. For example, some outpatient testing orders do not contain a justification for a particular service, such as an order for a routine blood test or other diagnostic procedure. The reasons for many types of outpatient diagnostic services will reside appropriately in an ordering clinician’s records.
- The rule does not discuss where information is contained within the record, and **CMS must ensure that surveyors allow continued flexibility in terms of how the justification, diagnosis and other elements of the rule are documented.** Hospitals must be able to record those elements in accordance with how certified EHR vendors have developed their CEHRT-compliant products.

CMS also would require all patient medical records to document discharge and transfer summaries “with outcomes of all hospitalizations, disposition of cases, and provisions for follow-up care for all inpatient and outpatient visits to reflect the scope of all services received by the patient.” Similar to our concerns expressed above, discharge summaries are unnecessary for certain diagnostic tests and should not be universally required. In addition, we note that CMS recently released a proposed rule to modify discharge planning requirements for hospitals and CAHs, and we urge the agency to ensure that rule is aligned with CMS’s current proposals. Further, we expect that as EHR vendors modify their software to comply with meaningful use requirements related to summary of care documents, it will be helpful for them to be aware of the

revised CoP standards related to discharge summaries. Therefore, we encourage CMS to communicate with the ONC about the provisions in the final CoP rule.

In addition, the proposed rule requires the content of the medical record to contain “final diagnoses with completion of medical records within 30 days following all inpatient stays, and within seven days following all outpatient visits.” We have two concerns about the seven-day requirement for outpatient services. First, some outpatient services are ongoing, such as wound care and therapy services (e.g., physical, occupational, speech and IV therapies). Thus, final completion of the medical record within seven days of a visit is not practical in all circumstances. Second, in some cases, the final diagnosis may not be known within seven days, such as if diagnostic studies are not completed within one week of a visit. **Instead of a universal seven-day standard for all outpatient visits, CMS should require the medical staff to develop policies for the appropriate timeframes for final diagnosis and completion of records.**

Privacy Standards. Currently, both the CoP and HIPAA regulations impose requirements related to medical record privacy on hospitals. However, CMS has frequently created standards that directly conflict with guidance issued by OCR regarding compliance obligations under the HIPAA rules. In addition, the HIPAA provisions generally provide a more comprehensive set of standards that protect both the privacy and security of all patients’ medical information. **CMS should rely on and defer to OCR’s interpretation, oversight and enforcement of the compliance obligations under the HIPAA privacy and security standards.**

As an example of the above, HIPAA permits a covered-entity hospital or other provider to share, without patient authorization, information about a patient with another provider for treatment, payment or certain health care operations – even if that provider is not a HIPAA-covered entity. The sharing of information is permitted as long as both providers have a current or past relationship with the patient and the shared information relates to that relationship. In contrast, CMS previously interpreted the more general CoP regulations to require specific patient authorization for the sharing of the patient’s medical information between a covered entity and a separate provider. Such conflicting interpretations create confusion for providers and interfere with effective confidentiality and security protections for patient medical information.

Further, compliance with HIPAA requirements is mandatory for all hospitals and providers because they are covered entities under the HIPAA rules. Determining whether any covered entity is in compliance with these existing obligations is a complex undertaking and remains most appropriately under the authority of OCR. OCR’s current processes and procedures, including comprehensive ongoing audits of compliance, provide for effective enforcement of hospitals’ and other providers’ existing obligation to be in compliance with the requirements of both HIPAA rules.

INFECTION PREVENTION AND CONTROL AND ANTIBIOTIC STEWARDSHIP PROGRAMS (HOSPITALS AND CAHS)

The AHA supports CMS's goals related to infection prevention and control and antibiotic stewardship programs. Further, we believe CMS has generally incorporated the right concepts into the proposed standards for hospitals and CAHs. Below we comment on specific aspects of these programs related to flexibility, leadership selection and performance improvement.

CMS should finalize its proposals that the infection control and antibiotic stewardship programs must reflect the scope and complexity of the services provided. After the rule is finalized, we urge CMS's Survey and Certification Group, which develops interpretive guidance, to work closely with stakeholders, such as hospitals, CAHs, and infectious disease experts, in further defining this provision and the expectations for meeting the infection control and antibiotic stewardship program standards. Flexibility will be important, as smaller hospitals in rural areas and CAHs confront difficulties in recruiting qualified staff with infectious disease specialty training.

Some rural hospitals have explored opportunities to tap into this expertise through telemedicine contracts or other such relationships with larger health systems of their choice, and some health systems that have smaller or rural hospitals as part of the system are examining ways that they can use the expertise within their system to effectively provide needed support for antibiotic stewardship and infection control activities in these smaller hospitals. **We urge CMS to finalize provisions that allow hospitals to have flexibility in choosing both the staffing models and activities employed to meet the antibiotic stewardship and infection control program requirements.** In particular, we support CMS's proposal that the leaders of these programs should be individuals who are qualified through education, training experience or certification, and urge CMS to recognize that the required expertise can be made available either by having the individuals on staff or through a variety of other arrangements.

Flexibility is equally important for large hospital systems. Multihospital systems should be able to have centralized infection control and antibiotic stewardship programs, as long as they consider and respond to any unique characteristics of each hospital and patient population. Standardizing programs across systems or parts of systems can enhance quality, improve education and promote performance improvement.

We do not support CMS's proposal to require that the leaders of the infection prevention and control and antibiotic stewardship programs be specifically appointed by the governing body. We agree that the governing body has ultimate responsibility for the conduct of the hospital/CAH and the quality of care provided. These concepts are currently incorporated into the CoPs. However, governing bodies must be able to determine how best to manage important hiring decisions and to decide how much of their involvement is needed. While the governing body must ensure that appropriate structures are in place for effective human resource management, as well as effective management of these two programs, CMS's proposal is too prescriptive in specifying how the leadership selection process is managed.

CMS should clarify further the process for selecting infection control and antibiotic stewardship leaders. The agency proposes that hospitals and CAHs appoint leaders for the infection control and antibiotic stewardship programs “based on the recommendations of the medical staff leadership and nursing leadership.” It is unclear what CMS means by the phrase “based on the recommendations...” Acquiring input from key medical and nursing staff leaders on the recruitment or promotion of individuals to fulfill these critical roles is an important step, because the success of the antibiotic stewardship and infection control efforts depends on the successful engagement of both medical and nursing staffs, as well as the broader hospital staff. This input could be acquired in a variety of effective ways that do not require a formal recommendation from the medical and nursing staffs. We suggest the language be changed to require that the process for selection of the individuals to lead these efforts “...must include meaningful opportunity for input from members of the medical and nursing staffs.”

We urge CMS to modify a proposed standard related to how hospitals would demonstrate improvements in antibiotic stewardship. In the rule, CMS proposes to require hospitals and CAHs to “demonstrate improvements, including sustained improvements, in proper antibiotic use, such as through reductions in [clostridium difficile infections] and antibiotic resistance in all departments and services in the hospital.” **Instead, CMS should require hospitals to demonstrate proper antibiotic use in accordance with national guidelines and hospital and medical staff policies.** We have strong concerns about the proposed provision. Specifically:

- **We do not believe it is appropriate or accurate to solely use antibiotic resistance within the hospital to demonstrate antibiotic stewardship program success or evaluate a hospital’s antibiotic stewardship efforts. Numerous external factors contribute to resistance patterns, including prescribing patterns of local practitioners who may not be connected to the hospital, community-onset infections and patient transfers from other facilities.** Further, it can be difficult to demonstrate meaningful improvement over a short period of time.
- Measuring antibiotic stewardship improvement is a very important concept, but we do not think the current quality measure related to antibiotic stewardship is sufficient at this stage. The National Quality Forum (NQF) has endorsed the National Healthcare Safety Network Antimicrobial Use measure (NQF #2720), which examines the actual use of antibiotics by a hospital. Use can vary for any number of legitimate reasons, including a community outbreak of an infectious disease caused by a bacteria or an increase in surgeries for which prophylactic use of antibiotics is deemed to be important. NQF #2720 is a predicate to developing a measure that will be able to assess *appropriate* use of antibiotics, which should be extremely useful in antibiotic stewardship efforts. When the CDC or another credible organization has developed a measure of appropriate antibiotic use and it has been endorsed by the NQF, we urge CMS to adopt that measure for use in its quality reporting programs. Until such time, we request that CMS require hospitals to monitor the use of antibiotics and, when identified, pursue opportunities to eliminate inappropriate usage.

- The CoPs and their corresponding compliance surveys are not the best mechanisms for measuring overall reductions in resistance levels. We are especially concerned that the proposed rule does not explain how compliance would be evaluated with the proposed requirement. Instead, CMS indicates that forthcoming interpretive guidance will provide insight on how hospitals could meet this standard. However, measuring a hospital's improvement in lowering resistance deserves a thorough public discussion of how to accurately evaluate performance as well as how much improvement would be sufficient over a designated time period. More specifically, a CoP standard requiring hospitals to achieve a specific outcome (versus requiring them to adopt certain standards, policies and procedures that improve outcomes) is unorthodox. Developing a quality measure to improve a hospital's performance with regard to a particular outcome, for example, typically involves a rigorous and transparent review of the proposed metric as well as an examination of the evidence supporting its adoption, the validity and reliability of its methods, any necessary risk adjustment elements, testing results, and other factors.
- CMS does not explain how it will address the fact that, as hospitals and CAHs improve antibiotic prescribing patterns, their performance will eventually plateau or become "topped out." Thus the requirement to "demonstrate improvements" will become more difficult to achieve in the future.

We believe it is important for CMS to continue working to develop and refine accurate quality measures that can drive and evaluate improvement in antibiotic prescribing as well as lowering resistance levels. We welcome the opportunity to collaborate with CMS and other stakeholders in these efforts.

PROVISION OF SERVICES (CAHS)

In the proposed rule, CMS offers additional flexibility for CAHs by permitting dietitians to order therapeutic diets where permitted by state law. **The AHA applauds this proposed change as it allows qualified health care professionals the freedom to practice at the top of their license. We urge CMS to finalize this proposed provision as written.**

QUALITY ASSESSMENT AND PERFORMANCE IMPROVEMENT (QAPI) (HOSPITALS AND CAHS)

In the proposed rule, CMS makes slight changes to the hospital QAPI standards and proposes new requirements for CAHs. The proposed rule calls upon CAHs to create, implement and maintain an "effective, ongoing, CAH-wide, data-driven QAPI program..." CMS recognizes that such QAPI programs would need to be appropriate for the complexity and range of services provided in the CAHs. The agency specifies that such a program would need to involve all departments and use objective measures to assess processes and services, and have indicators of "...improved health outcomes and prevention and reduction of medical errors, adverse events, CAH-acquired conditions, and transitions of care (including readmissions)."

The AHA supports the concept of encouraging CAHs to use proven quality improvement techniques to work to improve the quality and safety of care provided. We are glad to see that the Health Resources and Services Administration's FLEX program and Medicare Beneficiary Quality Improvement Program (MBQIP) are mentioned in the proposed rule as examples of the improvement program activity that CMS has in mind.

That said, we have concerns about several proposed provisions of this section of the rule. We discuss our specific concerns below:

- **We urge CMS to change the language of the proposed rule for both hospitals and CAHs to ensure that it does not require specific measures or target specific aspects of care for this improvement work.** It would be suitable to offer examples of the type of project that CMS has in mind as a means of clarifying the agency's expectations, but to require work on readmissions or specific hospital-acquired conditions in the regulatory language is problematic. Some hospitals and CAHs may already have engaged in projects to improve performance on those topics and may have little room left for further improvement. Others may simply have identified different topics that pose a greater risk to the patient population they serve. Further, the language of the CoPs is not changed rapidly, and over time, most hospitals and CAHs will improve performance to a point where further substantial improvements will be unlikely given current knowledge. When that happens, they should be able to pivot to different topics that have greater potential to improve patient outcomes. **The AHA believes CMS must use language clearly stating that hospitals and CAHs should make informed choices about where they focus rigorous improvement work to ensure their efforts provide clear and important benefits to the patients and communities served.**
- **Collecting and using accurate data in a CAH is more challenging than in a large general acute care hospital.** Small sample sizes and the lack of readily available outcome data within the CAH's records may make it hard for CAHs to determine how much progress they are making in improving care on some topics, particularly for fairly rare events. In some cases, where processes have been clearly demonstrated to be linked to outcomes through scientific research, it may be more fruitful to allow the CAHs to focus efforts on improving performance on the process measures, and assume that the outcomes are getting better as well. We also believe that CAHs should be allowed to count MBQIP participation towards compliance with the new CoP.
- **Technical assistance for data collection may be needed.** The technical assistance could include helping CAHs gain expertise to successfully and consistently abstract information from clinical records, analyze it and apply those learnings so that performance can improve. The FLEX program and the Quality Improvement Organizations (QIOs) are among the organizations that would be good at assisting CAHs, and we urge CMS to consider directing the QIOs to provide such help.

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- **In addition to technical assistance, CAHs will need time to come into compliance.** These requirements represent a substantial change for CAHs in their quality improvement activities. The AHA urges CMS to provide at least one year from the date of the final rule for CAHs to come into compliance with these requirements.

Thank you for the opportunity to comment. If you have any questions, please contact me or Nancy Foster, vice president for quality and patient safety policy, at nfoster@aha.org.

Sincerely,

/s/

Thomas P. Nickels
Executive Vice President