

July 11, 2016

## **CMS PROPOSES UPDATES TO HOSPITAL AND CAH CONDITIONS OF PARTICIPATION**

### ***AT A GLANCE***

#### ***At Issue:***

The Centers for Medicare & Medicaid Services (CMS) on June 16 issued a [proposed rule](#) to update select Conditions of Participation (CoPs) that hospitals and critical access hospitals (CAHs) must meet to participate in Medicare and Medicaid. CMS believes the changes are necessary to align the Medicare requirements with current practice standards, improve quality and reduce barriers to care. Among the proposed changes, CMS would:

- Require hospitals and CAHs to implement antibiotic stewardship programs that adhere to nationally recognized guidelines and best practices;
- Augment infection prevention and control regulations for both hospitals and CAHs;
- Update quality assessment and performance improvement (QAPI) requirements, including the establishment of robust, ongoing, data-driven QAPI programs for CAHs;
- Make several changes related to the content of hospital medical records;
- Allow qualified dietitians/nutrition professionals in CAHs to order patient diets, as authorized by the medical staff and state law; and
- Require hospitals and CAHs to implement written policies to prohibit discrimination on the basis of race, color, religion, national origin, sex (including gender identity), sexual orientation, age or disability, and to inform patients of their right to be free from discrimination.

**A detailed summary, prepared for the AHA by Health Policy Alternatives Inc., is attached. Comments are due to CMS by Aug. 15, 2016.**

#### ***Our Take:***

The AHA is pleased that CMS continues to update the CoPs for hospitals and CAHs. We particularly support the concept of hospital and CAH antibiotic stewardship programs and refer readers to the AHA Physician Leadership Forum's [Antimicrobial Stewardship Toolkit](#). The AHA will seek further refinements to CMS's proposals, based on member feedback, to reduce burden, promote clarity, and ensure the changes are as effective and efficient as possible.

#### ***What You Can Do:***

- ✓ Share this advisory with your chief quality officer, compliance managers, risk managers, and physician and nursing leaders.
- ✓ Submit comments directly to CMS on this proposed rule by 5:00 p.m. on Aug. 15 at <http://www.regulations.gov>.
- ✓ Share your feedback and/or your comments to CMS about this proposed rule with the AHA.

#### ***Further Questions or to Provide Feedback on CMS's proposals:***

Please contact the AHA's Evelyn Knolle, senior associate director of policy, at [eknolle@aha.org](mailto:eknolle@aha.org).

**Medicare and Medicaid Programs; Hospital and Critical Access Hospital (CAH) Changes  
to Promote Innovation, Flexibility, and Improvement in Patient Care**

**Proposed Rule  
[CMS-3295-P]**

**Summary**

On June 13, 2016, the Centers for Medicare & Medicaid Services (CMS) made public a proposed rule to update its requirements that hospitals and critical access hospitals (CAHs) must meet to participate in Medicare and Medicaid. These changes to the hospital and CAH **conditions of participation** are intended to conform the requirements to current standards of practice and support improvements in quality of care, reduce barriers to care, and reduce some issues that may exacerbate concerns about workforce shortages. The proposed rule appears in the June 16<sup>th</sup> *Federal Register* (pp. 39448-39480). **The 60-day comment period ends at 5 pm, August 15, 2016.**

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## **Background**

### A. Executive Summary

Among CMS' proposed major changes to the hospital and CAH conditions of participation (CoPs) are requirements—

- To establish and implement a policy prohibiting discrimination on the basis of race, color, religion, national origin, sex (including gender identity), sexual orientation, age, or disability;
- To establish hospital-wide infection prevention and control and antibiotic stewardship programs for the surveillance, prevention, and control of healthcare-associated infections and other infectious diseases, and for the appropriate use of antibiotics;

- To designate leaders of the infection prevention and control program and the antibiotic stewardship program respectively, who are qualified through education, training and experience; and
- That a hospital's Quality Assessment and Performance Improvement (QAPI) program incorporate quality indicator data related to hospital readmissions and hospital-acquired conditions.

Other changes would clarify the application of the existing regulations or make technical changes. CMS says that the proposed changes would reduce the incidence of healthcare-associated infections (HAIs); reduce inappropriate antibiotic use; and strengthen patient protections overall.

## B. Statutory Basis and Purpose of the Conditions of Participation for Hospitals and Critical Access Hospitals

CMS reviews the statutory and regulatory history of the conditions of participation (CoP) for hospitals and CAHs: Section 1861(e)(1) through (8) of the Social Security Act (SSA) requires a hospital participating in Medicare to meet specific conditions or standards. Section 1861(e)(9) specifies that a hospital also must meet such other requirements as the Secretary finds necessary in the interest of the health and safety of individuals furnished services in the institution. Using this authority, the Secretary has established regulatory requirements that a hospital must meet to participate in Medicare at 42 CFR part 482, CoPs for Hospitals. Section 1905(a) of the SSA provides that Medicaid payments from states may be applied to hospital services. Under 42 CFR 440.10(a)(3)(iii) and 42 CFR 440.20(a)(3)(ii), hospitals are required to meet the Medicare CoPs in order to participate in Medicaid.

Critical Access Hospitals participating in the Medicare Rural Hospital Flexibility Program, established by the Balanced Budget Act of 1997, must meet the conditions for designation specified under section 1820(c)(2)(B) of the SSA. To be certified, they also must meet other criteria the Secretary may require under section 1820(e)(3). Using this authority, the Secretary has established regulatory requirements that a CAH must meet to participate in Medicare at 42 CFR part 485, subpart F.

Compliance with the hospital and the CAH CoPs is assessed by state surveyors. Alternatively, the hospital or CAH may elect to be reviewed by a private CMS-approved accrediting organization (e.g., The Joint Commission or the American Osteopathic Association/Healthcare Facilities Accreditation Program) as having standards that meet or exceed the applicable Medicare standards and survey procedures comparable to those that CMS requires for state survey agencies.

## C. Why Revise the Conditions of Participation?

CMS proposes CoP revisions to address continuing stakeholder concerns. Also, despite recent revisions to the COPs, CMS believes that their modernization would result in improved quality of care and patient outcomes, including reduced readmissions, reduced incidence of hospital acquired conditions including healthcare-associated infections, improved use of antibiotics and

improved patient and workforce protections. These benefits would be consistent with current HHS quality initiatives which CMS briefly summarizes (see 81 *FR* 39449-50). In addition, principles of the National Quality Strategy supported by this proposed rule include eliminating disparities in care; improving quality; promoting consistent national standards while maintaining support for local, community, and state-level activities that are responsive to local circumstances; care coordination; and providing patients, providers, and payers with the clear information they need to make choices that are right for them. CMS' proposed revisions to prohibit discrimination would support eliminating disparities in care; its proposals about Quality Assessment and Performance Improvement (QAPI) and infection prevention and control and antibiotic stewardship programs would improve quality and promote consistent national standards. And its proposals related to "licensed independent practitioners" would support care coordination and quality of care.

### **Provisions of the Proposed Rule**

The proposed revisions are in 42 CFR Parts 482 and 485.

#### **A. Patients' Rights (§482.13)**

*1. Non-discrimination.* CMS would add to this section of the hospital CoPs new subparagraph (i) to establish explicit requirements that a hospital not discriminate on the basis of race, color, religion, national origin, sex (including gender identity), sexual orientation, age, or disability and that the hospital establish a written policy prohibiting discrimination on all of these bases. The hospital would also have to inform each patient (and/or support person, where appropriate), in a language he or she can understand, of his or her right to be free from discrimination against them. Part of the required information would instruct the individual on how to file a complaint if they encounter discrimination.

CMS notes in the preamble that while specific civil rights requirements (including section 1557 of the Affordable Care Act)<sup>1</sup> apply to providers who participate in the Medicare program, there is currently no explicit prohibition of discrimination contained within the Hospital and CAH CoPs. This may have created a barrier to seeking care by individuals who fear discrimination. Studies of the impact of discrimination (some of which are noted in the preamble) indicate that discriminatory behavior, or even the fear of discriminatory behavior, by healthcare providers remains an issue and can create barriers to care and result in adverse outcomes for patients. For this reason, CMS has proposed that the non-discrimination provisions described above be added to the regulatory text.

With respect to the proposed requirement that each patient and/or representative and/or "support person" be informed in a language that he or she can understand of the right to be free from discrimination when informed of other rights under this section of the regulations,<sup>2</sup> CMS states

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<sup>1</sup> This provision prohibits health programs and activities that receive federal financial assistance, such as Medicare and Medicaid, from excluding or denying beneficiaries participation based on their race, color, national origin, sex (including gender identity), age, or disability.

<sup>2</sup> Section 482.13 includes a long list of patients' rights. Examples include the right to be given certain information, a right to privacy, visitation rights and a right to safe implementation of restraint or seclusion by trained staff.

that a “support person” does not need to be the patient’s representative who is legally responsible for making decisions on the patient’s behalf but can be a family member, friend, or other individual present to support the patient during the course of the stay.

2. *Licensed independent practitioners.* Under current §482.13(e)(5), the use of restraint or seclusion must be in accordance with the order of a physician or other *licensed independent practitioner* who is responsible for the care of the patient as specified under §482.12(c) and authorized to order restraint or seclusion by hospital policy in accordance with state law. CMS proposes to delete “independent” from “licensed independent practitioner” in order to address concerns, including from the American Academy of Physician Assistants (AAPA), that this term is not used in the SSA or other federal law and that its use not only leads to confusion but also restricts the ability of hospitals to utilize physician assistants (PAs) to the extent of their educational preparation and scope of practice, as determined by state law. CMS reviews its considerations of this issue (see 81 *FR* 39451). It concludes that the deletion of “independent” from the patient rights section of the CoP is merited in subparagraph (e)(5) and also at (e)(8)(ii). The latter relates to the situation when a new order for the use of restraint or seclusion is written for the management of violent or self-destructive behavior. A physician or other licensed independent practitioner who is responsible for the care of the patient and authorized to order restraint or seclusion by hospital policy in accordance with state law must see and assess the patient. Additional sections in the regulations where this change would be made are at: §482.13(e)(10), (e)(11), (e)(12)(i)(A), (e)(14), and (g)(4)(ii).

CMS also proposes to remove the term “physician assistant” from the current provisions at §482.13(e)(12)(i)(B) and (e)(14). It explains that its use in these instances distinguishes the role of PAs from other licensed practitioners (such as advanced practice registered nurses (APRNs)) in ways that are confusing and that restrict the ability of hospitals to utilize PAs to the extent of their educational preparation and scope of practice. CMS says that this can create a burden for hospitals, particularly small hospitals, and is contrary to state laws that allow PAs to practice to the full extent of their training and credentialing. Also PA training and education is comparable in many ways to that of APRNs and, in some ways, more extensive. CMS does not believe that PAs should have to undergo additional training so that they can order restraint and seclusion.

3. *Access to Medical Records.* Under current §482.13(d)(2), the patient has the right to the confidentiality of his or her clinical records and the right to access information contained in their clinical records within a reasonable time frame. The hospital must not frustrate the legitimate efforts of individuals to gain access to their own medical records and must actively seek to meet these requests as quickly as its record keeping system permits.

These requirements, established in 2006, do not take into account that medical records may be maintained electronically, nor do they acknowledge that a patient has the right to access their medical records in an electronic format. Because CMS believes that the requirements should be updated to reflect the availability of electronic records, it proposes to clarify that the patient has the right to access their medical records, including current medical records, upon an oral or written request, in the form and format requested by the individual, if it is readily producible in such form and format (including in an electronic form or format when such medical records are maintained electronically); or, if not, in a readable hard copy form or such other form and format

as agreed to by the facility and the individual, within a reasonable time frame. CMS points to the recent FAQ issued by the Office of Civil Rights about medical records access. It clarifies that the requirement (implementing privacy provisions of the Health Insurance Portability and Accountability Act (HIPAA)) to send medical records to the individual is within 30 days (or 60 days if an extension is applicable) after receiving the request. “[H]owever, in most cases, it is expected that the use of technology will enable the covered entity to fulfill the individual’s request in far fewer than 30 days.”<sup>3</sup>

## B. Quality Assessment and Performance Improvement (QAPI) Program (§482.21)

CMS proposes a change to the QAPI program requirements at §482.21(b), which currently requires that the QAPI program incorporate quality indicator data including patient care and other relevant data submitted to or received from the hospital’s Quality Improvement Organization. (It further provides that the hospital use the data to monitor the effectiveness and safety of services and quality of care and identify opportunities for improvement and changes that will lead to improvement. The frequency and detail of data collection must be specified by the hospital's governing body.)

CMS proposes to revise this provision to require that the hospital QAPI program would have to incorporate quality indicator data including patient care data (such as data submitted to or received from quality reporting and quality performance programs) including but not limited to data related to hospital readmissions and hospital-acquired conditions. CMS notes that most hospitals collect and analyze data for several quality reporting and quality performance programs, such as the Hospital Inpatient Quality Reporting program, the Hospital Value-Based Purchasing Program, the Hospital-Acquired Condition Reduction Program, the Medicare and Medicaid Electronic Health Record Incentive Programs, and the Hospital Outpatient Quality Reporting program. It would therefore be efficient and cost-effective for a hospital to include at least some of these data in its QAPI program. The data are used to calculate measures, which are generally endorsed by the National Quality Forum (NQF). CMS sees them as a valuable resource for hospitals to use in QAPI programs.

CMS does not propose to require that hospitals develop and implement information technology (IT) systems as part of their QAPI program. However, it encourages them to use IT systems, including systems to exchange health information with other providers, which are designed to improve patient safety and quality of care. Facilities that are electronically capturing information should be doing so using certified health IT that will enable real time electronic exchange with other providers.

## C. Nursing Services (§482.23)

Under the current CoP for nursing services, paragraph (b) requires nursing services to have adequate numbers of licensed registered nurses, licensed practical (vocational) nurses, and other personnel to provide nursing care to all patients as needed. There must be supervisory and staff

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<sup>3</sup> <http://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/#newlyreleasedfaqs>. Individuals who have not been provided with their medical records within the 30-day timeframe or who experience other difficulties accessing their medical records can file a complaint with OCR.



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 recognizes that these requirements may be ambiguous and confusing due to unnecessary distinctions between inpatient and outpatient services, or may fail to account for the different ways in which a hospital may meet its nurse staffing requirements. For that reason, CMS proposes to revise paragraph (b) to delete the term “bedside” so that readers do not believe the requirement refers only to inpatient services. The revised regulatory text would be: “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 care of any patient.”

Because the term “immediate availability” has been interpreted to mean physically present on the unit or in the department although it is not necessary to have a nurse physically present in the case of some outpatient services, CMS proposes in new (b)(7) to allow a hospital to establish a policy specifying which, if any, outpatient departments would not be required to have an RN physically present as well as the alternative staffing plans that would be established under such policy. CMS would require such a policy to take into account factors such as the services delivered, the acuity of patients typically served by the facility, and the established standards of practice for such services. The policy would have to be approved by the medical staff and be reviewed at least once every three years. CMS specifically welcomes comments on the need for, the risks of establishing, and the appropriate criteria that it should require for such an exception.

Current §482.23(b)(4) requires the hospital to ensure that the nursing staff develops, and keeps current, a nursing care plan for each patient. The nursing care plan may be part of an interdisciplinary care plan. CMS proposes to clarify that while a nursing care plan is needed for every patient, the care plan should reflect the needs of the patient and the nursing care to be provided to meet those needs. CMS explains in the preamble that the care plan for a patient with complex medical needs and a longer anticipated hospitalization may be more extensive and detailed than the care plan for a patient with a less complex medical need expecting only a brief hospital stay. CMS notes its expectation that a nursing care plan is initiated and implemented in a timely manner, include patient goals as part of the patient’s nursing care assessment and, as appropriate, physiological and psychosocial factors (such as specific physical limitations and available support systems), physical and behavioral health comorbidities, and patient discharge planning. Moreover, it should be consistent with the plan for the patient’s medical care and demonstrate evidence of reassessment of the patient’s nursing care needs, response(s) to nursing interventions, and, as needed, revisions to the plan.

Under current paragraph (b)(6) of this section, non-employee licensed nurses who are working in the hospital must adhere to the policies and procedures of the hospital. In addition, the director of nursing service is required to provide for the adequate supervision and evaluation of the clinical activities of non-employee nursing personnel which occur within the responsibility of the nursing service. CMS would revise this provision to clarify that *all* licensed nurses who provide services in the hospital must adhere to the policies and procedures of the hospital. In addition, the director of nursing service must provide for the adequate supervision and evaluation of the clinical activities of *all* nursing personnel (that is, all licensed nurses and any non-licensed personnel such as nurse aides, orderlies, or other nursing support personnel who are under the direction of

the nursing service) which occur within the responsibility of the nursing service, regardless of the mechanism through which those personnel are obtained (hospital employee, contract, lease, other agreement, or volunteer). In the preamble, CMS states that while there are a variety of arrangements under which hospitals obtain the services of licensed nurses, ensuring the health and safety of patients requires that: 1) all nurses know and adhere to the policies and procedures of the hospital and 2) there be adequate supervision and evaluation of the clinical activities of all nursing personnel who provide services that occur within the responsibility of the nursing service. CMS expects non-licensed personnel to be supervised by a licensed nurse.

(See also “Removal of Inappropriate References to 482.12(c)(1) under “F. Technical Corrections,” summarized below, for additional changes made to the Nursing Services CoP.)

#### D. Medical Record Services (§482.24)

CMS notes that the Medicare hospital CoPs apply to services being provided to all patients, *regardless of insurer*, and to both inpatients and outpatients of a hospital. However, some of the regulatory language in §482.24 appears to apply to only inpatients, particularly with the use of terms such as “admission,” “hospitalization,” and “discharge.” So that the requirements are clearer regarding the distinctions between a patient’s inpatient and outpatient status and the “subtle differences” between certain aspects of medical record documentation related to each status, CMS proposes the following changes:

(1) Paragraph (c), which now requires the medical record to “contain information to justify admission and continued hospitalization, support the diagnosis, and describe the patient's progress and response to medications and services” would be revised to read “contain information to justify *all* admissions and continued hospitalizations, support the *diagnoses*, describe the patient's progress and response to medications and services, and *document all inpatient stays and outpatient visits to reflect all services provided to the patient*”[proposed changes noted in italics].

(2) Subparagraph (c)(4)(ii), which currently requires all records to document “admitting diagnosis” would be changed to “All diagnoses specific to each inpatient stay and outpatient visit” so as to include specifying any admitting diagnoses.

(3) CMS would update several terms to reflect more current terminology and standards of practice. In (c)(4)(iv), the content of the record would have to include documentation of complications, hospital-acquired conditions, healthcare associated infections, and adverse reactions to drugs and anesthesia. (It currently requires “documentation of complications, hospital acquired infections, and unfavorable reactions to drugs and anesthesia.”) In (c)(4)(vi), CMS proposes to add “progress notes... interventions, responses to interventions...” to the required documentation of “practitioners’ orders” to emphasize the necessary documentation for both inpatients and outpatients. The phrase “to reflect all services provided to the patient” would be added to the text so that the provision would say that the content of the record must contain “all practitioners' progress notes and orders, nursing notes, reports of treatment, interventions, responses to interventions, medication records, radiology and laboratory reports, and vital signs



and other information necessary to monitor the patient's condition and to reflect all services provided to the patient.”

(4) Under current (c)(4)(vii), the record must include a “discharge summary with outcome of hospitalization, disposition of case, and provisions for follow-up care.” CMS proposes to revise this to “[d]ischarge 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 services received by the patient.” This is meant to clarify the importance of discharge summaries for patients being discharged home as well as the importance of transfer summaries for patients being transferred to post-acute care facilities such as nursing homes or inpatient rehabilitation facilities. In addition, CMS recognizes the distinction between the services received by inpatients and those received by outpatients by proposing to include language that distinguishes between the inpatient and the outpatient experiences.

(5) To emphasize the distinctions between discharges and transfers as well as between inpatients and outpatients, CMS proposes to revise (c)(4)(viii) so that the content of the medical record would contain final diagnoses with completion of medical records within 30 days following all inpatient stays, and within 7 days following all outpatient visits. The current requirement is for “[f]inal diagnosis with completion of medical records within 30 days following discharge.”

#### E. Infection Prevention and Control and Antibiotic Stewardship Programs (§482.42)

CMS proposes revisions to §482.42 to clarify existing requirements related to infection control and to update the regulatory language to reflect state of the art practices and terminology. CMS also proposes to include in this section requirements that hospitals develop and maintain an antibiotic stewardship program to improve antibiotic prescribing practices and to curb the risk for potentially life-threatening antibiotic resistant infections.

CMS, in the preamble, describes its growing concern with hospital acquired infections (HAIs) and the increasing threat to patients posed by antibiotic resistant organisms. The Department of Health and Human Services (HHS) launched, in response to those threats, an action plan described in “HHS Action Plan to Prevent Healthcare-Associated Infections” available at ([www.hhs.gov/ash/initiatives/hai/actionplan/index.html](http://www.hhs.gov/ash/initiatives/hai/actionplan/index.html)).

Existing rules at §482.42 require hospitals to provide a sanitary environment to avoid sources and transmission of infections and communicable diseases and to have a designated infection control officer, (or officers) who are required to develop a system to identify, report, investigate and control infections and communicable diseases. The hospital’s chief executive officer, medical staff, and director of nursing are required to ensure that the problems identified by the infection control officer are addressed in hospital training and QAPI programs and are responsible for the implementation of corrective action plans in problem areas.

CMS proposes to broadly change these requirements beginning with the title. Formerly entitled “Infection control,” CMS would change the title to “Infection prevention and control and antibiotic stewardship programs” emphasizing the importance of preventing infections and combatting antibiotic resistance. The proposed standards would require hospitals to have an

active hospital-wide program for the surveillance, prevention, and control of HAIs and other infectious diseases and for the optimization for antibiotic use. The programs would need to adhere to nationally recognized infection prevention and control guidelines and best practices for antibiotic use, for reducing the development and transmission of HAIs and anti-biotic resistant organisms. They would also be required to address any infection and antibiotic issue identified in coordination with facility-wide QAPI programs.

CMS points out that the proposed rules incorporate the concept of surveillance into the requirements and describes two types of surveillance: one includes sampling and monitoring and the second includes the use of automated surveillance such as through data mining. CMS states that it has chosen to provide flexibility to hospitals by proposing that hospitals adhere to nationally recognized guidelines and best practices rather than requiring hospitals to adhere to any specific set of guidelines or practices and identifies other sources of guidelines in addition to those issued by the Centers for Disease Control and Prevention (CDC) including those of the Society for Healthcare Epidemiology of America and the Infectious Diseases Society of America.

In the preamble, CMS states that while the proposed programs would be required to demonstrate adherence to nationally recognized infection prevention and control guidelines for reducing the transmission of infections, best practices for improving antibiotic use, and for reducing the development and transmission of HAIs and antibiotic-resistant organisms, those requirements have been present in Interpretive Guidelines for hospitals since 2008.<sup>4</sup>

*Infection prevention and control program organization and policies (§482.42(a)).* CMS proposes that an infection prevention and control program of a hospital must meet the following standards:

- An individual (or individuals) who are qualified through education, training, experience, or are certified in infection prevention and control are appointed to be responsible for the infection prevention and control program. Their appointment would be based on the recommendations of medical staff and nursing leadership.
- The infection prevention and control program, documented in policies and procedures, would employ methods for preventing and controlling the transmission of infection within the hospital setting (for example, among patients, personnel, and visitors) as well as between the hospital (including outpatient services) and other institutions and healthcare settings.<sup>5</sup>
- Infection prevention and control programs must include surveillance, prevention, and control of HAIs including maintaining a clean and sanitary environment and address infection control issues identified by public health authorities.<sup>6</sup>

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<sup>4</sup> See A0747 at Appendix A - Survey Protocol, Regulations and Interpretive Guidelines for Hospitals [http://cms.gov/manuals/Downloads/som107ap\\_a\\_hospitals.pdf](http://cms.gov/manuals/Downloads/som107ap_a_hospitals.pdf).

<sup>5</sup> CMS expects hospitals to look to guidelines and provides one such example: “Guide to Infection Prevention for Outpatient Settings: Minimum Expectations for Safe Care.” (CDC, “Guide to Infection Prevention for Outpatient Settings” at <http://www.cdc.gov/HAI/settings/outpatient/outpatient-careguidelines.html>).

<sup>6</sup> CMS provides links to sources for hospitals to use to identify prominent HAIs including the “HHS Action Plan to Prevent Healthcare-Associated Infections” available at [www.hhs.gov/ash/initiatives/hai/actionplan/index.html](http://www.hhs.gov/ash/initiatives/hai/actionplan/index.html)); and

- The infection prevention and control program would reflect the scope and complexity of the services provided by the hospital. For example, a hospital that did not offer surgical services would not need to address infection control issues specific to surgical patients.

Antibiotic stewardship program organization and policies (§482.42(b)). CMS proposes that hospitals have in place a hospital-wide antibiotic stewardship program and provides a summary of research findings that support such a proposal. These include reports issued by the American Hospital Association and the CDC. Letters to CMS from the Infectious Diseases Society of America and the Society for Healthcare Epidemiology of America that detail supporting evidence and the rationale for such a program are described. (The discussion and links to the reports and letters are on 81 FR 39457). In proposed paragraph (b), the hospital would be required to ensure that:

- An individual who is qualified through education, training, or experience in infectious diseases and/or antibiotic stewardship is appointed as the leader of the antibiotic stewardship program and the appointment is based on the recommendations of medical staff and pharmacy leadership.
- The antibiotic stewardship program coordinates among all components of the hospital responsible for antibiotic use and resistance, including with the infection prevention and control and QAPI programs, medical staff, nursing and pharmacy services. It must document the evidence-based use of antibiotics and demonstrate improvements in their proper use, such as through reductions in CDI and antibiotic resistance in all departments and services of the hospital.
- The program adheres to nationally recognized guidelines and best practices for improving antibiotic use.
- The program reflects the scope and complexity of services offered.

CMS states that, after the rule is finalized, it will develop Interpretive Guidelines to instruct surveyors on how to determine whether a hospital is compliant with such requirements.

*Governing body for Infection prevention and control and Antibiotic stewardship programs (§482.42(c)).* The governing body or responsible individual would be required to ensure that any infection prevention and control issue identified by infection prevention and control professionals is addressed in collaboration with hospital leadership. The programs would be required to track all infection surveillance, prevention, and control, and antibiotic use activities in order to demonstrate the implementation, success, and sustainability of such activities; and to address, in collaboration with QAPI leadership, any issues related to HAIs, infectious diseases, or antibiotic use identified by the Infection prevention and control and Antibiotic stewardship programs.

CMS proposes, at §482.42(c)(2) and (3), the responsibilities of the infection prevention and control professionals and antibiotic stewardship program professionals. These would include: the development and implementation of facility-wide infection/antibiotic surveillance, prevention,

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the list that CMS publishes annually in its Inpatient Prospective Payment System final rule. For 2016, see 80 *FR* 49325.

and control policies and procedures that adhere to nationally recognized guidelines; documentation of the surveillance, prevention, and control activities; communicating and collaborating with each other and with the hospital's QAPI program; training and education of hospital personnel and staff including professional health care and contract staff on the practical applications of infection prevention and control/antibiotic use guidelines, policies and procedures; and prevention and control of HAIs, including auditing of adherence to infection prevention and control policies and procedures by hospital personnel.

#### F. Technical Corrections

*Technical Amendments to §482.27(b)(7)(ii) and (b)(11).* In the final rule “Medicare and Medicaid Programs; Hospital Conditions of Participation: Laboratory Services,” amending 42 CFR 482.27 (Aug. 24, 2007), CMS stated that hepatitis C virus (HCV) notification requirements for donors tested before February 20, 2008, would expire on August 24, 2015. Since the notification requirement period has expired, CMS proposes to remove §482.27(b)(11) and the “Applicability” and the corresponding requirements set out at §482.27(b)(7)(ii).

*Corrected Reference in §482.58.* CMS proposes to correct an incorrect cross reference at §482.58(b)(6), which currently reads “Discharge planning (§483.20(e))”. Section 483.20(e) addresses coordination of the preadmission screening and resident review program and not discharge planning. Skilled nursing facility (SNF) requirements for discharge plans are at §483.20(l). CMS would correct the reference to read “Discharge summary (§483.20(l))”.

*Removal of Inappropriate References to §482.12(c)(1).* Several provisions in the hospital CoP incorrectly reference §482.12(c)(1), which lists the types of physicians and applies only to patients who are Medicare beneficiaries. Section 482.12(c) states that the governing body of the hospital must ensure that every Medicare patient is under the care of one of a list of practitioners (see 81 FR 39460 for this list). The reference to this “Medicare beneficiary-only” requirement in other provisions of the CoPs inappropriately links it to *all* patients and not Medicare beneficiaries exclusively. Section 1861(e)(4) of the SSA provides that “every patient with respect to whom payment may be made under this title must be under the care of a physician except that a patient receiving qualified psychologist services (as defined in subsection (ii)) may be under the care of a clinical psychologist with respect to such services to the extent permitted under State law.” In accordance with that provision, CMS has chosen to apply §482.12(c) to Medicare patients. With the exception of a few provisions in the CoPs such as those directly related to §482.12(c) described here, *the remainder of the CoPs apply to all patients, regardless of payment source, and not just Medicare beneficiaries.* CMS provides examples, including that for the Nursing Services CoP at §482.23(c)(1), which requires all drugs and biologicals to be prepared and administered in accordance with federal and state laws, the orders of the practitioner or practitioners responsible for the patient's care as specified under §482.12(c), and accepted standards of practice. Since the CoPs clearly allow hospitals to determine which categories of practitioners would be responsible for the care of other patients, outside the narrow Medicare beneficiary restrictions of §482.12(c), this reference is inappropriate and unnecessarily restrictive of hospitals and their medical staffs to make these determinations based on State law and practitioner scope of practice. In order to clarify that these latter provisions apply to all patients and not only Medicare beneficiaries, CMS proposes to delete any inappropriate

references to §482.12(c). These include: §482.13(e)(5), (e)(8)(ii), (e)(14), and (g)(4)(ii) in the Patients' Rights CoP; and §482.23(c)(1) and (3) in the Nursing Services CoP. With respect to all of these provisions, the reference to services provided under the order of a physician or other practitioner would still apply.

## G. Critical Access Hospitals (CAHs)

### 1. Organizational structure (§485.627(b))

Existing rules governing the organizational structure of a CAH require, at §485.627(b)(1), disclosure of the names of the CAH's owners, those with a controlling interest in the CAH, and any subcontractor in which the CAH directly or indirectly has a 5 percent or more ownership interest. CMS proposes to delete those requirements at §485.627(b)(1) because they are duplicative of requirements at §420.206 (regarding the provider enrollment process).

### 2. Periodic Review of Clinical Privileges and Performance (§485.631(d)(1) through (2)).

Existing §485.641(b)(3) and (4) require a member of the CAH staff who is a doctor of medicine or osteopathy to evaluate the quality and appropriateness of the diagnosis and treatment furnished by non-physician providers at the CAH. Under those rules, the quality and appropriateness of the diagnosis and treatment furnished by physicians at the CAH must also be evaluated by: a hospital that is a member of the network (when applicable); a QIO or equivalent entity; another appropriate and qualified entity identified in the state rural health care plan; or, in the case of distant-site telemedicine services under an agreement between the CAH and a distant-site hospital, the distant-site hospital; or, in the case of distant-site physicians and practitioners providing telemedicine services to the CAH's patients under an agreement between the CAH and a distant-site telemedicine entity, one of the entities listed above. CMS proposes to move those provisions, without change, to §485.631 – a section primarily about staffing requirements and responsibilities and to relabel them as paragraphs (d)(1) and (2).

### 3. Provision of services

*Section 485.635(a)(3)(vii).* Existing §485.635(a)(3)(vii) requires that a CAH have in place procedures that ensure the nutritional needs of inpatients are met in accordance with recognized dietary practices and with the orders of the practitioner responsible for the care of the patients. CMS proposes to add flexibility to this requirement so that CAHs may also permit registered dietitians to order therapeutic diets for patients in accordance with state laws. The requirement, re-designated at §485.635(a)(3)(vi), would apply, as described in the preamble, to all qualified dietitians and any other clinically qualified nutrition professionals as long as such professionals meet the requirements of any applicable state laws, regulations or other professional standards. CMS outlines the existing literature that supports the use of dietician professionals to assess a patient's nutritional status, and to design and implement a nutritional treatment plan in calculation with the patient's interdisciplinary care team. Some of that literature concludes that outcomes are improved and costs are reduced with the care of professional dietitians.



In addition, proposed new paragraph (3)(vi) retains the existing requirement that the protection described at §483.25(i) applies to CAHs with respect to inpatients receiving post CAH SNF care. The provision ensures that a resident maintains acceptable parameters of nutritional status (for example, body weight and protein levels) unless it is not possible because of the patient's clinical condition and receives a therapeutic diet when there is a nutritional problem.

*Section 485.635(g).* CMS proposes to establish an explicit nondiscrimination standard applicable to CAHs that is consistent with section 1557 of the ACA, which prohibits health programs that receive federal assistance, such as Medicare and Medicaid, from excluding or denying beneficiaries' participation based on their race, color, national origin, sex (including gender identity), age, or disability. The proposed standards are intended to prevent discrimination which could potentially lead to a denial of services or to inadequate care which could be detrimental to a patient's health or safety. The CAH would be required to establish and implement a written policy prohibiting discrimination on the basis of race, color, religion, national origin, sex (including gender identity), sexual orientation, age, or disability. A CAH would be required to inform each patient (including the patient's support person, where appropriate) of the right to be free from discrimination in a language that the patient can understand and to inform the patient and/or their representative, about how to seek assistance if they encounter discrimination.

#### 4. Infection prevention and control and antibiotic stewardship programs (new §485.640)

Existing conditions of participation for CAHs include two provisions related to infection control. Current §485.635(a)(3)(vi) requires a CAH to include in its policies, a system to identify, report, investigate and control infections and communicable diseases of patients and personnel and §485.62(b)(2) requires a CAH to monitor its infection control program to ensure that policies and procedures are consistent with current practices in the field. CMS proposes to remove §485.635(a)(3)(vi) and replace the requirement with new §485.640 describing a comprehensive, facility wide program for the surveillance, prevention, and control of hospital-acquired infections (HAIs) and other infectious diseases and for the optimization of antibiotic use.

The proposed §485.640 is comprised of identical provisions as are proposed in §482.42 (and described above) but are applicable to CAHs.

#### 5. Quality Assessment and Performance Improvement (QAPI) Program (§485.641)

CMS proposes to broadly revise §485.641 which is currently titled "Condition of participation: Periodic evaluation and quality assurance review." The revisions reflect updates to conform to current industry standards that use a QAPI model to assess and improve patient care. CMS states that the current requirements, which call for evaluating whether the utilization of services at the CAH were appropriate and making any needed changes, is a reactive process instead of a process that proactively pursues quality improvement activities and programs even in the absence of specific deficiencies.

In the preamble of the proposed rule, CMS summarizes research that confirms that medical errors, patient injuries, and other adverse events continue to cause patient harm and presents the

conclusions of reports that describe approaches to improve quality, including in rural settings (see 81 *FR* 39462).

The proposed QAPI program would call for a CAH to develop, implement, and maintain an effective, ongoing, CAH-wide, data-driven QAPI program and to maintain evidence of such program.

The new standards are comprised of 6 parts: definitions, QAPI program design and scope, governance and leadership, program activities, performance improvement projects, and data collection and analysis. Each of those parts are summarized as follows.

*Definitions (§485.641(a)).* CMS proposes definitions for the terms “adverse event,” “error,” and “medical error.” The definition for adverse event is the same as currently found at §482.70 while the other two definitions are drawn largely from the Institute of Medicine.

*QAPI program design and scope (§485.641(b)).* A QAPI program in a CAH would be required to be ongoing, comprehensive, and appropriate for the complexity of the CAH’s organization and services. The program would be required to involve all departments and services (including those under contract); use objective measures to evaluate the CAH’s processes, function, and services; and address outcome indicators related to improved health outcomes and prevention and reduction of medical errors, adverse events, CAH-acquired conditions, and transitions of care (including readmissions).

*Governance and Leadership (§485.641(c)).* The CAH’s governing body or responsible individual would be responsible for the CAH’s QAPI program and would be responsible and accountable for ensuring that clear expectations for safety are communicated, implemented, and followed. The QAPI would be required to:

- Address priorities for improving quality of care and patient safety.
- Ensure improvement actions are evaluated and modified as needed.
- Ensure that adequate resources are allocated for measuring, assessing, improving, and sustaining the CAH’s performance and reducing risk to patients. (CMS will provide sub-regulatory guidance as to what constitutes “adequate resources.”)
- Determine, annually, the number of quality improvement projects the CAH would conduct.
- Develop and implement policies and procedures that address the actions the CAH staff should take to prevent and report unsafe patient care practices, medical errors, and adverse events.

*Program Activities (§485.641(d)).* For each of the areas identified in the two preceding paragraphs (QAPI Program Design and Scope and Governance and Leadership), the QAPI would be required to focus on proven health outcome measures, to analyze and track the CAHs’ performance, and to set priorities for performance improvement considering either high-volume, high-risk services or problem areas. CMS notes in the preamble that analyses should be conducted at regular intervals.

*Performance Improvement Projects (PIPs) (§485.641(e)).* The number and scope of PIPs would need to be proportional to the scope and complexity of the CAH’s services and operations. Written or electronic documentation of such projects would be required.

*Program data collection and analysis (§485.641(f)).* Quality indicator data must be incorporated and used to monitor the effectiveness and safety of services and quality of care and to identify opportunities for improvement.

**Collection of Information Requirements**

Under the Paperwork Reduction Act of 1995, CMS is required to provide 60-day notice in the Federal Register and to solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget for review and approval. CMS specifically solicits comment on the need for information collection, the accuracy of the agency’s burden estimates, the quality utility and clarity of the information to be collected, and any recommendations to minimize the burden on the affected parties. The costs of complying with these requirements are estimated by CMS and are incorporated in Table 1 below.

**Regulatory Impact Analysis**

CMS estimates that this proposed rule meets the threshold as “economically significant” (\$100 million or more in any one year), and therefore a regulatory impact analysis was conducted. The impact is estimated by CMS to include both costs as well as savings to hospitals and CAHs which are in part offsetting. The budgetary impact of those proposed reforms for which CMS estimates will have a measurable economic effect is summarized in Table 1, duplicated below. The table appears on 81 FR 39475 and incorporates both the costs of complying with information collection requirements (ICRs) as well as those costs attributed to the regulatory impact analysis (RIA).

**Table 1 – Section-by-Section Economic Impact Estimates**

<b>Issue</b>	<b>Frequency</b>	<b>Number of Affected Entities</b>	<b>Likely Savings (+) or Costs (-) to Society (\$ millions)</b>
Hospitals		4,900	
• Patients’ rights (ICR)	One-time	4,900	0.083(-)
• Nursing services (ICR)	Recurring	1,000	1.3(-)
• Nursing services (ICR)	annually	1,000	0.429(-)
• Medical record services (ICR)	One-time	4,900	6.3(-)
• Infection Prevention & Control and Antibiotic Stewardship (RIA)	One-time	4,900	20(-)
	One-time	2,940	> 693 to 1,193 (-)
	Recurring	2,940	1,020(+)
	annually		
CAHs		1,328	

<b>Issue</b>	<b>Frequency</b>	<b>Number of Affected Entities</b>	<b>Likely Savings (+) or Costs (-) to Society (\$ millions)</b>
<ul style="list-style-type: none"> <li>• Provision of services (ICR)</li> <li>• QAPI (ICR)</li> <li>• Food and dietary (RIA)</li> <li>• Infection Prevention &amp; Control and Antibiotic Stewardship (RIA)</li> </ul>	One-time	1,328	0.023(-)
	Recurring annually	1,004	2(-)
		650	Not estimated
	Recurring annually	1,328	5(-)
		1,328	45(-)
	One-time	1,328	37(-)
	Recurring annually		
	Recurring annually		
<b>Sub-Total Savings</b>			<b>1,057(+)</b>
<b>Sub-Total Costs</b>			<b>&gt; 773 to 1,273 (-)</b>
<b>Overall Savings Net of Costs</b>			<b>&lt; -216 to 284 (+)</b>

NOTE: The placement of the figures in this tables has been revised by HPA to reflect the discussion of the RIA in the preamble (81 *FR* 39469-39470).