

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 482 and 485

[CMS-3295-P]

RIN 0938-AS21

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

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would update the requirements that hospitals and critical access hospitals (CAHs) must meet to participate in the Medicare and Medicaid programs. These proposals 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 workforce shortage concerns.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on August 15, 2016.

ADDRESSES: In commenting, please refer to file code CMS-3295-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the "Submit a comment" instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-3295-P, P.O. Box 8010, Baltimore, MD 21244.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-3295-P, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments ONLY to the

following addresses prior to the close of the comment period:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244-1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786-9994 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: CDR Scott Cooper, USPHS, (410) 786-9465, Mary Collins, (410) 786-3189, Alpha-Banu Huq, (410) 786-8687, Lisa Parker, (410) 786-4665.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

Acronyms

Because of the many terms to which we refer by acronym in this proposed rule, we are listing the acronyms used and their corresponding meanings in alphabetical order below:

AAPA American Academy of Physician Assistants
 ACA Affordable Care Act
 AOA American Osteopathic Association
 APIC Association for Professionals in Infection Control and Epidemiology, Inc.
 APRN Advanced Practice Registered Nurse
 AS Antibiotic Stewardship
 BBA Balanced Budget Act
 CAHs Critical Access Hospitals
 CARB Combating Antibiotic-Resistant Bacteria
 CARE Continuity Assessment Record & Evaluation
 CBIC Certification Board of Infection Control and Epidemiology Inc.
 CDI Clostridium Difficile Infections
 CHA Children's Health Act
 CIHQ Center for Improvement in Healthcare Quality
 CLABSIs Central Line-Associated Bloodstream Infections
 CPOE Computerized Provider Order Entry
 CoPs Conditions of Participation
 DNV-GL DNV-GL Healthcare
 DO Doctor of Osteopathy
 DRA Deficit Reduction Act
 EM Emergency Medicine
 EHRs Electronic Health Records
 EWRs Executive WalkRounds
 FDA Food and Drug Administration
 HACs Hospital-Acquired Conditions
 HAIs Healthcare-Associated Infections
 HFAP Healthcare Facilities Accreditation Program
 HICPAC Healthcare Infection Control Practices Advisory Committee
 ICP Infection Control Professional
 IDSA Infectious Diseases Society of America
 IGs Interpretive Guidelines
 IOM Institute of Medicine
 IPPS Inpatient Prospective Payment System
 IT Information Technology
 LGBT Lesbian, Gay, Bisexual, and Transgender
 LIP Licensed Independent Practitioner
 MBQIP Medicare Beneficiary Quality Improvement Project
 MD Doctor of Medicine
 MDROs Multi-Drug Resistant Organisms
 MedPAC Medicare Payment Advisory Commission
 MRHFP Medicare Rural Hospital Flexibility Program
 NHSN National Healthcare Safety Network
 NQF National Quality Forum
 OBRA Omnibus Budget Reconciliation Act
 OCR Office for Civil Rights
 OIG Office of Inspector General
 PA Physician Assistant
 PCP Primary Care Provider
 PN Parenteral Nutrition
 QAPI Quality Assessment and Performance Improvement
 QIO Quality Improvement Organization
 RDs Registered Dietitians
 RPHs Rural Primary Care Hospitals

SHEA Society for Healthcare Epidemiology of America
 TJC The Joint Commission
 VBP Value-Based Purchasing

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I. Background

A. Executive Summary

These proposed changes would modernize hospital and critical access hospital (CAH) requirements, improve quality of care, and support HHS and CMS priorities. We believe that benefits of the proposed revisions would include; reduced incidence of hospital-acquired conditions (HACs), including reduced incidence of healthcare-associated infections (HAIs); reduced inappropriate antibiotic use; and strengthened patient protections overall. Specifically, we propose to revise the conditions of participation (CoPs) for hospitals and CAHs to address:

- Discriminatory behavior by healthcare providers that may create real or perceived barriers to care;
- Use of the term "Licensed Independent Practitioners" (LIPs) that may inadvertently exacerbate workforce shortage concerns;
- Requirements that do not fully conform to current standards for infection control;
- Requirements for antibiotic stewardship programs to help reduce

inappropriate antibiotic use and antimicrobial resistance; and

- The use of quality reporting program data by hospital Quality Assessment and Performance Improvement (QAPI) programs.

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

Sections 1861(e)(1) through (8) of the Social Security Act (the Act) provide that a hospital participating in the Medicare program must meet certain specified requirements. Section 1861(e)(9) of the Act 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. Under 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 Act provides that Medicaid payments from States may be applied to hospital services. Under regulations at 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.

On May 26, 1993, CMS published a final rule in the **Federal Register** entitled "Medicare Program; Essential Access Community Hospitals (EACHs) and Rural Primary Care Hospitals (RPCHs)" (58 FR 30630) that implemented sections 6003(g) and 6116 of the Omnibus Budget Reconciliation Act (OBRA) of 1989 and section 4008(d) of OBRA 1990. That rule established requirements for the EACH and RPCH providers that participated in the seven-state demonstration program that was designed to improve access to hospital and other health services for rural residents.

Sections 1820 and 1861(mm) of the Act, as amended by section 4201 of the Balanced Budget Act (BBA) of 1997, replaced the EACH/RPCH program with the Medicare Rural Hospital Flexibility Program (MRHFP), under which a qualifying facility can be designated and certified as a CAH. CAHs participating in the MRHFP must meet the conditions for designation specified in the statute under section 1820(c)(2)(B) of the Act, and to be certified must also meet other criteria the Secretary may require, under section 1820(e)(3) of the Act. Under this authority, the Secretary has established regulatory requirements that a CAH must meet to participate in Medicare at 42 CFR part 485, subpart F.

The CoPs for hospitals and CAHs are organized according to the types of services a hospital or CAH may offer,

and include specific, process oriented requirements for each hospital or CAH service or department. The purposes of these conditions are to protect patient health and safety and to ensure that quality care is furnished to all patients in Medicare-participating hospitals and CAHs. In accordance with Section 1864 of the Act, State surveyors assess hospital and CAH compliance with the conditions as part of the process of determining whether a hospital qualifies for a provider agreement under Medicare. However, under section 1865 of the Act, hospitals and CAHs can elect to be reviewed instead by private accrediting organizations approved by CMS as having standards that meet or exceed the applicable Medicare standards and survey procedures comparable to those CMS requires for State survey agencies. CMS-approved hospital and CAH accrediting programs include those of The Joint Commission (TJC), the American Osteopathic Association/Healthcare Facilities Accreditation Program (AOA/HFAP), and DNV-GL Healthcare (DNV-GL) (See 42 CFR part 488, Survey and Certification Procedures). The Center for Improvement in Healthcare Quality (CIHQ) also has a CMS-approved hospital accrediting program.

C. Why revise the conditions of participation?

CMS is aware, through conversations with stakeholders and federal partners, and as a result of internal evaluation and research, of continuing concerns about the conditions of participation for hospitals and CAHs despite recent revisions to the CoPs. We believe that the proposed revisions would address many of those concerns. In addition, modernization of the requirements would cumulatively result in improved quality of care and improved outcomes for all hospital and CAH patients. We believe that benefits would include reduced readmissions, reduced incidence of hospital-acquired conditions (including healthcare-associated infections), improved use of antibiotics at reduced costs (including the potential for reduced antibiotic resistance), and improved patient and workforce protections.

These benefits are consistent with current HHS Quality Initiatives, including efforts to prevent HAIs; the national action plan for adverse drug event (ADE) prevention; the national strategy for Combating Antibiotic-Resistant Bacteria (CARB); and the Department's National Quality Strategy (<http://www.ahrq.gov/workingforquality/index.html>). The *National Action Plan for Combating*

Antibiotic-Resistant Bacteria, which was developed by the interagency Task Force for Combating Antibiotic-Resistant Bacteria in response to Executive Order 13676: “Combating Antibiotic-Resistant Bacteria,” (79 FR 56931, Sept. 23, 2014), outlines steps for implementing the *National Strategy on Combating Antibiotic-Resistant Bacteria* and addressing the policy recommendations of the President’s Council of Advisors on Science and Technology report on *Combating Antibiotic Resistance*. The Action Plan includes activities to foster improvements in the appropriate use of antibiotics (that is, antibiotic stewardship) by improving prescribing practices across all healthcare settings, particularly establishment of antimicrobial stewardship programs in all acute care hospitals by 2020 (<https://www.whitehouse.gov/the-press-office/2015/03/27/fact-sheet-obama-administration-releases-national-action-plan-combat-ant>). Our proposal to require hospitals to establish and maintain antibiotic stewardship programs would directly support this goal. 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 (<http://www.ahrq.gov/workingforquality/nqs/principles.htm>). Our proposal to prohibit discrimination would support eliminating disparities in care, and we believe our proposals about QAPI and infection prevention and control and antibiotic stewardship programs would improve quality and promote consistent national standards. Our proposals regarding nursing services and the term “licensed independent practitioners” would support care coordination and quality of care. In sum, we believe our proposed changes are necessary, timely, and beneficial.

II. Provisions of the Proposed Rule

A. Patient’s Rights (§ 482.13)

1. Non-Discrimination

One of the basic requirements for providers who participate in the Medicare program is that, they must agree to meet the applicable civil rights requirements of Title VI of the Civil Rights Act of 1964, as implemented by 45 CFR part 80; section 504 of the

Rehabilitation Act of 1973, as implemented by 45 CFR part 84; the Age Discrimination Act of 1975, as implemented by 45 CFR part 90; Section 1557 of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148) (Section 1557); and other pertinent requirements enforced by the HHS Office for Civil Rights (OCR) (see 42 CFR 489.10(b)). Title VI prohibits discrimination based on race, color, and national origin. Section 504 prohibits discrimination based on disability. The Age Act prohibits discrimination based on age. Section 1557 of the Affordable Care Act prohibits discrimination on all of these bases and is the first federal civil rights law to prohibit discrimination based on sex, including gender identity, in covered health programs and activities. In addition, the Hospital and CAH Conditions of Participation (CoPs) require that hospitals and CAHs be in compliance with applicable Federal laws related to the health and safety of patients. However, there is currently no explicit prohibition of discrimination contained within the Hospital and CAH CoPs. We have been made aware that the historic lack of an explicit prohibition within the CoPs, and, in particular, the lack of civil rights protections regarding hospital patients’ gender identities, is regarded as having been a barrier to seeking care by individuals who fear such discrimination. 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. Numerous studies address the impact of discrimination or perceived discrimination on individuals seeking healthcare. Discrimination can be based on sexual orientation, racial or ethnic background, or other factors. The Institute of Medicine (IOM) noted in its 2011 report *The Health of Lesbian, Gay, Bisexual, and Transgender People: Building a Foundation for Better Understanding* that many lesbian, gay, bisexual, and transgender (LGBT) people refrain from disclosing their sexual orientation or gender identity to researchers and health care providers. The report goes on to note that:

Some LGBT individuals face discrimination in the health care system that can lead to an outright denial of care or to the delivery of inadequate care. There are many examples of manifestations of enacted stigma against LGBT individuals by health care providers. LGBT individuals have reported experiencing refusal of treatment by health care staff, verbal

abuse, and disrespectful behavior, as well as many other forms of failure to provide adequate care (Eliason and Schope, 2001; Kenagy, 2005; Scherzer, 2000; Sears, 2009 as cited in Institute of Medicine. *The Health of Lesbian, Gay, Bisexual, and Transgender People: Building a Foundation for Better Understanding*. Washington, DC: The National Academies Press, 2011.)

Perceived discriminatory behavior among African-American and white patients treated for osteoarthritis by orthopedic surgeons in two Veterans Affairs facilities negatively affected patient-provider communications (Leslie R.M. Hausmann, Ph.D., Michael J. Hannon, MA, Denise M. Kresevic, RN, Ph.D., Barbara H. Hanusa, Ph.D., C. Kent Kwoh, MD, and Said A. Ibrahim, MD, MPH. *Med Care*. 2011 July; 49(7): 626–633). Tracy MacIntosh et al report that racial/ethnic minorities who reported being socially-assigned as white are more likely to receive preventive vaccinations and less likely to report healthcare discrimination compared with those who are socially-assigned as minority. (MacIntosh T, Desai MM, Lewis TT, Jones BA, Nunez-Smith M (2013) Socially-Assigned Race, Healthcare Discrimination and Preventive Healthcare Services. *PLoS ONE* 8(5): e64522. doi:10.1371/journal.pone.0064522). In a 2012 study, the authors found that African-American and Asian immigrant participants reported experiencing different forms of medical discrimination related to class, race, and language. (Thu Quach, Ph.D., MPH, Amani Nuru-Jeter, Ph.D., MPH, Pagan Morris, MPH, Laura Allen, BA, Sarah J. Shema, MS, June K. Winters, BA, Gem M. Le, Ph.D., MHS, and Scarlett Lin Gomez, Ph.D. *Am J Public Health*. 2012;102:1027–1034. doi:10.2105/AJPH.201.1300554).

Because discriminatory behavior can affect perceived and actual access to and effectiveness of healthcare delivery, we propose to establish explicit requirements that a hospital not discriminate on the basis of race, color, national origin, sex (including gender identity), age, or disability and that the hospital establish and implement a written policy prohibiting discrimination on the basis of race, color, national origin, sex (including gender identity), age, or disability. We are proposing these requirements to ensure nondiscrimination as required by Section 1557 of the Affordable Care Act, which 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. In addition, we believe that discrimination by a hospital based on a patient's religion or sexual orientation can potentially lead to a denial of services or inadequate care in the hospital, which is detrimental to the patient's health and safety. We are therefore also proposing to establish explicit requirements that a hospital not discriminate on the basis of religion or sexual orientation and that a hospital establish and implement a written policy prohibiting discrimination on the basis of religion or sexual orientation. We are doing so under the statutory authority of Section 1861(e)(9) of the Act, which specifies that a hospital "must also meet other requirements as the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services in the facility." As noted, substantial academic research demonstrates that discrimination on the basis of sexual orientation is inconsistent with the health and safety of patients, as this may lead to a denial of services not justified by a medically appropriate rationale.

We propose to further require that each patient, and/or representative, and/or support person, where appropriate, is informed, in a language he or she can understand, of the right to be free from discrimination against them on any of these bases when he or she is informed of his or her other rights under § 482.13. In addition, we propose to require that the hospital inform the patient and/or representative, and/or support person, on how he or she can seek assistance if they encounter discrimination. A patient's "support person" does not necessarily have to be the patient's representative who is legally responsible for making medical decisions on the patient's behalf. A support person could be a family member, friend, or other individual who is there to support the patient during the course of the stay. We discuss the meaning of "support person" in the preamble to the final rule, "Medicare and Medicaid Programs: Changes to the Hospital and Critical Access Hospital Conditions of Participation To Ensure Visitation Rights for All Patients" (75 FR 70833, November 19, 2010).

2. Licensed Independent Practitioners

On May 16, 2012, we published a final rule entitled "Medicare and Medicaid Programs: Reform of Hospital and Critical Access Hospital Conditions of Participation" (77 FR 29034). Within the section of this rule discussing the changes to § 482.13, one commenter requested that CMS make a clarifying

statement regarding the requirements at § 482.13(e)(5) that would identify which practitioners could order restraint or seclusion in a hospital (77 FR 29043). The commenter noted that the current requirements use the term "LIP" and that this has been interpreted by many hospitals to mean that a physician assistant (PA) could not order restraint and/or seclusion. The commenter expressed opposition to this interpretation and suggested instead that CMS clarify that, where permitted by State law, a physician would be permitted to delegate the ordering of such measures to a physician assistant. The commenter also requested that CMS provide a clarifying statement that PAs would be authorized to order restraint and seclusion.

Our response to this comment in the final rule referred to Appendix A of the State Operations Manual, CMS Pub. 100-07, regarding § 482.13(e)(5), which provides, "For the purpose of ordering restraint or seclusion, an LIP is any practitioner permitted by State law and hospital policy as having the authority to independently order restraints or seclusion for patients." We also stated in our response in the final rule that, "if an individual physician assistant (PA) was authorized by State law and hospital policy to independently order restraints or seclusion for patients, then that PA could do so within the hospital. However, since PAs have traditionally defined themselves as 'physician-dependent' practitioners (as opposed to APRNs, who see themselves as independent practitioners), it is unlikely that a PA would be authorized by State law and hospital policy to 'independently' order restraints or seclusions for patients (as would be likely for licensed independent practitioners such as physicians, APRNs, and clinical psychologists). The supervising physician-PA team concept (and PA practice dependence on the supervising physician) is supported by the American Academy of Physician Assistants' description of the PA profession:

'Physician assistants are health professionals licensed or, in the case of those employed by the federal government, credentialed to practice medicine with physician supervision' (American Academy of Physician Assistants. (2009–2010). Policy Manual. Alexandria, VA.).

Moreover, a PA would not be allowed to order restraints or seclusion if the only authority to do so was delegated by a physician since this physician-delegated authority would establish that the PA was not independently authorized by State law and hospital

policy, which we stated is a prerequisite for this type of order."

After publication of the final rule in May of 2012, we became aware of the concerns of the American Academy of Physician Assistants (AAPA) regarding this issue, both through communications from the AAPA and through the AAPA's submissions in response to the Secretary's Request for Regulatory Issues Unfairly Impacting Rural Providers. The AAPA maintains that "Licensed Independent Practitioner" is not a term used in the Social Security Act, nor in any other federal law," and that "the LIP terminology is, at best, confusing regarding physician assistants' ability to order [restraint and seclusion]; at worst, it restricts the ability of hospitals to utilize PAs to the extent of their educational preparation and scope of practice, as determined by state law." The AAPA further contends that "'independent' practice is not a measure of a healthcare professional's educational preparation, competency, or ability to provide quality medical care," and that "the LIP terminology is inconsistent with the movement toward team-based health care delivery, as well as the need to fully utilize the healthcare workforce."

In drafting this proposed rule, we took these arguments into careful consideration. We also reviewed the Children's Health Act (CHA) of 2000 (Pub. L. 106-310), which necessitated the changes to the Patients' Rights CoP § 482.13, as well as the 2006 final rule that implemented these changes, and determined that the term "licensed independent practitioner" was carried over into the CoPs from an earlier version of the bill that eventually became law as the CHA. The CHA only uses the term "other licensed practitioner," dropping the "independent" modifier. Taking this into consideration, we are proposing to delete the modifying term "independent" from the CoP at § 482.13(e)(5), as well as at § 482.13(e)(8)(ii), and also propose to revise the provision to be in keeping with the language of the CHA regarding restraint and seclusion orders and licensed practitioners. Therefore, we are proposing that § 482.13(e)(5) would now read that the use of restraint or seclusion must be in accordance with the order of a physician or other licensed 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. We are also proposing that § 482.13(e)(8)(ii) would state that, after 24 hours, before writing

a new order for the use of restraint or seclusion for the management of violent or self-destructive behavior, a physician or other licensed 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 would have to see and assess the patient.

Other provisions in the current requirements regarding restraint and seclusion use the term “licensed independent practitioner”, and we are proposing to revise these provisions as well. Section 482.13(e)(10), (e)(11), (e)(12)(i)(A), (e)(14), and (g)(4)(ii) all contain the term “licensed independent practitioner.” Therefore, we are proposing to change the term from “licensed independent practitioner” to simply “licensed practitioner.” We are also proposing to remove the term “physician assistant” from the current provisions at § 482.13(e)(12)(i)(B) and (e)(14) because we believe its use in these instances distinguishes the role of PAs from other licensed practitioners (such as 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. The current requirements severely limit a PA’s scope of practice in ways that currently do not apply to an APRN practicing under the same circumstances. The AAPA has noted that by limiting a PA’s scope of practice, the CoPs create a burden for hospitals, particularly small hospitals, and are contrary to state laws that allow PAs to practice to the full extent of their training and credentialing. PAs are trained on a medical model that is similar in content, if not duration, to that of physicians. Further, PA training and education is comparable in many ways to that of APRNs and in some ways, more extensive. Therefore, we believe that PAs, like APRNs and physicians, should not have to undergo additional training so that they can order restraint and seclusion. Therefore, we are proposing to remove PAs from the two provisions noted above.

3. Patient Access to Medical Records

On December 8, 2006, CMS published final regulations which established requirements for patient’s rights in hospitals, and which included requirements for the confidentiality of patient records at § 482.13(d) (71 FR 71426). Specifically, § 482.13(d)(2) states that a patient has the right to access information contained in his or her clinical records within a reasonable time frame and that 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. However, the requirements as they are currently written do not take into account that medical records may be maintained electronically, nor do the requirements acknowledge that a patient has the right to access these medical records in an electronic format. Ideally, the patient should be able to access their medical records in a form or format requested by the patient, whether electronically or in a hard copy format. Therefore, we are proposing to clarify the requirement at § 482.13(d)(2) to state 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. OCR recently issued an FAQ document about medical records access clarifying that the requirement to send medical records to the individual is within 30 days (or 60 days if an extension is applicable) after receiving the request, “however, 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.” (<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 required by HIPAA or who experience other difficulties accessing their medical records can file a complaint with OCR at: <http://www.hhs.gov/hipaa/filing-a-complaint/index.html>.

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

On January 24, 2003, CMS published a final rule in the **Federal Register** entitled “Medicare and Medicaid Programs; Hospital Conditions of Participation: Quality assessment and performance improvement (QAPI)” (68 FR 3435). The QAPI rule set a minimum requirement that each hospital participating in the Medicare program systematically examine the quality of its services and implement specific improvement projects on an ongoing basis. As a result of the QAPI rule, as well as other efforts and advancements in the delivery of healthcare, hospitals

have made progress toward delivering safer, high-quality care.

The 2003 QAPI CoP final rule provided a framework to implement Department of Health and Human Services initiatives designed to help distinguish and avoid mistakes in the healthcare delivery system. The existing QAPI CoP requires each hospital to:

- Develop, implement, maintain, and evaluate its own QAPI program;
- Establish a QAPI program that reflects the complexity of its organization and services;
- Establish a QAPI program that involves all hospital departments and services and focuses on improving health outcomes and preventing and reducing medical errors; and
- Maintain and demonstrate evidence of its QAPI program for review by CMS.

We are proposing a minor change to the program data requirements at § 482.21(b). Currently, we require that hospitals incorporate quality indicator data including patient care data and other relevant data (for example, information submitted to, or received from, the hospital’s Quality Improvement Organization) into their QAPI programs. We propose to update this requirement to reflect and capitalize on the wealth of important quality data available to hospitals through several quality data reporting programs. Specifically, we propose to require that the hospital QAPI program incorporate quality indicator data including patient care 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. 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. Since a hospital is already collecting and reporting quality measures data for these programs, we believe that it is 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). We believe the resulting data are a valuable resource to hospitals that should be used in hospital QAPI programs.

While we are not proposing to require that hospitals develop and implement information technology (IT) systems as

part of their QAPI program, we encourage hospitals to use IT systems, including systems to exchange health information with other providers, that are designed to improve patient safety and quality of care. In addition, we believe that those facilities that are electronically capturing information should be doing so using certified health IT that will enable real time electronic exchange with other providers. By using certified health IT, facilities can ensure that they are transmitting interoperable data that can be used by other settings, supporting a more robust care coordination and higher quality of care for patients.

C. Nursing Services (§ 482.23)

As a result of our internal review of the CoPs for nursing services, we recognized that some of our requirements might be ambiguous and confusing due to unnecessary distinctions between inpatient and outpatient services, or might fail to account for the variety of ways through which a hospital might meet its nurse staffing requirements. We propose to make revisions to the nursing services CoP to improve clarity. Specifically, we propose to revise § 482.23(b), which currently states that 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 bedside care of any patient. We propose to delete the term “bedside,” which might imply only inpatient services to some readers. The nursing service must ensure that patient needs are met by ongoing assessments of patients’ needs and must provide nursing staff to meet those needs regardless of whether the patient is an inpatient or an outpatient. There must be sufficient numbers, and types of supervisory and staff nursing personnel to respond to the appropriate nursing needs and care of the patient population of each department or nursing unit. When needed, a registered nurse must be available to care for any patient. We understand that the term “immediate availability” has been interpreted to mean physically present on the unit or in the department. We further understand that there are some outpatient services where it might not be necessary to have a registered nurse physically present. For example, while it is clearly necessary to have an RN present in an outpatient ambulatory surgery recovery unit, it might not be necessary to have an RN on-site at an off-campus MRI facility at § 482.23(b)(7). We propose to allow a hospital to establish a policy that would specify 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 a policy. We 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. In addition, we would propose that the policy must be approved by the medical staff and be reviewed at least once every three years. We welcome comments on the need for, the risks of establishing, and the appropriate criteria we should require for such an exception.

We also propose to clarify in paragraph (b)(4) (which currently requires that the hospital must ensure that the nursing staff develops, and keeps current, a nursing care plan for each patient and that the plan may be part of an interdisciplinary care plan) 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. 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. We expect that a nursing care plan would be 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. In addition, 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.

Finally, we propose to revise paragraph (b)(6) (which currently states that non-employee licensed nurses working in the hospital must adhere to the policies and procedures of the hospital and that the director of nursing service must provide for the adequate supervision and evaluation of the clinical activities of non-employee nursing personnel) 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. We recognize that there are a variety of arrangements under which hospitals obtain the services of licensed nurses. Mechanisms may include direct employment, the use of contract or agency nurses, a leasing agreement, volunteer services or some other arrangement. No matter how the services of a licensed nurse are obtained, in order to ensure the health and safety of patients, all nurses must know and adhere to the policies and procedures of the hospital and there must 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. We would expect non-licensed personnel to be supervised by a licensed nurse.

In addition, we propose to delete inappropriate references to § 482.12(c) that are currently in paragraphs (c)(1) and (3). We discuss these technical corrections in detail below.

D. Medical Record Services (§ 482.24)

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 the Medical Record Services CoP (§ 482.24) appears to apply to only inpatients, particularly with the use of terms such as “admission,” “hospitalization,” and “discharge.” We are proposing to make changes to several of the provisions in this CoP 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.

The current requirements at § 482.24(c) state that the content of the medical record must contain information to justify admission and continued hospitalization, support the diagnosis, and describe the patient’s progress and response to medications and services. While we believe that these terms are appropriate for inpatients, they do not fully capture the specific documentation necessary for outpatients. For example, appropriate documentation for an outpatient would be a current progress note, often in the accepted standard of a SOAP (Subjective, Objective, Assessment, Plan) note. Therefore, we propose to

revise the current regulatory language to require that the content of the medical record must 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.

Similarly, we propose to revise § 482.24(c)(4)(ii) from the current requirement for documentation of "admitting diagnosis" to include "all diagnoses specific to each inpatient stay and outpatient visit," which would include specifying any admitting diagnoses. Within this same standard, we are proposing to update several terms to reflect more current terminology and standards of practice. Therefore, at § 482.24(c)(4)(iv), we propose to require that the content of the record include documentation of complications, hospital-acquired conditions, healthcare-associated infections, and adverse reactions to drugs and anesthesia. We also propose changes to § 482.24(c)(4)(vi) 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. And we propose to add the phrase "to reflect all services provided to the patient," so that the entire provision would now read 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.

Continuing under this standard detailing the contents of the medical record, we propose to make revisions to the final two provisions under this standard. We propose to change § 482.24(c)(4)(vii) to require that all patient medical records must 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. We believe that these changes would 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, we

recognize 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.

Finally, we emphasize the distinctions between discharges and transfers as well as between inpatients and outpatients by proposing to revise § 482.24(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.

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

Background

CMS introduced Infection Control as a hospital CoP in 1986 amidst growing recognition that infections and communicable diseases were potentially exposing hospital patients to significant pain and risk, and driving up direct hospital charges (51 FR 22010, 22027). The regulation increased hospital accountability and sought to ensure that hospitals identify, prevent, control, investigate, and report infections and communicable diseases of patients and hospital personnel. The regulation also established a requirement for hospitals to keep a log to identify problems and for improvement to be made when problems were identified.

The Infection Control CoP has essentially remained unchanged in its regulatory form, notwithstanding a final rule published in May 2012, "Reform of Hospital and Critical Access Hospital Conditions of Participation" (77 FR 29034), which removed the obsolete and redundant requirement for hospitals to maintain infection control logs, since hospitals are already required to monitor infections and currently do so through various surveillance methods, including electronic systems. The final rule also made a technical change to the CoP and replaced the outdated term, "quality assurance program," with the more current term, "quality assessment and performance improvement program."

The Department of Health and Human Services is particularly concerned about HAIs, as they are a significant cause of morbidity and mortality in the United States. In 2011, there were an estimated 722,000 cases of HAIs in US hospitals with 75,000 inpatients with HAIs that died during that same time period (Magill SS, Edwards JR, Bamberg W et al. Multistate Point Prevalence Survey of Health Care-Associated Infections.

New England Journal of Medicine 2014; 370:1198–208.) Additionally, HHS is concerned about the growing threat to patient safety posed by organisms that are resistant to antibiotics, referred to as "multi-drug resistant organisms (MDROs)." Options for treating patients with MDRO infections are very limited, resulting in increased mortality, as well as increased hospital lengths of stay and costs. In response, HHS launched an Action Plan in April 2013 toward the prevention and elimination of HAIs. (HHS. "HHS Action Plan to Prevent Healthcare-Associated Infections." Accessed 5 March 2014 <http://www.hhs.gov/ash/initiatives/hai/actionplan/index.html>.) The HHS Action Plan identifies policy changes, some addressed here in this proposed rule, in an effort to provide better, more efficient care.

We are proposing revisions to § 482.42 in an effort to further clarify existing requirements and update regulatory language to reflect state-of-the-art practices and terminology. We are also proposing revisions that would require a hospital to develop and maintain an antibiotic stewardship program as an effective means to improve hospital antibiotic-prescribing practices and curb patient risk for possibly deadly *Clostridium difficile* infections (CDIs), as well as other future, and potentially life-threatening, antibiotic-resistant infections. We would promote better alignment of a hospital's infection control and antibiotic stewardship efforts with nationally recognized guidelines and heighten the role and accountability of a hospital's governing body in program implementation and oversight. We believe that these changes, together, would promote a more patient-centered culture of safety focused on infection prevention and control as well as appropriate antibiotic use, while allowing hospitals the flexibility to align their programs with the guidelines best suited to them.

Summary of Changes to § 482.42

In its present form, the "Infection Control" CoP set forth at § 482.42 requires hospitals to provide a sanitary environment to avoid sources and transmission of infections and communicable diseases. Hospitals are presently required 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 of patients and personnel. The hospital's CEO, medical staff, and director of nursing services are charged with ensuring that the problems

identified by the infection control officer or officers are addressed in hospital training programs and their QAPI program. The CEO, medical staff, and director of nursing services are also responsible for the implementation of successful corrective action plans in affected problem areas.

At the outset, we propose a change to the title of this CoP to “Infection prevention and control and antibiotic stewardship programs.” By adding the word “prevention” to the CoP name, our intent is to promote larger, cultural changes in hospitals such that prevention initiatives are recognized on balance with their current, traditional control efforts. And by adding “antibiotic stewardship” to the title, we would emphasize the important role that a hospital should play in combatting antimicrobial resistance through implementation of a robust stewardship program that follows nationally recognized guidelines for appropriate antibiotic use. Along with these changes, we propose to change the introductory paragraph to require that a hospital’s infection prevention and control and antibiotic stewardship programs be active and hospital-wide for the surveillance, prevention, and control of HAIs and other infectious diseases, and for the optimization of antibiotic use through stewardship. We would also require that a program demonstrate adherence to nationally recognized infection prevention and control guidelines for reducing the transmission of infections, as well as best practices for improving antibiotic use, for reducing the development and transmission of HAIs and antibiotic-resistant organisms. While these particular changes are new to the regulatory text, it is worth noting that these requirements, with the exception of the new requirement for an antibiotic stewardship program, have been present in the Interpretive Guidelines for hospitals since 2008 (See A0747 at Appendix A—Survey Protocol, Regulations and Interpretive Guidelines for Hospitals, http://cms.gov/manuals/Downloads/som107ap_a_hospitals.pdf).

We also propose to introduce the term “surveillance” into the text of the regulation. The addition of this term, which is also already in use in CMS Interpretive Guidelines for hospitals, is being proposed to bring the regulation up to date by reflecting current terminology in the field. As has been described in the Interpretive Guidelines for this regulation, “surveillance” includes infection detection, data collection, and analysis, monitoring, and evaluation of preventive interventions. (See SOM, Appendix A—

Survey Protocol, Regulations and Interpretive Guidelines for Hospitals, pp.361–362, http://cms.gov/manuals/Downloads/som107ap_a_hospitals.pdf.) Surveillance practices include sampling or other mechanisms to permit identifying and monitoring infections occurring throughout the hospitals various locations or departments. In accordance with proposed § 482.42(c)(2)(ii), the hospital would be required to document its surveillance activities. Such documentation would likely include the measures selected for monitoring, and collection of data and analysis methods. Just as we would for other parts of the hospital’s infection prevention and control program, we would require surveillance activities to be conducted in accordance with nationally recognized infection control surveillance practices, such as the widely accepted CDC National Healthcare Safety Network (NHSN). In collaboration with the hospital’s QAPI program, the hospital would be required to develop and implement appropriate infection prevention and control interventions to address issues identified through its detection activities. Hospitals are encouraged to have mechanisms in place for the early identification of patients with targeted MDROs prevalent in their hospital and community, and for the prevention of transmission of such MDROs. When ongoing transmission of targeted MDROs in the hospital is identified, the infection prevention and control program would use this event to identify potential breaches in infection control practice.

As has previously been suggested in Interpretive Guidance, surveillance could also include “automated surveillance” by way of analyzing useful information from infection control data through the systematic application of medical informatics and computer science technologies. (See also Wright, M. Automated Surveillance and Infection Control: Toward a better tomorrow. *Am J Infect Control* 2008; 36:S1–S5.) Automated surveillance includes, but is not limited to, either data mining (discovering patterns and relationships which can be used to classify and predict) or query-based data management (requires user input, but does not seek patterns independently). A variety of automated systems exist and include both commercial and hospital-designed systems which, at a minimum, integrate portions of the medical record with laboratory, admission, discharge, transfer, and treatment information.

We are also proposing a new requirement that hospitals demonstrate

adherence to nationally recognized infection prevention and control guidelines, as well as best practices for improving antibiotic use, where applicable, for reducing the development and transmission of HAIs and antibiotic-resistant organisms. We realize that, in developing the patient health and safety requirements that are the hospital CoPs, particular attention must be paid to the ever-evolving nature of medicine and patient care. Moreover, a certain degree of latitude must be left in the requirements to allow for innovations in medical practice that improve the quality of care and move toward the reduction of medical errors and patient harm.

We are proposing to intentionally build flexibility into the regulation by proposing language that requires hospitals to demonstrate adherence to nationally recognized guidelines rather than any specific guideline or set of guidelines for infection prevention and control and for antibiotic stewardship. While the CDC guidelines represent one set, there are other sets of nationally recognized guidelines from which hospitals might choose, such as those established by SHEA and IDSA. We believe this approach would provide hospitals the flexibility they need to select and integrate those standards that best suit their individual infection prevention and control and antibiotic stewardship programs. We also believe this approach would allow hospitals the flexibility to adapt their policies and procedures in concert with any updates in the guidelines they have elected to follow.

§ 482.42(a) Standard: Infection Prevention and Control Program Organization and Policies

We propose substantive changes to § 482.42(a), which sets forth the standard on “Organization and policies.” First, we propose a change in the title of this standard that would now read, “Infection prevention and control program organization and policies.” Current requirements pertaining to an infection control officer or officers would be amended within § 482.42(a) and some would be moved to § 482.42(c)(2).

§ 482.42(a)(1) Infection Control Officer(s)

Specifically, at § 482.42(a)(1), we propose to require the hospital to appoint an infection preventionist(s)/infection control professional(s). Within this proposed change we are deleting the outdated term, “infection control officer,” and replacing it with the more current and accurate terms, “infection

preventionist/infection control professional." CDC has defined "infection control professional (ICP)" as "a person whose primary training is in either nursing, medical technology, microbiology, or epidemiology and who has acquired specialized training in infection control." In designating infection preventionists/ICPs, hospitals should ensure that the individuals so designated are qualified through education, training, experience, or certification (such as that offered by the Certification Board of Infection Control and Epidemiology Inc. (CBIC), or by the specialty boards in adult or pediatric infectious diseases offered for physicians by the American Board of Internal Medicine (for internists) and the American Board of Pediatrics (for pediatricians)). Infection preventionists/ICPs should maintain their qualifications through ongoing education and training, which can be demonstrated by participation in infection control courses, or in local and national meetings, organized by recognized professional societies, such as Association for Professionals in Infection Control and Epidemiology (APIC), Association of periOperative Registered Nurses (AORN), Society for Healthcare Epidemiology of America (SHEA), and the Infectious Diseases Society of America (IDSA).

We would also require hospitals to seek out and consider the recommendations of medical staff leadership and nursing leadership in making such appointments. The proposed requirement would be a subtle, but important, departure from the current requirement at § 482.42(a), which simply requires that an officer or officers be designated to implement and develop the program. We believe our proposed approach would require high-level hospital clinical leadership, such as those individuals responsible for the medical staff and for the nursing service, be involved in the process of selecting the infection preventionists/ICPs, and is in keeping with our aim of promoting a hospital-wide culture of safety and quality in which input across the hospital is solicited and acted upon.

While we are proposing a change to the qualifications for infection preventionists/ICPs, we wish to highlight that the other requirements for designating an individual or individuals would remain otherwise unchanged. A hospital can still designate one or more individuals to fulfill the responsibilities within an infection prevention and control program. In a setting with multiple infection preventionists/ICPs, we would expect them to work together as an integrated team. What is important

is that the functions of an infection prevention and control program are covered; it is not necessary for all functions to rest with one individual.

§ 482.42(a)(2) Preventing and Controlling the Transmission of Infections Within the Hospital and Between the Hospital and Other Institutions and Settings

We have proposed language at § 482.42(a)(2) that would adjust the scope of the hospitals' prevention and control programs from its current focus on transmission of infections between "patients and personnel" by proposing a focus on "transmission of infection" in the broader sense. This change is intended to reflect the efforts hospitals must make to prevent and control infections not just between patients and personnel, but also between individuals across the entire hospital setting (for example, among patients, personnel, and visitors) as well as between the hospital and other healthcare institutions and settings and between patients and the healthcare environment. In the case of transmission of infections within the hospital, we would expect hospitals to consider the impact of their outpatient facilities on their inpatient units. We would expect hospitals to look to guidelines, such as those summarized by the CDC in its recent publication, "Guide to Infection Prevention for Outpatient Settings: Minimum Expectations for Safe Care." (CDC. "Guide to Infection Prevention for Outpatient Settings" Accessed 18 November 2015 <http://www.cdc.gov/HAI/settings/outpatient/outpatient-care-guidelines.html>).

We believe this section reflects current best practices that are in place in most hospitals. The reality is that patients move between settings with great frequency and carry organisms with them, hence it is imperative that hospitals approach multi-drug resistant organism control from the broader perspective in order to protect their patients and staff. A concrete example of this already being part of current practice is that hospitals are already required to track both hospital- and community-onset cases of CDI, because research has shown that community-onset cases of CDI can impact hospitals. Likewise, the role of the environment is being increasingly recognized as an important source of infections and this change simply reflects this data and best practices. There are many good examples of hospitals working on preventing the spread of infection between healthcare environments. This update also fits with the clarification that these CoPs apply to both a

hospital's inpatient and outpatient locations.

§ 482.42(a)(3) Healthcare-Associated Infections (HAIs)

In this proposed rule, we are also expanding the focus on and the awareness of the sources of HAIs that a hospital must address through its infection prevention and control program. We believe this change is appropriate given the rise in HAIs related to inter-facility transfer of patients, as people move through the system and across the continuum of health care. Given the number of facilities through which a patient might travel, our proposal to increase the involvement of hospital infection prevention and control programs would facilitate communication across settings. The provision would also require the program to address any infection control issues identified by public health authorities. Hospitals could look to the HHS Action Plan to Prevent Healthcare-Associated Infections as a resource for identifying prominent HAIs. (HHS. "HHS Action Plan to Prevent Healthcare-Associated Infections." Accessed 3 August 2011 <http://www.hhs.gov/ash/initiatives/hai/actionplan/index.html>).

Hospitals could also find it helpful to refer to the list (which features several categories of HACs and includes specific types of HAIs) that CMS publishes annually in its FY 2016 Inpatient Prospective Payment System final rule (80 FR 49325), in accordance with section 5001(c) of the Deficit Reduction Act (DRA) of 2005.

§ 482.42(a)(4) Scope and Complexity

We also propose to add a requirement at § 482.42(a)(4) to clarify that we would expect hospitals to develop and manage an infection prevention and control program that "reflects the scope and complexity of the hospital services provided." For example, a hospital that offers surgical services (contrasted with a hospital that does not offer surgical services) would be expected to have an infection prevention and control program that addresses infection issues specific to the surgical patient. Also, the CDC's Healthcare Infection Control Practices Advisory Committee (HICPAC), as well as professional infection control organizations such as APIC and SHEA, publish studies and recommendations on resource allocation that hospitals might find useful.

§ 482.42(b) Standard: Antibiotic Stewardship Program Organization and Policies

We propose a new standard at § 482.42(b) titled, “Antibiotic stewardship program organization and policies,” in order to require hospitals to have policies and procedures for, and to demonstrate evidence of, an active and hospital-wide antibiotic stewardship program. Antibiotic stewardship, as an area of infection control, has long been recognized as one of the special challenges that hospitals must meet in order to address the problems of multidrug-resistant organisms and CDIs in hospitals.

As part of the antibiotic stewardship program, we propose that hospitals would be required to improve their internal coordination among all components responsible for antibiotic use and reducing the development of resistance, including, but not limited to, the infection prevention and control program, the QAPI program, the medical staff, nursing services, and pharmacy services. We also propose a requirement for hospitals to promote evidence-based use of antibiotics, and to reduce the incidence of adverse consequences of inappropriate antibiotic use including, but not limited to, CDIs and growth of antibiotic resistance in the hospital overall. CMS believes that the proposed requirement for a hospital to implement and maintain an active and hospital-wide antibiotic stewardship program will prove to be an effective means to improve hospital antibiotic-prescribing practices and thereby curb patient risk for potentially life-threatening, antibiotic-resistant infections, including CDI. We also believe that a robust antibiotic stewardship program that is coordinated with the hospital’s overall infection prevention and control program might provide a synergistic approach to addressing HAIs and antibiotic resistance. In a November 2013 report entitled “Appropriate Use of Medical Resources,” the American Hospital Association lists antibiotic stewardship as one of the top five ways that hospitals can improve the use of their medical resources (Combes J.R. and Arespacochaga E., *Appropriate Use of Medical Resources*. American Hospital Association’s Physician Leadership Forum, Chicago, IL, November 2013.).

Further supporting this call for hospital AS programs, CDC recently issued a detailed study through its Morbidity and Mortality Weekly Report (MMWR) released March 7, 2014 that found that antibiotic prescribing for inpatients is common, and that there is

ample opportunity to improve use and patient safety by reducing incorrect and inappropriate antibiotic prescribing (http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6309a4.htm?s_cid=mm6309a4_w Accessed March 14, 2014). Prior to the release of this study on MMWR, CDC also issued early releases of this information on both its *Vital Signs* and *Get Smart for Healthcare* sites (<http://www.cdc.gov/vitalsigns/antibiotic-prescribing-practices/index.html>; <http://www.cdc.gov/getsmart/healthcare/> both accessed March 4, 2014.). According to these reports:

- About one-third of the time, in prescribing the critical and common drug vancomycin and in the treatment of common urinary tract infections, patients were given antibiotics without proper testing or evaluation, were given drugs for too long, or were given antibiotics when evidence suggested they were not needed at all.
- Clinicians in some hospitals prescribed three times as many antibiotics as clinicians in other hospitals, even though patients were receiving care in similar areas of each hospital. This difference suggests the need to improve prescribing practices.
- A 30 percent reduction in the broad-spectrum antibiotics most likely to cause CDI could reduce these deadly infections by 26 percent.

Additionally and prior to CMS drafting this proposed rule, the Infectious Disease Society of America (IDSA) and SHEA wrote a letter to CMS (dated March 4, 2014) detailing “the supportive evidence and rationale to adopt Antimicrobial Stewardship (AS) as a Medicare Condition of Participation (CoP).” In the letter, IDSA and SHEA define “antibiotic stewardship” as “the optimal use of antimicrobials to achieve the best clinical outcomes while minimizing adverse events, limiting factors that lead to antimicrobial resistance, and reducing excessive costs attributable to suboptimal antimicrobial use.” They presented extensive evidence for the value that antibiotic stewardship programs could hold for patients and hospitals as well as for the overall healthcare system. The letter cited numerous studies that demonstrated that “AS programs provide significant cost savings or at least offset the cost of AS programs through reduction in drug acquisition costs, correlating with improved clinical outcomes.” (<http://www.shea-online.org/View/ArticleId/265/SHEA-IDSA-letter-to-CMS-advancing-Antimicrobial-Stewardship-as-a-Condition-of-Participation.aspx>)

As is the case for infection prevention and control programs, we believe there should be flexibility in how antibiotic stewardship programs are implemented. Guidance on best practices for implementing antibiotic stewardship programs is available from several organizations, including IDSA, SHEA, the American Society for Health System Pharmacists, and CDC.¹

Taken as a whole, the studies and the supportive evidence show overwhelmingly that hospital AS programs can be implemented in all hospitals and would, as IDSA and SHEA state in their letter, “better patient care, improve outcomes, and lower the healthcare costs associated with antibiotic overuse (that is, expenditures on antibiotics) as well as costs associated with infections and antimicrobial resistance.” Based on this evidence, we are proposing the requirement for hospitals to include AS programs as integral parts of their overall infection prevention and control efforts.

§ 482.42(b)(1) Leader of the Antibiotic Stewardship Program

We propose a new provision at § 482.42(b)(1) that would require the hospital, with the recommendations of the medical staff leadership and pharmacy leadership, to designate an individual, who is qualified through education, training, or experience in infectious diseases and/or antibiotic stewardship, as the leader of the antibiotic stewardship program. We believe that the importance of the antibiotic stewardship program to the hospital is great enough to warrant the leadership of a qualified individual, who would serve as the counterpart to his or her colleague(s) leading the hospital’s overall infection prevention and control program. The skills needed to lead each program are different. Infection prevention programs are often led by nursing staff who do not prescribe antibiotics. Antibiotic stewardship programs are led by physicians and pharmacists who have direct knowledge and experience with antibiotic prescribing. However, the ultimate goals of the programs on preventing healthcare complications

¹ “Antimicrobial Agent Use”. http://www.idsociety.org/Antimicrobial_Agents/. “Antimicrobial Stewardship: Guidelines”. <http://www.shea-online.org/PriorityTopics/AntimicrobialStewardship/Guidelines.aspx>. “Antimicrobial Stewardship Resources”. <http://www.ashp.org/menu/PracticePolicy/ResourceCenters/Inpatient-Care-Practitioners/Antimicrobial-Stewardship>. “Core Elements of Hospital Antibiotic Stewardship Programs” <http://www.cdc.gov/getsmart/healthcare/implementation/core-elements.html>.

like CDI and resistance are common and hence there is the need for collaboration. We believe that it is important for the overall success of both programs (and for the hospital) that each has its own distinct structure and leadership responsibilities, but that each works in close collaboration with the other.

§ 482.42(b)(2)(i), (ii), and (iii) Meeting the Goals of the Antibiotic Stewardship Program

Proposed requirements at § 482.42(b) would require the hospital to ensure that the following goals for an AS program are met: (1) Demonstrate coordination among all components of the hospital responsible for antibiotic use and factors that lead to antimicrobial resistance, including, but not limited to, the infection prevention and control program, the QAPI program, the medical staff, nursing services, and pharmacy services; (2) document the evidence-based use of antibiotics in all departments and services of the hospital; and (3) demonstrate improvements, including sustained improvements, in proper antibiotic use, such as through reductions in CDI and antibiotic resistance in all departments and services of the hospital. We believe that these components are essential for a robust and effective AS program. After this rule is finalized, CMS will develop Interpretive Guidelines that will instruct surveyors on how to determine hospital compliance with these goals.

§ 482.42(b)(3) and (4) Meeting Nationally Recognized Guidelines; and Scope and Complexity

Three new provisions would require the hospital ensure that the AS program adheres to nationally recognized guidelines, as well as best practices, for improving antibiotic use, and, similar to the requirements proposed for the hospital's infection prevention and control program at § 482.42(a)(4), the hospital also ensures that the AS program reflects the scope and complexity of services offered.

§ 482.42(c) Leadership Responsibilities

We propose to revise the requirements currently at § 482.42(b), "Leadership responsibilities," by proposing a new standard at § 482.42(c) that would enhance the accountability of hospital leadership for the infection prevention and control and antibiotic stewardship programs as well as delineate the responsibilities for the leaders of the infection prevention and control program and the AS program respectively. We wish to promote a hospital-wide culture of safety and

quality, and we are proposing these regulatory changes to introduce a catalyst at the leadership level. We believe these changes would result in the implementation of successful programs such as Executive Walk Rounds (EWRs), instituted by Brigham & Women's Hospital in Boston some years ago. The goals of these rounds (and others modeled on them) are to: Ensure safety is a high priority for senior leadership; increase staff awareness of safety issues; educate staff about patient safety concepts such as non-punitive reporting; and obtain information from staff about safety issues. We also propose to update the requirements by adopting a broader reference to "nursing leadership" rather than "the director of nursing services," which is used in the current regulation. In addition to consultation with nursing leadership, we would also require hospital governing body consultation with medical staff, pharmacy leadership, the infection preventionist(s)/infection control professional(s), and the leader of the antibiotic stewardship program. We believe these changes would provide hospitals with greater flexibility and open up the process and expand accountability and involvement at all levels.

§ 482.42(c)(1) The Governing Body

We propose requirements at § 482.42(c)(1) that provide greater specificity with respect to the responsibilities of hospital leadership at the governing body level. As previously set forth, we believe these changes are necessary to the hospital-wide culture of quality improvement we are promoting.

§ 482.42(c)(1)(i) Governing Body Responsibilities

In particular, we would require at § 482.42(c)(1)(i) that the governing body ensure that systems are in place and are operational for the tracking of all infection surveillance, prevention, and control, and antibiotic use activities, in order to demonstrate the implementation, success, and sustainability of such activities.

§ 482.42(c)(1)(ii) Governing Body Responsibilities (Cont.)

We are proposing at § 482.42(c)(1)(ii) that the governing body ensure that all HAIs and other infectious diseases identified by the infection prevention and control program as well as antibiotic use issues identified by the antibiotic stewardship program are addressed in collaboration with hospital QAPI leadership. As discussed, we believe that a closer, more streamlined connection between infection

prevention and control and antibiotic stewardship programs with hospitals' QAPI programs will translate to better quality and healthier patients. Ultimately, better quality and healthier patients reduce burden and create efficiencies in health care overall.

§ 482.42(c)(2) The Infection Preventionists/Infection Control Professionals

At § 482.42(c)(2), we establish the responsibilities of the infection preventionist(s)/infection control professional(s) for the hospital's infection prevention and control program.

§ 482.42(c)(2)(i) The Infection Preventionists'/Infection Control Professionals' Responsibilities

We propose to add a requirement at § 482.42(c)(2)(i) that would make the infection preventionist(s)/infection control professional(s) responsible for the development and implementation of hospital-wide infection surveillance, prevention, and control policies and procedures that adhere to nationally recognized guidelines. Current CMS Interpretive Guidelines (SOM, Appendix A, p. 353) for hospitals already guide hospitals to follow nationally recognized infection control practices or guidelines. This proposed requirement notwithstanding, we recognize and appreciate that a hospital might wish to implement safety practices as part of an investigation aimed to improve or modify accepted standards of infection prevention and control practice, but which have not yet been established as national guidelines or even emerged from the traditional peer review process. We do not intend to discourage these investigational methodologies or approaches. We would, however, expect to see the hospitals engaging in these sorts of innovative practices to also have an adequate program rooted in the traditional evidence-based model. There are ample recognized evidence-based approaches for hospitals to follow, and we believe our proposed requirement for hospitals to adhere to nationally recognized guidelines would not impede any hospital's ability to otherwise make progress in infection prevention and control.

Research tells us that healthcare-associated infections are one of the most preventable causes of mortality in the United States (U.S.). For example, in a seminal study on central line-associated bloodstream infections (CLABSIs), known as the Michigan Keystone study, researchers demonstrated the profound impact that the use of checklists can

have when applied to the medical field. The study demonstrated a 66 percent drop in central line-associated bloodstream infection rates, saving 1,500 lives and \$100 million. [Pronovost P, Needham D, Berenholtz S, Sinopoli D, Chu H, Cosgrove S, *et al.* An intervention to decrease catheter-related bloodstream infections in the ICU. *N Engl J Med.* 2006; 355(25):2725–32.] The study demonstrated that it was possible for a diverse array of hospitals with a diverse array of patients to adopt the same bundled set of best practices, apply them consistently and in a hospital-wide team-like fashion, and produce a massive reduction in CLABSIs over a sustained period. Importantly, the study also touched off a change in hospital culture, and weakened a long-held belief in the medical community that infections were inevitable, not truly preventable, and simply a cost of being a patient in a hospital. Since publication of this initial study, researchers have gone on to demonstrate how the reduction of CLABSIs also translates to reductions in mortality and in length of stay. [Lipitz-Snyderman A, Steinwachs D, Needham D, Colantuoni E, Morlock L, Pronovost P, Impact of a statewide intensive care unit quality improvement initiative on hospital mortality and length of stay: retrospective comparative analysis. *BMJ* 2011; 342:d219.] Reductions have been demonstrated for other HAIs as well, but much more remains to be done.

Finally, by requiring hospitals to adhere to “nationally recognized guidelines,” we aim to provide hospitals with a broad array of options and a large degree of flexibility. We recognize the potential for hospitals to become encumbered by competing initiatives and requirements whereby they are required to collect different data or implement varied solutions for the same problem. For this reason, we have drafted broad requirements to afford hospitals the flexibility to adopt the approaches which best fit their infection prevention and control needs.

§ 482.42(c)(2)(ii), (iii), (iv), (v), and (vi) The Infection Preventionist(s)/Infection Control Professionals’ Responsibilities (Cont.)

At § 482.42(c)(2)(ii), we propose to make the infection preventionist(s)/infection control professional(s) responsible for all documentation, written or electronic, of the prevention and control program, and its surveillance, prevention, and control activities. As used in this context, the word “documentation” would encompass both collecting and

maintaining pertinent information in a systematic fashion.

At § 482.42(c)(2)(iii), we would require that the infection preventionist(s)/infection control professional(s) communicate and collaborate with the hospital’s QAPI program on all infection prevention and control issues. By the word “issues” we mean all concerns, including ones which are emerging and ones which are already problematic. We believe this approach will foster and enhance a proactive culture around hospitals’ infection prevention and control programs.

At § 482.42(c)(2)(iv), we propose that the infection preventionist(s)/infection control professional(s) take a direct role in the competency-based training and education of hospital personnel and staff, including medical staff, and, as applicable, personnel providing contracted services in the hospital, on the practical applications of infection prevention and control guidelines, policies, and procedures. We believe that this proposed revision is more specific and more in keeping with current standards of practice in hospitals than the current provision at § 482.42(b)(1) that requires a hospital to ensure that its training programs address problems identified by the infection control officer or officers.

At § 482.42(c)(2)(v), we propose that the infection preventionist(s)/infection control professional(s) be responsible for preventing and controlling HAIs, including auditing of adherence to infection prevention and control policies and procedures by hospital personnel. We believe the infection preventionist(s)/infection control professional(s) would find a comprehensive and timely resource in the HHS Action Plan to Prevent Healthcare-Associated Infections (HHS. “HHS Action Plan to Prevent Healthcare-Associated Infections.” Accessed 3 August 2011 <http://www.hhs.gov/ash/initiatives/hai/actionplan/index.html>).

At § 482.42(c)(2)(vi), we propose that the infection preventionist(s)/infection control professional(s) be responsible for communication and collaboration with the antibiotic stewardship program. Based on the evidence provided by CDC, IDSA, SHEA, and others, we believe that collaboration between the hospital’s infection prevention and control and antibiotic stewardship programs will provide the optimal approach to reducing HAIs and antibiotic resistance.

§ 482.42(c)(3) The Antibiotic Stewardship Program Leader’s Responsibilities

Finally in this CoP, at § 482.42(c)(3), we propose new requirements for the hospital’s designated antibiotic stewardship program leader, similar to the responsibilities we have proposed for the hospital’s designated infection preventionist(s)/infection control professional(s). Based on the evidence, we believe that a hospital antibiotic stewardship program is the most effective means for ensuring appropriate antibiotic use and for reducing HAIs and antibiotic resistance, including deadly CDI. We also believe that such a program would require a dedicated and expert leader responsible and accountable for its success. Therefore, those responsibilities would be:

- The development and implementation of a hospital-wide antibiotic stewardship program, based on nationally recognized guidelines, to monitor and improve the use of antibiotics;
- All documentation, written or electronic, of antibiotic stewardship program activities;
- Communication and collaboration with medical staff, nursing, and pharmacy leadership, as well as the hospital’s infection prevention and control and QAPI programs, on antibiotic use issues; and
- The competency-based training and education of hospital personnel and staff, including medical staff, and, as applicable, personnel providing contracted services in the hospital, on the practical applications of antibiotic stewardship guidelines, policies, and procedures.

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 (72 FR 48562, 48573, Aug. 24, 2007), we stated that HCV notification requirements for donors tested before February 20, 2008, would expire on August 24, 2015, in accordance with 21 CFR 610.48.

Since the notification requirement period has expired, we propose to remove § 482.27(b)(11), “Applicability” and the corresponding requirements set out at § 482.27(b)(7)(ii).

Corrected Reference in § 482.58

In our review of the Hospital Conditions of Participation, we found 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, not discharge planning. SNF requirements for discharge plans are set out at § 483.20(l). Therefore, we propose to correct the reference to read “Discharge summary (§ 483.20(l))”.

Removal of Inappropriate References to § 482.12(c)(1)

Upon our review of the Hospital CoPs for this proposed rule, we discovered that there are several provisions that 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 the following practitioners:

- A doctor of medicine or osteopathy;
- A doctor of dental surgery or dental medicine who is legally authorized to practice dentistry by the State and who is acting within the scope of his or her license;
- A doctor of podiatric medicine, but only with respect to functions which he or she is legally authorized by the State to perform;
- A doctor of optometry who is legally authorized to practice optometry by the State in which he or she practices;
- A chiropractor who is licensed by the State or legally authorized to perform the services of a chiropractor, but only with respect to treatment by means of manual manipulation of the spine to correct a subluxation demonstrated by x-ray to exist; and
- A clinical psychologist as defined in § 410.71, but only with respect to clinical psychologist services as defined in § 410.71 and only to the extent permitted by State law.

The reference of this “Medicare beneficiary-only” requirement in other provisions of the CoPs inappropriately links it to *all* patients and not Medicare beneficiaries exclusively. In fact, the Act at section 1861(e)(4) states 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, we have 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. For example, the Nursing Services CoP, at § 482.23(c)(1), requires that all drugs and biologicals must 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 provisions apply to all patients and not only Medicare beneficiaries, in this rule we are proposing to delete any inappropriate references to § 482.12(c). Therefore, we propose to delete references to § 482.12(c) found in the following provisions: § 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

We have identified several priority areas in the CoPs for CAHs (42 CFR part 485, subpart F) for updates and revisions. We believe that these proposed regulations would benefit the quality of care provided with a positive impact on patient satisfaction, length of stay, and, ultimately, cost per patient. Additionally, without potentially jeopardizing the quality of healthcare in rural areas, we have proposed the following changes to the CAH CoPs considering the resource restrictions of remote and frontier CAHs.

1. Organizational Structure (§ 485.627(b))

The CoP at § 485.627 provides that the CAH has a governing body or an individual that assumes full legal responsibility for determining, implementing and monitoring policies governing the CAH’s total operation and for ensuring that those policies are administered so as to provide quality health care in a safe environment. The current standard at § 485.627(b) requires the disclosure of names and addresses of the person(s) principally responsible for the operation and medical direction

of the CAH in addition to the disclosure of individuals with a controlling interest in the CAH or in any subcontractor in which the CAH directly or indirectly has a 5 percent or more ownership interest. Since the disclosure of persons having ownership, financial, or control interest is required via the provider enrollment process as discussed at § 420.206, we do not believe that it is appropriate to repeat the requirement under the health and safety regulations. Therefore, we are proposing to delete the same disclosure requirement at § 485.627(b)(1).

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

The current CoP at § 485.641 requires a CAH to have an agreement with respect to credentialing and quality assurance with a hospital that is a member of the rural health network (when applicable) as defined in § 485.603; one Quality Improvement Organization (QIO) or equivalent entity; or one other appropriate and qualified entity identified in the State rural health care plan to evaluate the quality and appropriateness of the diagnosis and treatment furnished by doctors of medicine (MDs) or osteopathy (DOs) at the CAH. In addition, the MD and DO (on staff or under contract with the CAH) must evaluate the quality and appropriateness of the diagnosis and treatment furnished by the CAH’s non-physician practitioners.

We are proposing to change the current CoP at § 485.641 to reflect the current QAPI format used in hospitals. As such, we propose to retain the requirements under paragraphs § 485.641(b)(3) through (4), that are currently found under the “Periodic evaluation and quality assurance” CoP, and relocate them under a new standard under the “Staffing and staff responsibilities” CoP at § 485.631. We are not changing these requirements and believe that they are still appropriate for the CAH regulations. Since the current CoP under § 485.631 discusses staffing requirements and responsibilities, we believe that relocating the requirement under a new standard, entitled “Periodic Review of Clinical Privileges and Performance” (§ 485.631(d)) is a more appropriate placement for the current provisions requiring a CAH to evaluate the quality of care provided by their nurse practitioners, clinical nurse specialists, certified nurse midwives, physician assistants, doctors of medicine, or doctors of osteopathy.

3. Provision of Services (§ 485.635(a)(3)(vii))

We currently require CAHs at § 485.635(a)(3)(vii) to have procedures that ensure that the nutritional needs of inpatients are met in accordance with recognized dietary practices and the orders of the practitioner responsible for the care of the patients and that the requirement of § 483.25(i) is met with respect to inpatients receiving post-hospital SNF care. This current requirement asserts that a therapeutic diet must be prescribed only by the practitioner or practitioners responsible for the care of the patient.

We finalized a change in the May 12, 2014 **Federal Register** (79 FR 27106) to the hospital requirement for Food and Dietetic services (§ 482.28) that all patient diets, including therapeutic diets, must be ordered by a practitioner responsible for the care of the patient, or by a qualified dietician or qualified nutrition professional as authorized by the medical staff and in accordance with State law governing dietitians and nutrition professionals. We are proposing a similar change for CAHs because we believe that these rural providers and beneficiaries would benefit from such a change. The responsibility for the care of the patient in a CAH has traditionally been the responsibility of the physician, more specifically the MD and DO, and the APRN and PA. We believe that a team-based approach that allows for professionals to practice in their area of expertise and to the fullest extent allowed by state law would be of great benefit to CAH patients. We further believe that patients in these traditionally underserved areas deserve the same standard of care as patients receive in better-served areas.

Based on feedback from the provider community, we have come to the conclusion that the regulatory language is too restrictive and lacks the reasonable flexibility to allow CAHs to permit registered dietitians (RDs) to order therapeutic diets for patients in accordance with State laws. Because some States elect not to use the regulatory term “registered” and choose instead to use the term “licensed” (or no modifying term at all), or because some States also recognize other nutrition professionals with equal or possibly more extensive qualifications, we propose to use the term “qualified dietitian.” In those instances where we have used the most common abbreviation for dietitians, “RD,” in this preamble, our intention is to include all qualified dietitians and any other clinically qualified nutrition

professionals, regardless of the modifying term (or lack thereof), as long as each qualified dietitian or qualified nutrition professional meets the requirements of his or her respective State laws, regulations, or other appropriate professional standards.

Based on a review of the professional literature on this subject, we believe that RDs are the professionals who are best qualified to assess a patient’s nutritional status and to design and implement a nutritional treatment plan in consultation with the patient’s interdisciplinary care team. In order for patients to receive timely nutritional care, the RD must be viewed as an integral member of the CAH’s interdisciplinary care team, one who, as the team’s clinical nutrition expert, is responsible for a patient’s nutritional diagnosis and treatment in light of the patient’s medical diagnoses. Without the proposed regulatory changes allowing them to grant appropriate ordering privileges to RDs, CAHs would not be able to effectively realize the improved patient outcomes and overall cost savings that we believe would be possible with such changes. The literature also supports the conclusion that, in addition to providing safe patient care with improved outcomes, RDs with ordering privileges contribute to decreased patient lengths of stay and provide nutrition services more efficiently, resulting in lower costs for hospitals, including small and rural hospitals as well as CAHs. (Kinn TJ. Clinical order writing privileges. Support Line. 2011; 33; 4; 3–10). A 2010 retrospective cohort study of 1,965 patients at an academic medical center looked at the influence of the RD with ordering privileges on appropriate parenteral nutrition (PN) usage (Peterson SJ, Chen Y, Sullivan CA, et al. Assessing the influence of registered dietician order-writing privileges on parenteral nutrition use. *J Am Diet Assoc.* 2010; 110; 1702–1711). The study showed that inappropriate PN usage decreased from 482 patients to 240 patients during the pre- and post-ordering privileges periods, respectively. The data from this study also demonstrated a 20 percent cost savings in PN usage. Additionally, this proposed change might also help CAHs to realize other significant quality and patient safety improvements as well as savings. A 2008 study indicates that patients whose PN regimens were ordered by RDs have significantly fewer days of hyperglycemia (57 percent versus 23 percent) and electrolyte abnormalities (72 percent versus 39 percent) compared with patients whose

PN regimens were ordered by physicians (Duffy JK, Gray RL, Roberts S, Glanzer SR, Longoria SL. Independent nutrition order writing by registered dietitians reduces complications associated with nutrition support [abstract]. *J Am Diet Assoc.* 2008; 108 (suppl 1):A9).

Physicians, APRNs, and PAs might lack the training and educational background to manage the sometimes complex nutritional needs of patients with the same degree of efficiency and skill as RDs who have benefited from curriculums that devote a significant number of educational hours to this area of medicine. The addition of ordering privileges enhances the ability that RDs already have to provide timely, cost-effective, and evidence-based nutrition services as the recognized nutrition experts on a hospital and a CAH interdisciplinary team and saves valuable time in the care and treatment of patients, time that is now often wasted as RDs must seek out physicians, APRNs, and PAs to write or co-sign dietary orders. A 2011 literature review discusses a number of additional studies that provide further evidence for the extensive training and education in nutrition that RDs experience as opposed to the limited exposure that physicians receive to this area of medicine, along with several other studies supporting the cost-effectiveness and positive patient outcomes that hospitals might achieve by granting RDs ordering privileges (Kinn TJ. Clinical order writing privileges. Support Line. 2011; 33; 4; 3–10).

In order for patients to have access to the timely nutritional care that can be provided by RDs, especially in rural and remote areas, a CAH must have the regulatory flexibility either to appoint RDs to the medical staff and grant them specific nutritional ordering privileges or to authorize the ordering privileges without appointment to the medical staff. In either instance, medical staff oversight of RDs and their ordering privileges would be ensured. Therefore, we are proposing revisions to § 485.635(a)(3)(vii) that would require that individual patient nutritional needs be met in accordance with recognized dietary practices and the orders of the practitioner responsible for the care of the patients, or by a qualified dietician or qualified nutrition professional as authorized by the medical staff in accordance with State law governing dietitians and nutrition professionals. In addition, we are also proposing that the requirement of § 483.25(i) is met with respect to inpatients receiving post hospital SNF care. Evidence shows that if CAHs choose to grant these specific

ordering privileges to RDs they might achieve a higher quality of care for their patients by allowing these professionals to fully and efficiently function as important members of the patient care team in the role for which they were trained. As a result, it is expected that CAHs would realize cost savings in many of the areas affected by nutritional care. We welcome public comments on this proposed change.

Provision of Services (§ 485.635(g))

At § 485.635(g) we propose a new requirement regarding non-discriminatory behavior. As discussed in this preamble at § 482.13 with regard to hospitals, we are aware that discriminatory behavior by healthcare providers can create barriers to care and result in adverse outcomes for patients. The fear of discrimination alone can limit the extent to which a person accesses health services.

While the CAH CoPs at § 485.608 require that a CAH be in compliance with applicable Federal laws related to the health and safety of patients, there is currently no explicit prohibition of discrimination in the CAH CoPs. We propose to require that a CAH not discriminate on the basis of race, color, religion, national origin, sex (including gender identity), sexual orientation, age, or disability. We are proposing these requirements to ensure nondiscrimination as required by Section 1557 of the Affordable Care Act, which 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. As discussed in section II.A.1 of this proposed rule, we believe that discrimination based on a patient's religion or sexual orientation can potentially lead to a denial of services or inadequate care, which is detrimental to the patient's health and safety. We are therefore also proposing to establish explicit requirements that a CAH not discriminate on the basis of religion or sexual orientation and that a CAH establish and implement a written policy prohibiting discrimination on the basis of religion or sexual orientation. We are doing so under the statutory authority of Section 1820(e)(3) of the Act, which sets forth the conditions for designating certain hospitals as CAHs.

We further propose that CAHs establish and implement a written policy prohibiting discrimination. As noted in our explanation of the proposed policy applicable to hospitals, freedom from discrimination correlates

with improved health outcomes. The same would be true of CAHs.

CAHs 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. In addition, we propose to require that the CAH inform the patient and/or representative, and/or support person, on how he or she can seek assistance if they encounter discrimination.

4. Infection Prevention and Control and Antibiotic Stewardship Programs (§ 485.640)

CMS retained the former Essential Access Community Hospitals and Rural Primary Care Hospitals (EACH/RPCH) Infection Control regulation for CAHs in the 1997 **Federal Register** (62 FR 46008, August 29, 1997) in the subsequent CoP requirements at § 485.635(a)(3)(vi) and at § 485.641(b)(2). The infection control requirements for CAHs have remained unchanged since 1997. We are proposing to remove the current requirements at §§ 485.635(a)(3)(vi) and 485.641(b)(2) and are adding a new infection prevention and control and antibiotic stewardship CoP for CAHs because the existing standards for infection control do not reflect the current nationally recognized standards of practice for the prevention and elimination of healthcare-associated infections and for the appropriate use of antibiotics.

We discuss at length in this preamble at § 482.42 the issues and concerns regarding infection control, healthcare-associated infections, antibiotic overuse, and the industry recommendations for addressing these serious and growing problems. Therefore, we will not have a lengthy discussion of the background and rationale in this section. Additionally, note that a March 6, 2014 article of the Health Leaders Media entitled, "Size Matters in Antibiotic Overuse," discusses the variation in prescribing practices among hospitals (Cheryl Clark, Health Leaders Media Council Quality e-Newsletter, March 6, 2014). Some hospitals are prone to give antibiotics as much as three times more often than other hospitals, despite a similar patient mix. The article features research results authored by clinicians at a large hospital system with more than 80 hospitals in 21 states. The research showed that antibiotic prescribing practices at 69 hospitals had significant variations in the use of antibiotics across the 69 hospitals. They found that the lower the "case mix index," or severity of illness at a particular hospital, and the smaller the

hospital in terms of number of beds, the more antibiotics were used on patients and the more money was spent on the cost of those drugs. The report discussed that one possible cause could be that hospitals located in smaller, perhaps rural areas, or CAHs might lack access to rapid, sophisticated lab equipment to identify the type of microbes their patients might have.

The report also theorized that it was likely that smaller hospitals do not have as robust of an antimicrobial stewardship program as larger hospitals. The research documented several factors associated with higher antibiotic use at smaller or rural hospitals:

- Lack of awareness on judicious antibiotic use;
- Lack of teamwork among pharmacists and physicians;
- Lack of a formal process on appropriate indications for broad spectrum agent use;
- Lack of prospective monitoring on continuation of broad spectrum agent use, such as de-escalation of use after negative result from culture and sensitivity testing; and
- Lack of resistance trend monitoring and making appropriate process changes to reduce resistance.

We are therefore proposing that each CAH has facility-wide infection prevention and control and antibiotic stewardship programs. The programs would be coordinated with the CAH QAPI program, for the surveillance, prevention, and control of HAIs and other infectious diseases and for the optimization of antibiotic use through stewardship. We are emphasizing the importance of antibiotic stewardship because it could play a vital role in a CAH's successful efforts in combatting antimicrobial resistance. The programs would demonstrate adherence to nationally recognized infection control guidelines, where applicable, for reducing the transmission of infections, as well as best practices for improving antibiotic use and reducing the development and transmission of HAIs and antibiotic-resistant organisms. We believe that this approach would provide CAHs the flexibility they need to select and integrate standards and best practices which are best suited to their individual infection prevention and control program.

§ 485.640(a)(1) and (2) Infection Control Officer(s); and Prevention and Control of Infections Within the CAH and Between the CAH and Other Healthcare Settings

At § 485.640(a)(1) we propose that the CAH ensure that an individual (or individuals), who are qualified through

education, training, experience, or certified in infection, prevention and control, are appointed by the governing body, or responsible individual, as the infection preventionist(s)/infection control professional(s) responsible for the infection prevention and control program at the CAH and that the appointment is based on the recommendations of medical staff and nursing leadership. We recognize that CAHs use a variety of staffing models including direct employment, contracted services, and shared service agreements. In § 485.640, we do not require any specific staffing model(s) for the professional(s) responsible for the facility-wide infection prevention and control and antibiotic stewardship programs. The CAH's staffing for these programs should be appropriate to the scope and complexity of the services offered at the CAH.

We propose at § 485.640(a)(2) that the infection prevention and control program, as documented in its policies and procedures, employ methods for preventing and controlling the transmission of infections within the CAH and between the CAH and other healthcare settings. We believe that a coordinated, overall quality approach would enable CAHs to achieve results that would better serve their patients and reduce cost. The program, as documented in its policies and procedures, would have to employ methods for preventing and controlling the transmission of infection within the CAH setting (for example, among patients, personnel, and visitors) as well as between the CAH (including outpatient services) and other institutions and healthcare settings. As discussed at section II.G of this preamble, we would expect CAHs to look to the CDC guidelines for guidance (http://www.cdc.gov/hai/pdfs/guidelines/Ambulatory-Care+Checklist_508_11_2015.pdf).

§ 485.640(a)(3) Healthcare-Associated Infections (HAIs)

We propose at § 485.640(a)(3) that the infection prevention and control program include surveillance, prevention, and control of HAIs, including maintaining a clean and sanitary environment to avoid sources and transmission of infection, and that the program also address any infection control issues identified by public health authorities.

§ 485.640(a)(4) Scope and Complexity

We are proposing at § 485.640(a)(4) that the infection prevention and control program reflects the scope and

complexity of the services provided by the CAH.

§ 485.640(b)(1) Leader of the Antibiotic Stewardship Program

We propose at § 485.640(b)(1) that the CAH's governing body 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 that the appointment is based on the recommendations of medical staff and pharmacy leadership.

§ 485.640(b)(2)(i),(ii), and (iii) Goals of the Antibiotic Stewardship Program

The proposed requirements at § 485.640(b)(2)(i),(ii), and (iii) would ensure that the following goals for an antibiotic stewardship program are met: (i) Demonstrate coordination among all components of the CAH responsible for antibiotic use and resistance, including, but not limited to, the infection prevention and control program, the QAPI program, the medical staff, and nursing and pharmacy services; (ii) document the evidence-based use of antibiotics in all departments and services of the CAH; and (iii) demonstrate improvements, including sustained improvements, in proper antibiotic use, such as through reductions in, CDI and antibiotic resistance in all departments and services of the hospital. We believe that these three components are essential for an effective program.

§ 485.640(b)(3) and (4) Nationally Recognized Guidelines; and Scope and Complexity

These provisions would require the CAH to ensure that the antibiotic stewardship program adheres to the nationally recognized guidelines, as well as best practices, for improving antibiotic use. The CAH's stewardship program would have to reflect the scope and complexity of services offered. For example, we would not expect a CAH that did not offer surgical services to address antibiotic stewardship issues specific to surgical patients. We believe these proposed requirements are necessary to promote a facility-wide culture of quality improvement.

§ 485.640(c)(1), (2), and (3) Governing Body; Infection Prevention and Control Professionals'; and Antibiotic Stewardship Program Leader's Responsibilities

We would require that the governing body or responsible individual ensure that the infection prevention and control issues identified by the infection

prevention and control professionals be addressed in collaboration with CAH leadership. We therefore propose at § 485.640(c)(1)(i) and (ii), requirements that the governing body or responsible individual ensure that:

- Systems are in place and operational for the tracking of all infection surveillance, prevention, and control, and antibiotic use activities in order to demonstrate the implementation, success, and sustainability of such activities; and
- All HAIs and other infectious diseases identified by the infection prevention and control program and antibiotic use issues identified by the antibiotic stewardship program are addressed in collaboration with CAH QAPI leadership.

At § 485.640(c)(2)(i)–(vi), we propose that the responsibilities of the infection prevention and control professionals would include the development and implementation of facility-wide infection surveillance, prevention, and control policies and procedures that adhere to nationally recognized guidelines.

The governing body or responsible individual would be responsible for all documentation, written or electronic, of the infection prevention and control program and its surveillance, prevention, and control activities. Additionally, the infection preventionist(s)/infection control professional(s) would be responsible for:

- Communication and collaboration with the CAH's QAPI program on infection prevention and control issues;
- Competency-based training and education of CAH personnel and staff including professional health care staff and, as applicable, personnel providing services in the CAH under agreement or arrangement, on the practical applications of infection prevention and control guidelines, policies and procedures;
- Prevention and control of HAIs, including auditing of adherence to infection prevention and control policies and procedures by CAH personnel; and
- Communication and collaboration with the antibiotic stewardship program.

Finally in this CoP, at § 485.640(c)(3), we propose requirements for the leader of the antibiotic stewardship program similar to the proposed responsibilities for the CAH's designated infection preventionist(s)/infection control professional(s) at paragraph (c)(2). We believe that a CAH's antibiotic stewardship program is the most effective means for ensuring appropriate antibiotic use. We also believe that such

a program would require a leader responsible and accountable for its success. Therefore, we propose that the leader of the antibiotic stewardship program would be responsible for the development and implementation of a facility-wide antibiotic stewardship program, based on nationally recognized guidelines, to monitor and improve the use of antibiotics. We also propose that the leader of the antibiotic stewardship program would be responsible for all documentation, written or electronic, of antibiotic stewardship program activities. The leader would also be responsible for communicating and collaborating with medical and nursing staff, pharmacy leadership, and the CAH's infection prevention and control and QAPI programs, on antibiotic use issues.

Finally, we propose that the leader would be responsible for the competency-based training and education of CAH personnel and staff, including medical staff, and, as applicable, personnel providing contracted services in the CAHs, on the practical applications of antibiotic stewardship guidelines, policies, and procedures.

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

Since May 26, 1993 (58 FR 30630), the "Periodic evaluation and quality assurance review" CoP (§ 485.641) has not been updated to reflect current industry standards that utilize the QAPI model (§ 482.21) to assess and improve patient care. Currently, a CAH is required to evaluate its total program (for example, policies and procedures and services provided) annually. The evaluation must include reviewing the utilization of the CAH services using a representative sample of both active and closed clinical records, as well as reviewing the facility's health care policies. The purpose of the evaluation is to determine whether the utilization of services was appropriate, the established policies were followed, and if any changes are needed. The CAH's staff considers the findings of the evaluation and takes the necessary corrective action. These requirements focus on how well the CAH adhered to the evaluation standards and require the CAH to document its efforts. The existing annual evaluation and quality assurance review requirements at § 485.641 are reactive; that is, once a problem has been identified, the health care facility takes action to correct it.

The focus of a QAPI program is to proactively maximize quality improvement activities and programs,

even in areas where no specific deficiencies are noted. A QAPI program enables the organization to review systematically its operating systems and processes of care to identify and implement opportunities for improvement.

An effective QAPI program that is engaged in continuous improvement efforts is essential to a provider's ability to provide high quality and safe care to its patients, while reducing the incidence of medical errors and adverse events. However, patient harm still remains a considerable problem in our nation's hospitals. The IOM report, "To Err Is Human: Building a Safer Health System," focused widespread attention on the problem of adverse events and is a call to action for the entire health care system. (L.T. Kohn, J.M. Corrigan, and M.S. Donaldson, eds., *To Err Is Human: Building a Safer Health System*, A Report of the Committee on Quality of Health Care in America, p. 102, IOM, National Academy Press, 2000.) The report highlighted patient injuries associated with medical errors. More recent reports, however, document that the problems identified in "To Err is Human" have not yet been resolved. A 2010 Office of the Inspector General Report estimated that during October 2008, 13.5 percent of hospitalized Medicare beneficiaries experienced adverse events during their hospital stays (Department of Health and Human Services Office of Inspector General, "Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries" (OEI-06-09-00090). A 2013 literature review concluded that at least 210,000 deaths per year were associated with preventable harm in hospitals. The evidence indicates that patients are being harmed every day in hospitals across the country and that more work is needed to reduce this harm.

In "To Err is Human," an error is defined as "the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim." Examples of medical errors include:

- Medication administration errors (for example, wrong medication, wrong dosage, wrong route, wrong time, wrong patient.);
- Equipment failures (for example, defibrillator without working batteries, etc.); and
- Diagnostic errors.

A 2003 report by The National Advisory Committee on Rural Health and Human Services to the Secretary of the HHS notes that the general concept of health care quality does not change from urban to rural settings (The

National Advisory Committee on Rural Health and Human Services. *Health Care Quality: The Rural Context*. April, 2003; p. 6–10). The focus remains on providing the right service at the right time in the right way to achieve the optimal outcome. The only rural-urban variable within that equation is the context. While the notion of quality remains constant, the settings in which the care is provided—including their structures and processes (for example, transferring patients to larger facilities vs. being able to keep them for observation)—can be quite different. The most elementary differences have to do with scope and scale.

The 2004 IOM Report, "Quality Through Collaboration: The Future of Rural Health," reports that to improve quality, rural providers, like their urban counterparts, must adopt a comprehensive approach to quality improvement (National Research Council. *Quality Through Collaboration: The Future of Rural Health Care*. Washington, DC: The National Academies Press, 2005. <http://www.iom.edu/Reports/2004/Quality-Through-Collaboration-The-Future-of-Rural-Health.aspx#sthash.2zF6T8kE.dpuf>). This approach needs to encompass clinical knowledge and the tools necessary to apply this knowledge to practice, including practice guidelines and computer-aided decision support, standardized performance measures, performance measurement and data feedback capabilities, and quality improvement processes and resources.

A QAPI program would enable a CAH to systematically review its operating systems and processes of care to identify and implement opportunities for improvement. We also believe that the leadership or governing body or responsible individual of a CAH must be responsible and accountable for patient safety, including the reduction of medical errors in the facility.

We propose to revise § 485.641 to set forth new explicit requirements for a QAPI program at a CAH. We believe that much of the work and resources that are currently required under the existing periodic evaluation and quality assurance CoP would be utilized to adhere to the new QAPI requirement. As noted previously, we propose to retain the requirements under paragraphs § 485.641(b)(3) and (4) regarding the evaluation of the diagnosis and treatment furnished by physicians and non-physician practitioners; we are proposing that this be moved from the "Periodic evaluation and quality assurance" CoP, and relocate them to a

new standard under the “Staffing and staff responsibilities” CoP at § 485.631.

CAHs are currently required to have an effective quality assurance program to evaluate the quality and appropriateness of the diagnosis and treatment furnished in the CAH and of the treatment outcomes. We are proposing that, under § 485.641, the CAH be required to develop, implement, and maintain an effective, ongoing, facility-wide, and data-driven QAPI program. The QAPI program would have to be appropriate for the complexity of the CAH’s organization and services provided.

We propose to rename the current “Periodic evaluation and quality assurance review” provisions at § 485.641 “Condition of participation: Quality assessment and performance improvement program.” At § 485.641, we also propose to revise and replace the current standards with the new proposed QAPI program containing the following six parts: (a) Definitions; (b) QAPI program design and scope; (c) Governance and leadership; (d) Program activities; (e) Performance improvement projects; and (f) Program data collection and analysis.

§ 485.641(a) Definitions

We have proposed at paragraph § 485.641(a) to provide definitions for the following terms: “adverse event,” “error,” and “medical error.” We propose the same definition of “adverse event” currently found at § 482.70. We are also proposing the definitions of “error” and “medical error” that are largely drawn from the IOM. We believe that most CAHs are aware of these terms, but we are proposing to provide the following standard definitions:

- “Adverse event” means an untoward, undesirable, and usually unanticipated event that causes death or serious injury or the risk thereof;
- “Error” means the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim. Errors can include problems in practice, products, procedures, and systems; and
- “Medical error” means an error that occurs in the delivery of healthcare services.

§ 485.641(b) QAPI Program Design and Scope

At proposed § 485.641(b)(1) “Program design and scope,” we would require the CAH to have a QAPI program that would be appropriate for the complexity of the CAH’s organization and services. This means that every CAH would utilize performance improvement measures that would be sensitive to that

CAH’s specific context. The QAPI program would be designed to monitor and evaluate performance of all services and programs of the CAH. In proposed paragraphs (b)(2) and (3), we would require the CAH to design a QAPI program that would be on-going and comprehensive, involving all departments of the CAH and services, including those services furnished under contract or arrangement. In proposed paragraph (b)(4), we would require CAHs to use objective measures in their QAPI program to evaluate its organizational processes, functions, and services. We also propose at paragraph (b)(5) that the CAH’s QAPI program would address outcome indicators related to improved health outcomes and the prevention and reduction of medical errors, adverse events, hospital-acquired conditions, and transitions of care, including readmissions.

§ 485.641(c) Governance and Leadership

We propose at § 485.641(c) that the CAH’s governing body or responsible individual be ultimately responsible for the CAH’s QAPI program and at paragraph (c)(1) be responsible and accountable for ensuring that clear expectations for safety are communicated, implemented, and followed throughout the CAH. At § 485.641(c)(2), we propose that the QAPI efforts address priorities for improving quality of care and patient safety. At paragraph (c)(3), all improvement actions would be evaluated and modified as needed by the designated CAH staff. We propose at paragraph (c)(4) that the governing body or responsible individual exercising management authority over the CAH ensure that adequate resources are allocated for measuring, assessing, improving, and sustaining the CAH’s performance and reducing risk to patients. Once this rule is finalized, CMS will develop the appropriate subregulatory guidance so that surveyors will be able to determine what constitutes “adequate resources.” In proposed paragraphs (c)(5) and (6), we would require the governing body or responsible individual to be responsible for annually determining the number of distinct quality improvement projects the CAH would conduct. They would also be responsible for the CAH developing and implementing policies and procedures for QAPI that address what actions the CAH staff should take to prevent and report unsafe patient care practices, medical errors, and adverse events.

485.641(d) Program Activities

We propose at § 485.641(d), “Program activities”, that for each of the areas discussed in paragraphs (b) and (c) of this section, the CAH would have to:

- Focus on measures related to improved health outcomes that are shown to be predictive of desired patient outcomes;
- Use the measures to analyze and track its performance; and
- Set priorities for performance improvement, considering either high-volume, high-risk services, or problem-prone areas.

Analyses would be expected to be conducted at regular intervals to enable the CAH to identify areas or opportunities for improvement.

§ 485.641(e) Performance Improvement Projects

We propose at § 485.641(e), “Performance Improvement Projects,” that a CAH would have to conduct distinct performance improvement projects that are proportional to the scope and complexity of the CAH’s services and operations. We also propose that the CAH would be required to maintain and demonstrate written or electronic evidence and documentation of its QAPI projects.

§ 485.641(f) Program Data Collection and Analysis

Collecting and analyzing data is fundamental to quality improvement. The CAH should be able to demonstrate that the data it collects measure the quality of patient care. Therefore, we propose at § 485.641(f)(1) and (2) that a CAH’s QAPI program be required to incorporate quality indicator data including patient care data, quality measures data, and other relevant data. The CAH must use the data collected to monitor the effectiveness and safety of services provided and quality of care. A CAH must also identify opportunities for improvement and changes that will lead to improvement. Since 2011, the Medicare Beneficiary Quality Improvement Project (MBQIP), supported by the Federal Office of Rural Health Policy’s Medicare Rural Hospital Flexibility Grant Program, has encouraged CAHs to collect and report quality data and has provided a means for CAHs to monitor the quality of care they provide and identify opportunities for improvement. To the extent that the MBQIP meets the proposed requirements for incorporating quality indicator data in its QAPI program, CAH adherence to the requirements of MBQIP is one such way that the CAH’s QAPI program data collection

requirements can be satisfied. MBQIP uses a rural-relevant subset of data based on Medicare quality reporting program. Current MBQIP measures and information resources for data analysis and performance improvement can be found at <https://www.ruralcenter.org/tasc/mbqip>. We propose at paragraph (f)(3) that the CAH's governing body or responsible individual must approve the frequency and the details of data collection.

6. Technical Corrections

We propose to correct a typographical error in the regulations at § 485.645 by correcting the word "provided" to "provide" in the lead first sentence.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs).

A. ICRs Regarding Patient's Rights (§ 482.13)

Proposed § 482.13(i) would establish explicit requirements that a hospital not discriminate against a patient or applicant for services on the basis of race, color, religion, national origin, sex (including gender identity), sexual orientation, or disability and that the hospital establish and implement a written policy prohibiting discrimination against a patient or applicant for services on the basis of race, color, religion, national origin, sex (including gender identity), sexual orientation, or disability. We propose to further require that each patient or applicant for services, and/or support

person, where appropriate, is informed of the right to be free from discrimination against them on any of the aforementioned bases when he or she is informed of his or her other rights under § 482.13(a)(1). The burden associated with this requirement is the time and effort necessary for a hospital to develop written policies and procedures with respect to the rights of patients to be free from discrimination and to distribute that information to the patients.

We believe that most hospitals already have established policies and procedures regarding the rights of patients to be free from discrimination. Additionally, we believe that most hospitals include the anti-discrimination policies and procedures as part of their standard notice of patient rights. The burden associated with the notice of patient rights is currently approved under OMB control number 0938-0328.

We will be submitting a revision of the currently approved information collection request to account for the following burden.

We estimate that 4,900 hospitals must comply with the aforementioned information collection requirements. We further estimate that it will take each hospital 0.25 hours to comply with the requirement in proposed § 482.13(i). The total estimated annual burden associated with this requirement is 1,225 hours (4,900 hospitals × .25) at a cost of \$83,300 (1,225 hours × \$68 for a nurse's hourly salary).

B. ICRs Regarding Quality Assessment and Performance Improvement (§ 482.21)

The existing QAPI CoP requires each hospital to:

- Develop, implement, maintain, and evaluate its own QAPI program;
- Establish a QAPI program that reflects the complexity of its organization and services;
- Establish a QAPI program that involves all hospital departments and services and focuses on improving health outcomes and preventing and reducing medical errors; and
- Maintain and demonstrate evidence of its QAPI program for review by CMS.

We are proposing a minor change to the program data requirements at § 482.21(b). Currently, we require that hospitals incorporate quality indicator data including patient care data, and other relevant data, for example, information submitted to, or received from, the hospital's Quality Improvement Organization.

We propose to update this requirement to reflect and capitalize on

the wealth of important quality data available to hospitals through several quality data reporting programs. Specifically, we propose to require that the hospital QAPI program must incorporate quality indicator data including patient care data, and other relevant 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. Hospitals are likely to be participating in one or more existing 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, Hospital Compare, the Medicare and Medicaid Electronic Health Record Incentive Programs, the Hospital Outpatient Quality Reporting program, and the Joint Commission's Quality Check™. Since a hospital is already collecting and reporting quality measures data for these programs, we do not believe that this proposed change would increase the information collection burden for hospitals.

C. ICRs Regarding Nursing Services (§ 482.23)

We propose to revise § 482.23(b), which currently states "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 bedside care of any patient," to delete the term "bedside," which might imply only inpatient services to some readers. The nursing service must ensure that patient needs are met by ongoing assessments of patients' needs and must provide nursing staff to meet those needs regardless of whether the patient is an inpatient or an outpatient. We propose to allow a hospital to establish a policy that would specify which, if any, outpatient units would not be required to have an RN physically present as well as the alternative staffing plans that would be established under such a policy. We 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. In addition, we would propose that the policy must be approved by the medical staff and be reviewed annually. TJC-accredited hospitals are already allowed this flexibility in nursing services policy. Those hospitals that use their TJC accreditation for deeming purposes are required to have "Leaders [who] provide

for a sufficient number and mix of individuals to support safe, quality care, treatment, and services. (Note: The number and mix of individuals is appropriate to the scope and complexity of the services offered.)” (CAMH, Standard LD.03.06.01, EP 3). Further, TJC-accredited hospitals also require the “nurse executive, registered nurses, and other designated nursing staff [to] write: Nursing policies and procedures.” (CAMH, Standard NR.02.02.01, EP 3). Therefore, we expect that TJC-accredited hospitals already have the policies and procedures that satisfy the requirements in this subsection, including medical staff approval and annual review. If there are any tasks that a TJC-accredited hospital may need to complete to satisfy the requirement for this subsection, we expect that the burden imposed would be negligible. Thus, for the approximately 3,900 TJC-accredited hospitals the development of policies and procedures that would satisfy this subsection would constitute a usual and customary business practice as defined at 5 CFR 1320.3(b)(2).

The non TJC-accredited hospitals would need to review their current policies and procedures and update them so that they comply with the requirements in proposed § 482.23(b). This would be a one-time burden on the hospital. We estimate that this would require a physician, a nurse, and one administrator. Physicians earn an average hourly salary of \$187, administrators earn an average hourly salary of \$174, and registered nurses earn an hourly salary of \$68 (2014 BLS Wage Data by Area and Occupation at <http://www.bls.gov/bls/blswage.htm>, adjusted upward by 100 percent to include fringe benefits and overhead costs). We estimate that each person would spend three hours on this activity for a total of nine hours at a cost of \$1,287 (3 hours × \$68 for a nurse’s hourly salary + 3 hours × \$174 for an administrator’s hourly salary + 3 hours × \$187 for a physician’s hourly salary = \$1,287). For all 1,000 non-TJC-accredited hospitals to comply with this requirement, we estimate a total one-time cost of approximately \$1.3 million (1,000 hospitals × \$1,287). We estimate that annual review of the policies and procedures would take one hour for each individual included for a total annual cost of \$429,000 ((1 hour × \$68 for a nurse’s hourly salary + 1 hour × \$174 for an administrator’s hourly salary + 1 hour × \$187 for a physician’s hourly salary) × 1,000 hospitals). The burden associated with these requirements is captured in an

information collection request (0938–NEW).

D. ICRs Regarding Medical Record Services (§ 482.24)

We are proposing to make changes to several of the provisions in this CoP 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.

The current requirements at § 482.24(c) state that the content of the medical record must contain “information to justify admission and continued hospitalization, support the diagnosis, and describe the patient’s progress and response to medications and services.” While we believe that these terms are appropriate for inpatients, they do not fully capture the specific documentation necessary for outpatients. Therefore, we propose to revise the current regulatory language to require that the content of the medical record must 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 and outpatient visits to reflect the scope of all services received by the patient.”

Similarly, we propose to revise § 482.24(c)(4)(ii) from the current requirement for documentation of “admitting diagnosis” to include “all inpatient and outpatient diagnoses,” which would include any admitting diagnoses. Within this same standard, we are proposing to update several terms to reflect more current terminology and standards of practice. Therefore, at § 482.24(c)(4)(iv), we propose to require that the content of the record include “documentation of complications, hospital-acquired conditions, healthcare-associated infections, and unfavorable reactions to drugs and anesthesia.” We also propose changes to § 482.24(c)(4)(vi) to add “progress notes” to the required documentation of “practitioners’ orders” to emphasize the necessary documentation for both inpatients and outpatients. And we propose to add the phrase “to reflect the scope of all services received by the patient.”

Continuing under this standard detailing the contents of the medical record, we propose to make revisions to the final two provisions under this standard. We propose to change § 482.24(c)(4)(vii) to require that all patient medical records must 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. We believe that these changes would 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, we recognize the distinction between the services received by inpatient and those received by outpatients by proposing to include language that distinguishes between the inpatient and the outpatient experiences.

Finally, we emphasize the distinctions between discharges and transfers as well as between inpatients and outpatients by proposing to revise § 482.24(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.”

We believe that hospitals would need to review their current policies and procedures and update them so that they comply with the requirements in proposed § 482.24(c). This would be a one-time burden on the hospital. We estimate that this would require a physician, a nurse, and one administrator. Physicians earn an average hourly salary of \$187, administrators earn an average hourly salary of \$174, and registered nurses earn an hourly salary of \$68 (2014 BLS Wage Data by Area and Occupation at <http://www.bls.gov/bls/blswage.htm>, adjusted upward by 100 percent to include fringe benefits and overhead costs). We estimate that each person would spend three hours on this activity for a total of nine hours at a cost of \$1,287 (3 hours × \$68 for a nurse’s hourly salary + 3 hours × \$174 for an administrator’s hourly salary + 3 hours × \$187 for a physician’s hourly salary = \$1,287). For all 4,900 hospitals to comply with this requirement, we estimate a total one-time cost of approximately \$6.3 million (4,900 hospitals × \$1,287). The burden associated with these requirements is captured in an information collection request (0938–NEW).

E. ICRs Regarding Provision of Services (§ 485.635)

Section 485.635(g) would require that a CAH not discriminate against patients or applicants for service on the basis of race, color, religion, national origin, sex (including gender identity), sexual orientation, or disability and that the

CAH establish and implement a written policy prohibiting discrimination against patients or applicants for service on the basis of race, color, religion, national origin, sex (including gender identity), sexual orientation, or disability. We propose to further require that each patient, and/or support person, where appropriate, be informed, in a language he or she can understand, of the right to be free from discrimination against them on any of the aforementioned bases (HHS OCR Compliance Review Initiative: "Advancing Effective Communication In Critical Access Hospitals" April 2013 http://www.hhs.gov/sites/default/files/ocr/civilrights/activities/agreements/compliancereview_initiative.pdf). The burden associated with this requirement is the time and effort necessary for a CAH to develop written policies and procedures with respect to the rights of patients to be free from discrimination and to distribute that information to the patients.

We estimate that 1,328 CAHs must comply with the aforementioned information collection requirements. We further estimate that it will take each CAH 0.25 hours to comply with the requirement in proposed § 485.635(g). The total estimated annual burden associated with this requirement is 332 hours (1,328 hospitals × .25) at a cost of \$22,576 (332 hours × \$68 for a nurse's hourly salary).

F. ICRs Regarding Condition of Participation: Quality Assessment and Performance Improvement Program (§ 485.641)

Proposed § 485.641 would require CAHs to develop, implement, and maintain an effective, ongoing, CAH-wide, data-driven QAPI program. The QAPI program must be appropriate for the complexity of the CAH's organization and the services it provides. In addition, CAHs must comply with all of the requirements set forth in proposed § 485.641(b) through (g).

The current CAH CoPs at § 485.641 require CAHs to have an effective quality assurance program to evaluate the quality and appropriateness of the diagnosis and treatment furnished in the CAH and the treatment outcomes. CAHs are currently required to conduct a periodic evaluation and quality assurance review (42 CFR 485.641(a)). They are required to evaluate its total program (for example, policies and procedures and services provided) annually. The evaluation must include reviewing the utilization of the CAH services using a representative sample of both active and closed clinical

records, as well as reviewing the facility's health care policies. The purpose of the evaluation is to determine whether the utilization of services was appropriate, the established policies were followed, and if any changes are needed. The CAH's staff considers the findings of the evaluation and takes corrective action, if necessary (42 CFR 485.641(b)(5)(i)). Thus, we believe that all of the CAHs are performing the activities that are required to comply with many of the requirements in proposed § 485.641. However, we also believe that the CAHs would need to review their current quality assurance program and revise and, if needed, develop new provisions to ensure compliance with the proposed requirements.

TJC accreditation standards for performance improvement (PI) already require that CAHs collect, compile, and analyze to monitor their performance (TJC Accreditation Standard PI.01.01.01 and PI.02.01.01). These TJC-accredited CAHs must also improve their performance on an ongoing basis (TJC Accreditation Standard PI.03.01.01). Thus, we believe that the 324 TJC-accredited CAHs are already in compliance with the requirements in proposed § 485.641. However, each CAH would need to review their current practice to ensure that they are in compliance with all of the requirements under § 485.641. Any additional tasks those CAHs would need to comply with the requirements for this section should result in a negligible burden, if any. Thus, the burden for these activities for the 324 TJC-accredited CAHs will be excluded from the burden analysis because they constitute usual and customary business practices in accordance with 5 CFR 1320.3(b)(2).

The 1,004 non TJC-accredited CAHs would need to review their current programs and then revise and develop new provisions of their programs to ensure compliance with the proposed requirements. We believe that the CAH QAPI leadership (consisting of a physician, and/or administrator, mid-level practitioner, and a nurse) would need to have at least two meetings to ensure that the current annual evaluation and quality assurance (QA) program is transitioned into the proposed QAPI format. The first meeting would be to discuss the current quality assurance program and what needs to be included based on the new proposed QAPI provision. The second meeting would be to discuss strategies to update the current policies, and then to discuss the process for incorporating those changes. We believe that these meetings would take approximately two

hours each. We would estimate that the physician would have a limited amount of time, approximately 1 hour to devote to the QAPI activities. Additionally, we estimate these activities would require 4 hours of an administrator's time, 4 hours of a mid-level practitioner's time, 14 hours of a nurse's time, and 2 hours of a clerical staff person's time for a total of 25 burden hours. We believe that the CAH's QAPI leadership (formerly the periodic evaluation and quality assurance leadership) would need to meet periodically to review and discuss the changes that would need to be made to their program. We also believe that a nurse would likely spend more time developing the program with the mid-level practitioner. The physician would likely review and approve the program. The clerical staff member would probably assist with the program's development and ensure that the program was disseminated to all of the necessary parties in the CAH.

Since a CAH is currently required to evaluate its total program and evaluate the quality and appropriateness of the services furnished, take appropriate action to address deficiencies and document such activities, we believe that the resources utilized on the current QA program would be utilized for the ongoing QAPI activities under proposed § 485.641(b)-(f). Thus, we estimate that for each CAH to comply with the requirements in this section it would require 25 burden hours (1 for a physician + 4 for an administrator + 4 for a mid-level practitioner + 14 for a nurse + 2 for a clerical staff person = 25 burden hours) at a cost of \$1,975 (\$187 for a physician + \$392 for an administrator (4 hours × \$98) + \$380 for a mid-level practitioner (4 hours × \$95) + \$952 (14 hours × \$68 for a nurse) + \$64 for a clerical staff person (2 hours × \$32). Therefore, for all 1,004 non TJC-deemed CAHs to comply with these requirements, it would require 25,100 burden hours (25 × 1,004 non TJC-deemed CAHs) at a cost of approximately \$2 million (\$1,975 for each CAH × 1,004 non TJC-deemed CAHs). We note here the difference in hourly salary between a hospital CEO/administrator (\$174) and a CAH CEO/administrator (\$98). The burden associated with these requirements is captured in an information collection request (0938-NEW).

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: CMS Desk Officer, CMS-3295-P, Fax: (202) 395-6974; or Email: OIRA_submission@omb.eop.gov.

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Regulatory Impact Analysis

A. Statement of Need

CMS is aware, through conversations with stakeholders and federal partners, and as a result of internal evaluation and research, of outstanding concerns about CoPs for hospitals and CAHs, despite recent revisions. We believe that the proposed revisions would alleviate many of those concerns. In addition, modernization of the requirements would cumulatively result in improved quality of care and improved outcomes for all hospital and CAH patients. We believe that benefits would include reduced readmissions, reduced incidence of hospital-acquired conditions (including healthcare-associated infections), improved use of antibiotics at reduced costs (including the potential for reduced antibiotic resistance), and improved patient and workforce protections.

These benefits are consistent with current HHS Quality Initiatives, including efforts to prevent HAIs; the national action plan for adverse drug event (ADE) prevention; the national strategy for Combating Antibiotic-Resistant Bacteria (CARB); and the Department’s National Quality Strategy (<http://www.ahrq.gov/workingforquality/index.html>). 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 (<http://www.ahrq.gov/workingforquality/nqs/principles.htm>). Our proposal to prohibit discrimination would support eliminating disparities in care, and we believe our proposals about QAPI and infection prevention and control and antibiotic stewardship programs will improve quality and promote consistent national standards. Our proposals regarding the term licensed independent practitioners and establishing policies and protocols for when the presence of an RN is needed will support care coordination and quality of care. In sum, we believe our proposed changes are necessary, timely, and beneficial.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action that is likely to result in a rule: (1) Having an annual effect on the economy of \$100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as “economically

significant”); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). We estimate that this rulemaking is “economically significant” as measured by the \$100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we have prepared a Regulatory Impact Analysis (RIA) that, to the best of our ability, presents the costs and benefits of the rulemaking.

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each chamber of the Congress and to the Comptroller General of the United States. HHS will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**.

This proposed rule would create ongoing cost savings to hospitals and CAHs in many areas. We believe these savings would largely, but not entirely, offset any costs to hospitals and CAHs that would be incurred by other changes we have proposed in this rule. The financial savings and costs are summarized in the table that follows. We welcome public comments on all of our burden assumptions and estimates. As discussed later in this regulatory impact analysis, substantial uncertainty surrounds these estimates and we especially solicit comments on either our estimates of likely savings/costs or the specific regulatory changes that drive these estimates.

TABLE 1—SECTION-BY-SECTION ECONOMIC IMPACT ESTIMATES

Issue	Frequency	Number of affected entities	Likely savings (+) or costs (-) to society (\$ millions)
Hospitals	4,900	
• Patients’ rights (ICR)	One-time	4,900	0.083(-)

TABLE 1—SECTION-BY-SECTION ECONOMIC IMPACT ESTIMATES—Continued

Issue	Frequency	Number of affected entities	Likely savings (+) or costs (-) to society (\$ millions)
• Nursing services (ICR)	Recurring Annually	1,000	1.3(-)
• Nursing services (ICR)	One-time	1,000	0.429(-)
• Medical record services (ICR)	One-time	4,900	6.3(-)
		4,900	20(-)
• Infection Prevention & Control and Antibiotic Stewardship (RIA).	One-time	2,940	>693 to 1,193(-)
	Recurring annually		
	Recurring Annually	2,940	1,020(+)
CAHs		1,328	
• Provision of services (ICR)	One-time	1,328	0.023(-)
• QAPI (ICR)	Recurring annually	1,004	2(-)
• Food and dietary (RIA)	Recurring annually	650	Not estimated
• Infection Prevention & Control and Antibiotic Stewardship (RIA).	One-time	1,328	5(-)
	Recurring Annually	1,328	45(-)
	Recurring Annually	1,328	37(+)
Sub-Total Savings			1,057(+)
Sub-Total Costs			>773 to 1,273(-)
Overall Savings Net of Costs			<- 216 to 284(+)

Note: This table includes entries only for those proposed reforms that we believe would have a measurable economic effect; includes estimates from ICRs and RIAs.

C. Anticipated Effects

1. Effects on Hospitals and CAHs

There are about 4,900 hospitals and 1,300 CAHs that are certified by Medicare and/or Medicaid. We use these figures to estimate the potential impacts of this proposed rule. In the estimates that were shown in the Collection of Information Requirements section of the preamble and in the Regulatory Impact Analysis here, we estimate hourly costs as follows. Using data from the Bureau of Labor Statistics, we have estimates of the national average hourly wage for all medical professions (for an explanation of these data see http://www.bls.gov/news.release/archives/ocwage_03252015.htm). These data do not include the employer share of fringe benefits such as health insurance and retirement plans, the employer share of OASDI taxes, or the overhead costs to employers for rent, utilities, electronic equipment, furniture, human resources staff, and other expenses that are incurred for employment. The HHS-wide practice is to account for all such costs by adding 100 percent to the hourly cost rate, doubling it for purposes of estimating the costs of regulations. We use the following average hourly wages for registered dietitians and nutrition professionals, registered nurses, advanced practice registered nurses, physician assistants, pharmacists, network data analysts, hospital CEO/administrators, CAH CEO/administrators, clerical staff workers, and physicians respectively: \$56, \$68, \$95, \$95, \$113, \$70, \$174, \$98, \$30, and \$187 (2014 BLS Wage Data by Area and Occupation, including both hourly

wages and fringe benefits, at <http://www.bls.gov/bls/blswage.htm> and <http://www.bls.gov/ncs/ect/>).

Licensed Independent Practitioners (Patients’ Rights § 482.13)

We propose to delete the modifying term “independent” from the CoP at § 482.13(e)(5), as well as at § 482.13(e)(8)(ii). Therefore, we are proposing that § 482.13(e)(5) would now state that the use of restraint or seclusion must be in accordance with the order of a physician or other licensed 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. We are proposing that § 482.13(e)(8)(ii) would now state that after 24 hours, before writing a new order for the use of restraint or seclusion for the management of violent or self-destructive behavior, a physician or other licensed 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. While we believe that hospitals might be able to achieve some costs savings through these changes (by having additional licensed practitioners such as PAs allowed to write restraint and seclusion orders and thus relieve some of the burden from physicians), we do not have a reliable means of quantifying these possible cost savings. We seek comment as to whether the assumption of cost savings is reasonable and welcome any data that may help inform the costs and benefits of this provision.

Infection Control and Antibiotic Stewardship (Infection Prevention and Control § 482.42)

We are revising the hospital requirements at 42 CFR 482.42, “Infection control,” which currently require hospitals to provide a sanitary environment to avoid sources and transmission of infections and communicable diseases. Hospitals are also currently required 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 of patients and personnel. The hospital’s CEO, medical staff, and director of nursing services are charged with ensuring that the problems identified by the infection control officer or officers are addressed in hospital training programs and their QAPI program. The CEO, medical staff, and director of nursing services are also responsible for the implementation of successful corrective action plans in affected problem areas.

We are proposing a change to the title of this CoP to “Infection prevention and control and antibiotic stewardship programs.” By adding the word “prevention” to the CoP name, our intent is to promote larger, cultural changes in hospitals such that prevention initiatives are recognized on balance with their current, traditional control efforts. And by adding “antibiotic stewardship” to the title, we would emphasize the important role that a hospital could play in improving patient care and safety and combatting antimicrobial resistance through implementation of a robust stewardship

program that follows nationally recognized guidelines for appropriate antibiotic use. Along with these changes, we propose to change the introductory paragraph to require that a hospital's infection prevention and control and antibiotic stewardship programs be active and hospital-wide for the surveillance, prevention, and control of HAIs and other infectious diseases, and for the optimization of antibiotic use through stewardship. We would also require that a program demonstrate adherence to nationally recognized infection prevention and control guidelines for reducing the transmission of infections, as well as best practices for improving antibiotic use, for reducing the development and transmission of HAIs and antibiotic-resistant organisms. While these particular changes are new to the regulatory text, it is worth noting that these requirements, with the exception of the new requirement for an antibiotic stewardship program, have been present in the Interpretive Guidelines (IGs) for hospitals since 2008 (See A0747 at Appendix A—Survey Protocol, Regulations and Interpretive Guidelines for Hospitals, http://cms.gov/manuals/Downloads/som107ap_a_hospitals.pdf).

Infection Prevention and Control

Specifically, at § 482.42(a)(1), we propose to require the hospital to appoint an infection preventionist(s)/infection control professional(s). Within this proposed change we are deleting the outdated term, “infection control officer,” and replacing it with the more current and accurate terms, “infection preventionist/infection control professional.” CDC has defined “infection control professional (ICP)” as “a person whose primary training is in either nursing, medical technology, microbiology, or epidemiology and who has acquired specialized training in infection control.” In designating infection preventionists/ICPs, hospitals should ensure that the individuals so designated are qualified through education, training, experience, or certification (such as that offered by the CBIC, or by the specialty boards in adult or pediatric infectious diseases offered for physicians by the American Board of Internal Medicine (for internists) and the American Board of Pediatrics (for pediatricians). Since this requirement has been present in the IGs since 2008, we believe that hospitals have been aware of CMS' expectations for the qualifications of infection control officers. The Joint Commission has a similar requirement (TJC Accreditation Standard IC.01.01.01) and so we believe that hospitals accredited by TJC (over 75

percent of all hospitals (http://www.jointcommission.org/facts_about_hospital_accreditation/) would already be in compliance, or near compliance, with this requirement. The Joint Commission requires that a hospital identify the individual(s) responsible for its infection prevention and control program, including the individual(s) with clinical authority over the infection prevention and control program. For the 25 percent of hospitals not accredited by TJC, we are calculating the burden for these hospitals to come into compliance with this requirement.

Based on our experience with hospitals, we believe that most ICPs would be registered nurses with experience, education, and training in infection control. Twenty-five percent of hospitals not accredited by TJC is 1,225 hospitals. Each hospital would be required to employ at least one ICP fulltime (52 weeks × 40 hours = 2,080 hours) at \$68 per hour. The cost per hospital would be \$141,440 annually (2,080 hours × \$68 = \$141,440). The total cost for all non-TJC-accredited hospitals would be approximately \$173 million annually (1,225 × \$141,440 = 173,264,000).

We believe that the other proposed requirements in this section of the CoP would constitute additional burden. Each hospital would be required to review their current infection control program and compare it to the new requirements contained in this section. After performing this comparison, each hospital would be required to revise their program so that it complied with the requirements in this section. Based on our experience with hospitals, we believe that a physician and a nurse on the infection control team would conduct this review and revision of the program. We believe both the physician and the nurse would spend 16 hours each for a total of 32 hours. Physicians earn an average of \$187 an hour. Nurses earn an average salary of \$68 an hour. Thus, to ensure their infection control program complied with the requirements in this section, we estimate that each hospital would require 32 burden hours (16 hours for a physician and 16 hours for a nurse = 32 burden hours) at a cost of \$4,080 (\$2,992 (\$187 an hour for a physician × 16 burden hours) + \$1,088 (\$68 an hour for a nurse × 16 burden hours)). Based on the estimate, for all 4,900 hospitals, complying with this requirement would require 156,800 burden hours (32 hours for each hospital × 4,900 hospitals = 156,800 burden hours) at a one-time cost of approximately \$20 million

(\$4,080 for each hospital × 4,900 hospitals = \$19,992,000 estimated cost).

Antibiotic Stewardship

Similarly at § 482.42(b), we believe that the proposed requirements for a hospital to have an active antibiotic stewardship program, and for its organization and policies, would constitute additional regulatory burden, as will be discussed in more detail below. However, we believe that the estimated costs of an AS program would be greatly offset by the savings that a hospital would achieve through such a program. The most obvious savings would be from decreased inappropriate antibiotic use leading to overall decreased drug costs for a hospital. Our review of the literature showed significant savings in this area, with annual savings proportional to bed size of the hospital or hospital unit. Reported annual savings ranged from \$27,917 (Canadian dollars) for a 12-bed medical/surgical intensive care unit to \$2.1 million for an 880-bed academic medical center (Leung V, Gill S, Sauve J, Walker K, Stumpo C, Powis J. Growing a “positive culture” of antimicrobial stewardship in a community hospital. The Canadian journal of hospital pharmacy. 2011; 64(5):314–20; Beardsley JR, Williamson JC, Johnson JW, Luther VP, Wrenn RH, Ohl CC. Show me the money: Long-term financial impact of an antimicrobial stewardship program. Infection control and hospital epidemiology: The official journal of the Society of Hospital Epidemiologists of America. 2012; 33(4):398–400). We specifically note the \$177,000 in annual drug cost savings achieved by a 120-bed community hospital with its AS program and would use that as the average cost savings for the average-sized 124-bed hospital discussed above (LaRocco 2003, CID “Concurrent antibiotic review programs—a role for infectious diseases specialists at small community hospitals”). Using this assumption, we believe that the annual drug cost savings for 60 percent of all 4,900 hospitals under this proposed rule would be \$520,380,000 or approximately \$520 million (2,940 hospitals × \$177,000 in drug cost savings).

In addition to these savings, we also believe that the proposed requirement for an AS program would assist hospitals in significantly reducing rates of CDI and the attendant costs. Based on an AS program model developed by the CDC, a hospital combined IC/AS program with an average effectiveness rate of 50 percent would reduce the number of CDIs among Medicare beneficiaries annually by 101,000

(Rachel B. Slayton, Ph.D., MPH; R. Douglas Scott II, Ph.D.; James Baggs, Ph.D.; Fernanda C. Lessa, MD; L. Clifford McDonald, MD; John A. Jernigan, MD. "The Cost-Benefit of Federal Investment in Preventing Clostridium difficile Infections through the Use of a Multifaceted Infection Control and Antimicrobial Stewardship Program," *Infection Control & Hospital Epidemiology* 2015;00(0):1-7). The costs examined in the model were costs for patients who developed CDIs while they were in the hospital or had to be re-admitted to the hospital for a case of CDI that was a result of a recent hospitalization, so the costs are much higher than what would be associated with outpatient cases. The 101,000-reduction is an annual reduction in the number of cases of CDI among patients who develop the infection because of medical care; that is, they were admitted for something else and then acquired CDI while getting care. It should be noted that the 101,000 number actually comprises two types of CDI—cases that occur while the patient is in the hospital and cases that are directly attributable to a recent hospitalization, but which manifest after the patient is discharged and requires a readmission. The cost for patients who develop the infection while they are already in the hospital is between \$4,323 and \$8,146. However, the infections related to a recent hospital stay that require readmission are more expensive, on average, because they require an entirely new admission. The cost of those cases is between \$7,061 and \$11,601. Slayton et al. estimate \$2.5 billion in federal savings over five years, or an annual average of \$0.5 billion.² We believe that the combined annual savings that hospitals could achieve with the proposed AS program and the proposed revisions to infection control would be \$1,020,000,000 or \$1 billion.

We note that these savings would be both to hospitals as well as healthcare insurers, including Medicare. However, we are not able to distinguish the savings that would accrue to each group in this analysis. Healthcare-associated

² Slayton et al. appear not to account for the increased Medicare costs that would result from IC/AS program-associated reductions in CDI-related deaths. Although such an accounting would be appropriate to include in this regulatory impact analysis, its negative effect on estimated net benefits would almost certainly be more than offset by the inclusion of a willingness-to-pay estimate of the value of life extension. Willingness-to-pay approaches can also be used to monetize the decrease in pain and suffering associated with reductions in non-fatal morbidity, so we request data that would allow for more thorough estimation of all of these effects (*i.e.*, the societal benefits of reduced non-fatal CDI illness and the societal benefits and costs of reduced fatal CDI illness).

infections are known to be expensive to insurers, including CMS. Preventing these infections will reduce CMS and other insurer expenditures, both on direct hospital costs and through reduced re-admissions. The cost-savings estimates for CDI included in the RIA provide an example of the savings Medicare and other insurers could realize through reductions in just one HAI.³

We anticipate that the drug savings accrue to the hospitals. The CDI savings are likely shared by hospitals and insurers. Hospitals do bear some of these costs of CDI infections, especially if the CDI case complicates a hospitalization—for example if a patient admitted for pneumonia gets CDI, under bundled payment rules, the hospital would likely make less money from that admission. Also, CDI now also factors into annual payment updates under the inpatient quality reporting program, so hospitals with high CDI rates could face payment reductions.

We believe that the burden of implementing and maintaining an AS program includes the salaries of the qualified personnel needed to establish and manage such a hospital program. Our review of the literature, consultations with CDC, and experience with hospitals suggests that the establishment and maintenance of a hospital antibiotic stewardship program as proposed here, for an average-size hospital (approximately 124 beds), would require the services of a physician (preferably one with training in infectious diseases) and a clinical pharmacist, and also a network data analyst, at the following proportions of full-time employee salaries respectively: 0.10, 0.25, and 0.05. We believe that these personnel costs would constitute the real burden for these proposed requirements. To determine the cost of this burden, we added the proportion of full-time salaries required of a physician, a clinical pharmacist, and a network analyst. We also based our estimates on the assumption that 60 percent of hospitals do not yet have programs that implement all of the CDC core elements (based on data from the 2015 NHSN survey). Based on these assumptions, the total annual cost for a hospital to establish and maintain an antibiotic stewardship program would be \$100,900 ($(\$187 \times 0.10 \times 2,000 \text{ hours per year} = \$37,400 \text{ for a physician}) + (\$113 \times 0.25 \times 2,000 \text{ hours per year} = \$56,500 \text{ for a clinical pharmacist}) + (\$70 \text{ per hour} \times 0.05 \times 2,000 \text{ hour per year}$

³ We invite data that would allow for quantification of the rule's impacts on HAIs other than CDI.

= \$7,000 for a network data analyst)). The total annual labor cost for 60 percent of hospitals ($\$100,900 \times 2,940$) would be approximately \$297 million.

As shown above, however, we estimate that the drug cost savings of implementing and maintaining IC/AS programs would be \$520.4 million. For hospitals to not have voluntarily implemented such programs indicates that their costs are at least as great as their savings; therefore, either labor costs are underestimated at \$297 million or there are non-labor costs involved in the implementation and maintenance of IC/AS programs. We therefore estimate \$520.4 million as a lower bound on the costs associated with this provision of the proposed rule. Moreover, as discussed previously, non-drug cost savings may also accrue to hospitals; if so, then lack of voluntary implementation indicates that costs associated with this provision would be at least \$1.0 billion. We invite public comment regarding the amount by which costs exceed savings in cases of non-voluntary IC/AS program adoption.

Ordering Privileges for Qualified Dietitians (RDs) and Qualified Nutrition Professionals (Provision of Services § 485.635)

We propose to revise the CAH requirements at 42 CFR 485.635(a)(3)(vii), which currently requires that the nutritional needs of inpatients are met in accordance with recognized dietary practices and the orders of the practitioner responsible for the care of the patients. Specifically, we are proposing revisions that would change the CMS requirements to allow for flexibility in this area by requiring that all patient diets, including therapeutic diets, must be ordered by a practitioner responsible for the care of the patient, or by a qualified dietitian or qualified nutrition professional as authorized by the medical staff in accordance with State law governing dietitians and nutrition professionals.

With these proposed changes to the current requirements, a CAH would have the regulatory flexibility to grant qualified dietitians/nutrition professionals specific dietary ordering privileges (including the capacity to order specific laboratory tests to monitor nutritional interventions and then modify those interventions as needed). We believe that this is another area of change to the requirements that might produce savings since our proposal would allow physicians to delegate to a qualified dietitian or qualified nutrition professional the task of prescribing patient diets, including therapeutic diets, to the extent allowed by state law.

We further believe that dietitians or other clinically qualified nutrition professionals are already performing patient dietary assessments and making dietary recommendations to the physician (or PA or APRN) who then evaluates the recommendations and writes orders to implement them. Our analysis does not take into account improved quality of life nor improved clinical outcomes for the patient. We do not currently have data to more precisely estimate the savings that this proposed revision could produce in CAHs. We welcome commenters to provide data that might assist in a more precise estimate. However, we believe that it might allow for better use of both physician/PA/APRN and dietitian/nutrition professional time and could result in improved quality of life and improved clinical outcomes for CAH patients.

More obviously, dietitians/nutrition professionals with ordering privileges would be able to provide dietary/nutritional services at lower costs than physicians (as well as APRNs and PAs, two categories of non-physician practitioners that have traditionally also devised and written patient dietary plans and orders). This cost savings stems in some part from significant differences in the average salaries between the professions and the time savings achieved by allowing dietitians/nutrition professionals to autonomously plan, order, monitor, and modify services as needed and in a more complete and timely manner than they are currently allowed. Savings would be realized by CAHs through the physician/APRN/PA time and salaries saved.

Physicians, APRNs, and PAs often lack the training and educational background to manage the nutritional needs of patients with the same efficiency and skill as dietitians/nutrition professionals. The addition of ordering privileges enhances the ability that dietitians/nutrition professionals already have to provide timely, cost-effective, and evidence-based nutrition services as the recognized nutrition experts on a CAH interdisciplinary team.

It might seem natural to calculate these cost savings for CAHs based on the following assumptions:

- There is an average hourly cost difference of \$70 between dietitians/nutrition professionals on one side (\$56 per hour) and the hourly cost average for physicians, APRNs, and PAs (\$126 per hour) on the other;
- There were 282,584 inpatient visits by Medicare beneficiaries in 2011 (According to a December 2013 OIG

report (<http://oig.hhs.gov/oei/reports/oei-05-12-00081.pdf>) with each of these stays requiring at least one dietary plan and orders;

- On average, each dietary order, including ordering and monitoring of laboratory tests, subsequent modifications to orders, and dietary orders for discharge/transfer/outpatient follow-up as needed, will take 30 minutes (0.5 hours) of a physician's/APRN's/PA's/dietitian's/nutrition professional's time per patient during an average stay; and

- We estimate that approximately 50 percent of CAHs (or approximately 650 CAHs) have not already granted ordering privileges to dietitians and nutrition professionals, reducing the number of total number of CAH inpatient stays to 141,292.

The resulting savings would be \$7,608 annually on average for each CAH (141,292 inpatient hospital stays \times 0.50 hours of a physician's/APRN's/PA's/dietitian's/nutrition professional's time \times \$70 per hourly cost difference \div 650 CAHs) for a total annual savings of approximately \$5 million. We note that these estimates exclude some categories of cost increases (for example, internal CAH meetings to plan changes and the time and other costs of training physicians, dietitians/nutrition professionals, and other staff on the new dietary ordering procedures). Even more importantly, this estimate does not account for barriers, other than federal regulation, to RDs receiving ordering privileges; Weil et al. (2008) provide evidence on the existence of such barriers, which would likely prevent at least some of these cost savings from being realized.⁴ If such barriers are not relevant, then there is another adjustment that would need to be made to the calculation. Specifically, the dietitian wage estimate would need to be revised because the May 2014 wage data do not account for the increase in demand for dietitians we projected would result from the hospital burden reduction rule finalized that same month. For the savings estimates accompanying that rule to be achieved would require at least 6.7 percent of the dietitian FTEs in the U.S. to be newly allocated to providing nutrition services to hospital patients.⁵ This shift in

⁴ Weil, Sharon D., et al. "Registered Dietitian Prescriptive Practices in Hospitals." *Journal of the American Dietetic Association* 108:1688–1692. October 2008.

⁵ BLS data show employment of 59,490 dietitians, with a mean hourly wage of \$27.62. Assuming all dietitians are employed full-time (2,080 hours annually) yields a total sector value of \$3.4 billion, or \$6.8 billion when doubled to account for fringe benefits and overhead. For the May, 2014, final

activity entails a substantial movement along the supply curve for dietitian labor, thus raising the dietitian wage and reducing the cost savings estimated with the method outlined. For these reasons, as well as our lack of data on CAH outpatient visits for nutritional services and the impact that the proposed regulatory changes might have on hospital costs in this area, we present the \$10 million estimate for discussion purposes only and do not include it in the summary estimates of costs and cost savings attributable to the proposed rule.

§ 485.640 Condition of participation: Infection prevention and control and antibiotic stewardship programs

As we proposed for hospitals, we are also proposing new infection prevention and control and antibiotic stewardship requirements for CAHs. The infection control requirements for CAHs have remained unchanged since 1997. We are adding a new infection prevention and control (as well as antibiotic stewardship) CoP for CAHs because the existing standards for infection control do not reflect the current nationally recognized practices for the prevention and elimination of healthcare-associated infections.

Infection Prevention and Control

Each CAH would be required to review their current infection control program and compare it to the new requirements contained in this section. After performing this comparison, each CAH would be required to revise their program so that it complied with the requirements in this section. Based on our experience with CAHs, we believe that a physician and a nurse on the infection control team would conduct this review and revision of the program. We believe both the physician and the nurse would spend 16 hours each for a total of 32 hours. Physicians earn an average of \$187 an hour. Nurses earn an average salary of \$68 an hour. Thus, to ensure their infection control program complied with the requirements in this section, we estimate that each CAH would require 32 burden hours (16 hours for a physician and 16 hours for a nurse = 32 burden hours) at a cost of \$4,080 (\$2,992 (\$187 an hour for a physician \times 16 burden hours = \$2,992) + \$1,088 (\$68 an hour for a nurse \times 16

rule, we estimated \$459 million of loaded wage savings associated with dietary ordering switching from physicians, nurse practitioners and physician assistants to lower-paid dietitians. Thus the relevant portion of the savings estimate equals roughly 6.7 percent (= \$459 million \div \$6.8 billion) of the sector as a whole—and would exceed 6.7 percent, to the extent that some current dietitian positions are part-time.

burden hours = \$1,088) = \$4,080 estimated cost). Based on the estimate, for all 1,300 CAHs, complying with this requirement would require 41,600 burden hours (32 hours for each CAH \times 1,300 CAHs = 41,600 burden hours) at a one-time cost of approximately \$5 million (\$4,080 for each CAH \times 1,300 CAHs = \$5,304,000 estimated cost).

Antibiotic Stewardship

Similarly, we believe that the proposed requirements for a CAH to have an active antibiotic stewardship program, and for its organization and policies, would constitute additional regulatory burden. However, we believe that the burden of implementing and maintaining an AS program includes the salaries of the qualified personnel needed to establish and manage such a CAH program. Our review of the literature, consultations with CDC, and experience with CAHs suggests that the establishment and maintenance of a CAH antibiotic stewardship program as proposed here, for a statutorily mandated 25-bed CAH, would require the services of a physician (preferably an infectious disease physician or physician with training in antibiotic stewardship) and a clinical pharmacist (preferably with training in infectious diseases or antibiotic stewardship), and also a network data analyst at the following proportions of full-time employee salaries respectively: 0.05, 0.10, and 0.025. We believe that these personnel costs would constitute a real burden for these proposed requirements. To determine the cost of this burden, we have added the proportion of full-time salaries required of a physician, a clinical pharmacist, and a network analyst. Based on these assumptions, the total annual cost for a CAH to establish and maintain an antibiotic stewardship program would be \$44,800 ($(\$187 \text{ per hour} \times 0.05 \times 2,000 \text{ hours per year} = \$18,700 \text{ for a physician}) + (\$113 \text{ per hour} \times 0.10 \times 2,000 \text{ hours per year} = \$22,600 \text{ for a clinical pharmacist}) + (\$70 \text{ per hour} \times 0.025 \times 2,000 \text{ hours per year} = \$3,500 \text{ for a network data analyst})$). According to CDC, 97 of 397 (or approximately 24 percent) of hospitals with fewer than 25 beds reported having an AS program that meets all of the CDC's core elements. However, we have no way of determining from the data how many of these less-than-25-bed hospitals are actually CAHs. For the purposes of this burden estimate, we assume that 24 percent of the total 1,328 CAHs (or approximately 319 CAHs) have already implemented an AS program. Therefore, 1,009 CAHs have not implemented an AS program. The total annual cost for these CAHs

($\times 1,009$) would be approximately \$45 million.

However, we believe that the estimated costs of an AS program would be somewhat offset by the savings that a CAH would achieve through such a program. The most obvious savings would be from decreased inappropriate antibiotic use leading to overall decreased drug costs for a CAH. Our review of the literature showed significant savings in this area, with annual savings proportional to bed size of the hospital. Reported annual savings ranged from \$27,917 for a 12-bed medical/surgical intensive care unit to \$2.1 million for an 880-bed academic medical center. We specifically note the \$177,000 in annual drug cost savings achieved by a 120-bed community hospital with its AS program (LaRocco 2003, CID "Concurrent antibiotic review programs—a role for infectious diseases specialists at small community CAHs") and would use that as the basis to calculate average annual cost savings for a 25-bed CAH ($\$177,000 \text{ annual savings} \div 120 \text{ beds} = \$1,475 \text{ annual cost savings per bed}$) at \$36,875 per CAH ($\$1,475 \text{ annual cost savings} \times 25 \text{ beds}$). Using this assumption, we believe that the annual drug cost savings for 1,009 CAHs under this proposed rule would be approximately \$37 million ($1,009 \text{ CAHs} \times \$36,875 \text{ in drug cost savings}$).

In addition to these savings, we also believe that the proposed requirement for an AS program would assist CAHs in significantly reducing rates of CDI and the attendant costs. Based on an AS program model developed by the CDC, a CAH combined IC/AS program with an average effectiveness rate of 50 percent would reduce the number of CDIs among Medicare beneficiaries annually by 101,000. However, we do not have a reliable means to distinguish this cost savings for CAHs from the cost savings for hospitals that we have already calculated.

2. Effects on Small Entities

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, we estimate that the great majority of the providers that would be affected by CMS rules are small entities as that term is used in the RFA. The great majority of hospitals and most other healthcare providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business. Accordingly, the usual practice of HHS is to treat all providers and suppliers as

small entities in analyzing the effects of our rules.

This proposed rule would cost affected entities approximately \$0.6 to 1.1 billion a year, largely, but not entirely, offset by savings. While this is a large amount in total, the average cost per affected hospital is less than one half million dollars per year. Although the overall magnitude of the paperwork, staffing, and related cost reductions to hospitals and CAHs under this rule is economically significant, these savings are likely to be a fraction of one percent of total hospital costs. Total national inpatient hospital spending is approximately nine hundred billion dollars a year, or an average of about \$150 million per hospital, and our primary estimate of the net (though possibly not the gross) effect of these proposals on increasing hospital costs is less than \$1 billion annually.

Under HHS guidelines for RFA, actions that do not negatively affect costs or revenues by more than 3 percent a year are not economically significant. We believe that no hospitals of any size will be negatively affected to this degree. Accordingly, we have determined that this proposed rule would not have a significant economic impact on a substantial number of small entities, and certify that an Initial RFA is not required. Notwithstanding this conclusion, we believe that this RIA and the preamble as a whole meet the requirements of the RFA for such an analysis.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. For the preceding reasons, we have determined that this proposed rule will lead to net savings and will therefore not have a significant negative impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2016, that is approximately \$144 million. This proposed rule does not contain any mandates.

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule (and subsequent final rule) that would impose substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This rule would not have a substantial direct effect on State or local governments, preempt States, or otherwise have a Federalism implication.

D. Alternatives Considered

As we stated, CMS is aware, through conversations with stakeholders and federal partners, and as a result of internal evaluation and research, of outstanding concerns about the CoPs for hospitals and CAHs, despite recent

revisions. This subset of the universe of standards is the focus of this proposed rule.

One alternative we did consider was combining the infection prevention and control leader position with that of the antibiotic stewardship leader position. While this would certainly reduce the costs for hospitals by eliminating one of these positions, we also believe that it might reduce the overall effectiveness of the program and, thus, the overall societal benefits that might be achieved. The skills needed to lead each program are different. Infection prevention programs are often led by nursing staff who do not prescribe antibiotics. Antibiotic stewardship programs are led by physicians and pharmacists who have direct knowledge and experience with antibiotic prescribing. For these

reasons, we decided to propose the requirement as it is contained in this rule.

For all of the proposed provisions, we considered not making these changes. Ultimately, based on our analysis of these issues and for the reasons stated in this preamble, we believe that it is best to propose changes at this time. We welcome comments on whether we properly selected the best candidates for change, and welcome suggestions for additional reform candidates from the entire body of CoPs.

E. Accounting Statement and Table

As required by OMB Circular A-4 (available at <http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf>), we have prepared an accounting statement.

TABLE 2—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED COSTS AND BENEFITS
[\$ In millions]

Category	Estimates	Units		
		Year dollar	Discount rate	Period covered
Benefits				
Annualized	1,057	2015	7%	2016–2020
Monetized (\$million/year)	1,057	2015	3%	2016–2020
Qualitative	Potential Reductions in morbidity and mortality for hospital and CAH patients			
Costs *				
Annualized	748 to 1,248	2015	7%	2016–2020
Monetized (\$million/year)	748 to 1,248	2015	3%	2016–2020

F. Conclusion

The impact of this proposed rule lies primarily with the estimated costs (approximately \$773 million to \$1.1 billion) of revising the hospital and CAH infection control CoPs, including the new requirements for antibiotic stewardship programs. However, these costs may be more than offset by the savings, and the overall benefits to patients, that would be achieved with these changes (net savings to society of up to \$284 million). The analysis, together with the remainder of this preamble, provides a Regulatory Impact Analysis and an Initial Regulatory Flexibility Analysis.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 482

Grant programs—health, Hospitals, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 485

Grant programs—health, Health facilities, Medicaid, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

■ 1. The authority citation for part 482 continues to read as follows:

Authority: Secs. 1102, 1871 and 1881 of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr), unless otherwise noted.

■ 2. Section 482.13 is amended by revising paragraphs (d)(2), (e)(5), (e)(8)(ii), (e)(10), (e)(11), (e)(12)(i), (e)(14), and (g)(4)(ii) and by adding paragraph (i) to read as follows:

§ 482.13 Condition of participation: Patient's rights.

* * * * *

(d) * * *

(2) The patient has the right to access their 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, including current medical 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.

(e) * * *

(5) The use of restraint or seclusion must be in accordance with the order of a physician or other licensed 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.

* * * * *

(8) * * *

(ii) After 24 hours, before writing a new order for the use of restraint or seclusion for the management of violent or self-destructive behavior, a physician or other licensed 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.

* * * * *

(10) The condition of the patient who is restrained or secluded must be monitored by a physician, other licensed practitioner, or trained staff that have completed the training criteria specified in paragraph (f) of this section at an interval determined by hospital policy.

(11) Physician and other licensed practitioner training requirements must be specified in hospital policy. At a minimum, physicians and other licensed practitioners authorized to order restraint or seclusion by hospital policy in accordance with State law must have a working knowledge of hospital policy regarding the use of restraint or seclusion.

(12) * * *

(i) By a—

(A) Physician or other licensed practitioner.

(B) Registered nurse who has been trained in accordance with the requirements specified in paragraph (f) of this section.

* * * * *

(14) If the face-to-face evaluation specified in paragraph (e)(12) of this section is conducted by a trained registered nurse, the trained registered nurse must consult the attending physician or other licensed practitioner who is responsible for the care of the patient as soon as possible after the completion of the 1-hour face-to-face evaluation.

* * * * *

(g) * * *

(4) * * *

(ii) Each entry must document the patient's name, date of birth, date of death, name of attending physician or other licensed practitioner who is

responsible for the care of the patient, medical record number, and primary diagnosis(es).

* * * * *

(i) *Standard: Non-discrimination.* A hospital must meet the following requirements:

(1) Not discriminate on the basis of race, color, religion, national origin, sex (including gender identity), sexual orientation, age, or disability.

(2) 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.

(3) 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 and how to file a complaint if they encounter discrimination when he or she is informed of his or her other rights under this section.

■ 3. Section 482.21 is amended by revising paragraph (b)(1) to read as follows:

§ 482.21 Condition of participation: Quality assessment and performance improvement program.

* * * * *

(b) * * *

(1) The program must incorporate quality indicator data including patient care data, and other relevant data such as data submitted to or received from Medicare quality reporting and quality performance programs, including but not limited to data related to hospital readmissions and hospital-acquired conditions.

* * * * *

■ 4. Section 482.23 is amended by revising paragraphs (b) introductory text, (b)(4) and (6), (c)(1) introductory text, and (c)(3), and by adding paragraph (b)(7) to read as follows:

§ 482.23 Condition of participation: Nursing services.

* * * * *

(b) *Standard: Staffing and delivery of care.* The nursing service must 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 personnel for each department or nursing unit to ensure, when needed, the immediate availability of a registered nurse for the care of any patient.

* * * * *

(4) The hospital must ensure that the nursing staff develops, and keeps current for each patient, a nursing care

plan that reflects the patient's goals and the nursing care to be provided to meet the patient's needs. The nursing care plan may be part of an interdisciplinary care plan.

* * * * *

(6) All licensed nurses who provide services in the hospital must adhere to the policies and procedures of the hospital. The director of nursing service must provide for the adequate supervision and evaluation of the clinical activities of all nursing personnel which occur within the responsibility of the nursing service, regardless of the mechanism through which those personnel are providing services (that is, hospital employee, contract, lease, other agreement, or volunteer).

(7) The hospital must have policies and procedures in place establishing which outpatient departments, if any, are not required under hospital policy to have a registered nurse present. The policies and procedures must:

(i) Establish the criteria such outpatient departments must meet, taking into account the types of services delivered, the general level of acuity of patients served by the department, and the established standards of practice for the services delivered;

(ii) Establish alternative staffing plans;

(iii) Be approved by the medical staff;

(iv) Be reviewed at least once every three years.

(c) * * *

(1) Drugs and biologicals must be prepared and administered in accordance with Federal and State laws, the orders of the practitioner or practitioners responsible for the patient's care, and accepted standards of practice.

* * * * *

(3) With the exception of influenza and pneumococcal vaccines, which may be administered per physician-approved hospital policy after an assessment of contraindications, orders for drugs and biologicals must be documented and signed by a practitioner who is authorized to write orders in accordance with State law and hospital policy, and who is responsible for the care of the patient.

(i) If verbal orders are used, they are to be used infrequently.

(ii) When verbal orders are used, they must only be accepted by persons who are authorized to do so by hospital policy and procedures consistent with Federal and State law.

(iii) Orders for drugs and biologicals may be documented and signed by other practitioners only if such practitioners are acting in accordance with State law,

including scope-of-practice laws, hospital policies, and medical staff bylaws, rules, and regulations.

* * * *

■ 5. Section 482.24 is amended by revising paragraphs (c) introductory text and (c)(4)(ii), (iv), (vi), (vii), and (viii) to read as follows:

§ 482.24 Condition of participation: Medical record services.

* * * *

(c) *Standard: Content of record.* The medical record must 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.

* * * *

(4) * * *

(ii) All diagnoses specific to each inpatient stay and outpatient visit.

* * * *

(iv) Documentation of complications, hospital-acquired conditions, healthcare-associated infections, and adverse reactions to drugs and anesthesia.

* * * *

(vi) 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.

(vii) 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.

(viii) Final diagnoses with completion of medical records within 30 days following all inpatient stays, and within 7 days following all outpatient visits.

■ 6. Section 482.27 is amended by revising paragraph (b)(7) and removing paragraph (b)(11) to read as follows:

§ 482.27 Condition of participation: Laboratory services.

* * * *

(b) * * *

(7) *Timeframe for notification.* For notifications resulting from donors tested on or after February 20, 2008 as set forth at 21 CFR 610.46 and 610.47 the notification effort begins when the blood collecting establishment notifies the hospital that it received potentially

HIV or HCV infectious blood and blood components. The hospital must make reasonable attempts to give notification over a period of 12 weeks unless—

(i) The patient is located and notified; or

(ii) The hospital is unable to locate the patient and documents in the patient's medical record the extenuating circumstances beyond the hospital's control that caused the notification timeframe to exceed 12 weeks.

* * * *

■ 7. Section 482.42 is revised to read as follows:

§ 482.42 Condition of participation: Infection prevention and control and antibiotic stewardship programs.

The hospital must have active hospital-wide programs for the surveillance, prevention, and control of HAIs and other infectious diseases, and for the optimization of antibiotic use through stewardship. The programs must demonstrate adherence to nationally recognized infection prevention and control guidelines, as well as best practices for improving antibiotic use, where applicable, for reducing the development and transmission of HAIs and antibiotic-resistant organisms. Infection prevention and control problems and antibiotic use issues identified in the programs must be addressed in collaboration with the hospital-wide quality assessment and performance improvement (QAPI) program.

(a) *Standard: Infection prevention and control program organization and policies.* The hospital must ensure all of the following:

(1) An individual (or individuals), who are qualified through education, training, experience, or certification in infection prevention and control, are appointed by the governing body as the infection preventionist(s)/infection control professional(s) responsible for the infection prevention and control program and that the appointment is based on the recommendations of medical staff leadership and nursing leadership.

(2) The hospital infection prevention and control program, as documented in its policies and procedures, employs methods for preventing and controlling the transmission of infections within the hospital and between the hospital and other institutions and settings.

(3) The infection prevention and control program includes surveillance, prevention, and control of HAIs, including maintaining a clean and sanitary environment to avoid sources and transmission of infection, and

addresses any infection control issues identified by public health authorities.

(4) The infection prevention and control program reflects the scope and complexity of the hospital services provided.

(b) *Standard: Antibiotic stewardship program organization and policies.* The hospital must ensure all of the following:

(1) An individual, who is qualified through education, training, or experience in infectious diseases and/or antibiotic stewardship, is appointed by the governing body as the leader of the antibiotic stewardship program and that the appointment is based on the recommendations of medical staff leadership and pharmacy leadership.

(2) An active hospital-wide antibiotic stewardship program must:

(i) Demonstrate coordination among all components of the hospital responsible for antibiotic use and resistance, including, but not limited to, the infection prevention and control program, the QAPI program, the medical staff, nursing services, and pharmacy services.

(ii) Document the evidence-based use of antibiotics in all departments and services of the hospital.

(iii) Demonstrate improvements, including sustained improvements, in proper antibiotic use, such as through reductions in CDI and antibiotic resistance in all departments and services of the hospital.

(3) The antibiotic stewardship program adheres to nationally recognized guidelines, as well as best practices, for improving antibiotic use.

(4) The antibiotic stewardship program reflects the scope and complexity of the hospital services provided.

(c) *Standard: Leadership responsibilities.* (1) The governing body must ensure all of the following:

(i) Systems are in place and operational for the tracking of all infection surveillance, prevention, and control, and antibiotic use activities, in order to demonstrate the implementation, success, and sustainability of such activities.

(ii) All HAIs and other infectious diseases identified by the infection prevention and control program as well as antibiotic use issues identified by the antibiotic stewardship program are addressed in collaboration with hospital QAPI leadership.

(2) The infection preventionist(s)/infection control professional(s) are responsible for:

(i) The development and implementation of hospital-wide infection surveillance, prevention, and

control policies and procedures that adhere to nationally recognized guidelines.

(ii) All documentation, written or electronic, of the infection prevention and control program and its surveillance, prevention, and control activities.

(iii) Communication and collaboration with the hospital's QAPI program on infection prevention and control issues.

(iv) Competency-based training and education of hospital personnel and staff, including medical staff, and, as applicable, personnel providing contracted services in the hospital, on the practical applications of infection prevention and control guidelines, policies, and procedures.

(v) The prevention and control of HAIs, including auditing of adherence to infection prevention and control policies and procedures by hospital personnel.

(vi) Communication and collaboration with the antibiotic stewardship program.

(3) The leader of the antibiotic stewardship program is responsible for:

(i) The development and implementation of a hospital-wide antibiotic stewardship program, based on nationally recognized guidelines, to monitor and improve the use of antibiotics.

(ii) All documentation, written or electronic, of antibiotic stewardship program activities.

(iii) Communication and collaboration with medical staff, nursing, and pharmacy leadership, as well as the hospital's infection prevention and control and QAPI programs, on antibiotic use issues.

(iv) Competency-based training and education of hospital personnel and staff, including medical staff, and, as applicable, personnel providing contracted services in the hospital, on the practical applications of antibiotic stewardship guidelines, policies, and procedures.

■ 8. Section 482.58 is amended by revising paragraph (b)(6) to read as follows:

§ 482.58 Special requirements for hospital providers of long-term care services ("swing-beds").

* * * * *

(b) * * *

(6) Discharge summary (§ 483.20(l)).

* * * * *

PART 485—CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS

■ 9. The authority citation for part 485 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395(hh)).

§ 485.627 [Amended]

■ 10. Section 485.627 is amended by removing paragraph (b)(1) and redesignating paragraphs (b)(2) and (3) as paragraphs (b)(1) and (2), respectively.

■ 11. Section 485.631 is amended by adding paragraph (d) to read as follows:

§ 485.631 Condition of participation: Staffing and staff responsibilities.

* * * * *

(d) *Standard: Periodic review of clinical privileges and performance.* The CAH requires that—

(1) The quality and appropriateness of the diagnosis and treatment furnished by nurse practitioners, clinical nurse specialist, and physician assistants at the CAH are evaluated by a member of the CAH staff who is a doctor of medicine or osteopathy or by another doctor of medicine or osteopathy under contract with the CAH.

(2) The quality and appropriateness of the diagnosis and treatment furnished by doctors of medicine or osteopathy at the CAH are evaluated by—

(i) One hospital that is a member of the network, when applicable;

(ii) One Quality Improvement Organization (QIO) or equivalent entity;

(iii) One other appropriate and qualified entity identified in the State rural health care plan;

(iv) In the case of distant-site physicians and practitioners providing telemedicine services to the CAH's patient under an agreement between the CAH and a distant-site hospital, the distant-site hospital; or

(v) In the case of distant-site physicians and practitioners providing telemedicine services to the CAH's patients under a written agreement between the CAH and a distant-site telemedicine entity, one of the entities listed in paragraphs (d)(2)(i) through (iii) of this section.

(3) The CAH staff consider the findings of the evaluation and make the necessary changes as specified in paragraphs (b) through (d) of this section.

■ 12. Section 485.635 is amended by removing paragraph (a)(3)(vi), redesignating paragraph (a)(3)(vii) as paragraph (a)(3)(vi), revising newly designated paragraph (a)(3)(vi), and adding paragraph (g) to read as follows:

§ 485.635 Condition of participation: Provision of services.

(a) * * *

(3) * * *

(vi) Procedures that ensure that the nutritional needs of inpatients are met

in accordance with recognized dietary practices. All patient diets, including therapeutic diets, must be ordered by the practitioner responsible for the care of the patients or by a qualified dietitian or qualified nutrition professional as authorized by the medical staff in accordance with State law governing dietitians and nutrition professionals and that the requirement of § 483.25(i) of this chapter is met with respect to inpatients receiving post CAH SNF care.

* * * * *

(g) *Standard: Non-discrimination.* A CAH must meet the following requirements:

(1) Not discriminate on the basis of race, color, religion, national origin, sex (including gender identity), sexual orientation, age, or disability.

(2) 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.

(3) 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 and how to file a complaint if they encounter discrimination.

■ 13. Add § 485.640 to read as follows:

§ 485.640 Condition of participation: Infection prevention and control and antibiotic stewardship programs.

The CAH must have active facility-wide programs, for the surveillance, prevention, and control of HAIs and other infectious diseases and for the optimization of antibiotic use through stewardship. The programs must demonstrate adherence to nationally recognized infection prevention and control guidelines, as well as best practices for improving antibiotic use, where applicable, for reducing the development and transmission of HAIs and antibiotic-resistant organisms. Infection prevention and control problems and antibiotic use issues identified in the programs must be addressed in coordination with the facility-wide quality assessment and performance improvement (QAPI) program.

(a) *Standard: Infection prevention and control program organization and policies.* The CAH must ensure all of the following:

(1) An individual (or individuals), who are qualified through education, training, experience, or certification in infection prevention and control, are appointed by the governing body, or responsible individual, as the infection preventionist(s)/infection control professional(s) responsible for the

infection prevention and control program and that the appointment is based on the recommendations of medical staff leadership and nursing leadership.

(2) The infection prevention and control program, as documented in its policies and procedures, employs methods for preventing and controlling the transmission of infections within the CAH and between the CAH and other healthcare settings.

(3) The infection prevention and control includes surveillance, prevention, and control of HAIs, including maintaining a clean and sanitary environment to avoid sources and transmission of infection, and that the program also addresses any infection control issues identified by public health authorities.

(4) The infection prevention and control program reflects the scope and complexity of the CAH services provided.

(b) *Standard: Antibiotic stewardship program organization and policies.* The CAH must ensure that:

(1) An individual, who is qualified through education, training, or experience in infectious diseases and/or antibiotic stewardship, is appointed by the governing body, or responsible individual, as the leader of the antibiotic stewardship program and that the appointment is based on the recommendations of medical staff leadership and pharmacy leadership.

(2) An active facility-wide antibiotic stewardship program must:

(i) Demonstrate coordination among all components of the CAH responsible for antibiotic use and resistance, including, but not limited to, the infection prevention and control program, the QAPI program, the medical staff, nursing services, and pharmacy services.

(ii) Document the evidence-based use of antibiotics in all departments and services of the CAH.

(iii) Demonstrate improvements, including sustained improvements, in proper antibiotic use, such as through reductions in CDI and antibiotic resistance in all departments and services of the CAH.

(3) The antibiotic stewardship program adheres to nationally recognized guidelines, as well as best practices, for improving antibiotic use.

(4) The antibiotic stewardship program reflects the scope and complexity of the CAH services provided.

(c) *Standard: Leadership responsibilities.* (1) The governing body, or responsible individual, must ensure all of the following:

(i) Systems are in place and operational for the tracking of all infection surveillance, prevention and control, and antibiotic use activities, in order to demonstrate the implementation, success, and sustainability of such activities.

(ii) All HAIs and other infectious diseases identified by the infection prevention and control program as well as antibiotic use issues identified by the antibiotic stewardship program are addressed in collaboration with the CAH's QAPI leadership.

(2) The infection prevention and control professional(s) are responsible for:

(i) The development and implementation of facility-wide infection surveillance, prevention, and control policies and procedures that adhere to nationally recognized guidelines.

(ii) All documentation, written or electronic, of the infection prevention and control program and its surveillance, prevention, and control activities.

(iii) Communication and collaboration with the CAH's QAPI program on infection prevention and control issues.

(iv) Competency-based training and education of CAH personnel and staff, including medical staff, and, as applicable, personnel providing contracted services in the CAH, on the practical applications of infection prevention and control guidelines, policies and procedures.

(v) The prevention and control of HAIs, including auditing of adherence to infection prevention and control policies and procedures by CAH personnel.

(vi) Communication and collaboration with the antibiotic stewardship program.

(3) The leader of the antibiotic stewardship program is responsible for:

(i) The development and implementation of a facility-wide antibiotic stewardship program, based on nationally recognized guidelines, to monitor and improve the use of antibiotics.

(ii) All documentation, written or electronic, of antibiotic stewardship program activities.

(iii) Communication and collaboration with medical staff, nursing, and pharmacy leadership, as well as the CAH's infection prevention and control and QAPI programs, on antibiotic use issues.

(iv) Competency-based training and education of CAH personnel and staff, including medical staff, and, as applicable, personnel providing contracted services in the CAHs, on the

practical applications of antibiotic stewardship guidelines, policies, and procedures.

■ 14. Section 485.641 is revised to read as follows:

§ 485.641 Condition of participation: Quality assessment and performance improvement program.

The CAH must develop, implement, and maintain an effective, ongoing, CAH-wide, data-driven quality assessment and performance improvement (QAPI) program. The CAH must maintain and demonstrate evidence of the effectiveness of its QAPI program.

(a) *Definitions.* For the purposes of this section:

Adverse event means an untoward, undesirable, and usually unanticipated event that causes death or serious injury or the risk thereof.

Error means the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim. Errors can include problems in practice, products, procedures, and systems; and

Medical error means an error that occurs in the delivery of healthcare services.

(b) *Standard: QAPI program design and scope.* The CAH's QAPI program must:

(1) Be appropriate for the complexity of the CAH's organization and services provided.

(2) Be ongoing and comprehensive.

(3) Involve all departments of the CAH and services (including those services furnished under contract or arrangement).

(4) Use objective measures to evaluate its organizational processes, functions and services.

(5) Address outcome indicators related to improved health outcomes and the prevention and reduction of medical errors, adverse events, CAH-acquired conditions, and transitions of care, including readmissions.

(c) *Standard: Governance and leadership.* The CAH's governing body or responsible individual is ultimately responsible for the CAH's QAPI program and is responsible and accountable for ensuring that the QAPI program meets the requirements of paragraph (b) of this section and that:

(1) Clear expectations for safety are communicated, implemented, and followed throughout the CAH.

(2) The QAPI efforts address priorities for improved quality of care and patient safety.

(3) All improvement actions are evaluated and modified as needed.

(4) Adequate resources are allocated for measuring, assessing, improving,

and sustaining the CAH's performance and reducing risk to patients.

(5) The determination of the number of distinct improvement projects is made annually.

(6) The CAH develops and implements policies and procedures for QAPI that address what actions the CAH staff should take to prevent and report unsafe patient care practices, medical errors, and adverse events.

(d) *Standard: Program activities.* For each of the areas listed in paragraph (b) and (c) of this section, the CAH must:

(1) Focus on measures related to improved health outcomes that are shown to be predictive of desired patient outcomes.

(2) Use the measures to analyze and track its performance.

(3) Set priorities for performance improvement, considering either high-volume, high-risk services, or problem-prone areas.

(e) *Performance improvement projects.* As part of its QAPI program, the CAH must:

(1) Conduct performance improvement projects. The number and

scope of the distinct improvement projects conducted must be proportional to the scope and complexity of the CAH's services and operations.

(2) The CAH maintains and demonstrates written or electronic evidence and documentation of its QAPI projects.

(f) *Standard: Program data collection and analysis.* (1) The program must incorporate quality indicator data including patient care data, and other relevant data, such as data submitted to or received from national quality reporting and quality performance programs including but not limited to data related to hospital readmissions and hospital-acquired conditions.

(2) The CAH must use the data collected to:

(i) Monitor the effectiveness and safety of services provided and quality of care.

(ii) Identify opportunities for improvement and changes that will lead to improvement.

(3) The frequency and detail of data collection must be approved by the

CAH's governing body or responsible individual.

■ 15. Section 485.645 is amended by revising the introductory text to read as follows:

§ 485.645 Special requirements for CAH providers of long-term care services (“swing-beds”).

A CAH must meet the following requirements in order to be granted an approval from CMS to provide post-CAH SNF care, as specified in § 409.30 of this chapter, and to be paid for SNF-level services, in accordance with paragraph (c) of this section.

* * * * *

Dated: January 28, 2016.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: May 11, 2016.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

[FR Doc. 2016–13925 Filed 6–13–16; 4:15 pm]

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