

POLICY UPDATE

JULY 2016

Editor's note: This is the first in a series of brief updates focusing on current policy issues related to antimicrobial stewardship and antibiotic resistance. This update highlights a number of recent initiatives in the United States to enhance antimicrobial stewardship in hospitals and long-term care facilities. Subsequent updates, to be posted quarterly to CIDRAP's Antimicrobial Stewardship Project website, will focus on other national and international policy issues, including legislation, regulatory initiatives, and national and state activities. We welcome feedback and discussion, as well as suggestions for topics to explore in greater depth. If you have comments or questions please email the CIDRAP ASP staff at asp-cid@umn.edu.

Antimicrobial Stewardship in Hospitals and Long-Term Care Facilities

Several recently announced initiatives, led by federal agencies, collaborative public-private sector groups, and professional organizations, focus on policy changes designed to enhance antimicrobial stewardship in a variety of healthcare settings. In this update, we highlight the following major developments:

- **The Department of Health and Human Services, Centers for Medicare and Medicaid Services** proposed rules that include provisions requiring antibiotic stewardship programs (ASPs) in hospitals and critical access hospitals (June 2016) and long-term care facilities (July 2015) as Conditions of Participation in Medicare and Medicaid.
- **The Joint Commission** issued new Medication Management Standards requiring ASPs for accreditation of hospitals, critical access hospitals, and nursing care centers (June 2016).
- **The National Quality Forum** published detailed recommendations and best practices for ASPs in acute care (May 2016).
- **The Infectious Diseases Society of America and the Society for Healthcare Epidemiology of America** published new evidence-based, voluntary guidelines for implementing and measuring antibiotic stewardship interventions in inpatient populations (April 2016).

Centers for Medicare and Medicaid Services: Proposed Rules

By the end of 2017, two new federal rules are on track to be in effect, requiring, as a Condition of Participation (CoP) in Medicare and Medicaid payment programs, ASPs in hospitals, critical access hospitals, and long-term care and nursing home facilities:

- *Hospital and Critical Access Hospital (CAH) Changes to Promote Innovation, Flexibility and Improvement in Patient Care* ([42 CFR 482 and 485](#)), proposed rule published Jun 16, 2016.
- *Reform of Requirements for Long-Term Care Facilities* ([42 CFR Parts 405, 431, 447, et al.](#)), proposed rule published Jul 16, 2015.

Proposed rules from the Centers for Medicare and Medicaid Services (CMS) represent the first national regulatory requirements designed to optimize the use of antibiotics through ASPs. The Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB) [2016 report](#) noted that CMS's proposed rules will be important drivers for antibiotic stewardship in non-federal inpatient settings and long-term care facilities. CMS's proposed rules would be the first to create a strong incentive to establish ASPs nationwide under expert leadership and to monitor antibiotic usage.

According to findings from the largest national assessment of ASPs in the United States, the 2014 National Healthcare Safety Network Annual Hospital Survey, fewer than 40% of US hospitals reported having an ASP that implemented all seven of the core elements of hospital ASPs, as defined by the Centers for Disease Control and Prevention (CDC) ([Pollack et al. 2016](#); [CDC 2014](#)). These seven elements are outlined in Table 1. Recent national advisory committees have focused on the need for incentives, particularly from reimbursement or credentialing agencies, to stimulate the widespread implementation of hospital ASPs at a pace sufficient to address the growing crisis of antibiotic resistance ([Bartlett et al. 2013](#)).

Leadership Commitment	Dedicating necessary human, financial, and information technology resources
Accountability	Appointing a single leader responsible for program outcomes (experience with successful programs demonstrates that a physician leader is effective)
Drug Expertise	Appointing a single pharmacist leader responsible for working to improve antibiotic use
Action	Implementing at least one recommended action, such as systemic evaluation of ongoing treatment need after a set period of initial treatment (ie, “antibiotic time out” after 48 hours)
Tracking	Monitoring antibiotic prescribing and resistance patterns
Reporting	Regular reporting of information on antibiotic use and resistance (to doctors, nurses, and relevant staff)
Education	Educating clinicians about resistance and optimal prescribing
<i>Source: CDC. Core elements of hospital antibiotic stewardship programs. Atlanta GA, 2014.</i>	

The President’s Council of Advisors on Science and Technology (PCAST) [2014 report](#) recommended that CMS use reimbursement incentives to drive ASP development in hospitals and long-term care facilities, specifying that “by the end of 2017, CMS should have Federal regulations (Conditions of Participation) in place that will require US hospitals, critical access hospitals, and long-term care and nursing home facilities to develop and implement robust antibiotic stewardship programs that adhere to best practices.” The 2014 [National Strategy for Combating Antibiotic-Resistant Bacteria](#), further highlighted the goal of strengthening antibiotic stewardship in inpatient, outpatient, and long-term care settings by expanding existing programs, developing new ones, and monitoring progress and efficacy.

The President’s 2014 [Executive Order 13676](#), *Combating Antibiotic-Resistant Bacteria*, called for the federal government to improve antibiotic stewardship through the following actions: “By the end of calendar year 2016, HHS shall review existing regulations and propose new regulations or other actions, as appropriate, that require hospitals and other inpatient healthcare delivery facilities to implement robust antibiotic stewardship programs that adhere to best practices, such as those identified by the CDC... [and] shall, as appropriate, define, promulgate, and implement stewardship programs in other healthcare settings, including office-based practices, outpatient settings, emergency departments, and institutional and long-term care facilities such as nursing homes, pharmacies, and correctional facilities.”

The 2015 [National Action Plan for Combating Antibiotic-Resistant Bacteria](#) set a 3-year milestone on this goal with the following objective: “All hospitals that participate in Medicare and Medicaid programs must comply with Conditions of Participation (CoP). The Centers for Medicare & Medicaid Services (CMS) will issue new CoPs or revise current CoP Interpretive Guidelines to advance compliance with recommendations in CDC’s Core Elements of Hospital Antibiotic Stewardship Programs. ...All acute-care hospitals governed by the CMS CoP will implement antibiotic stewardship programs. CMS will expand CoP requirements to apply to long-term acute care hospitals, other post-acute facilities, ambulatory surgery centers, and dialysis centers.”

CMS’s proposed rule for hospitals and critical-access hospitals (42 CFR Parts 482 and 485) was published Jun 16, 2016, with §482.42 and §485.640 addressing issues pertaining to ASPs. The public comment period is currently open until Aug 15, 2016. The final rule will be released following review and revision. Excerpts from the proposed rule pertaining to antibiotic stewardship in hospitals and critical access hospitals are shown below in Table 2. Sections pertaining to ASPs focus on two aspects: organization and policies of the programs in hospitals and critical access hospitals; and leadership responsibilities.

The proposed rule would require 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, such as the CDC *Core Elements of Hospital Antibiotic Stewardship Programs* (2014). The intent of this approach is to “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” and to “adapt their policies and procedures in concert with any updates in the guidelines they have elected to follow.”

Table 2. CMS Proposed Rule (42 CFR Parts 482 and 485) Published June 16, 2016* Conditions of Participation in Medicare and Medicaid: Highlights Pertaining to Antibiotic Stewardship in Hospitals (§482.42) and Critical-Access Hospitals (§485.640)	
ASP Organization and Policies	
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 ASP and that appointment is based on the recommendations of medical staff leadership and pharmacy leadership.	
The ASP must:	
<ul style="list-style-type: none"> » Demonstrate coordination among all components of the hospital/critical access hospital (CAH) responsible for antibiotic use and resistance, including, but not limited to the infection prevention and control program (IPCP), the quality assessment and performance improvement (QAPI) program, the medical staff, nursing services, and pharmacy services. » Document the evidence-based use of antibiotics in all departments and services of the hospital/CAH. » Demonstrate improvements, including sustained improvements, in proper antibiotic use, such as through reductions in <i>Clostridium difficile</i> infection (CDI) and antibiotic resistance in all departments and services of the hospital/CAH. » Adhere to nationally recognized guidelines, as well as best practices, for improving antibiotic use. » Reflect the scope and complexity of the hospital/CAH services provided. 	
ASP Leadership Responsibilities	
The ASP leader is responsible for:	
<ul style="list-style-type: none"> » Development and implementation of a hospital/CAH-wide ASP, based on nationally recognized guidelines, to monitor and improve the use of antibiotics. » All documentation, written or electronic, of ASP 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. » Competency-based training and education of hospital/CAH 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. 	
<p>*The public comment period on this proposed rule closes on Aug 15, 2016; the final rule has not yet been released. <i>Abbreviations:</i> ASP (antibiotic stewardship program); CAH (critical-access hospitals); CDI (<i>Clostridium difficile</i> infection); CFR (Code of Federal Regulations); CMS (Centers for Medicare and Medicaid Services); IPCP (infection prevention and control program); QAPI (quality assessment and performance improvement).</p>	

CMS’s proposed rule for long-term care facilities (42 CFR Parts 405, 431, 447, 482, 483, 485, and 488), published in 2015, includes a section (§ 483.80) addressing new infection prevention and control

standards that require antibiotic stewardship. The extended public comment period, drawing over 9,000 [comments](#), closed Oct 14, 2015. The final rule has not yet been released. Excerpts from the proposed rule pertaining to antibiotic stewardship in long term care facilities are shown below in Table 3.

**Table 3. CMS Proposed Rule (42 CFR Parts 405, 431, 447, 482, 483, 485, and 488) Published Jul 16, 2015*
Conditions of Participation in Medicare and Medicaid: Highlights Pertaining to Antibiotic Stewardship in
Long-Term Care Facilities (§483.80)**

Infection Prevention and Control
<p>The long-term care facility must establish and maintain an infection prevention and control program (IPCP) designed to provide a safe, sanitary, and comfortable environment and to help prevent the development and transmission of communicable diseases and infections. The IPCP must include, at a minimum, the following elements:</p> <ul style="list-style-type: none"> » A system for preventing, identifying, reporting, investigating, and controlling infections and communicable diseases for all residents, staff, volunteers, visitors, and other individuals providing services under a contractual arrangement based upon the facility assessment conducted according to §483.75(e) and following accepted national standards. » Written standards, policies, and procedures for the program, which must include, but are not limited to: (i) A system of surveillance designed to identify possible communicable diseases or infections before they can spread to other persons in the facility; (ii) When and to whom possible incidents of communicable disease or infections should be reported; (iii) Standard and transmission-based precautions to be followed to prevent spread of infections; (iv) When isolation should be used for a resident; (v) The circumstances under which the facility must prohibit employees with a communicable disease or infected skin lesions from direct contact with residents or their food, if direct contact will transmit the disease; and (vi) The hand hygiene procedures to be followed by staff involved in direct resident contact. » An antibiotic stewardship program that includes antibiotic use protocols and a system to monitor antibiotic use. » A system for recording incidents identified under the facility’s IPCP and the corrective actions taken by the facility.
<p>The facility must designate one individual as the infection prevention and control officer (IPCO) for whom the IPCP at that facility is a major responsibility. The IPCO must:</p> <ul style="list-style-type: none"> » Be a clinician who works at least part-time at the facility. » Have specialized training in infection prevention and control beyond their initial professional degree. » Be a member of the facility’s quality assessment and assurance (QAA) committee and report to the committee on the IPCP on a regular basis.
<p>*The public comment period for this proposed rule closed on Oct 14, 2015; the final rule has not yet been released. <i>Abbreviations:</i> ASP (antibiotic stewardship program); CFR (Code of Federal Regulations); CMS (Center for Medicare and Medicaid Services); IPCO (infection prevention and control officer); PCP (infection prevention and control program); LTC (long-term care); QAA (quality assessment and assurance); QAPI (quality assessment and performance improvement).</p>

Given that the majority of nursing homes in the United States receive CMS reimbursement, the finalized rule is expected to have a broad reach ([Johnson et al. 2016](#)). This proposed rule revises the regulatory description of infection control as “infection prevention and control” and requires that IPCPs establish “an antibiotic stewardship program that includes antibiotic use protocols and a system to monitor antibiotic use.” As currently written, the rule specifies a flexible standard; it does not require that ASPs adhere to CDC’s *Core Elements of Antibiotic Stewardship for Nursing Homes* ([2015](#)), but does specify “adherence to national recognized guidelines” for antibiotic stewardship. CMS noted that the ASP requirements are intended to improve antibiotic use by ensuring that the residents who require antibiotics are prescribed the appropriate antibiotics for the medically necessary time, thereby reducing unnecessary antibiotic use and the risk to residents from being prescribed an unnecessary antibiotic or

an inappropriate antibiotic for an inappropriate time. The 2016 [PACCARB report](#) noted above recommends the development of evidence-based guidelines for implementing ASPs and interpretive guidelines to enable CMS to evaluate the quality of ASPs in healthcare facilities.

The Joint Commission: Medication Management Standards

The Joint Commission (TJC), an independent, nonprofit organization that accredits and certifies more than 20,000 US healthcare organizations and programs, recently issued updated antimicrobial stewardship accreditation standards aligned with national goals. TJC's new antimicrobial stewardship [Medication Management Standards](#) (MM.09.01.01), which take effect Jan 1, 2017, require hospitals, critical access hospitals, and nursing care centers to implement ASPs "based on current scientific literature". The standards include eight ASP "elements of performance" on which hospitals and nursing care centers will be surveyed and evaluated in accreditation:

1. Establish antimicrobial stewardship as an organizational priority.
2. Educate staff and licensed independent practitioners involved in antimicrobial ordering, dispensing, administration, and monitoring about antimicrobial resistance and antimicrobial stewardship practices.
3. Educate patients, and their families as needed, regarding the appropriate use of antimicrobial medications.
4. Establish an antimicrobial stewardship multidisciplinary team that includes the following members, when available in the setting: infectious disease physician, infection preventionists(s), pharmacist(s), and practitioner.
5. Document the inclusion of the core elements of ASPs identified in the CDC's *Core Elements of Hospital Antibiotic Stewardship Programs* (CDC 2014) or *Core Elements of Antibiotic Stewardship for Nursing Homes* (CDC 2015).
6. Document the use of TJC-approved multidisciplinary protocols, such as:
 - a. Antibiotic formulary restrictions
 - b. Assessment of appropriateness of antibiotics for community-acquired pneumonia
 - c. Assessment of appropriateness of antibiotics for skin and soft tissue infections
 - d. Assessment of appropriateness of antibiotics for urinary tract infections (for hospital settings) or care of the long term care patient with a urinary tract infection (for nursing care centers)
 - e. Care of the patient with *Clostridium difficile*
 - f. Guidelines for antimicrobial use in adults
 - g. Guidelines for antimicrobial use in pediatrics (for hospital settings)
 - h. Plan for parenteral to oral antibiotic conversion
 - i. Preauthorization requirement for specific antimicrobials
 - j. Use of prophylactic antibiotics
7. Document the collection, analysis, and reporting of ASP data pertaining to program evaluation, antimicrobial prescribing patterns, and antimicrobial resistance patterns.
8. Document taking action on improvement opportunities identified in its ASP.

National Quality Forum: A Practical Playbook

Following the release of CDC's guidance for ASPs in hospitals (2014) and nursing homes (2015), the National Quality Forum (NQF) launched a collaborative public and private sector initiative to accelerate the adoption of effective, high-quality and sustainable ASPs in acute-care hospitals. NHF's [Antibiotic Stewardship in Acute Care: A Practical Playbook](#), published in May 2016, provides detailed, practical

guidance for creating or strengthening ASPs in hospitals settings. For each of CDC's core elements of ASPs, the NQF Playbook provides a brief rationale and overview of the element; practical guidance on implementation at a range of levels; potential barriers to adoption and suggested solutions; and specific tools and resources for additional support.

NQF's Playbook provides further guidance in establishing a measurement framework to help ASPs assess performance, identify problem areas, target interventions, and monitor improvement. For example, the Playbook details the use of an NQF-endorsed, risk-adjusted measure (#2720) to permit benchmarking of antibiotic use in hospitals using medication administration data analyzed in Standardized Antimicrobial Administration Ratio (SAAR) values, which reflect observed-to-predicted antibacterial use across 16 combinations of antibacterial agent-patient care locations. SAAR values may provide high-level indicators for possible overuse, underuse, or inappropriate use of antimicrobial agents within the institution. Suggested measures also are provided to analyze other aspects of antibiotic consumption, as well as various process indicators, outcomes, and financial aspects of antimicrobial use in acute care settings.

IDSA/SHEA: Guidelines for Implementing Antibiotic Stewardship Programs

The Infectious Diseases Society of America (IDSA) and the Society for Healthcare Epidemiology of America (SHEA) recently published a comprehensive set of evidence-based guidelines for implementing and evaluating ASPs in inpatient settings ([Barlam et al. 2016](#)). The unique focus of this effort was on providing practical input, based on scientific evidence, to support decision making regarding ASP interventions.

A multidisciplinary team of clinicians and investigators with expertise across a range of medical specialties conducted a critical review of the published scientific evidence pertaining to five groups of ASP components (interventions, optimization of antibiotic administration, microbiology and laboratory diagnostics, measurement and analysis, and antibiotic stewardship in special populations). The team reviewed 28 recommendations and systematically evaluated the strength (strong or weak) and quality (moderate or low) of the evidence supporting them. Five strongly recommended interventions were identified: preauthorization and/or prospective audit and feedback; reduction in the use of antibiotics associated with a high risk of *Clostridium difficile* infection; dedicated pharmacokinetic monitoring and adjustment programs for aminoglycosides; increase in the appropriate use of oral antibiotics for initial therapy and timely transition of patients from intravenous to oral antibiotics; and reduction in antibiotic therapy to the shortest effective duration.

Although the evidence was adequate to identify several core interventions for effective ASPs and to suggest other interventions that could be implemented on a facility-specific basis, the panel noted the need to improve the scientific basis for all ASP interventions, as well as the need for ASP implementation research to guide further application of ASP initiatives.

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