PANEL 1: Innovation in an Era of Stewardship

Overview of CMS Rule Changes to Promote Antimicrobial Stewardship Programs

Scott J. Cooper, MMSc, PA-C
Captain, United States Public Health Service
Senior Technical Advisor
Centers for Medicare & Medicaid Services

Wednesday, February 26, 2020
Public Meeting
Great Hall, Hubert H. Humphrey Building
Centers for Medicare & Medicaid Services (CMS)

- CMS is responsible for administering the Medicare and Medicaid programs.

- CMS sets Medicare payment rates for diagnostic tests and certain antibiotics that are used to treat Medicare beneficiaries in hospitals.

- CMS also determines the **Conditions of Participation (CoPs) and Conditions for Coverage (CfCs)**, which are **the health and safety requirements aimed at protecting all patients**, for health care providers and suppliers—such as hospitals, critical access hospitals, and long-term care facilities—that wish to participate in the Medicare and Medicaid programs.

- CMS also administers multiple programs designed to improve the quality of health care provided not only to Medicare and Medicaid beneficiaries, but to all patients in the United States.
In October of 2016, with CDC support, CMS published revised Requirements of Participation for Long-Term Care Facilities (skilled nursing facilities and nursing facilities participating in the Medicare program), requiring, in a phased-in manner, that these facilities provide more robust infection prevention and control programs, along with new requirements for these facilities to have active ASPs.

As of November of 2016, each facility must have had a system and policies and procedures in place to identify, report, investigate, and control infections and communicable diseases among residents, staff, and visitors.

As of November of 2017, each facility must have had an antibiotic stewardship program in place as part of their infection prevention and control program. The antibiotic stewardship program must include the use of antibiotic use protocols and a system to monitor antibiotic use.

The guidance developed after the rule published incorporates CDC’s Core Elements of Antibiotic Stewardship for Nursing Homes.
In September of 2019, CMS, after close collaboration with CDC, published a final rule revising a number of the CoP requirements for all Medicare and Medicaid-participating hospitals and CAHs in an effort to update those requirements that do not fully conform to current standards of practice.

The rule specifically updates the current requirements for hospitals to have active and hospital-wide infection prevention and control programs for surveillance, prevention, and control of healthcare-associated and other infections (and establishes new requirements for CAHs to have the same).

Most significantly, this rule also establishes new requirements for hospitals and CAHs to now have active and facility-wide ASPs to help reduce inappropriate antibiotic use and antimicrobial resistance.

These CoPs also require hospitals and CAHs to designate qualified leaders in these facilities to guide and oversee these efforts.

These new CoP requirements for hospitals and CAHs must be implemented by March 30, 2020.
Reducing the Barriers for Implementing Antibiotic Stewardship

- Additionally, as part of its Omnibus Burden Reduction Final Rule, also published in September of 2019, CMS revised specific hospital CoP requirements aimed at reducing regulatory burden in ways that will allow innovative best practices to emerge for patient care.

- Most importantly, with regard to infection control, antibiotic stewardship, and improving the overall quality of patient care, these revisions now allow Medicare-certified hospitals (particularly those hospitals that are small and/or rural hospitals) that are part of larger multi-hospital systems to effectively draw from the more extensive resources and clinical expertise of their larger hospital systems in order to benefit their patients in two significant areas.

- These hospitals will be able to use both the unified and integrated quality assessment and performance improvement programs and the infection prevention & control/antibiotic stewardship programs that might now be provided by the larger system as allowed under this new rule.

- CMS believes that this regulatory flexibility will make it easier to effectively implement best practices that result in a higher quality of patient care for all of the hospitals within a system.
The interpretive guidance currently under review will incorporate CDC’s 7 Core Elements of Antibiotic Stewardship in Hospitals.

CMS, in concert with its internal and external partners, will publish interpretive guidelines (IGs) for the new hospital and CAH CoPs that are designed for the training and education of surveyors and the public on infection prevention and control/antibiotic stewardship programs that reflect nationally recognized guidance and standards to reduce HAIs on a facility, local, state, and national level and that demonstrate appropriate use of antibiotics in order to combat the development and transmission of antibiotic-resistant pathogens.

For example, IGs for the Quality Assessment and Performance Improvement program requirements for hospitals and CAHs may incorporate antibiotic stewardship performance measures developed by the CDC, the Agency for Healthcare Research and Quality, and other nationally recognized professional and scientific organizations.

CMS projects the release of IGs between mid-2020 and early 2021 given that release is subject to extensive coordination with stakeholders as well as clearance and publication processes.

CMS will eventually look to propose and expand ASP requirements to apply to post-acute care services providers (such as home health agencies), ambulatory surgery centers, dialysis centers, and other providers and suppliers that participate in the Medicare program and that are subject to the CoPs and CfCs.
Scott J. Cooper, MMSc, PA-C
Captain, United States Public Health Service

Senior Technical Advisor
Clinical Standards Group
Center for Clinical Standards & Quality
Centers for Medicare & Medicaid Services

scott.cooper@cms.hhs.gov