

Summary

CMS Conditions of Participation: Final Rule on Antimicrobial Stewardship

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Highlights

- ▶ Centers for Medicare & Medicaid Services, Effective date: Nov. 29, 2019
- ▶ Per CMS, “This [final rule](#) reforms Medicare regulations that are identified as unnecessary, obsolete or excessively burdensome on health care providers and this final rule will create savings and reduce burden in many areas. Several of the changes will create measurable monetary savings for providers” Due to the revisions in the infection control and prevention and antibiotic stewardship regulations, CMS estimates the savings for hospitals will be approximately \$115 million each year.
- ▶ New requirement for antibiotic stewardship programs in hospitals (including critical access hospitals)

Highlights

- ▶ The person in charge of the infection prevention and control program is appointed by the governing body and that appointment is based on the recommendations of medical staff leadership and nursing leadership
- ▶ The person in charge of the antibiotic stewardship program is appointed by the governing body and that appointment is based upon recommendations of medical staff leadership and pharmacy leadership. (Note requirements for person filling this role)

Highlights

- ▶ Antibiotic Stewardship: “Documents any improvements, including sustained improvements, in proper antibiotic use.”
 - ▶ Note: There is no mention of requiring hospitals to utilize NHSN or similar reporting option. Use of the AUR module is still the gold standard for tracking but is not mandated.
- ▶ Hospitals that are part of a multi-hospital system, “the system governing body may elect to have unified and integrated infection prevention and control and antibiotic stewardship programs for all of its

Highlights

- ▶ Regulations pertaining to hospital (and critical access hospital) antibiotic stewardship programs must be implemented by **March 30, 2020**. (Please note: there is a conflicting date requirement that could potentially indicate an implementation date of May 29, 2020).
- ▶ The regulation has flexibility when determining which nationally recognized guidelines will be used (while the CDC core elements are one guideline, there are other guidelines hospitals might choose to use)

Recommendations

- ▶ 1. Review the entire [final rule](#) thoroughly, as there are applicable supplemental comments throughout the document (the final regulation is on p. 51820).
- ▶ 2. Begin to identify gaps in the program and pursue solutions

Key Documents

- ▶ CMS Final Rule - <https://www.govinfo.gov/content/pkg/FR-2019-09-30/pdf/2019-20736.pdf>
- ▶ CDC: [The Core Elements of Hospital Antibiotic Stewardship Programs](#)
- ▶ CDC: [Implementation of Antibiotic Stewardship Core Elements at Small and Critical Access Hospitals](#)

Details: § 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 to **best practices** for improving antibiotic use where applicable, and 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 demonstrate that:

- ▶ (1) An individual (or individuals), who is qualified through education, training, experience, or certification in infection prevention and control, is 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;

(a) Standard: Infection prevention and control program organization and policies.

The hospital must demonstrate that:

- ▶ (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; and
- ▶ (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 demonstrate that

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

(b) Standard: Antibiotic stewardship program organization and policies.

The hospital must demonstrate that

- ▶ (2) The hospital-wide antibiotic stewardship program:
 - ▶ (i) **Demonstrates 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) **Documents the evidence-based use of antibiotics** in all departments and services of the hospital; and
 - ▶ (iii) **Documents any improvements**, including sustained improvements, in proper antibiotic use;

(b) Standard: Antibiotic stewardship program organization and policies.

The hospital must demonstrate that

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

(c) Standard: Leadership responsibilities

- ▶ (2) The **infection preventionist(s)/ infection control professional(s)** is 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.

(c) Standard: Leadership responsibilities

- ▶ (3) The leader(s) 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 with 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.

(d) Standard: Unified and integrated infection prevention and control and antibiotic stewardship programs for multi-hospital systems.

If a hospital is part of a hospital system consisting of multiple separately certified hospitals using a system governing body that is legally responsible for the conduct of two or more hospitals, the system governing body can elect to have unified and integrated infection prevention and control and antibiotic stewardship programs for all of its member hospitals after determining that such a decision is in accordance with all applicable State and local laws.

The system governing body is responsible and accountable for ensuring that each of its separately certified hospitals meets all of the requirements of this section.

Each separately certified hospital subject to the system governing body must demonstrate that:

(d) Standard: Unified and integrated infection prevention and control and antibiotic stewardship programs for multi-hospital systems.

- ▶ **Each separately certified hospital subject to the system governing body must demonstrate that:**
- ▶ (1) The unified and integrated infection prevention and control and antibiotic stewardship programs are established in a manner that takes into account each member hospital's unique circumstances and any significant differences in patient populations and services offered in each hospital;
- ▶ (2) The unified and integrated infection prevention and control and antibiotic stewardship programs establish and implement policies and procedures to ensure that the needs and concerns of each of its separately certified hospitals, regardless of practice or location, are given due consideration;

(d) Standard: Unified and integrated infection prevention and control and antibiotic stewardship programs for multi-hospital systems.

Each separately certified hospital subject to the system governing body must demonstrate that:

- ▶ (3) The unified and integrated infection prevention and control and antibiotic stewardship programs have mechanisms in place to ensure that issues localized to particular hospitals are duly considered and addressed; and
- ▶ (4) A qualified individual (or individuals) with expertise in infection prevention and control and in antibiotic stewardship has been designated at the hospital as responsible for communicating with the unified infection prevention and control and antibiotic stewardship programs, for implementing and maintaining the policies and procedures governing infection prevention and control and antibiotic stewardship as directed by the unified infection prevention and control and antibiotic stewardship programs, and for providing education and training on the practical applications of infection prevention and control and antibiotic stewardship to hospital staff.

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