

REGULATORY — ANTIMICROBIAL STEWARDSHIP UPDATE

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Infection prevention and control requirements for health care providers are growing. The Centers for Disease Control and Prevention estimates that 1 in 25 hospitalized patients have a health care-acquired infection at any given time. Annually, that is more than 650,000 patient in the U.S. In particular, hospitals, ambulatory surgical centers, and long-term care nursing facilities are experiencing increased regulatory requirements related to infection prevention and control, as well as requirements aimed at reducing the number of “superbugs” that are difficult to treat. The increased regulatory requirements continue to grow primarily because we know infection control programs in health care work. Despite reductions in hospital-acquired infections, further work is needed. Reporting expectations are coupled with the expectation that data will be analyzed to identify areas of concern and related actions for improvement will be implemented. The Centers for Medicare & Medicaid Services is holding health care facilities accountable by withholding payments to organizations that do not report and meet threshold performance requirements. It’s imperative to stay informed on proposed and final regulatory changes at the federal and state level.

On June 16, 2016, CMS released [proposed](#) changes to the Conditions of Participation. The proposed rule would update the requirements that hospitals and critical access hospitals must meet to participate in Medicare and Medicaid programs. MHA commented on the proposed changes, highly encouraging hospitals to review the changes. There are significant changes to infection control CoPs (starting on Page 27 of the document), including the following.

- CoP name change to “infection prevention and control and antibiotic stewardship programs”
- requiring infection prevention and control, and antibiotic [stewardship](#) programs be separate and include active hospitalwide programs with governing body involvement
- integration of infection reporting into the Quality Assurance and Performance Improvement Program
- demonstration of adherence to nationally recognized guidelines, including transmission guidelines that require [outpatient](#) focus

- hospital appointment of an infection prevention/ control professional, including qualification guidelines
- hospital appointment of an antibiotic stewardship leader, including qualification guidelines
- New standards §482.42 (c) that would enhance the accountability of hospital leadership for infection prevention and control, and antibiotic stewardship programs. Section 482.42 (c)(1) would create new requirements and responsibilities of the governing body. Section 482.42 (c)(2) (i) would focus on evidence-based practices.

These proposed changes have not yet been finalized.

The Joint Commission [released](#) pre-publication standards for antimicrobial stewardship programs. The standards took effect for accredited organizations on Jan. 1. In addition, annually, the inpatient PPS regulations are updated. On April 17, CMS [released](#) the fiscal year 2018 payment and policy [updates](#) to the acute inpatient and long-term care PPS. The rule, more than 1,800 pages, has been summarized by MHA in a recently released [issue brief](#).

Missouri is the first state to pass aggressive legislation aimed specifically at reducing antimicrobial resistance. [Senate Bill 579](#) enacted and signed in the 2016 Missouri legislative session modifies existing infection control standards and regulates development of an antimicrobial stewardship program by Aug. 28. The legislation requires the following.

- **Aug. 28, 2016** – Hospitals were to begin reporting carbapenem-resistant *Enterobacteriaceae*, as specified by the department, along with vancomycin-resistant *Enterococcus* and methicillin-resistant *Staphylococcus*. Since there are many strains of CRE, we are waiting on the department to specify which strains to report. Any cases of carbapenemase-producing CRE should be reported to DHSS immediately.
- **Jan. 1, 2017** – The Infection Control Advisory Panel, established in 2004 legislation, was to make recommendations to DHSS on which hospitals, as a condition of licensure, will be required to report through National Healthcare Safety Network for data collection; the use of NHSN for risk adjustment and analysis of hospital submitted data; and the use of Hospital Compare for public reporting of the incidence of HAI. Additionally, DHSS, upon review of panel recommendations, will specify the reporting of four surgical site infections (current requirement is three). The panel has formulated their recommendations and submitted them to DHSS. Currently, regulations are being written and reviewed.
- **Aug. 28, 2017** – Each hospital and ASC, excluding mental health facilities, must establish an antimicrobial stewardship program. The program is to be designed to evaluate that hospitalized patients receive the appropriate antimicrobial, at the appropriate dose, at the appropriate time, and for the appropriate duration. This legislation requires the use of CDC's Antimicrobial Use and Resistance module when regulations concerning Stage 3 of meaningful use are effective. MHA hosted a CDC [webinar](#) explaining the requirements of AUR reporting.
- **Jan. 1, 2018** – The department is required to adopt new regulations regarding the above by this date. Whether or not the regulations will be in effect by this time is questionable. Beginning Jan. 1, 2018, and every year thereafter, DHSS must report statewide antimicrobial-resistant infections data to the General Assembly.

MHA, DHSS and the CDC have been working collaboratively to try and understand what resources are needed to meet the requirements of SB 579. Some progress has been made. Currently, DHSS is working on regulations and looking at different levels in which a hospital may participate. We know the capabilities of all hospitals are not the same; however, every hospital can implement good infection control and antimicrobial stewardship practices that align with services offered. DHSS is working to identify, based on size and services offered, what ASP practices are essential to have in place. However, hospitals cannot wait on these guidelines to establish their ASP.

Across the nation, nearly 39 percent of hospitals have an ASP that reflects the following CDC Core Elements of Antibiotic Stewardship; in Missouri, the estimated percentage is 29. The CDC's core [elements](#) include:

- Leadership Commitment: Dedicating necessary human, financial and information technology resources
- Accountability: Appointing a single leader responsible for program outcomes; experience with successful programs show that a physician leader is effective
- Drug Expertise: Appointing a single pharmacist leader responsible for improving antibiotic use
- Action: Implementing at least one recommended action, such as systemic evaluation of ongoing

treatment need after a set period of initial treatment (i.e. "antibiotic time out" after 48 hours)

- Tracking: Monitoring antibiotic prescribing and resistance patterns
- Reporting: Regular reporting information on antibiotic use and resistance to doctors, nurses and relevant staff
- Education: Educating clinicians about resistance and optimal prescribing

Utilization of the AUR module requires clinical documentation architecture. In addition, the vendor system has to have the service and software that allows participation in the AUR pharmacy option through direct reporting. According to the CDC, there are only nine vendors that have the software and services, and are actively reporting: EPIC, Asolva, MedMinded, Bacter (ICNet), Intelligent Medical Systems (Meditab), RL Solutions, Senti7, TheraDoc and Vigilanz. Keep in mind, even though you may have one of these vendors, you may not have the specific software needed to begin reporting. The CDC warns that "homegrown" systems experience a lot of difficulty and haven't proven effective.

What you can do to prepare:

- Share this information with quality, IT, infection control, pharmacy, administration, compliance, nursing, human resources and medical staff.
- Review the CDC Core Elements and proposed CMS CoP changes.
- Review SB 579.
- Assess current policies and the need for additional policies on integration of QAPI, infection control and ASP.
- Ask pharmacy staff what current processes are in place. How closely aligned are they to CDC's core elements for an ASP? Who will lead your ASP? CMS sees the ASP as primarily being led by medical staff and pharmacy, not infection control.
- Conduct a gap analysis of where you are compared to where you will need to be, and conduct a timeline for implementation: current situation, potential/real new requirements, actions needed and comments.
- Verify that laboratory staff know about the ASP requirement.
- Submit regulatory concerns to [Sarah Willson](#) at MHA.
- Overall, ensure that hospital policies are being revised to reflect the needed involvement of hospital administration, medical staff and the governing body when it comes to quality, infection prevention and control, and antibiotic use and resistance. Show how your actions reflect your policies.
- Verify that the terms transmission, surveillance, infection detection, data collection and analysis, monitoring and evaluation of preventive interventions are clearly defined and familiar to your organization.

How is MHA supporting Missouri hospitals?

- Convening monthly with the CDC and DHSS to help identify educational and practical resources to meet requirements.
- Advocating for hospitals at infection control advisory panel meetings.
- Working with facilities and other providers to enhance support for ASP development and reporting.
- Offered the [Antimicrobial Stewardship Program Immersion Project](#) in November 2016.
- Consistently updating resources on [MHAnet.com](#).
- Communicating requirements and providing updates.
- Offering education ([What's Up Wednesday Webinar](#) on ASP, June 14).

How is DHSS supporting Missouri hospitals?

- Developing antimicrobial stewardship guidance for hospitals and ASCs that will allow them to tailor an ASP to their facility's size and resources.
- Creating an antimicrobial stewardship website with resources for a variety of health care facilities.
- Working with CDC experts in antimicrobial stewardship and NHSN AUR module reporting to ensure Missouri health care facilities are provided with the most up-to-date resources and information.
- Holding quarterly meetings with the infection control advisory panel to bring experts and

stakeholders to the table as Missouri implements new SB 579 requirements.

- State Public Health Lab is preparing to accept certain CRE specimens for carbapenemase mechanism testing, allowing hospitals to quickly identify, control and prevent outbreaks of CP-CRE.

The importance of antimicrobial stewardship is increasingly drawing the attention of media, regulators and legislators. There is no sign that interest in this topic will fade as illnesses related to overuse of antibiotics become harder to treat, the costly and grim outcomes of sepsis continue to rise, and the development of new antimicrobial agents is at an all-time low. Contact [Sarah Willson](#) for any regulatory questions; [Alison Williams](#) for any clinical quality improvement needs; or [Kate Henschel](#) with DHSS for questions about AUR module reporting or to report carbapenemase-producing CRE cases.