



**Center for Clinical Standards and Quality/Quality, Safety & Oversight Group**

**Ref: QSO-22-20-Hospitals**

**DATE:** July 6, 2022  
**TO:** State Survey Agency Directors  
**FROM:** Director, Quality, Safety & Oversight Group (QSOG)  
**SUBJECT:** Infection Prevention and Control and Antibiotic Stewardship Program Interpretive Guidance Update

**Memorandum Summary**

- **Updates to interpretive guidance for hospital requirements**– CMS published the final rule Medicare and Medicaid Programs; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction Final Rule which revised the regulatory requirements for hospitals related to infection prevention and control and antibiotic stewardship programs. We made conforming revisions to the interpretive guidelines.

**Background:**

On September 30, 2019 The Centers for Medicare & Medicaid Services (CMS) published the final rule [\*Medicare and Medicaid Programs; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction Final Rule\*](#), which included revisions for the hospital Conditions of Participation (CoP) for 42 CFR §482.42 Infection preventions and control and antibiotic stewardship programs.

**Discussion:**

The intent of the regulatory revisions was to promote more broad changes and focus in hospitals on surveillance and prevention initiatives to control hospital acquired infections (HAI) and other infectious diseases. The addition of the antibiotic stewardship program requires hospitals to demonstrate efforts, including best practices to follow nationally recognized standards for appropriate antibiotic usage. We recognize that hospitals play a critical role in combatting antimicrobial resistance through implementation of a robust stewardship program. The infection prevention and control program may be viewed separate from the antibiotic stewardship program as these two programs approach the prevention of HAIs and infectious disease from different angles. The regulations allow for flexibility and do not require hospitals to adhere to a specific set of regulatory guidelines or best practices. Lastly, the regulations now allow hospital systems to have unified and integrated infection prevention and control and antibiotic stewardship programs.

Revised requirements include:

- Infection prevention and control program organization and policies
- Antibiotic stewardship program organization and policies
- Leadership responsibilities
- Unified and integrated infection prevention and control and antibiotic stewardship programs for multi-hospital systems

**Contact:**

For questions or concerns relating to this memorandum, please contact  
QSOG\_Hospital@cms.hhs.gov.

**Effective Date:**

Immediately. Please communicate to all appropriate staff within 30 days.

/s/

David R. Wright  
Director, Quality, Safety & Oversight Group

Attachment(s)- SOM Appendix A Infection prevention and control and Antibiotic stewardship  
Interpretive Guidance

**A-0747**

*(Rev.)*

## **§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.**

### **Interpretive Guidelines §482.42**

*The hospital must have an active infection control program throughout the hospital for the surveillance, prevention, and control of Healthcare Associated Infections (HAIs) and other infectious diseases and a program for the optimization of antibiotic use through stewardship. These hospital-wide programs must include, at a minimum, a system for preventing, identifying, reporting, investigating, and controlling infections and communicable diseases for all patients, staff, and visitors and a system for improving antibiotic use for patients.*

*The programs are based on the individual hospital's assessment while demonstrating adherence to nationally recognized infection prevention and control standards of practice, 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. The hospital should have written standards, policies, and procedures and issues identified in the infection control program must be addressed more broadly through the hospital QAPI program.*

### **Survey Procedures §482.42**

- Review policies and procedures of the infection control program for evidence that the hospital has an active, hospital-wide program for surveillance, prevention, and control of health associated infections and other infectious diseases based on national standards of practice and best practices.*
- Review the antibiotic stewardship program for evidence that the hospital has an active hospital-wide program for the optimization of antibiotic use through stewardship based on national standards of practice and best practices.*
- Review the infection control program for evidence that the hospital is working collaboratively between infection control and hospital QAPI when infection control issues are identified.*

- *Review the antibiotic stewardship program for evidence that the hospital is working collaboratively between antibiotic stewardship and hospital QAPI when antibiotic use issues are identified.*

## **A-0748**

*(Rev. )*

### **§482.42(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;**

#### **Interpretive Guidelines §482.42(a)(1)**

*Individuals responsible for the hospital infection prevention and control program are often referred to as “hospital epidemiologists (HEs),” “infection control professionals (ICPs)” and/or “infection preventionists.” CDC has defined “infection control professional” as “a person whose primary training is in either nursing, medical technology, microbiology, or epidemiology and who has acquired specialized training in infection control.”*

*The hospital must designate an individual or group of individuals as its **infection preventionist(s)/infection control professional(s)**. The individual(s) must be appointed by the hospital governing body based on the recommendations of the medical staff leadership and nursing leadership. The hospital should ensure high-level hospital clinical leadership, specifically leadership from the medical staff and the nursing service, are involved in the process of selecting the infection preventionist(s)/infection control professional(s). This high-level participation promotes a hospital-wide culture of safety and quality in which input across the hospital is solicited and acted upon.*

*In designating infection preventionist(s)/infection control professional(s), hospitals should assure that the individuals so designated are qualified through education, training, experience, or certification in infection prevention and control.*

*CMS does not specify either the number of infection preventionist(s)/infection control professional(s) to be designated or the number of infection preventionist(s)/infection control professional(s) hours that must be devoted to the infection prevention and control programs. However, resources must be adequate to accomplish the tasks required for the infection prevention and control program. In hospitals with more than one infection preventionist(s)/infection control professional(s), the staff members should work as an integrated team to ensure the functions of an infection prevention and control program are covered. A prudent hospital would consider patient census, characteristics of the patient population, and complexity of the healthcare services it offers in determining the size and scope of the resources it commits to infection prevention and control.*

*Survey Procedures §482.42(a)*

- *Determine whether an infection preventionist(s)/infection control professional(s) was appointed by the governing body based on recommendations of the medical staff leadership and nursing leadership and has the responsibility for the infection prevention and control program.*
- *Review the personnel file of the infection preventionist(s)/infection control professional(s) to determine whether he/she is qualified through professional education, training, experience, or certification to oversee the infection prevention and control program.*
- *Review the criteria the hospital used to determine the resources necessary to operate effectively and ensure the resource allocation matches the determined needs.*

**A-0749**

**(Rev. )**

**§482.42(a)(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;**

**Interpretive Guidelines §482.42(a)(2)**

The hospital infection prevention program must establish policies and procedures for implementing methods of preventing and controlling the transmission of infection in the broader sense, to include not only the hospital but between the hospital and other institutions or settings. The development of such policies and procedures will require hospitals focus efforts 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. It is expected that hospitals consider the impact of their outpatient facilities on their inpatient units with the development and implementation of a hospital wide infection control and prevention program policies.

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 and MRSA, because research has shown that community onset cases of these pathogens can impact hospitals. Hospitals should consider how they can partner with facilities with whom they frequently share patients (e.g. nursing homes) to establish ways to share information on patients

who harbor potentially transmissible pathogens. 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.

#### **Survey Procedures §482.42(a)(2)**

- *Review the hospital policies and procedures for infection control and prevention to provide evidence that the hospital is following policies and procedures that employ the methods for preventing and controlling the transmission of infections within the hospital and between the hospital and other healthcare settings.*
- *Determine whether the infection control program is being applied throughout the hospital to both inpatient and outpatient settings.*

#### **A-0750**

*(Rev. )*

**§482.42(a)(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**

#### **Interpretive Guidelines §482.42(a)(3)**

*The hospital must provide and maintain a clean and sanitary environment to avoid sources and transmission of infections and communicable diseases. All areas of the hospital must be clean and sanitary. This includes all hospital departments and off-site locations. The infection prevention and control program should include appropriate monitoring of housekeeping, maintenance (including repair, renovation and construction activities), and other activities to ensure that the hospital maintains a sanitary environment. Examples of areas to monitor would include the hospital's: onsite laundry facilities, food storage, preparation, serving and dish rooms, refrigerators, ice machines, air handlers, autoclave rooms, venting systems, inpatient rooms, treatment areas, labs, waste handling, surgical areas, supply storage, equipment cleaning, etc.*

*CMS expects Medicare certified hospitals to have water management policies and procedures to reduce the risk of growth and spread of Legionella and other opportunistic pathogens in building water systems. An industry standard calling for the development and implementation of water management programs in large or complex building water systems to reduce the risk of legionellosis was published in 2015 by American Society of Heating, Refrigerating, and Air Conditioning Engineers (ASHRAE). In 2016, the CDC and its partners developed a toolkit to facilitate implementation of this ASHRAE Standard (<https://www.cdc.gov/legionella/maintenance/wmp-toolkit.html>). Environmental, clinical, and epidemiologic considerations for healthcare facilities are described in this toolkit.*

*To ensure that water is not the source of infections, hospitals should consider*

*implementing a water management program that considers the ASHRAE industry standard and the CDC toolkit. A documented water management program includes a hospital risk assessment to identify where Legionella and other opportunistic waterborne pathogens (e.g. Pseudomonas, Acinetobacter, Burkholderia, Stenotrophomonas, nontuberculous mycobacteria, and fungi) could grow and spread in the hospital water system. In addition, the water management program should specify testing protocols and acceptable ranges for control measures, and document the results of testing and corrective actions taken when control limits are not maintained.*

*The hospital must conduct surveillance on a hospital-wide basis in order to identify infectious risks or communicable disease problems at any particular location. This does not imply all areas and locations of the hospital at all times, but it does mean that the hospital must have reliable sampling or other mechanisms in place to permit identifying and monitoring infections and communicable diseases occurring throughout the hospital's various locations or departments. The hospital must document its surveillance activities, including the measures selected for monitoring, and collection and analysis methods. Surveillance activities should be conducted in accordance with recognized infection control surveillance practices, such as those set forth by the CDC's National Healthcare Safety Network (NHSN).*

*The hospital should know how to recognize and contain infectious disease outbreaks. An outbreak is the occurrence of more cases than expected in a given area or among a specific group of people over a particular period of time. In the event of an outbreak of an infectious disease, hospitals should have policies and procedures in place to address the appropriate steps to diagnose and manage cases, implement appropriate precautions, and prevent further transmission of the disease as well as documentation of follow-up activity in response and comply with state and local public health authority requirements for identification, reporting, and containing communicable diseases and outbreaks.*

### **Survey Procedures §485.42(a)(3)**

- *Observe the hospital for the sanitary condition of their environments of care, noting the cleanliness of patient rooms, floors, horizontal surfaces, patient equipment, air inlets, mechanical rooms, food service activities, treatment and procedure areas, surgical areas, central supply, storage areas, medication preparation etc.*
- *Review policies and procedures of the infection control program for evidence that the program has a mechanism for surveillance to identify the transmission of infection and also address transmission of infections that have been reported by public health authorities. Ensure there is a process in place for reporting to public health authorities when the transmission of infections occur.*
- *Review any water management program documentation, if a water management program has been implemented, for the hospital risk assessment, and water quality monitoring.*
- *Review policies and procedures for the detection, investigation and control of outbreaks.*

*(Rev. )*

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

**Interpretive Guidelines §482.42(a)(4)**

*All hospitals are required to have an infection prevention and control program. The program should reflect the scope of services offered throughout the organization. The hospital is expected to demonstrate how its infection prevention and control program adequately represents the services provided to the community it serves. In addition, the hospital program should have mechanisms in place for assessment and reevaluation of the infection prevention and control program to ensure it responds to changes in the hospital environment on an ongoing basis.*

**Survey Procedures §482.42(a)(4)**

- Determine whether the infection control and prevention program is hospital-wide and program-specific in gathering and assessing infection and communicable disease data and in taking steps to reduce the risks of infections.*
- Review the hospital infection control and prevention program for evidence of the parameters of the active surveillance program to determine whether it is consistent with infection control standards of practice and is suitable to the scope and complexity of the hospital's services.*

**A-0760**

*(Rev. 03/20)*

**§482.42(b)(1) 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;**

**Interpretive Guidelines §482.42(b)(1)**

*Antibiotic stewardship, has long been recognized as one of the special challenges that facilities must meet in order to address the problems of infectious disease treatment, medication safety and multidrug-resistant organisms in hospitals.*

*The hospital must designate an individual or group of individuals as its antibiotic stewardship program leaders. Ideally, an antibiotic stewardship program is jointly led by a physician and pharmacist. The individual(s) must be appointed by the hospital's governing body based on the recommendations of the medical staff leadership and pharmacy leadership. The hospital must ensure high-level hospital clinical leadership, specifically leadership from the medical staff and the pharmacy service, are involved in*

*the process of selecting the antibiotic stewardship leaders. This high-level participation promotes a hospital-wide culture of safety and quality in which input across the hospital is solicited and acted upon.*

*In designating antibiotic stewardship leaders, hospitals must assure that the individuals so designated are qualified through education, training, experience, or certification in antibiotic stewardship. Training and/or certification may be obtained through organizations such as the specialty boards in adult or pediatric infectious diseases offered for physicians by the American Board of Internal Medicine (for internists), the American Board of Pediatrics (for pediatricians), and the Society for Infectious Disease Pharmacists (for pharmacists)*

*Antibiotic stewardship staff should maintain their qualifications through ongoing education and training, which can be demonstrated by participation in antibiotic stewardship courses, or in local and national meetings organized by recognized professional societies. Organizations that provide ongoing training and education include the Society for Healthcare Epidemiology of America (SHEA), and the Infectious Diseases Society of America (IDSA) and the Society for Infectious Disease Pharmacists (SIDP).*

*CMS does not specify either the number of antibiotic stewardship staff to be designated or the number of antibiotic stewardship hours that must be devoted to the antibiotic stewardship programs. However, resources must be adequate to accomplish the tasks required for the antibiotic stewardship program. In hospitals with more than one antibiotic stewardship staff member, the staff members should work as an integrated team to ensure the functions of an antibiotic stewardship program are covered. A prudent hospital would consider patient census, characteristics of the patient population, and complexity of the healthcare services it offers in determining the size and scope of the resources it commits to antibiotic stewardship. SHEA has studies and recommendations on resource allocation that hospitals may find useful.*

*The antibiotic stewardship staff must develop and implement policies governing the optimal use of antibiotics. Antibiotic stewardship policies should address the roles and responsibilities for antibiotic stewardship and use within the hospital; how the various hospital committees and departments interface with the antibiotic stewardship program; and how to optimize antibiotic use.*

#### **Survey Procedures §482.42(b)(1)**

- *Determine whether antibiotic stewardship leadership and staff was/were appointed by the governing body based on recommendations of the medical staff leadership and pharmacy leadership and has the responsibility for the antibiotic stewardship program.*
- *Review the personnel file of the antibiotic stewardship staff to determine whether he/she/they is/are qualified through ongoing education, training, experience, or certification to oversee the antibiotic stewardship program.*
- *Determine whether the antibiotic stewardship staff have developed and implemented hospital antibiotic stewardship policies.*

- *Review the criteria the hospital used to determine the resources necessary to operate effectively and ensure the resource allocation matches the determined needs.*

## **A-0761**

*(Rev. 03/20)*

### **§482.42(b)(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;**

#### **Interpretive Guidelines §482.42(b)(2)(i)**

*Hospitals must develop and implement appropriate antibiotic stewardship interventions to address issues identified through its assessment activities, and then monitor the effectiveness of interventions through further data collection and analysis. Hospitals should improve their internal coordination among all components responsible for antibiotic use and reducing the development of resistance, including, but not limited to, the antibiotic stewardship programs, the infection prevention and control program, the QAPI program, the medical staff, nursing services, laboratory services, and pharmacy services. Hospitals must promote evidence-based use of antibiotics, to reduce the incidence of adverse consequences of inappropriate antibiotic use including, but not limited to, treatment failures, C. difficile infections (CDIs), and growth of antibiotic resistance in the hospital overall.*

*The hospital must implement and maintain an active and hospital-wide antibiotic stewardship program as an effective means to improve hospital antibiotic-prescribing practices and thereby curb patient risks for adverse drug events, treatment failures and for potentially life-threatening, antibiotic-resistant infections, including CDIs. A robust antibiotic stewardship program must be coordinated with the hospital's overall infection prevention and control program to address healthcare acquired infections and antibiotic resistance.*

#### **Survey Procedures §485.640(b)(2)(i)**

*Review the hospital's antibiotic stewardship policies and procedures for evidence that the hospital has a process in place for coordination among all components of the hospital responsible for antibiotic use and resistance, including, but not limited to, the antibiotic stewardship program, the infection prevention and control program, the QAPI program, the medical staff, nursing services, and pharmacy services.*

## **A-0762**

*(Rev. 03/20)*

### **[§482.42(b)(2) The hospital-wide antibiotic stewardship program:]**

**(ii) Documents the evidence-based use of antibiotics in all departments and services of the hospital; and**

#### **Interpretive Guidelines §482.42(b)(2)(ii)**

*Hospitals must promote evidence-based use of antibiotics to reduce the incidence of adverse consequences of inappropriate antibiotic use including, but not limited to, adverse drug events, CDIs, and growth of antibiotic resistance in the hospital overall.*

**Survey Procedures §485.640(b)(2)(ii)**

- *Verify that the hospital's antibiotic use is consistent with their documented evidence-based hospital-wide antibiotic stewardship program recommendations.*

**A-0763**

*(Rev. 03/20)*

**[§482.42(b)(2) The hospital-wide antibiotic stewardship program:]**

**(iii) Documents 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;**

**Interpretive Guidelines §482.42(b)(2)(iii)**

*The hospital must provide documentation of improvements and the sustained improvement toward the proper use of antibiotics through the implementation of the hospital wide antibiotic stewardship program. It is expected that the hospital will reduce patient risk for adverse drug events and potentially life-threatening, antibiotic-resistant infections, including CDIs. The antibiotic stewardship program should be updated with any advancing evidence-based improvements in antibiotic-prescribing practices.*

**Survey Procedures §485.640(b)(2)(iii)**

- *Review documentation of improvements and/or sustainment of improvements through the use of the evidence-based hospital-wide antibiotic stewardship program recommendations.*

**A-0764**

*(Rev. 03/20)*

**§482.42(b)(3) The antibiotic stewardship program adheres to nationally recognized guidelines, as well as best practices, for improving antibiotic use; and**

**Interpretive Guidelines §482.42(b)(3)**

*Hospitals must implement and maintain an active and hospital-wide antibiotic stewardship program consistent with nationally recognized standards for improving antibiotic use. Optimizing the use of antibiotics is critical to effectively treat infections, protect patients from harms caused by unnecessary antibiotic use, and combat antibiotic resistance.*

*For example, the Centers for Disease Control and Prevention (CDC) provides “Core Elements of Antibiotic Stewardship” at <https://www.cdc.gov/antibiotic-use/core-elements/index.html>. CDC’s Core Elements of Antibiotic Stewardship offer providers and facilities a set of key principles to guide efforts to improve antibiotic use and,*

*therefore, advance patient safety and improve outcomes. There is no “one size fits all” approach to optimize antibiotic use for all settings. The complexity of medical decision-making surrounding antibiotic use and the variability in hospital size and types of care in U.S. healthcare settings require flexible programs and activities.*

*Examples of other organizations that promulgate nationally recognized antibiotic stewardship guidelines and/or recommendations include, and are not limited to: the Society for Healthcare Epidemiology of America (SHEA), and the Infectious Diseases Society of America (IDSA), the American Society for Health System Pharmacists (ASHP) and the Society for Infectious Disease Pharmacists (SIDP).*

#### **Survey Procedures §482.42(b)(3)**

- *Verify evidence that nationally recognized standards have been implemented for their evidence-based hospital-wide antibiotic stewardship program.*
- *Verify that core elements of best practices have been included within the hospital-wide antibiotic stewardship program that may include: hospital leadership commitment, accountability, pharmacy expertise, tracking, reporting, education, and appropriate interventions or actions being taken to improve antibiotic use to reduce adverse events, prevent emergence of resistance, and ensure better outcomes for patients in this setting.*

#### **A-0765**

*(Rev. 03/20)*

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

#### **Interpretive Guidelines §482.42(b)(4)**

*Hospitals must implement and maintain an active and hospital-wide antibiotic stewardship program that reflects the scope and complexity of the hospital services provided.*

#### **Survey Procedures §485.640(b)(4)**

- *Review the parameters of the antibiotic stewardship program to determine whether it is suitable to the scope and complexity of the hospital's services.*

#### **A-0770**

*(Rev. )*

#### **§482.42(c)(1) 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.**

#### **Interpretive Guidelines §482.42(c)(1)(i)**

*The hospital's governing body must ensure that an infection prevention and control program is in place and operational for the monitoring and prevention of healthcare associated infections and the transmission of pathogens and an antibiotic stewardship program is in place and operational for the monitoring and improvement of antibiotic use. The development and implementation of both the infection control and antibiotic stewardship programs should include leadership support and accountability via the participation of the medical director, pharmacy director, nursing and administrative leadership, and individuals with designated responsibility for the infection control program and the antibiotic stewardship program; however the governing body or responsible individual is responsible to demonstrate the implementation, success, and sustainability of such activities.*

*Hospital policies should address the roles and responsibilities for infection prevention and control within the hospital; how the various hospital committees and departments interface with the infection prevention and control program; how to prevent infectious/communicable diseases; and how to report infectious/communicable diseases to the infection prevention and control program.*

*Likewise, hospitals policies should address the roles and responsibilities for antibiotic stewardship within the hospital; how the various hospital committees and departments interface with the antibiotic stewardship program; and how to monitor and improve antibiotic use.*

#### **Survey Procedures §485.640(c)(1)(i)**

- *Review the hospital policies and governing body meeting minutes for record of support for the infection control and antibiotic stewardship programs.*
- *Verify that the hospital policies are being followed for the tracking of all infection surveillance, prevention and control, and the monitoring of hospital antibiotic use activities.*

#### **A-0771 (Rev. )**

**[§482.42(c)(1) The governing body must ensure all of the following:]**

**(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.**

#### **Interpretive Guidelines §482.42(c)(1)(ii)**

*Hospitals are required to coordinate internally among all components responsible for infection control and antibiotic stewardship including, but not limited to, the infection prevention and control program, the antibiotic stewardship program, the QAPI program, the medical staff, nursing services, laboratory services, and pharmacy services.*

*The hospital's governing body, the medical staff, and the director of nursing must ensure that the hospital-wide Quality Assessment and Performance Improvement (QAPI) program and staff in-service training programs address problems identified through the infection prevention and control program and the antibiotic stewardship program. To*

*reflect the importance of infection control and antibiotic stewardship, the regulations specifically require that the hospital's QAPI and training programs must be involved in addressing problems identified by the infection control program and antibiotic stewardship program, and hold the leadership jointly responsible for linking the infection control program and antibiotic stewardship program with the QAPI and training programs. These hospital leaders are also held explicitly responsible for implementing successful corrective action plans. In order to accomplish this, hospital leaders must monitor adherence to corrective action plans, as well as assess the effectiveness of actions taken, with implementation of revised corrective actions as needed.*

*Education on the principles and practices for preventing infections and the transmission of infectious agents and the appropriate use of antibiotics within the hospital should be provided to anyone who has an opportunity for contact with patients or medical equipment or prescribing, preparing or administering antibiotics, e.g., nursing and medical staff; pharmacy staff, therapists and technicians, such as those involved in respiratory, physical, and occupational therapy and radiology and cardiology services; phlebotomists; housekeeping and maintenance staff; volunteers; and all students and trainees in healthcare professions.*

#### **Survey Procedures §482.42(c)(1)(ii)**

- *Confirm that the hospital's infection control program and antibiotic stewardship program are being coordinated with their QAPI leadership, medical staff, nursing services, and pharmacy services.*
- *Determine whether the hospital's QAPI program and staff in-service training programs address problems identified by the infection control officer(s) and antibiotic stewardship staff.*
- *Determine whether infection control and antibiotic use problems identified are reported to the hospital's leadership. Verify that hospital leadership takes steps to assure that corrective actions are implemented and successful.*

**A-0772**  
**(Rev. )**

#### **§482.42(c)(2) 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.**

#### **Interpretive Guidelines §482.42(c)(2)(i)**

*Hospitals must implement and maintain an active and hospital-wide infection control program consistent with nationally recognized standards for preventing infections and the transmission of pathogens. The infection preventionist(s) and/or infection control professional(s) is responsible for the development and implementation of hospital-wide infection surveillance, prevention, and control policies and procedures that adhere to nationally recognized guidelines.*

*Hospitals have the flexibility to adopt the approaches which best fit their infection prevention and control needs. CMS does not discourage innovative methodologies or approaches; however, does expect to see the hospitals engaging in these sorts of innovative practices while also having an adequate program rooted in the traditional evidence-based model. There are ample recognized evidence-based approaches for hospitals to follow in order to adhere to nationally recognized guidelines without impeding any hospital's ability to otherwise make progress in infection prevention and control.*

**Survey Procedures §482.42(c)(2)(i)**

- *Verify that the hospital's infection prevention and control program, including its hospital-wide infection surveillance, prevention, and control policies and procedures, is consistent with nationally recognized standards.*

**A-0773**

*(Rev.)*

**[§482.42(c)(2) The infection preventionist(s)/infection control professional(s) is responsible for:]**

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

**Interpretive Guidelines §482.42(c)(2)(ii)**

*The hospital's infection preventionist(s) and/or infection control professional(s) is responsible for all documentation, written or electronic, of the prevention and control program, and its surveillance, prevention, and control activities. "Documentation" encompasses both collecting and maintaining pertinent information in a systematic fashion.*

*When considering priority activities, the infection preventionist(s) and/or infection control professional(s) can review the HHS Action Plan to Prevent Healthcare-Associated Infections (HHS. "HHS Action Plan to Prevent Healthcare-Associated Infections." Accessed 9 January 2020, <https://health.gov/hcq/prevent-hai-action-plan.asp>.*

**Survey Procedures §482.42(c)(2)(ii)**

- *Verify that the hospital's infection preventionist(s) and/or infection control professional(s) is documenting, in written or electronic form, the prevention and control program, and its surveillance, prevention, and control activities.*

**A-0774**

*(Rev.)*

**[§482.42(c)(2) The infection preventionist(s)/infection control professional(s) is responsible for:]**

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

### **Interpretive Guidelines §482.42(c)(2)(iii)**

*The hospital's infection preventionist(s) and/or infection control professional(s) must communicate and collaborate with the hospital's QAPI program on all infection prevention and control issues. Such issues include all concerns, including ones which are emerging and ones which are already problematic. This communication and collaboration is intended to foster and enhance a proactive culture around a hospital's infection prevention and control programs.*

### **Survey Procedures §485.640(c)(2)(iii)**

- *Verify that the hospital's infection preventionist(s) and/or infection control professional(s) is communicating and collaborating with the hospital's QAPI program on all infection prevention and control issues.*

### **A-0775**

*(Rev.)*

**[§482.42(c)(2) The infection preventionist(s)/infection control professional(s) is responsible for:]**

**(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.**

### **Interpretive Guidelines §482.42(c)(2)(iv)**

*The hospital's infection preventionist(s) and/or infection control professional(s) must take an active 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. This training and education must include the practical applications of infection prevention and control guidelines, policies, and procedures.*

### **Survey Procedures §482.42(c)(2)(iv)**

- *Review the hospital's policies and procedures on training and educating staff.*
- *Confirm that the hospital's infection preventionist(s) and/or infection control professional(s) training and education of hospital personnel and staff is competency based.*
- *Verify that training on the practical applications of infection prevention and control guidelines is occurring by reviewing the staff records on completed competencies.*

### **A-0776**

*(Rev.)*

**[§482.42(c)(2) The infection preventionist(s)/infection control professional(s) is responsible for:]**

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

**Interpretive Guidelines §482.42(c)(2)(v)**

*The hospital's infection preventionist(s) and/or infection control professional(s) are responsible for preventing and controlling healthcare acquired infections, and transmission of pathogens, including auditing of adherence to infection prevention and control policies and procedures by hospital personnel.*

**Survey Procedures §482.42(c)(2)(v)**

- *Verify that the hospital's infection preventionist(s) and/or infection control professional(s) has an active role in auditing the adherence to infection prevention and control policies and procedures by hospital personnel.*

**A-0777**

**(Rev.)**

**[§482.42(c)(2) The infection preventionist(s)/infection control professional(s) is responsible for:]**

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

**Interpretive Guidelines §482.42(c)(2)(vi)**

*The hospital's infection preventionist(s) and/or infection control professional(s) is responsible for communication and collaboration with the antibiotic stewardship program. Collaboration between the hospital's infection prevention and control and antibiotic stewardship programs provides the optimal approach to reducing healthcare acquired infections and antibiotic resistance.*

**Survey Procedures §482.42(c)(2)(vi)**

- *Verify that the hospital's infection preventionist(s) and/or infection control professional(s) is communicating and collaborating with the antibiotic stewardship program.*

**A-0778**

**(Rev.)**

**§482.42(c)(3) 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.**

**Interpretive Guidelines §482.42(c)(3)(i)**

*The hospital's designated antibiotic stewardship program leader, similar to the responsibilities of the hospital's designated infection preventionist(s) and/or infection control professional(s) ensures the appropriate antibiotic use for reducing adverse drug events, treatment failures and antibiotic resistance, including deadly C. difficile infections. The antibiotic stewardship program must have dedicated and expert leadership responsible and accountable for its success, whose responsibilities include the development and implementation of a hospital-wide antibiotic stewardship program, based on nationally recognized guidelines, to monitor and improve the use of antibiotics.*

**Survey Procedures §482.42(c)(3)(i)**

- *Verify that the hospital's designated antibiotic stewardship program leader develops and implements the hospital-wide antibiotic stewardship program, based on nationally recognized guidelines, to monitor and improve the use of antibiotics.*

**A-0779**

*(Rev. )*

**[§482.42(c)(3) The leader(s) of the antibiotic stewardship program is responsible for:]**

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

**Interpretive Guidelines §482.42(c)(3)(ii)**

*The hospital's designated antibiotic stewardship program leader is responsible for documentation, written or electronic, of antibiotic stewardship program activities and antibiotic-use issues.*

**Survey Procedures §482.42(c)(3)(ii)**

- *Verify that the hospital's designated antibiotic stewardship program leader documents the hospital's antibiotic stewardship program activities and antibiotic use issues*

**A-0780**

*(Rev. )*

**[§482.42(c)(3) The leader(s) of the antibiotic stewardship program is responsible for:]**

**(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.**

**Interpretive Guidelines §482.42(c)(3)(iii)**

*The hospital's designated antibiotic stewardship program leader is responsible for 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.*

### Survey Procedures §485.640(c)(3)(iii)

- *Verify that the hospital's designated antibiotic stewardship program leader communicates and collaborates with medical staff, nursing, and pharmacy leadership, as well as the hospital's infection prevention and control and QAPI programs*

### A-0781

*(Rev. )*

[§482.42(c)(3) The leader(s) of the antibiotic stewardship program is responsible for:]

**(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.**

### Interpretive Guidelines §482.42(c)(3)(iv)

*The hospital's designated antibiotic stewardship program leader is responsible for 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.*

### Survey Procedures §482.42(c)(3)(iv)

- *Verify that the hospital's designated antibiotic stewardship program leader provides 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.*

### A-0785

*(Rev. )*

**§482.42(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:**

## **Interpretive Guidelines §482.42(d)**

*The hospital must have an infection prevention and control program and antibiotic stewardship program for the entire hospital (including all campuses, provider-based locations, satellites, remote locations, etc.). In the case of a hospital system, it is permissible for the system to have unified and integrated infection prevention and control and antibiotic stewardship programs (hereafter referred to as a “unified infection prevention and control and antibiotic stewardship”) for multiple, separately certified hospitals.*

*If the hospital uses a unified and integrated program that it shares with other hospitals that are part of a multi-hospital system, this does not change the requirement that each separately certified hospital is held responsible and accountable to the system’s governing body for meeting all of the requirements of an infection prevention and control program and antibiotic stewardship program as outlined in the regulations at §482.42.*

## **Survey Procedures §482.42(d)**

- *Surveyors assess the manner and degree of noncompliance with the standards within this condition to determine whether there is condition-level noncompliance.*

## **A-0786**

**(Rev.)**

**§482.42(d)(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;**

## **Interpretive Guidelines §482.42(d)(1)**

*Although a hospital system has the flexibility to develop a unified and integrated infection prevention and control program and antibiotic stewardship program for all of the separately certified hospitals within its system, there must be evidence that the system-wide programs have taken in to account the significant differences in patient populations and services offered that provide unique circumstances for each member hospital.*

## **Survey Procedures §482.42(d)(1)**

- *Review the infection prevention and control program and antibiotic stewardship program and identify unified infection prevention and control and antibiotic stewardship policies and activities and how these take into account the hospitals population and services offered.*
- *Identify the process for which the hospitals’ population and services are integrated into the infection prevention and control and antibiotic stewardship programs.*

## **A-0787**

**(Rev.)**

**§482.42(d)(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;

**Interpretive Guidelines §482.42(d)(2)**

*The unified infection prevention and control and antibiotic stewardship programs must develop and implement policies and procedures for each certified hospital to address the needs and concerns of each hospital separately. The practice and location of the hospital must be given consideration when developing these policies and procedures.*

**Survey Procedures §482.42(d)(2)**

- *Review the infection prevention and control and antibiotic stewardship programs and identify unified infection prevention and control and antibiotic stewardship policies and procedures and identify how each separately certified hospital's unique needs and areas of concern have been considered in the development of those policies and procedures..*

**A-0788**

*(Rev. )*

**§482.42(d)(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**

**Interpretive Guidelines §482.42(d)(3)**

*Each hospital must also demonstrate that the unified and integrated programs have mechanisms in place to ensure that issues localized to particular hospitals in the system are also considered and addressed. Therefore, each hospital should be able to identify and address QAPI issues particularly specific to their hospital in addition to any of the issues being addressed in the unified and integrated programs.*

**Survey Procedures §482.42(d)(2)**

- *Review the QAPI program and identify unified QAPI elements and identify QAPI elements that are unique to the particular hospital.*
- *Identify the process for which these unique elements are integrated into the QAPI program.*

**A-0789**

*(Rev. )*

**§482.42(d)(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.**

**Interpretive Guidelines §482.42(d)(4)**

*The hospital must designate an individual or group of individuals with expertise in infection prevention and control and antibiotic stewardship. This individual or group of individuals are responsible for communicating, implementing, and maintaining the policies and procedures governing infection prevention and control and antibiotic stewardship. They are directed by the unified infection prevention and control and antibiotic stewardship programs. Additionally, they are responsible for providing education and training on the practical applications of infection prevention and antibiotic stewardship to hospital staff.*

**Survey Procedures §482.42(d)(4)**

- *Review governing body policies for evidence that a qualified individual(s) has/have been designated as responsible for communicating with the unified infection prevention program and antibiotic stewardship program, for implementing and maintaining policies and procedures governing the infection prevention and control and antibiotic stewardship programs, and training of hospital staff.*
- *Review documentation that the designated individual(s) communicate(s) with the unified program leadership related to issues with infection prevention and antibiotic stewardship.*
- *Review hospital training documents related to education in infection prevention and antibiotic stewardship as evidence of training of hospital staff.*