



# **Antimicrobial Stewardship Forum**

June 6, 2023  
12 – 1 PM EDT

# Antimicrobial Stewardship Forum

## ■ Co-chairs



### **Amy Fabian, PharmD, BCPS, BCIDP**

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# Antimicrobial Stewardship Forum

- Agenda
  - ◆ Audience Ice Breaker Question
  - ◆ Speaker Introduction
  - ◆ CE Presentation: Charting a Course in the Sea of Changing Antimicrobial Stewardship Regulations and Requirements  
Speaker: Monica Dorobisz, PharmD, BCIDP, Clinical Pharmacy Specialist – Infectious Diseases, Kent Hospital, Warwick, RI
  - ◆ Audience Questions
    - Please type questions in the Question box on the webinar screen

# Ice-Breaker Question

**Which of the following accrediting agencies does your facility utilize?**

1. The Joint Commission (TJC)
2. Det Norske Veritas (DNV)
3. Accreditation Commission for Health Care (ACHC)
4. Center for Improvement in Healthcare Quality (CIHQ)
5. Other
6. Unsure

# Speaker Introduction

## **Monica Dorobisz, PharmD, BCIDP**

Monica Dorobisz received her doctor of pharmacy degree from Northeastern University in 2008. She then completed a PGY1 Pharmacy Practice Residency at the Seton Family of Hospitals in Austin, TX followed by a PGY2 Infectious Diseases Pharmacy Residency at the University of Pittsburgh Medical Center in Pittsburgh, PA where she also completed the Mastery of Teaching Program. Upon conclusion of her training in 2010, Monica joined the pharmacy team at Kent Hospital as the clinical pharmacy specialist in infectious diseases and is the director of the Kent Hospital Antimicrobial Stewardship Program which she was responsible for developing in 2012. Monica maintains an active role in promoting antimicrobial stewardship throughout the state as a member of the Rhode Island Department of Health Antimicrobial Stewardship and Environmental Cleaning Task Force. She is also a member of the Rhode Island and American Societies of Health Systems Pharmacists as well as the Infectious Diseases Society of America. Outside of her career, Monica is passionate about helping animals through volunteering and rescue.

 *Care New England*

# Charting a Course in the Sea of Changing Antimicrobial Stewardship Regulations and Requirements

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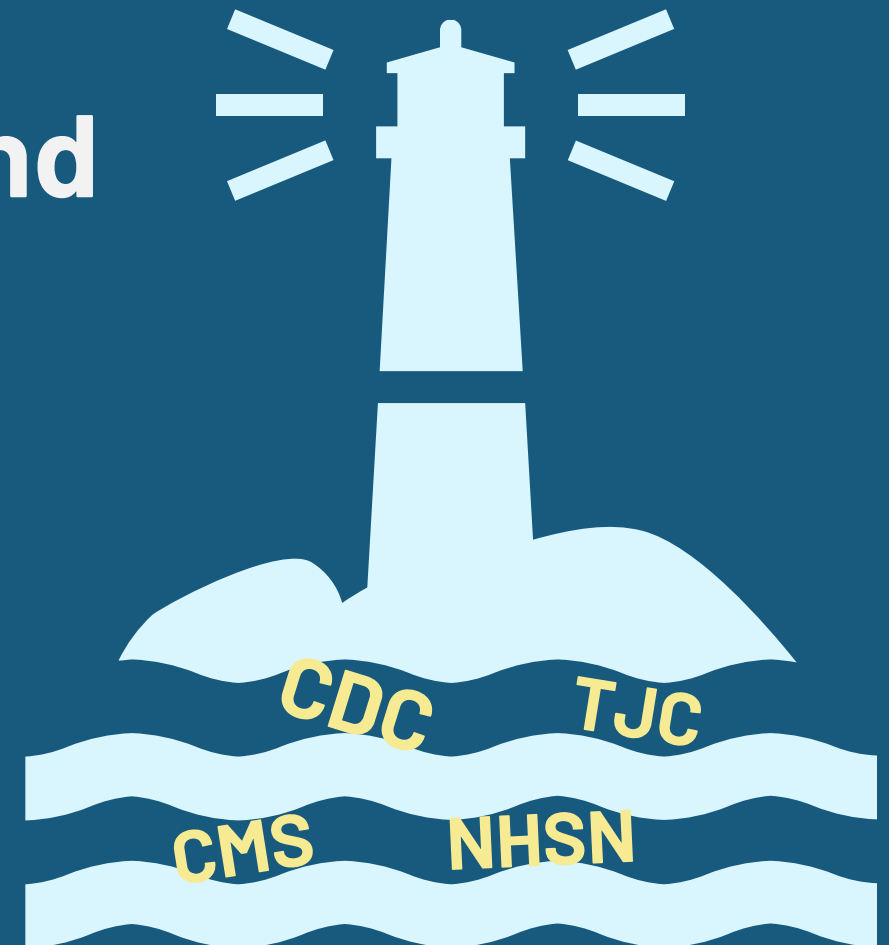
**Monica Dorobisz, PharmD, BCIDP**

Clinical Pharmacy Specialist – Infectious Diseases

Director – Kent Hospital Antimicrobial Stewardship Program

Warwick, Rhode Island

June 6, 2023



# Disclosures

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- The speaker, Dr. Dorobisz, has no relevant financial relationships with ineligible companies to disclose.
- None of the planners, nor the moderator for this activity, has relevant financial relationships with ineligible companies to disclose.

# Objectives

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## Pharmacists

- Discuss the CDC Core Elements for Antimicrobial Stewardship Programs in the hospital, outpatient and resource-limited settings
- Identify The Joint Commission standards and CMS Conditions of Participation related to antimicrobial stewardship in hospital, ambulatory and critical access hospital settings
- Describe examples on how to overcome regulatory implementation challenges in antimicrobial stewardship
- Recognize future reporting requirements for Antibiotic Use and Resistance to the CDC National Healthcare Safety Network (NHSN)

## Pharmacy Technicians

- List the regulatory agencies that set standards for antimicrobial stewardship in hospital, ambulatory and critical access hospital settings
- Recognize the challenges faced by institutions in meeting antimicrobial stewardship regulatory requirements
- Identify ways for pharmacy technicians to help meet regulatory requirements, especially in resource-limited settings
- Describe how pharmacy technicians in informatics could help implement antibiotic use reporting requirements





# Definitions

**AMS**

- Antimicrobial Stewardship

**ASP**

- Antimicrobial Stewardship Program

**AUR**

- Antibiotic Use and Resistance

**CAH**

- Critical Access Hospital

**CDC**

- Centers for Disease Control and Prevention

**CMS**

- Centers for Medicare and Medicaid Services

**IDSA**

- Infectious Disease Society of America

**IPC**

- Infection Prevention and Control

**NHSN**

- National Healthcare Safety Network

**QAPI**

- Quality assessment and performance improvement

**SHEA**

- Society for Healthcare Epidemiology

**TJC**

- The Joint Commission

# Antimicrobial Stewardship Guidance and Regulatory Timeline



- **1988** **IDSA Guidelines:** Improving antibiotic use in hospitals
- **2007** **IDSA/SHEA Guidelines:** Developing an Institutional Program to Enhance AMS
- **2009** **CDC:** First educational effort to promote improved antibiotic use in hospitals
- **2013** **CDC:** First Antibiotic Resistance Threats Report
- **2014** **CDC:** Core Elements for Acute Care Hospitals  
**CDC:** Launches NHSN AUR Module
- **2015** **National Action Plan** for Combating Antibiotic Resistance  
**CDC:** Core Elements for - Nursing Homes
- **2016** **CDC:** Core Elements - Outpatient  
**IDSA/SHEA Guidelines:** Hospital ASP updated
- **2017** **CDC:** Core Elements - Resource Limited Hospitals  
**TJC Standards:** Acute and CAH, nursing care centers
- **2019** **CDC:** Hospital Core Elements updated
- **2020** **TJC Standards:** Ambulatory Care  
**CMS Rule:** Acute and CAH Conditions of Participation (COP)
- **2022** **CDC:** Hospital Core Element Priorities for Implementation  
**CMS Rule:** Acute and CAH updated COP
- **2023** **TJC Standards:** Acute and CAH revised
- **2024** **CMS rule:** NHSN reporting requirement



# CDC Core Elements: Hospitals





## The Core Elements of Hospital Antibiotic Stewardship Programs: 2019

- Updated from 2014 with a focus on priorities versus optional and supplemental activities



## Implementation of Antibiotic Stewardship Core Elements at Small and Critical Access Hospitals

- Provides core element implementation ideas for hospitals with < 25 beds

<https://www.cdc.gov/antibiotic-use/core-elements/small-critical.html>



## The Core Elements of Human Antibiotic Stewardship Programs in Resource-Limited Settings: National and Hospital Levels

- Provides framework and ideas for AMS implementation in hospitals of lower-income countries with less regulatory and healthcare system resources

<https://www.cdc.gov/antibiotic-use/core-elements/resource-limited.html>

## Core Elements of Hospital Antibiotic Stewardship Programs



### Hospital Leadership Commitment

Dedicate necessary human, financial, and information technology resources.



### Accountability

Appoint a leader or co-leaders, such as a physician and pharmacist, responsible for program management and outcomes.



### Pharmacy Expertise (previously “Drug Expertise”):

Appoint a pharmacist, ideally as the co-leader of the stewardship program, to help lead implementation efforts to improve antibiotic use.



### Action

Implement interventions, such as prospective audit and feedback or preauthorization, to improve antibiotic use.



### Tracking

Monitor antibiotic prescribing, impact of interventions, and other important outcomes, like *C. difficile* infections and resistance patterns.



### Reporting

Regularly report information on antibiotic use and resistance to prescribers, pharmacists, nurses, and hospital leadership.



### Education

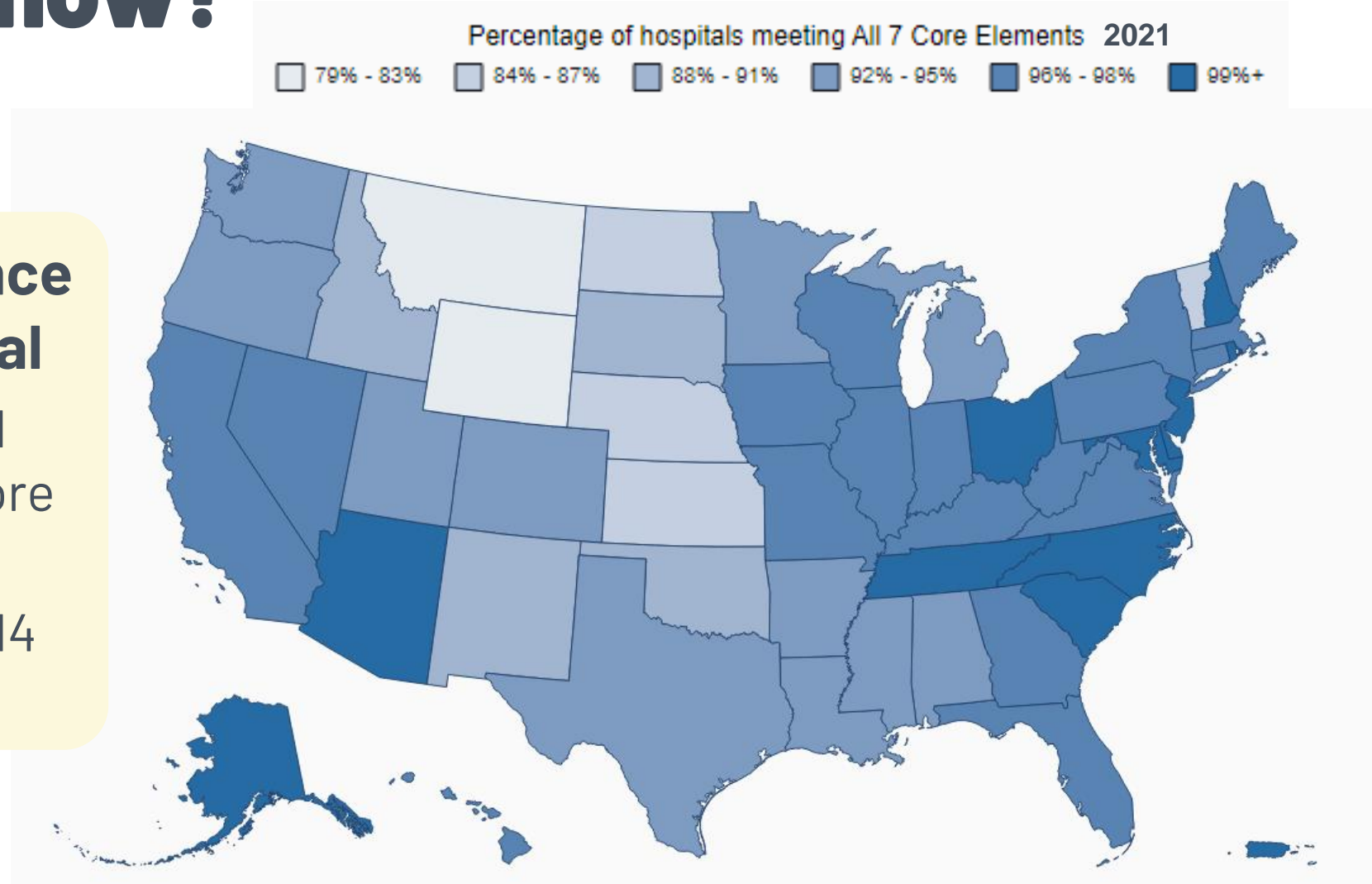
Educate prescribers, pharmacists, nurses, and patients about adverse reactions from antibiotics, antibiotic resistance, and optimal prescribing.

<https://www.cdc.gov/antibiotic-use/core-elements/hospital.html>

# Hospital Core Elements: Where are we now?








## CDC Antibiotic Resistance and Patient Safety Portal

- **95%** of hospitals reported implementation of all 7 Core Elements in 2021
- Increased from 41% in 2014 to 89% in 2019



# CDC Core Elements 2022 Priorities Update

Created to help further enhance the quality and impact of existing ASPs

Hospital Core Elements	Priorities for Hospital Core Element Implementation
<b>Hospital Leadership Commitment</b>	
 <p>Dedicate necessary human, financial, and information technology resources.</p>	Antibiotic stewardship physician and/or pharmacist leader(s) have antibiotic stewardship responsibilities in their contract, job description, or performance review.
<b>Accountability</b>	
 <p>Appoint a leader or co-leaders, such as a physician and pharmacist, responsible for program management and outcomes.</p>	Antibiotic stewardship program is co-led by a physician and pharmacist.*
<b>Pharmacy/Stewardship Expertise</b>	
 <p>Appoint a pharmacist, ideally as the co-leader of the stewardship program, to help lead implementation efforts to improve antibiotic use.</p>	Antibiotic stewardship physician and/or pharmacist leader(s) have completed infectious diseases specialty training, a certificate program, or other training on antibiotic stewardship.
<b>Action</b>	
 <p>Implement interventions, such as prospective audit and feedback or preauthorization, to improve antibiotic use.</p>	Antibiotic stewardship program has facility-specific treatment recommendations for common clinical condition(s) and performs prospective audit/feedback or preauthorization.
<b>Tracking</b>	
 <p>Monitor antibiotic prescribing, impact of interventions, and other important outcomes, like <i>C. difficile</i> infections and resistance patterns.</p>	Hospital submits antibiotic use data to the NHSN Antimicrobial Use Option.
<b>Reporting</b>	
 <p>Regularly report information on antibiotic use and resistance to prescribers, pharmacists, nurses, and hospital leadership.</p>	Antibiotic use reports are provided at least annually to target feedback to prescribers. In addition, the antibiotic stewardship program monitors adherence to facility-specific treatment recommendations for at least one common clinical condition.
<b>Education</b>	
 <p>Educate prescribers, pharmacists, nurses, and patients about adverse reactions from antibiotics, antibiotic resistance, and optimal prescribing.</p>	No implementation priority identified.

\* For critical access hospitals (CAHs), this criterion can be met if the hospital has a physician leader with a pharmacist involved in stewardship (recognizing that some CAHs do not have pharmacists on staff, so co-leadership is not possible).

# Audience Polling Question #1

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**What size hospital do you practice in?**

- a)  $\geq 500$  beds
- b) 101 – 499 beds
- c) 26 – 100 beds
- d)  $\leq 25$  beds or Critical Access Hospital
- e) I do not practice in a hospital / I don't know



# TJC Standards: Hospitals





# TJC Standards: 2017 to 2023 Comparison

2017	2023
<p><b>Standard MM.09.01.01: (EP 1-11)</b>            The hospital has an antimicrobial stewardship program based on current scientific literature.</p>	<p><b>Standard MM.09.01.01: (EP 10-21)</b>            The hospital <b>establishes antibiotic stewardship as an organizational priority</b> through support of its antibiotic stewardship program.</p>
<p><b>EP 1: Leaders establish AMS as an organizational priority</b></p> <p><i>Examples of leadership commitment to an ASP are as follows:</i></p> <ul style="list-style-type: none"> <li>• Accountability documents</li> <li>• Budget plans</li> <li>• Infection prevention plans</li> <li>• Performance improvement plans</li> <li>• Strategic plans</li> <li>• Using the electronic health record to collect AMS data</li> </ul>	<p><b>EP 10: The hospital <b>allocates financial resources for staffing and information technology to support the ASP</b></b></p> <p><b><i>How it will be surveyed:</i></b>  <i>Hospital leaders should be prepared to discuss:</i></p> <ul style="list-style-type: none"> <li>• <i>How AMS has been established as a patient safety priority</i></li> <li>• <i>Resources that have been allocated to the ASP to support its activities</i></li> </ul>

# TJC Standards: 2017 to 2023 Comparison

2017	2023
<p><b>EP 2: The hospital educates staff and licensed independent practitioners involved in antimicrobial ordering, dispensing, administration, and monitoring about antimicrobial resistance and AMS practices.</b></p> <p>Education occurs upon hire or granting of initial privileges and periodically thereafter, based on organizational need.</p>	<p><b>DELETED</b></p> <p><i>Incorporated into the responsibilities of the ASP leader in EP12 as competency-based education (no specific requirement with timing upon hire, etc.)</i></p>
<p><del><b>EP 3: The hospital educates patients, and their families as needed, regarding the appropriate use of antimicrobial medications, including antibiotics.</b> (For more information on patient education, refer to Standard PC.02.03.01)</del></p> <p><b>Subsequently deleted</b></p>	<p><b>No specific patient education component</b></p> <p><i>Continues to be assessed under general patient care medication education PC.02.03.01</i></p>

# TJC Standards: 2017 to 2023 Comparison

2017	2023
<p><b>EP 4: The hospital has an AMS multidisciplinary team that includes the following members, when available in the setting:</b></p> <ul style="list-style-type: none"><li>• Infectious disease physician</li><li>• Infection preventionist(s)</li><li>• Pharmacist(s)</li><li>• Practitioner</li></ul> <p><i>Part-time, consultant or telehealth staff are acceptable as members of the AMS multidisciplinary team.</i></p>	<p><b>EP 13: The hospital has a multidisciplinary committee that oversees the ASP</b></p> <ul style="list-style-type: none"><li>• The committee <b>may be</b> composed of representation from the medical staff, pharmacy services, IPC, nursing, microbiology, information technology, and QAPI</li><li>• May include part-time or consultant staff, and <b>participation may occur on site or remotely</b></li></ul>

# TJC Standards: 2017 to 2023 Comparison

2017	2023
<p><b>EP 5: The hospital's ASP includes the following core elements:</b></p> <p>Leadership commitment, Accountability, Drug expertise, <b>Action, Tracking,</b> Reporting, Education (actual verbiage from 2014 core elements was listed)</p>	<p><b>EP 16: The ASP monitors the hospital's antibiotic use by analyzing data on days of therapy (DOT) per 1000 days present or 1000 patient days, or by reporting data to the NHSN Antimicrobial Use Option of the AUR Module</b></p> <ul style="list-style-type: none"> <li>• <i>NHSN reporting not currently required</i></li> <li>• <i>Hospitals contracting with external pharmacy management organizations that may be unable to calculate DOT directly may use an estimated metric for DOT</i></li> </ul> <p><b>EP 17: The ASP implements one or both of the following strategies to optimize antibiotic prescribing:</b></p> <ul style="list-style-type: none"> <li>• <u>Preauthorization</u> for specific antibiotics (internal review and approval process prior to use)</li> <li>• <u>Prospective review and feedback</u> regarding antibiotic prescribing practices, including the treatment of positive blood cultures, by a member of the ASP</li> <li>• <i>Implemented based on the ASP's expertise and the organization's complexity</i></li> <li>• <i>Prospective review must be performed by a member of the ASP team</i></li> <li>• <i>Organizations should consider multiple pharmacists on the ASP team to minimize potential delays in patient care</i></li> </ul>

# TJC Standards: 2017 to 2023 Comparison

2017	2023
<p><b>EP 6: The hospital's ASP uses organization-approved multidisciplinary protocols (for example, policies and procedures)</b></p> <p>Examples of protocols are as follows: Antibiotic formulary restrictions, assessment of appropriateness of antibiotics for CAP, SSTI and/or UTI, <i>C. difficile</i>, guidelines for antimicrobial use in adults and/or pediatrics, IV to PO conversion, preauthorization requirements for specific antimicrobials, use of prophylactic antibiotics</p>	<p><b>EP 18: The ASP implements <b>at least two</b> evidence-based guidelines to improve antibiotic use for the most common indications</b></p> <p>Examples include, but are not limited to, the following:</p> <ul style="list-style-type: none"> <li>• CAP, UTI, SSTI, <i>C. difficile</i> colitis, asymptomatic bacteriuria, IV to PO antibiotic conversion, surgical prophylactic antibiotics</li> </ul> <p>Evidence-based guidelines must be based on national guidelines and also reflect local susceptibilities, formulary options, and the patients served, as needed.</p> <ul style="list-style-type: none"> <li>• <i>Be prepared to discuss how the guidelines were selected and implemented</i></li> </ul> <p><b>EP 19: The ASP <b>evaluates adherence</b> (including antibiotic selection and duration of therapy, where applicable) to <b>at least one</b> of the evidence-based guidelines the hospital implements</b></p> <ul style="list-style-type: none"> <li>• Adherence may be measured at the group level (e.g., departmental, unit, clinician subgroup) or at the individual prescriber level</li> <li>• Adherence data for a sample of patients may be obtained from relevant clinical areas by analyzing electronic health records or by conducting chart reviews</li> <li>• <i>Methods used depend on informatics resources and data available to the ASP</i></li> </ul>

# TJC Standards: 2017 to 2023 Comparison

2017	2023
<p><b>EP 7: The hospital collects, analyzes, and reports data on its ASP</b></p> <p>Examples of topics to collect and analyze data on may include evaluation of the ASP, antimicrobial prescribing patterns, and antimicrobial resistance patterns.</p>	<p><b>EP 15: The ASP documents the evidence-based use of antibiotics in all departments and services of the hospital</b></p> <ul style="list-style-type: none"> <li><i>The goal is for the ASP to document that all departments and services of the hospital are using antibiotics in a manner supported by evidence as determined by the hospital</i></li> <li><i>Be prepared to verify that the hospital's antibiotic use is consistent with the documented evidence-based ASP recommendations</i></li> </ul> <p><b>EP 20: The ASP collects, analyzes, and reports data to hospital leadership and prescribers</b></p> <p>Examples of data include antibiotic resistance patterns, antibiotic prescribing practices, or an evaluation of AMS activities.</p>
<p><b>EP 8: The hospital takes action on improvement opportunities identified in its ASP</b></p>	<p><b>EP 21: The hospital takes action on improvement opportunities identified by the ASP (no change)</b></p> <ul style="list-style-type: none"> <li><i>When the ASP identifies improvement opportunities, the hospital develops an action plan</i></li> <li><i>Be prepared to discuss the actions taken to improve antibiotic prescribing practices</i></li> </ul>

# TJC Standards: 2017 to 2023 Comparison

2017	2023
<p><b>EP 9:</b> Hospitals using TJC accreditation for deemed status* purposes:  <b>An individual(s) who is qualified through education, training, or experience in infectious diseases and/or AMS, is appointed by the governing body as the leader(s) of the ASP.</b></p> <p>The appointment is based on recommendations of medical staff leadership and pharmacy leadership.</p>	<p><b>EP 11:</b> The governing body appoints a <b>physician and/or pharmacist</b> who is qualified through education, training, or experience in infectious diseases and/or AMS as the <b>leader(s) of the ASP</b></p> <p>The appointment(s) is based on recommendations of medical staff leadership and pharmacy leadership. (no change)</p> <ul style="list-style-type: none"> <li>• <i>Choice of physician, pharmacist, or both as co-leads depends on organization size, structure, and complexity</i></li> <li>• <i>ASP leader(s) may be assigned at the corporate or system level, as long as the leader is able to coordinate and implement AMS activities at each location</i></li> </ul>

\* If deemed status is granted by CMS, then the institution would not be re-surveyed by CMS if it passes TJC accreditation

# TJC Standards: 2017 to 2023 Comparison

2017	2023
<p><b>EP 10:</b> <i>Hospitals using TJC accreditation for deemed status purposes:</i> <b>The ASP demonstrates coordination among all components of the hospital responsible for antibiotic use and resistance, including, but not limited to, the IPC program, the QAPI program, the medical staff, nursing services, and pharmacy services</b></p>	<p><b>EP 14: The ASP demonstrates coordination among all components of the hospital responsible for antibiotic use and resistance, including, but not limited to, the IPC program, the QAPI program, the medical staff, nursing services, and pharmacy services (no change)</b></p> <ul style="list-style-type: none"><li><i>The ASP is expected to have a process in place that demonstrates this coordination</i></li></ul>



# TJC Standards: 2017 to 2023 Comparison

2017	2023
<p><b>EP 11:</b> <i>Hospitals using TJC accreditation for deemed status purposes:</i></p> <p><b>The leader of the ASP is responsible for the following:</b></p> <ul style="list-style-type: none"> <li>• Developing and implementing a hospital-wide ASP, based on nationally recognized guidelines, to monitor and improve the use of antibiotics</li> <li>• Documenting AMS activities</li> <li>• Communicating and collaborating with the medical staff, nursing, and pharmacy leadership, as well as with the hospital's IPC and QAPI programs on antibiotic use issues</li> <li>• Training and educating staff, including medical staff, on the practical applications of AMS guidelines, policies, and procedures</li> </ul>	<p><b>EP 12: The leader(s) of the ASP is responsible for the following:</b></p> <ul style="list-style-type: none"> <li>• Developing and implementing a hospital-wide ASP that is based on nationally recognized guidelines to monitor and improve the use of antibiotics (no change)</li> <li>• Documenting AMS activities, including any new or sustained improvements (no change)</li> <li>• Communicating and collaborating with the medical staff, nursing leadership, and pharmacy leadership, as well as with the hospital's IPC and QAPI programs on antibiotic use issues (no change)</li> <li>• Providing <b>competency-based training and education</b> for staff, including medical staff, on the practical applications of AMS guidelines, policies, and procedures             <ul style="list-style-type: none"> <li>• <i>Competency: combination of observable and measurable knowledge, skills, and abilities</i></li> <li>• <i>Organizations have flexibility to define competencies associated with practical applications of their AMS guidelines, policies, and procedures</i></li> <li>• <i>Examples include observable and measurable methods (e.g., written test or demonstrate accurate completion of procedure / process)</i></li> </ul> </li> </ul>



# CMS Conditions of Participation: Hospitals



# CMS Antimicrobial Stewardship Conditions of Participation (COP) Timeline



2016

- **CMS planned** to release AMS COP

2019

- **CMS published** Hospital §482.42(b) and CAH §485.640(b) AMS COP in September 2019 for implementation by March 30, 2020
  - This release did not include interpretive guidance which was planned to be released in Spring 2020

2020

- **COVID** delayed everything

2022

- **CMS published updated interpretive guidance** for Hospital §482.42(b) AMS COP
  - Still no interpretive guidance for CAH §485.640(b) as of April 2023

**CMS announced updated requirements** in the August 2022 federal register:

- Beginning CY2024: hospitals participating in the Medicare Promoting Interoperability Program will be required to report data to NHSN AUR module (currently optional)

# CMS Conditions of Participation (COP)

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## CMS COP Rule

(§482.42 Hospital and §485.640 CAH – *the rules are identical*)



## Match to 2023 TJC Standard EP



**Consult CDC Core Elements for implementation ideas**

# Audience Polling Question #2

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**What do you feel is the main barrier to meeting AMS regulations in your institution?**

- a) Lack of time (FTE resources not adequate)
- b) Lack of information technology support
- c) Lack of ID / AMS expertise for ASP leader
- d) Not an institutional priority
- e) No barriers

# §482.42: Infection Prevention and Control (IPC) and Antibiotic Stewardship Programs (ASP)

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.



## CMS Interpretive Guidance

- *Review the ASP 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](#).*
  - *Is working collaboratively between AMS and hospital QAPI when antibiotic use issues are identified.*

### TJC 2023

#### Standard MM.09.01.01:

The hospital establishes antibiotic stewardship as an organizational priority through support of its ASP

**Example:**  
Implement  
CDC Core  
Elements



# §482.42(b): Antibiotic stewardship program organization and policies

§482.42(b)(1) The hospital must demonstrate that:

An **individual(s)** who is **qualified through education, training, or experience in ID and/or AMS**, is **appointed by the governing body** as the leader(s) of the ASP and that the **appointment is based on the recommendations of medical staff leadership and pharmacy leadership**



## TJC 2023 EP 11:

The governing body appoints a **physician and/or pharmacist** who is qualified through education, training, or experience in ID and/or AMS as the leader(s) of the ASP. The appointment(s) is based on recommendations of medical staff leadership and pharmacy leadership.

## CMS Interpretive Guidance

- *Ideally jointly led by physician and pharmacist*
- *Ensure high-level clinical leadership are involved in the selection process*
- *Ensure qualifications: specialty residencies, specialty board certifications, specialty certificates, etc.*
- *Must maintain qualifications through ongoing education and training (e.g. AMS courses, attendance at local and national professional society meetings such as SHEA/IDSA/SIDP)*
- *Specific number of staff is not specified, but resources must be adequate to accomplish the tasks of the ASP*

# IMPLEMENTATION IDEAS

## §482.42(b)(1): Governing body appoints qualified ASP leader(s)

*MOST IMPORTANT* rule to ensure your ASP has adequate and **protected FTE** resources

### CDC CORE ELEMENT PRIORITIES



#### Hospital Leadership Commitment

Antibiotic stewardship physician and/or pharmacist leader(s) have antibiotic stewardship responsibilities in their contract, job description, or performance review.



#### Accountability

Antibiotic stewardship program is co-led by a physician and pharmacist.\*



#### Pharmacy / Stewardship Expertise

Antibiotic stewardship physician and/or pharmacist leader(s) have completed infectious diseases specialty training, a certificate program, or other training on antibiotic stewardship.

### AMS Hospital Policy should include:

- Description of *how* the leader is selected and who is involved
  - *Pharmacy (e.g., director, clinical coordinator / manager, other clinical pharmacists / specialists)*
  - *Medical Staff (e.g., CMO, ID provider(s), P&T chair, hospitalist and / or intensivist leader, etc.)*
  - *Others (e.g., IPC, microbiology, QAPI)*
- Leader qualifications and ongoing education / training requirements
  - *Personnel files will be reviewed → maintain records of training, certifications, CE credits from conferences*



# IMPLEMENTATION IDEAS

## §482.42(b)(1): Governing body appoints qualified ASP leader(s)

- **Resource allocation:**

- CMS will be reviewing the criteria the hospital used to determine the resources necessary to operate effectively and ensuring the resource allocation matches the determined needs
  - *Use this rule to your advantage → governing body of hospital will be held accountable if resources are inadequate to fulfill AMS requirements*

### **CMS commented on potential FTE requirements to fulfill the rules effectively in 2019 Federal Register:**

- *The latest research on the resources required for an effective ASP suggest that the minimum full time equivalent (FTE) support recommended for a hospital of this size (**~124 beds**) may be somewhat more burdensome, due to the leadership of a **pharmacist** and **physician** at the FTE of their salaries of **1.0** and **0.4** respectively.*

# IMPLEMENTATION IDEAS

## §482.42(b)(1): Governing body appoints qualified ASP leader(s)

CMS FTE comments based on 2 main references:

### Veterans Affairs Health System:

- Validated staffing calculator incorporated into VHA Directive 1031 (January 2019)
- 1 pharmacist FTE / 100 beds**

TABLE 1: Minimum FTE by Medical Facility Complexity Level

Position Title	1a and 1b	1c and 2	3	Additional Staffing for CLC
Infectious Diseases Physician	0.50	0.25 – 0.5	0.25 – 0.375	See Note 1 below
Antimicrobial Stewardship				
Clinical Pharmacist – Antimicrobial Stewardship	1.5 – 4.0	1.0 – 2.0	0.25 – 0.5 See Note 2 below	0.0 – 0.25 See Note 2 below
Nurse Practitioner and/or Physician Assistant – Antimicrobial Stewardship	0.5	0.5	0.0 – 0.25	See Note 1 below

Complexity level	Description
<b>1a and 1b – Highest</b>	Medium-high / high volume, high risk patients, many complex clinical programs, medium-large research / teaching programs
<b>1c and 2 – Medium / Mid-High</b>	Medium / medium-high volume, low-medium risk patients, few-some complex clinical programs, no or small-medium research / teaching program
<b>3 – Low</b>	Low volume, low risk patients, no / few complex clinical programs, no / small research / teaching programs

Echevarria, AJHP 2017;74:e493-8

VHA Directive 1039: Antimicrobial Stewardship Programs: <https://www.va.gov/vhapublications/publications.cfm?pub=1>; Accessed 4/18/23

# IMPLEMENTATION IDEAS

## §482.42(b)(1): Governing body appoints qualified ASP leader(s)

CMS FTE comments based on 2 main references:

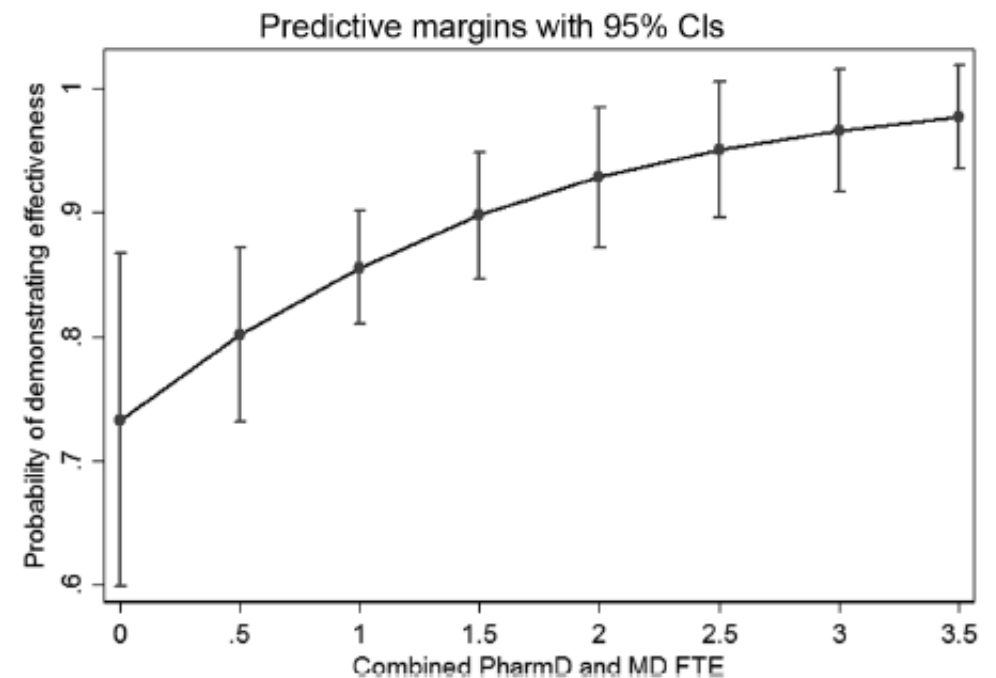
**Doernberg S, et al (2018): Essential Resources and Strategies for Antibiotic Stewardship Programs in the Acute Care Setting** – survey of IDSA, SHEA, PIDS members

- Each 0.50 increase in pharmacist and physician full-time equivalent (FTE) support predicted a 1.48-fold increase in the odds of demonstrating effectiveness
- Lack of time and financial resources were most cited barriers

**Table 6. Minimal Full-time Equivalent Support Recommended by Bed Size**

Variable	Bed Size			
	100–300	301–500	501–1000	>1000
Pharmacist	1.0	1.2	2.0	3.0
Physician	0.4	0.4	0.6	1.0
Total	1.4	1.6	2.6	4.0

For hospitals with <100 beds, there were limited data to make recommendations.



# §482.42(b): Antibiotic stewardship program organization and policies

§482.42(b)(2) The hospital-wide ASP:

**Demonstrates coordination** among all components of the hospital responsible for antibiotic use and resistance, including, but not limited to, **the IPC and QAPI programs, medical staff, nursing services, and pharmacy services.**



## TJC 2023 EP 14:

The ASP demonstrates coordination among all components of the hospital responsible for antibiotic use and resistance, including, but not limited to, the IPC and QAPI programs, medical staff, nursing services, and pharmacy services

## TJC 2023 EP 13:

The hospital has a multidisciplinary committee that oversees the antibiotic stewardship program

## CMS Interpretive Guidance

- *Must develop and implement appropriate AMS interventions to address issues identified through its assessment activities, then monitor their effectiveness through further data collection and analysis*
- *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*
- *A robust ASP must be coordinated with the hospital's overall IPC program to address healthcare acquired infections and antibiotic resistance*

# IMPLEMENTATION IDEAS

## §482.42(b)(2): Demonstrate coordination among all services

### CDC CORE ELEMENT PRIORITIES



#### Reporting

Report outcomes at ASP committee meetings consisting of these members but also go to their meetings and present there as well to gain ideas



#### Action

Highlight which services are involved in implemented actions resulting from tracking / reporting



#### Education

Track which services receive education on action items (e.g., physicians, pharmacists, nurses, IPC and lab all may be educated on new blood culture PCR)

### AMS Hospital Policy should include:

- Evidence that the hospital has a process in place for coordination among all components of the hospital responsible for antibiotic use and resistance
  - *Ensure your committee consists of members from IPC, QAPI, medical staff, nursing and pharmacy services (and micro lab)*

# §482.42(b): Antibiotic stewardship program organization and policies

§482.42(b)(2) The hospital-wide ASP:

**Documents the evidence-based use of antibiotics** in all departments and services of the hospital

**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;



## TJC 2023 EP 15:

The ASP documents the evidence-based use of antibiotics in all departments and services of the hospital

## TJC 2023 EP 16:

The ASP monitors the hospital's antibiotic use by analyzing data on days of therapy (DOT) / 1000 days present or 1000 patient days, or by reporting data to the NHSN Antimicrobial Use Option of the AUR Module

## CMS Interpretive Guidance

- *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.*
- *Must provide documentation of [sustained] improvements - expected reductions in patient risk for adverse drug events and potentially life-threatening, antibiotic-resistant infections, including CDIs.*
- *The ASP should be updated with any advancing evidence-based improvements in antibiotic-prescribing practices*

# IMPLEMENTATION IDEAS

## §482.42(b)(2): Document sustained improvements in outcomes

### CDC CORE ELEMENT PRIORITIES



#### Tracking

- Track antibiotic use outcomes and NHSN SAARs over time
- Conduct MUEs on specific antibiotics
- Track % susceptible for specific antibiotics over time and if that increases with decreased use (use data from antibiograms)
- Obtain CDI rates from IPC and track over time in relation to decreases in broad-spectrum antibiotic use
- Track process measures: % IV to PO converted, % acceptance rate of AMS recommendations, % of vancomycin levels in range



#### Reporting

- Report these outcomes to specific services:
- e.g., IPC will be interested in how CDI and MDRO rates relate to antibiotic use increases / decreases

### Provide CMS / TJC with examples of data:

- Be prepared to explain how data outcomes relate to AMS recommendations

# §482.42(b): Antibiotic stewardship program organization and policies

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



## TJC 2023 EP 17:

The ASP implements one or both of the following strategies to optimize antibiotic prescribing:

- Preauthorization for specific antibiotics (internal review and approval process prior to use)
- Prospective review and feedback regarding antibiotic prescribing practices, including the treatment of positive blood cultures, by a member of the ASP

## CMS Interpretive Guidance

- *Must implement and maintain an active and hospital-wide ASP consistent with nationally recognized standards for improving antibiotic use (e.g., CDC's Core Elements)*
- *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: SHEA, IDSA, ASHP, and SIDP*



# IMPLEMENTATION IDEAS

## §482.42(b)(3): Actions reflect scope and complexity of hospital

### CDC CORE ELEMENT PRIORITIES → ALL



#### Action

##### Prospective audit and feedback

- Most cannot review all patients on all antibiotics
- Determine priorities (duplicate coverage, specific antibiotics, specific disease states such as bacteremia or CDI, specific organism result, etc.)

##### Preauthorization

- Most programs do not have 24-hr or 7-day/week coverage
- Computerized restriction can help during off hours
  - Require rationale or pre-built appropriate rationale for use but allow order verification if relatively appropriate and have ASP review as soon as available



#### Tracking

Track process measures from these actions

- Examples: % recommendations accepted, recommendation types, time to authorization, etc.

**Provide CMS / TJC with examples of how each Core Element has been implemented**

# §482.42(b): Antibiotic stewardship program organization and policies

§482.42(b)(4) The ASP reflects the **scope and complexity** of the hospital **services provided**



## TJC 2023 EP 18:

The ASP implements at least two evidence-based guidelines to improve antibiotic use for the most common indications

- Examples: CAP, UTI, SSTI, *C. difficile* colitis, asymptomatic bacteriuria, IV to PO antibiotic conversion, surgical prophylactic antibiotics

Must be based on national guidelines and reflect local susceptibilities, formulary options, and the patients served, as needed.

## TJC 2023 EP 19:

The ASP evaluates adherence (including antibiotic selection and duration of therapy, where applicable) to at least one of the evidence-based guidelines the hospital implements

- Can measure at group or individual prescriber level;
- Data for a sample of patients may be obtained from relevant clinical areas by analyzing EHR or chart reviews

## CMS Interpretive Guidance

- *CMS will review the parameters of the ASP to determine whether it is suitable to the scope and complexity of the hospital's services*

# IMPLEMENTATION IDEAS

## §482.42(b)(4): Adhere to national guidelines and best practices

### CDC CORE ELEMENT PRIORITIES



#### Action

##### Facility-specific treatment recommendations

- Choose antibiotics from national guidelines / literature based on hospital formulary antibiotics, resistance patterns from antibiogram, dosing strategies if resistance rates are high (e.g., extended infusions)
- Partner with IPC and QAPI on already ongoing initiatives like CDI, SSI, sepsis, etc.
- Incorporate guidelines into order sets to ensure providers follow



#### Tracking

Conduct chart reviews on specific areas of concern

- Examples: Antibiotics used in asymptomatic bacteriuria, antipseudomonal use in CAP, etc.

### CMS is not as prescriptive as TJC with this measure

- Provide examples of guidelines
- Provide examples of data from reports or chart reviews

# §482.42(c): Leadership Responsibilities

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

**Systems are in place** and operational for the **tracking of all... antibiotic use activities**, in order to demonstrate the implementation, success, and sustainability of such activities.



## TJC 2023 EP 10:

The hospital allocates financial resources for staffing and information technology to support the ASP

## CMS Interpretive Guidance

- *The development and implementation of the ASP 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 ASP*
- *Hospital policies should address the roles and responsibilities for AMS within the hospital, how various hospital committees and departments interface with the ASP, and how to monitor and improve antibiotic use*

# IMPLEMENTATION IDEAS

## §482.42(c)(1): Hospital leadership responsible for resources

### CDC CORE ELEMENT PRIORITIES



#### Hospital Leadership Commitment

##### Prepare hospital leaders to discuss with reviewers:

- How AMS has been established as a safety priority
- The resources allocated to the ASP to support its activities
  - *Ensure they know how FTE requirements were determined*



#### Reporting

Report outcomes (antibiotic use outcomes, AMS process measures, etc.) to executive leadership at least annually

#### AMS policy:

- Ensure section on leadership commitment
- Provide escalation mechanism if AMS policies not being followed
- Ensure section on reporting of antibiotic use outcomes to leadership

**CMS will be reviewing meeting minutes from executive meetings for record of support for ASP**

# §482.42(c): Leadership Responsibilities

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

All ...antibiotic use **issues** identified by the ASP are **addressed in collaboration** with hospital **QAPI leadership**



## TJC 2023 EP 20:

The ASP collects, analyzes, and reports data to hospital leadership and prescribers. Examples of data include resistance patterns, prescribing practices, or an evaluation of AMS activities.

## TJC 2023 EP 21:

The hospital takes action on improvement opportunities identified by the ASP

## CMS Interpretive Guidance

- *Regulations specifically require the hospital's QAPI and training programs must be involved in addressing problems identified by the ASP to reflect the importance of these issues and hold the leadership jointly responsible for linking the ASP with these programs*
- *Hospital leaders are also held explicitly responsible for implementing successful corrective action plans*
- *Hospital leaders must monitor adherence to these plans and assess the effectiveness of actions taken, with implementation of revised corrective actions as needed*
- *Education on the principles and practices of appropriate antibiotic use should be provided to anyone who has an opportunity for contact with patients, prescribing, preparing or administering antibiotics, e.g., nursing, medical staff; pharmacy, all students and trainees in healthcare professions, etc. – essentially all staff*

# IMPLEMENTATION IDEAS

## §482.42(c)(1): Hospital leadership ensure QAPI involvement

### CDC CORE ELEMENT PRIORITIES



#### Hospital Leadership Commitment

##### Document how leadership and QAPI have helped support action plan implementation

- Help connect ASP with specific departments
- Helped organize education / training opportunities
- Provided space for ASP slides in mandatory staff annual modules
- Help overcome barriers with specific groups or departments



#### Reporting

Report ASP outcomes to executive leadership and QAPI at least annually

- Update leadership and QAPI on action item progress and / or barriers

#### AMS policy:

- Ensure section on reporting of antibiotic use outcomes to leadership and QAPI
- Discuss how leadership and QAPI are involved in supporting action plans

**Inform leadership and QAPI members that reviewers will ask how they are supporting the ASP**

# §482.42(c): Leadership Responsibilities

§482.42(c)(3) The leader(s) of the ASP is responsible for:

The **development** and **implementation** of a **hospital-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, IPC and QAPI programs, on antibiotic use issues.

**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.



**TJC 2023 EP 12:**  
Same verbiage as CMS rule

## CMS Interpretive Guidance

- *Reviewers will verify that a qualified ASP leader is accomplishing all of the above responsibilities*



# IMPLEMENTATION IDEAS

## §482.42(c)(3): ASP leader responsibilities

### CDC CORE ELEMENT PRIORITIES - ALL



#### Hospital Leadership Commitment

**Must ensure adequate resources are provided for the ASP leader to accomplish all responsibilities**



#### Education

Competency-based education may be challenging to implement

- Use existing computer-based learning (CBL) systems
- Incorporate general ASP education into annual mandatory CBLs for all staff
- Choose selective CBLs for providers when rolling out new initiatives - keep questions brief and to the point

#### AMS policy:

- Includes defined responsibilities for ASP leader(s)

**ASP leader should document all ASP Core Elements in an annual report**

# §482.42(d1-4): Unified and integrated ASPs for multi-hospital systems

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- **Take home points**

- **Each certified hospital** must meet all specified requirements of the rule
- Must take into account each member hospital's **unique circumstances and significant differences in patient populations / services offered**
- Must develop and implement policies / procedures for each certified hospital to **address the needs and concerns of each hospital separately**
- Must demonstrate that mechanisms are in place to ensure that **issues localized to particular hospitals in the system are also considered and addressed**
- **Each hospital must still designate a qualified individual(s)** to implement the ASP leadership responsibilities (as previously defined) under the direction of the unified ASP

# Audience Polling Question #3

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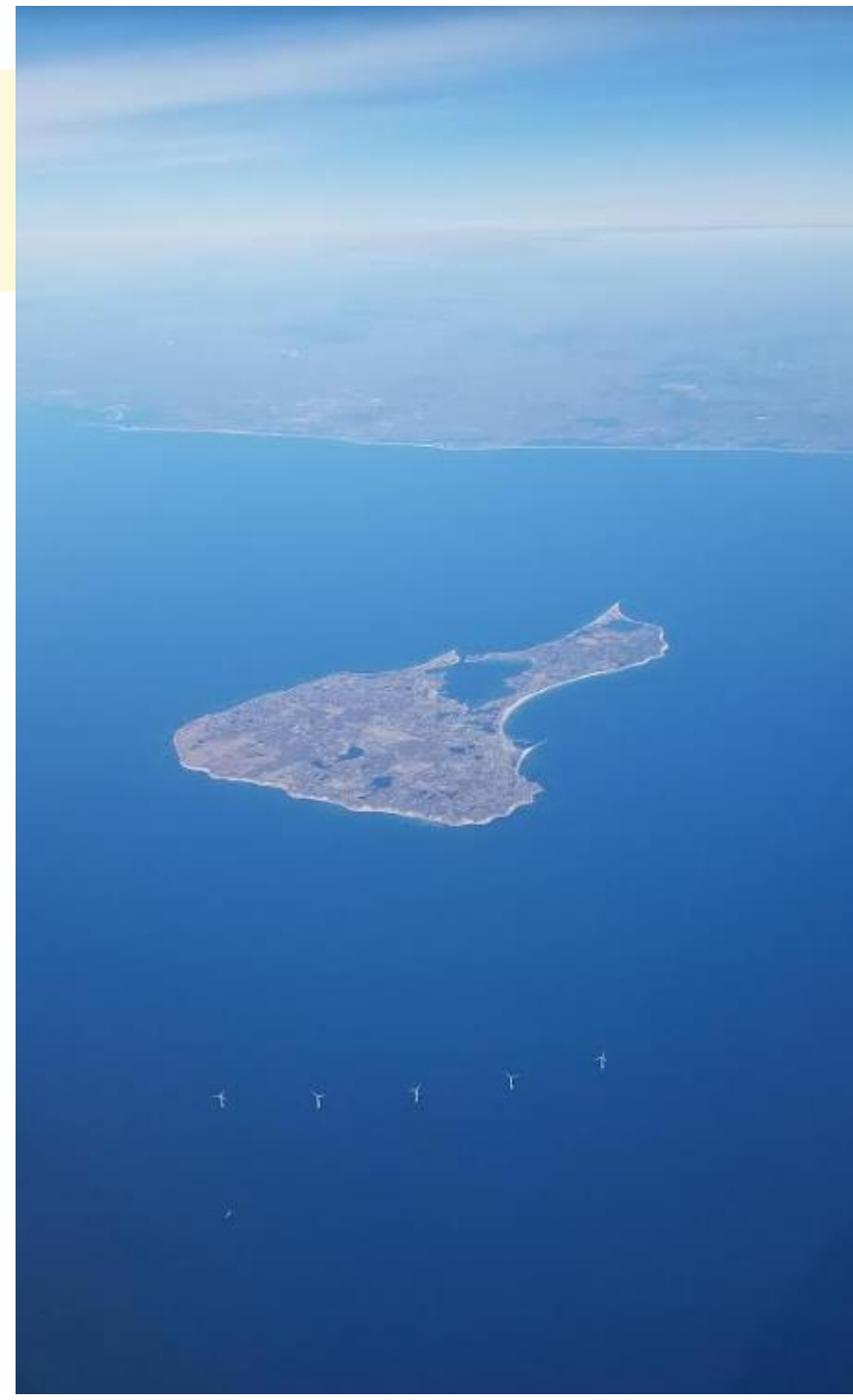
**What is the best way to overcome barriers to AMS regulation implementation?**

- a) Add these responsibilities to an existing full-time pharmacist in another role
- b) Discuss appropriate evidence-based FTE allocations needed to meet these regulations with hospital executives and explain their accountability in the CMS COPs
- c) Require all pharmacist staff to complete AMS certification courses
- d) Require your ASP pharmacist to work long hours to ensure compliance

# IMPLEMENTATION IDEA SUMMARY

## How to Keep Track

- Provide TJC or CMS surveyors with a report or packet with all required information
  - List all ASP personnel and committee members
  - Outline the ASP goals
  - Include ASP policies
  - Create a section on each CDC Core Element → track implementation progress
    - Can include things that are “in progress” or “planned” in addition to completed
  - Include appendix with examples of data, educational tool / handouts, guidelines, etc.



# IMPLEMENTATION IDEAS

## Report / Packet Tracking Examples

### Hospital Leadership Commitment

- Letters of commitment from hospital leadership and / or minutes from executive meetings supporting ASP
- FTE allotment for AMS physician and /or pharmacist – keep track on any additions / subtractions
- Consider CMO as administrative member of ASP and include in escalation policy
- Funding of informatics software and / or prioritizing personnel time (building alerts, NHSN exporting, etc.)
- Funding for conferences, board certifications, certificates, etc.
- Any leadership recognitions the ASP receives (featured in hospital news, highlighted program, etc.)

### Accountability

- Name the pharmacist and / or physician leader(s) responsible for ASP outcomes (ASP Director(s)) and specific training including continued training
- Hospital executive accountable (often this is the CMO)

### Pharmacy / Stewardship Expertise

- List training (e.g., residency), certificate courses (e.g., SIDP, MAD-ID, etc.), board certifications (e.g., BCIDP)
- List CE activities related to AMS (e.g., IDWeek attendance years, board certification credits, etc.)
- List the training the pharmacist staff receives (e.g., ASP pharmacist leader trains pharmacists on AMS policies upon hire – further examples can be explained in Education Core Element)

# IMPLEMENTATION IDEAS

## Report / Packet Tracking Examples

### Action

- **Priority interventions:**
  - Prospective audit and feedback: describe what is reviewed (blood cultures, antibiotic priorities, history *C. difficile* patients, etc.)
  - Preauthorization: should have an AMS policy, describe what antibiotics are restricted and process for approval
- **Facility-specific treatment guidelines:** list all established and in-progress guidelines, where located (AMS web site?), incorporated into order sets, track update dates
- **Infection-based Interventions:** list projects completed around disease states (e.g., pneumonia, UTI, SSTI, bacteremia, *C. difficile*, sepsis, surgical site infections, COVID, etc.)
  - Indicate if guideline / order set exists, any project evaluating adherence, education on topic, who collaborated (e.g., IPC, QAPI, nursing, hospitalists, etc.)

# IMPLEMENTATION IDEAS

## Report / Packet Tracking Examples

### Action

- **Pharmacy-based Interventions:**
  - Required indication field on antibiotic orders
  - Clinical pharmacist responsibilities (e.g., renal dose adjustments, vancomycin monitoring, assessing pre-op antibiotic orders, IV to PO, therapeutic duplications, drug interactions, upholding restrictions, etc.)
  - Antimicrobial use evaluations
  - Antimicrobial formulary management (new additions / deletions, class reviews, etc.)
- **Microbiology-based Interventions:**
  - Antibiogram, resistance pattern assessment (track % susceptible across years, MICs)
  - Diagnostic and susceptibility testing: rapid diagnostic tests (blood cultures identification, etc.), choosing susceptibility testing panels, updating CLSI breakpoints, developing suppression rules and verbiage in micro results

# IMPLEMENTATION IDEAS

## Report / Packet Tracking Examples

### Action

- **Nursing-based Interventions:**
  - Nurse involvement in patient education (e.g., CDC handouts when patient started on antibiotic)
  - Expanded penicillin allergy questionnaires on admission
  - Help with antibiotic time-out question discussions with providers
- **Other Interventions:**
  - Antibiotic use on discharge (optimizing default durations, OPAT)
  - Hospital – at – home programs (developing guidelines, antibiotics in provider med boxes)
  - Residency training – require ID / AMS as a core rotation
  - Ambulatory care stewardship



# IMPLEMENTATION IDEAS

## Report / Packet Tracking Examples

### Tracking

- **Antibiotic Use Measures:**
  - Include graphs on antibiotic DOT / 1000 days present or patient days over time (overall antibiotics, broad spectrum, IV, oral, individual antibiotics, can select some to look at monthly or quarterly)
  - [Include quarterly / annual NHSN SAARs](#)
- **Antibiotic Expenditures and Costs:**
  - Overall purchasing costs or expenditures dispensed, subsets (broad-spectrum), cost / unit to track if can purchase another product (e.g., premix versus vial)
- **Process Measures:**
  - Prospective audit and feedback tracking: # of interventions, % acceptance, recommendation category % (de-escalation, discontinued, etc.), % by provider type (hospitalist, intensive care, surgery, residents, etc.), top antibiotics requiring recommendations, cost avoidance
  - Preauthorization tracking: # of approved / not approved, time to approval
  - Clinical pharmacist tracking: non-ASP personnel → capture recommendations on rounds, etc.

# IMPLEMENTATION IDEAS

## Report / Packet Tracking Examples

### Tracking

- **Medication Use Evaluations:**
  - Include results from specific antibiotic MUEs
- **Hospital-Onset *C. difficile* Infections:**
  - Obtain rates from IPC
  - Can track what antibiotics are involved in HA-CDI cases to identify restriction targets (e.g. quinolones, etc.)
  - Outcomes of new testing methods (e.g., 2-step testing) on oral vancomycin / fidaxomicin use
- **Antibiotic Resistance Patterns:**
  - Show graphs on % susceptible for select antibiotics and select bacteria over time (e.g., ciprofloxacin in *Pseudomonas*)
  - Can obtain Hospital-acquired Multi-drug Resistant Organism (MDRO) data from IPC (e.g., MRSA, VRE, ESBL, CRE rates, etc.)

# IMPLEMENTATION IDEAS

## Report / Packet Tracking Examples

### Reporting

- AMS committee meeting schedule
- Annual Report / tracking packet → send to IPC, QAPI, P&T, executive leadership, hospital board
- Antibiogram, resistance patterns, antibiotic use outcomes
  - Report to pharmacists and prescribers (can post on AMS web site if available, attend meetings to present)
  - Report at IPC and / or QAPI meeting, quality council / board meetings
- Other committees / sub-committees as needed

# IMPLEMENTATION IDEAS

## Report / Packet Tracking Examples

### Education

- Initial ASP education to stakeholders, leadership, board members, etc.
- **All employees:** include slides in new employee orientation, annual mandatory coursework (computer-based learning CBLs), flyers in learning boards throughout the hospital, awareness weeks
- **Pharmacists:** new pharmacist AMS training, periodic competency lectures with exam questions, pharmacy residents and students
- **Providers:** direct education during recommendations in prospective audit/feedback, newsletters, memos, attending department meetings, CME presentations (with assessment questions), GME resident lectures, create specific CBLs for new initiatives / guidelines with assessment questions
- **Nurses:** Involve in overall annual training through CBLs, new initiatives, flyers, attend meetings
- **Patients:** information in waiting areas, nurse to patient education when new antibiotic started (flyers), involve marketing for social media educational posts

# CMS NHSN AUR Reporting Requirement: 2024



## Beginning in CY 2024, AUR Module data are required under the Public Health and Clinical Data Exchange Objective of the CMS Promoting Interoperability Program

- Applies to eligible hospitals and CAHs that participate in the CMS PI Program  
*(previously referred to as “meaningful use” of certified electronic health record technology)*
- NHSN AUR reporting was previously one option to meet PI program requirements but will now be a required component
- Measure includes submission of both Antibiotic Use (AU) and Antibiotic Resistance (AR) data

<https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms> - accessed 4/18/23

<https://www.cdc.gov/nhsn/cdaportal/datainteroperability.html> - accessed 4/18/23

Federal Register / Vol. 87, No. 153 / Wednesday, August 10, 2022 / Rules - and Regulations -  
<https://www.govinfo.gov/content/pkg/FR-2022-08-10/pdf/2022-16472.pdf> - accessed 4/14/23

# NHSN AUR Reporting

- **For CY 2024 facilities must attest to either:**
  - Being in active engagement with NHSN to submit AUR data *or*
  - Claim an applicable exclusion

<b>2 ways to be in “active engagement” with NHSN</b>	
<b>Option 1</b>	<b>Option 2</b>
<b>Pre-production and validation:</b> <ul style="list-style-type: none"><li>• Registration with NHSN</li><li>• Testing and validation of the CDA files</li></ul>	<b>Production submission</b> <ul style="list-style-type: none"><li>• Submitting production files to NHSN<ul style="list-style-type: none"><li>• CY2023: 90 continuous days of AUR data submission</li><li>• CY2024: 180 continuous days of AUR data submission</li></ul></li></ul>
<b><i>Beginning in CY2024, facilities can only spend one calendar year in Option 1</i></b>	

# NHSN AUR Reporting – Software Requirements

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- Involve informatics (especially pharmacy informatics) to work with the software vendor on setting up the CDA files for exporting
- Selecting a vendor: *check with IPC to see if they are already using a vendor; vendors are often your EHR program or a 3<sup>rd</sup> party program*
  - Vendor / homegrown software must be validated by NHSN to submit data to the AUR Module
    - See the lists of AU and AR validated vendor software:  
<https://www.cdc.gov/nhsn/cdaportal/sds/au-vendor-list.html>  
<https://www.cdc.gov/nhsn/cdaportal/sds/ar-vendor-list.html>  
*Note: vendor software is not required to be validated for AR submission until May 2023*
  - For the CMS PI Program: vendor software must also be certified by the Office of the National Coordinator for Health Information Technology Health IT Certification Program for NHSN Antimicrobial Use and Resistance reporting
    - Use this site to check if your vendor has been certified: <https://chpl.healthit.gov/#/search>

# NHSN AUR PI Program Guidance

- Access the guidance document:  
Promoting Interoperability – Guidance for NHSN Facilities – March 2023  
<https://www.cdc.gov/nhsn/pdfs/cda/PHDI-Facility-Guidance-508.pdf>
- NHSN user interface includes an AUR Promoting Interoperability (PI) Program registration of intent page
  - *Only the NHSN Facility Administrator has access to register the facility's AUR PI Program intent*
    - **This is likely the IPC director who is already exporting HAI data**

## Prerequisites for registering intent and sending electronic AUR Clinical Document Architecture (CDA) data:

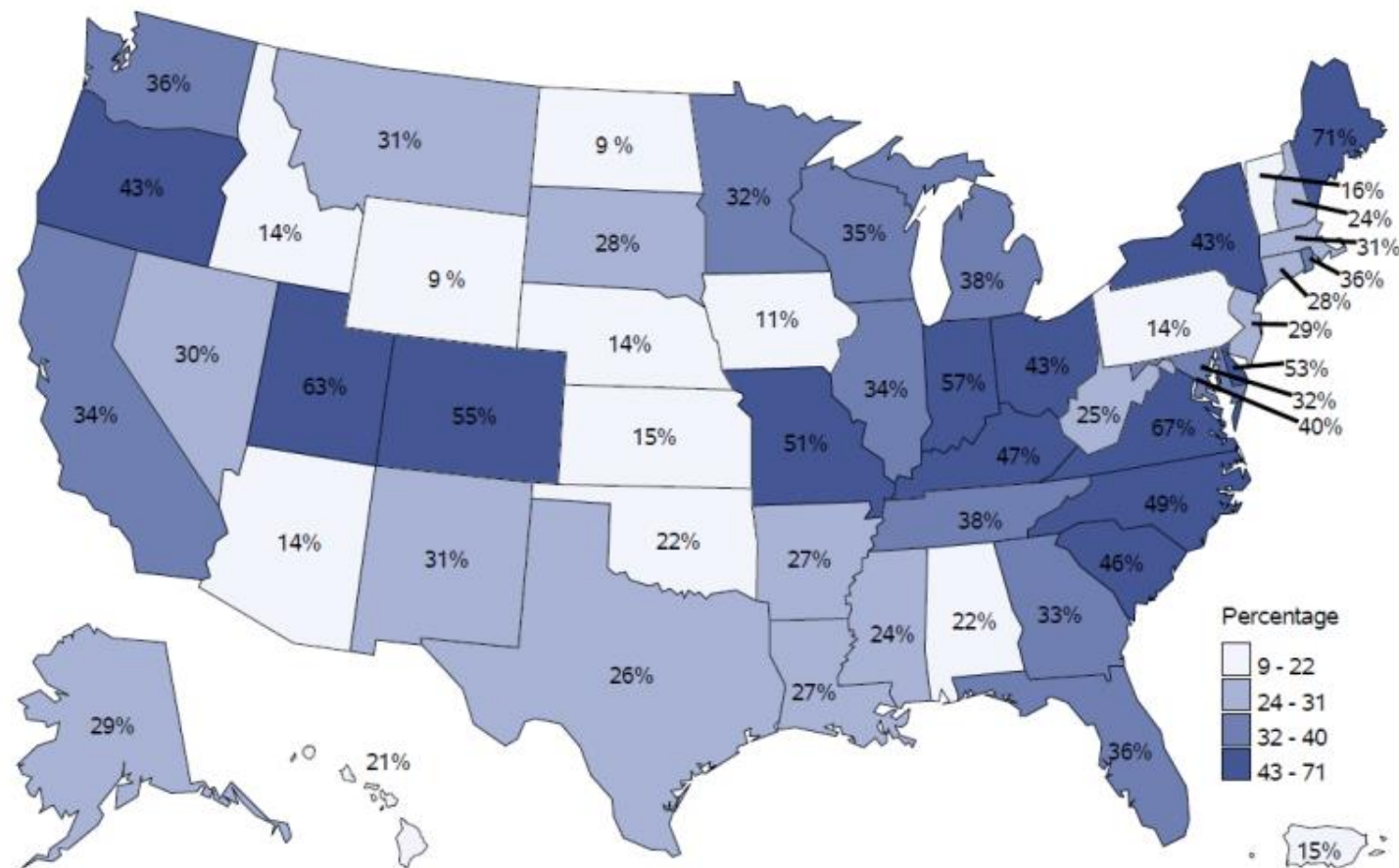
- Facility is enrolled in NHSN
  - **IPC is likely already enrolled since reporting HAIs is required in most cases**
- Facility locations are mapped within NHSN, monthly reporting plans are set up, NHSN Object Identifier (OID) is entered
  - **Most of this is already done if hospital is reporting HAIs - Check with NHSN Facility Administrator**



# NHSN AUR Reporting

- Reports are uploaded to NHSN monthly after initial setup and testing
- Data can be used to create DOT / 1000 days present antibiotic use metrics for tracking and reporting
  - Standardized antibiotic administration ratios (SAAR) can be used for benchmarking
  - Currently not publicly reported like other HAIs

**Figure 1.** Percentage of active NHSN acute care facilities\* reporting at least one month of data to the AU Option as of December 1, 2021.



\*Facility types that have reported at least one month of data to the AU Option as of December 1, 2021, include: critical access, children's, general acute care, long-term acute care, military, oncology, orthopedic, psychiatric, inpatient rehabilitation, surgical, Veterans Affairs, women's, and women's and children's hospitals.

**2,772 facilities as of 2023**

# Pharmacy Technicians in AMS

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- Meeting all these requirements requires DATA TRACKING and ANALYSIS which takes up a significant amount of ASP pharmacist time (administrative duties can be up to 30-50%)
- Consider adding Pharmacy Informatics Technicians to the ASP team to help with data collection, NHSN reporting and analysis, putting together annual reports, etc.
- AMS programs in Europe and Australia have been expanding technician roles in AMS and publishing positive results
- ASHP Resource Site for Pharmacy Technician Informatics Specialist:  
<https://www.ashp.org/pharmacy-practice/resource-centers/informatics/pharmacy-technician-informatics-specialist>

# Pharmacy Technicians in AMS

ASHP REPORT

## ASHP Statement on the Pharmacy Technician's Role in Pharmacy Informatics

- **Roles and responsibilities include:**

- Automation and technology systems management → *can work with NHSN AUR vendors, troubleshooting*
- Project management → *Collaborate with vendor to create CDA files and implement reporting process*
- End-user training and education → *Create educational flyers when a new AMS process is created in the EHR*
- Policy and governance → *Stay updated on changes to reporting policies*
- Process improvement → *Collaborate with AMS pharmacist on data improvement*
- Analytics and reporting – provide timely compliance with regulatory guidelines
  - *Create reports to identify drug targets for audit/feedback*
  - *Build AMS rules and forms for documentation in the chart*
  - *Pull reports and compile data for AMS process measures (e.g., # interventions, intervention types, etc.)*
  - *Run and upload monthly NHSN reports, compile output data for tracking over time (graphs, tables, etc.)*
- Inventory and financial management → *help with flexing products during antibiotic shortages*



# CDC Core Elements and TJC Standards: Outpatient / Ambulatory Care Practices



# Did you know?

- The CDC estimates that:

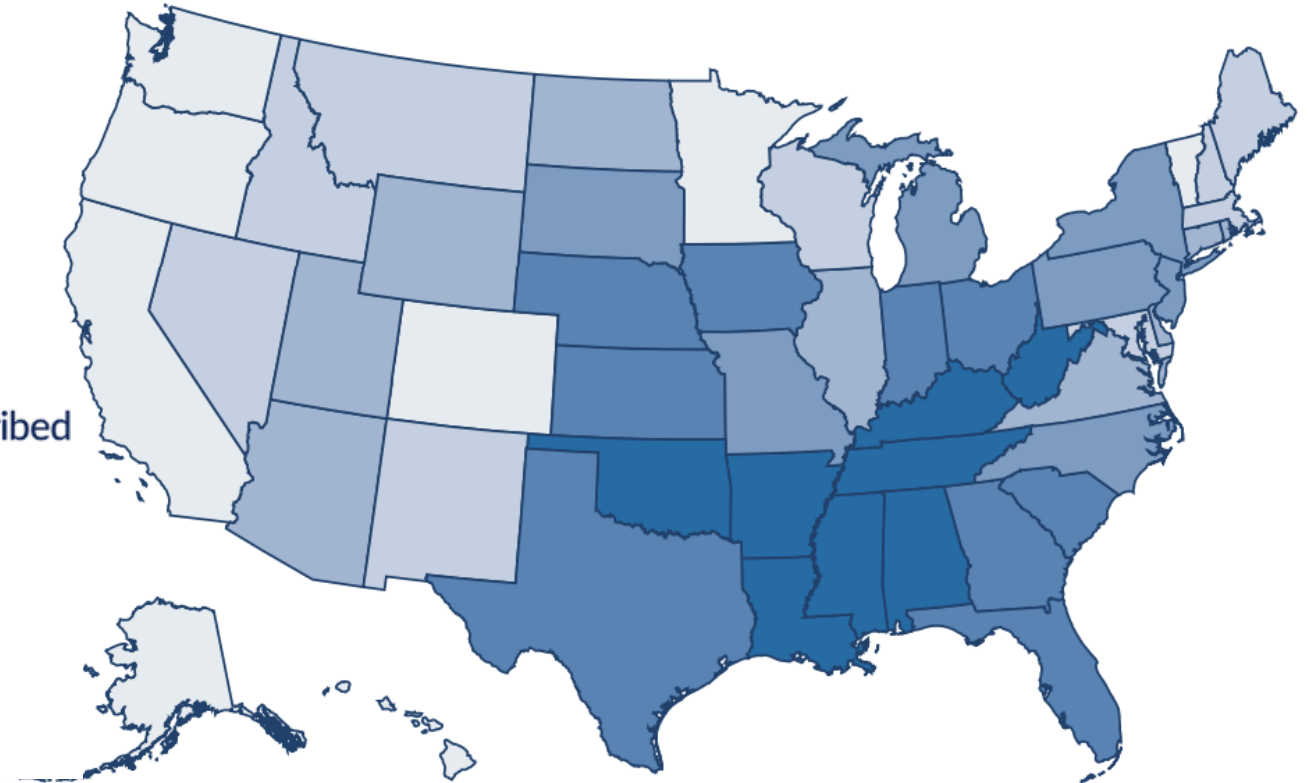
Outpatient settings account for **the majority** of antibiotics prescribed in human health care in the U.S.



**1 in 3**

**antibiotic prescriptions** written in doctors' offices, emergency rooms, and hospital-based clinics is **unnecessary**—this equals about **47 million prescriptions** each year.

- **50%** of these are the **incorrect drug, dose or duration**



All Antibiotic Classes Prescriptions Dispensed per 1,000 Population



# Standards for Outpatient Antibiotic Stewardship

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## • 2016: CDC



The Core Elements of  
**Outpatient Antibiotic Stewardship**

## • January 2020:



**The Joint Commission**

- Standards for Antibiotic Stewardship in Ambulatory Health Care: 5 elements of performance

# The Reality of Outpatient Antibiotic Stewardship

Settings report having fully functioning ASPs:



7% of ambulatory care settings

VS



88% of inpatient settings

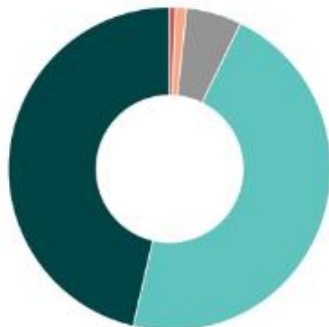
Physicians Recognize the Need for Antibiotic Stewardship, but Need Help With Implementation

Inappropriate antibiotic prescribing in outpatient health care settings accelerates the emerge of antibiotic-resistant bacteria

I would need a lot of help to implement antibiotic stewardship interventions in my practice



2020 Survey



Strongly agree **46%**  
 Agree **47%**  
 Neither agree nor disagree **6%**  
 Disagree **1%**  
 Strongly disagree **1%**



Strongly agree **11%**  
 Agree **37%**  
 Neither agree nor disagree **27%**  
 Disagree **21%**  
 Strongly disagree **5%**



## The Core Elements of Outpatient Antibiotic Stewardship



**Commitment:** demonstrated dedication to and accountability for optimizing antibiotic prescribing and patient safety



**Action for policy and practice:** implement at least one policy or practice to improve antibiotic prescribing, assess whether it is working, and modify as needed



**Tracking and reporting:** monitor antibiotic prescribing practices and offer regular feedback to clinicians or have clinicians assess their own antibiotic use



**Education and expertise:** provide educational resources to clinicians and patients on antibiotic prescribing and ensure access to needed expertise on antibiotic prescribing



## The organization:

1. Identifies an individual(s) responsible for developing, implementing, and monitoring activities to promote appropriate antimicrobial medication prescribing practices.
2. Sets at least one annual antimicrobial stewardship goal.
3. Uses evidence-based practice guidelines related to its annual antimicrobial stewardship goal(s).
4. Provides all clinical staff and licensed independent practitioners with educational resources related to its goal(s) and strategies that promote appropriate antimicrobial medication prescribing practices.
5. Collects, analyzes, and reports data pertaining to the antimicrobial stewardship goal(s) to organizational leadership and prescribers



# Hospital ASP Expansion to Ambulatory Practices

- Depends on resources available → ASPs that are more well-established may be able to begin branching out

## Implementation ideas using some hospital ASP resources

Commitment	Action	Tracking & Reporting	Education
<ul style="list-style-type: none"> <li>• Identify a physician champion to work with at each site and create a tracking tool</li> <li>• Identify a goal (e.g., implement each Core Element; decrease % of visits resulting in antibiotic prescriptions)</li> <li>• Provide public commitment posters to display in offices</li> </ul>	<ul style="list-style-type: none"> <li>• Provide evidence-based practice guidelines based on local susceptibilities from hospital antibiograms (e.g., UTI, URI (pharyngitis, sinusitis, bronchitis), CAP, SSTI)</li> <li>• Provide communication skills training</li> </ul>	<ul style="list-style-type: none"> <li>• Provide data on antibiotic prescribing at clinic (e.g. % of visits with antibiotic prescription, by class and/or specific antibiotics, comparison to providers and / or clinics in the system)               <ul style="list-style-type: none"> <li>• Data could be provided before and after implementation then annually</li> </ul> </li> <li>• Prescriber survey before and after implementation</li> </ul>	<ul style="list-style-type: none"> <li>• Provide educational presentations               <ul style="list-style-type: none"> <li>• Create a recurring AMS lecture series</li> </ul> </li> <li>• Provide patient educational materials</li> <li>• Provide access to hospital AMS team for expertise</li> </ul>

# Summary

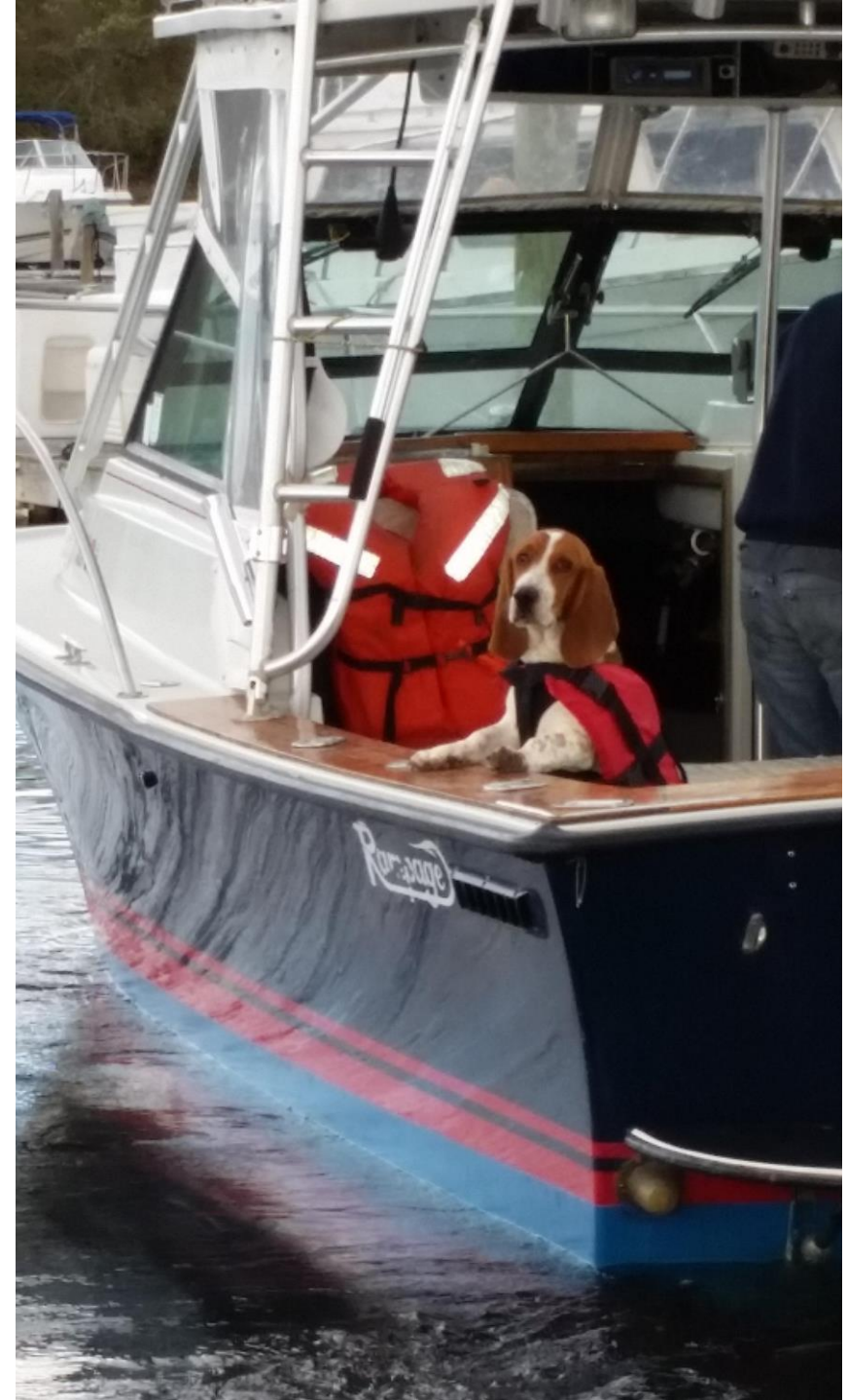


- CMS Conditions of Participation went into effect March 2020
- TJC Standards have been updated for 2023 to better align with CMS COPs
- CDC Core Elements provide implementation ideas to meet regulations
- NHSN AUR module reporting will be required in 2024 to meet CMS Promoting Interoperability Requirements for participating hospitals
- Hospitals must ensure and justify adequate FTEs for ASP personnel to ensure regulations are met
- Pharmacy Technicians can be trained to become members of the ASP for data tracking, analysis, and NHSN reporting

# ...Wishing you smooth sailing through your regulatory visits

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