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CENTERS FOR MEDICARE & MEDICAID SERVICES

Great Plains
Quality Innovation Network

Antibiotic Stewardship: Regulated or Voluntarily Mandated?

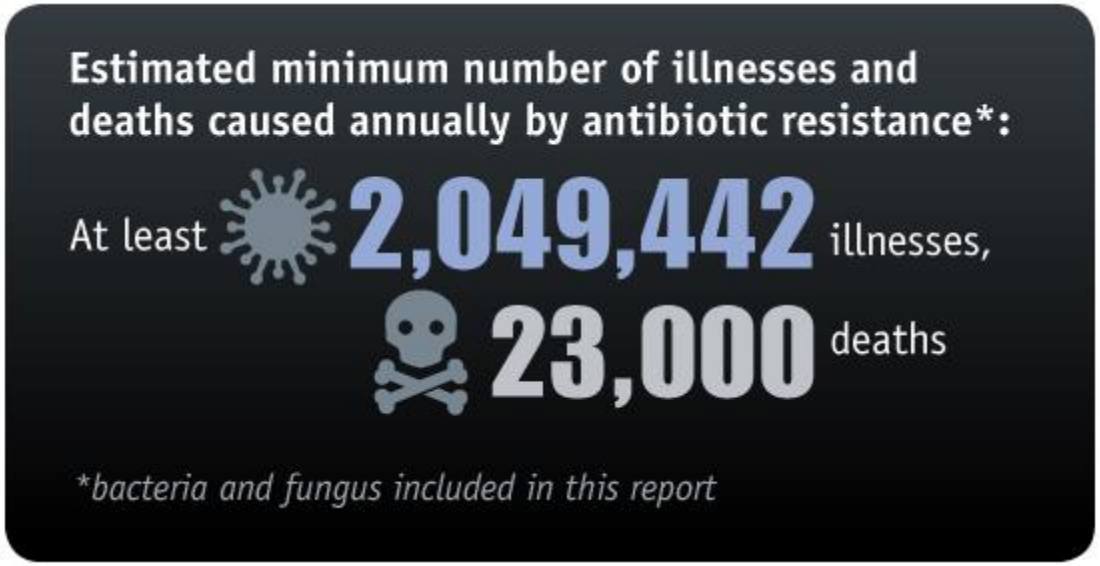
"What would your children look like if they had a respiratory challenge and we could not trust or could not have an antibiotic that would be effective on it? That would be very scary."

~Mark Gardiner, Kansas Rancher

https://www.bovinevetonline.com/article/stewardship-and-resistance-ranchers-perspective-antibiotics

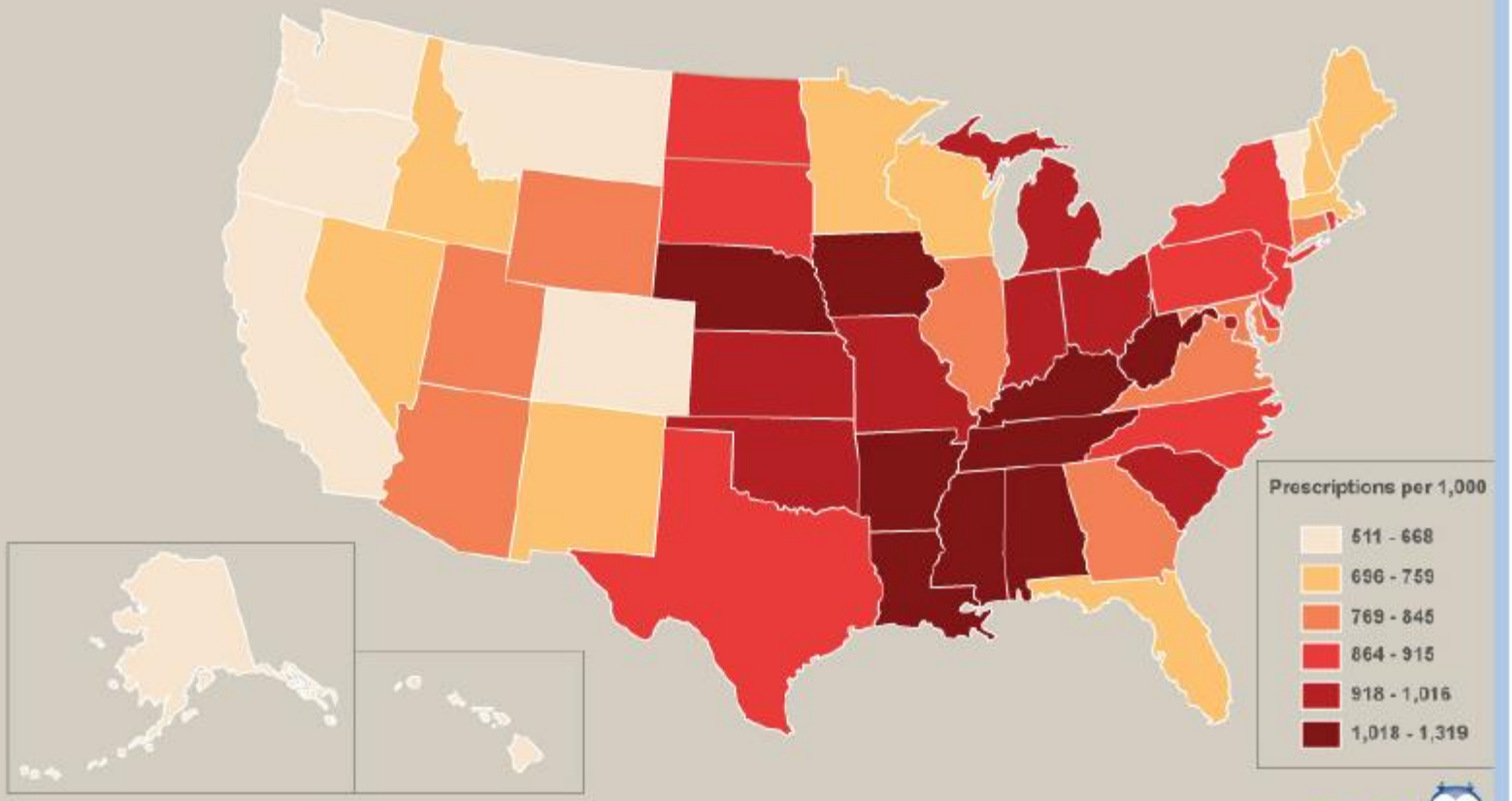
Why?

Antibiotic resistance is among the greatest public health threats today, leading to an estimated 2 million infections and 23,000 deaths per year in the United States.



Community Antibiotic Prescriptions per 1,000 Population by State - 2015

At least 30% of antibiotics prescribed in doctors' offices, emergency departments and hospital clinics are unnecessary.*

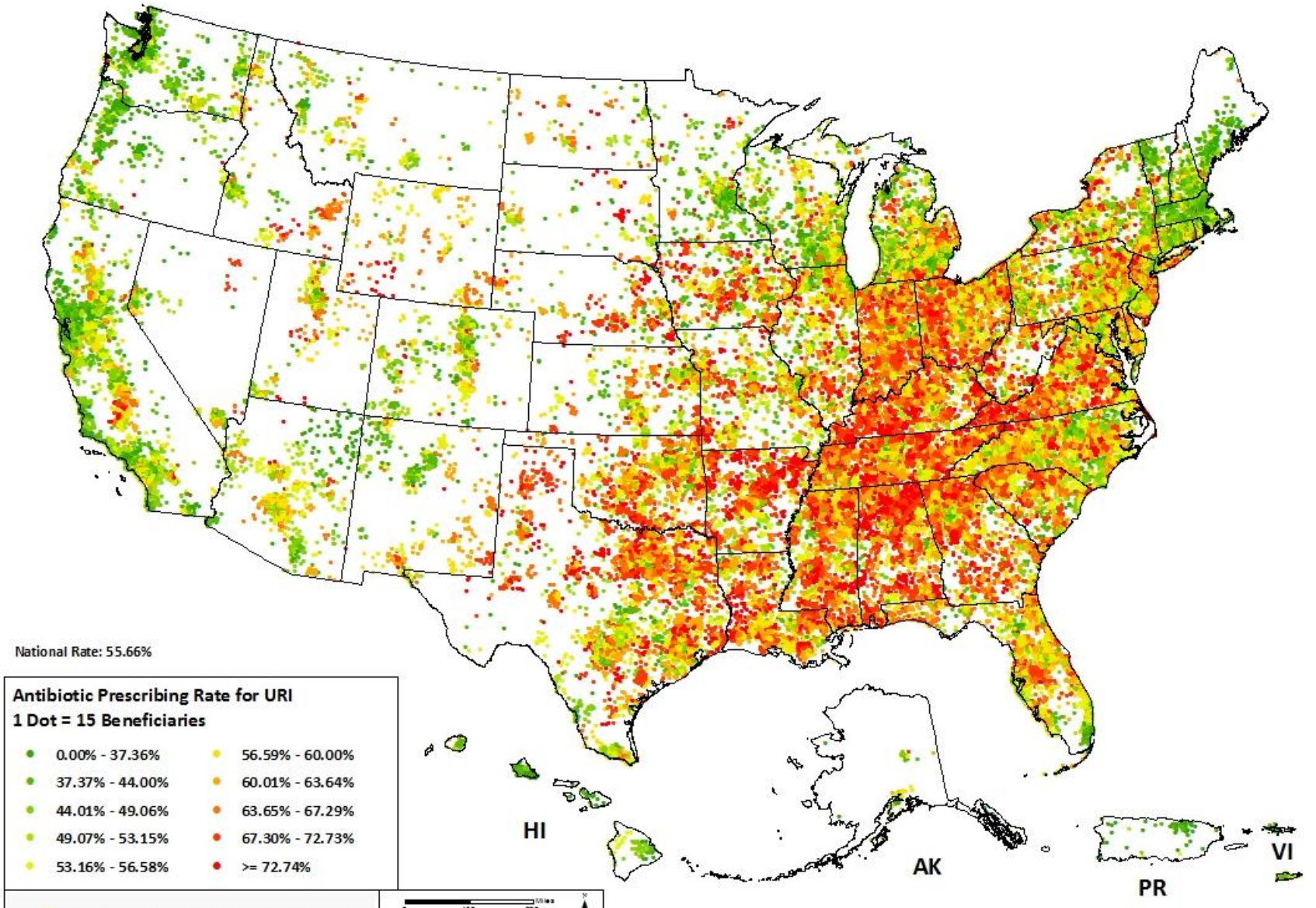


Data source: IMS Health Xponent 2014

"Fleming-Dutra, K., et al. (2016). "Prevalence of Inappropriate Antibiotic Prescriptions Among US Ambulatory Care Visits, 2010-2011." **JAMA, the Journal of the American Medical Association** 315(17): 1864-1873

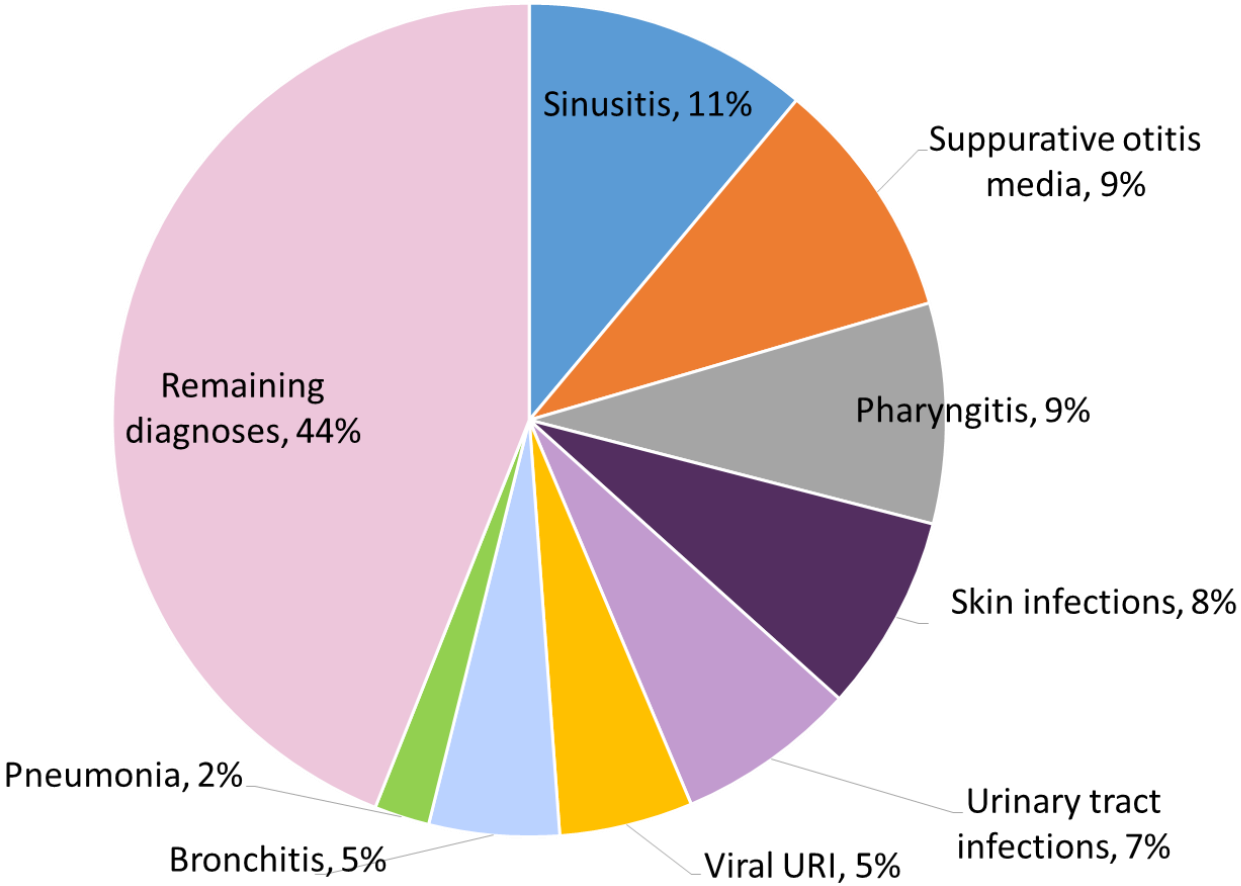
GET SMART
Know When Antibiotics Work

ZIP Code Level FFS Beneficiary Density for Antibiotic Prescribing Rates for Upper Respiratory Infections (URI) (10/1/16-9/30/17)



This material was prepared by Telligen, the Quality Innovation Network National Coordinating Center, under contract with the Centers for Medicare & Medicaid Services (CMS), an agency of the U.S. Department of Health and Human Services. The contents presented do not necessarily reflect CMS policy. [11SOW-QINNCC-02118-05/17/18]

Diagnoses Leading to Antibiotics — United States, 2010–11



Fleming-Dutra et al. JAMA 2016;315(17): 1864-1873.
The Pew Charitable Trusts. May 2016.

ESTABLISHED RISKS OF ANTIBIOTIC USE

INCREASED INFECTION RISK

Even though antibiotics are used to treat infections, they can also increase the risk of some types of infections. For example, people who have recently taken an antibiotic are at more risk of diarrhea caused by bacteria while traveling (i.e., traveler's diarrhea) or are at more risk of infection during outbreaks of foodborne illness caused by bacteria. In addition, infections caused by *C. difficile* bacteria and Candida fungi are common when taking antibiotics.

Clostridium difficile (C. difficile)

Each year nearly half a million illnesses and 15,000 deaths are caused by *C. difficile* infections. People taking antibiotics are 7 to 10 times more likely to get *C. difficile* while on the drugs, or in the month after taking them, than people not taking antibiotics.[1-4]

Candida

When a person's microbiome is disrupted by taking an antibiotic, there is increased risk for fungus (yeast) such as *Candida* species to grow. Common types of *Candida* infection are diaper rashes caused by yeast, vaginal yeast infections, and infections of the mouth and throat (also called thrush). In patients hospitalized for serious conditions or who have weak immune systems, *Candida* can cause severe illness, including bloodstream infections, or death.

ALLERGIC REACTIONS

Among children, antibiotics are the most common cause of emergency department visits for reactions to drugs. Most of these visits are for allergic reactions, which can range from mild rashes and itching to life-threatening swelling of the face and throat and breathing problems (called anaphylaxis).

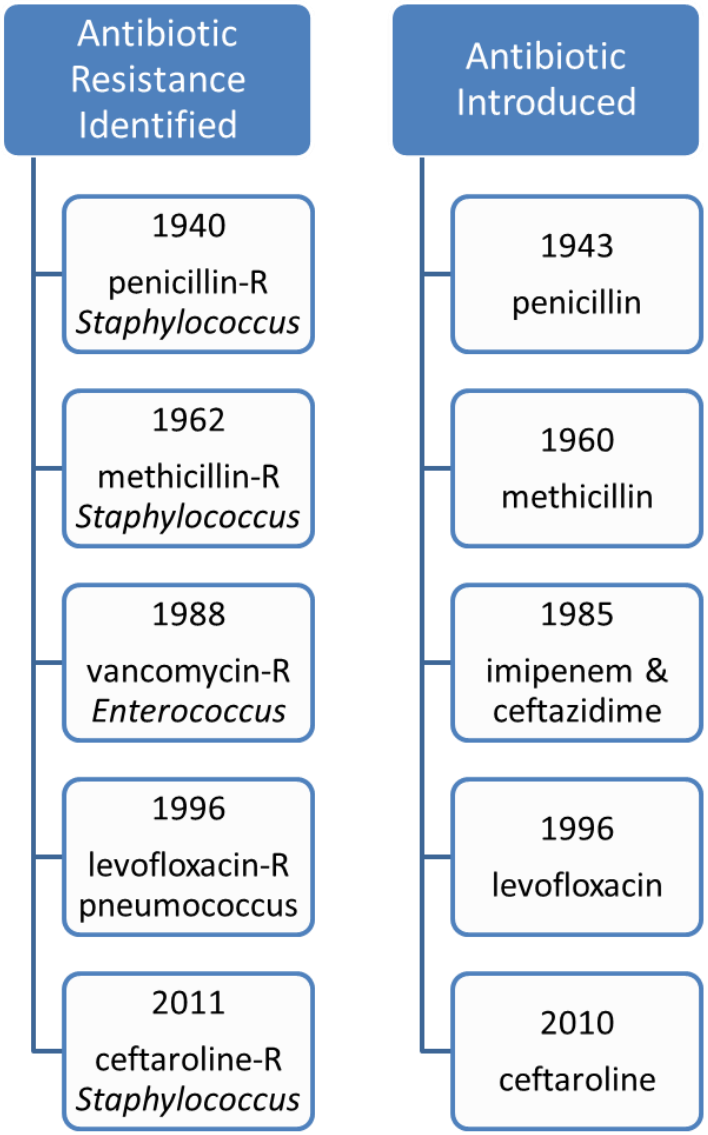
DRUG INTERACTIONS

Antibiotics can interact with other drugs patients take. Then, those drugs, or the antibiotics, become less effective or the patient has worse side effects.

ANTIBIOTIC RESISTANCE

When a patient takes an antibiotic, the bacteria it is fighting might adapt to develop new resistance against the drug. The resistant bacteria can then cause resistant infections in that patient and/or spread to other people.

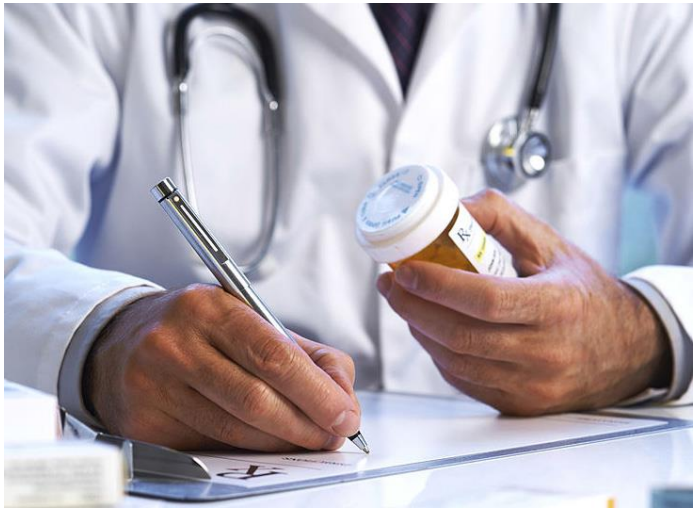
History of Antibiotics



https://www.cdc.gov/drugresistance/about.html

What is Antibiotic Stewardship?

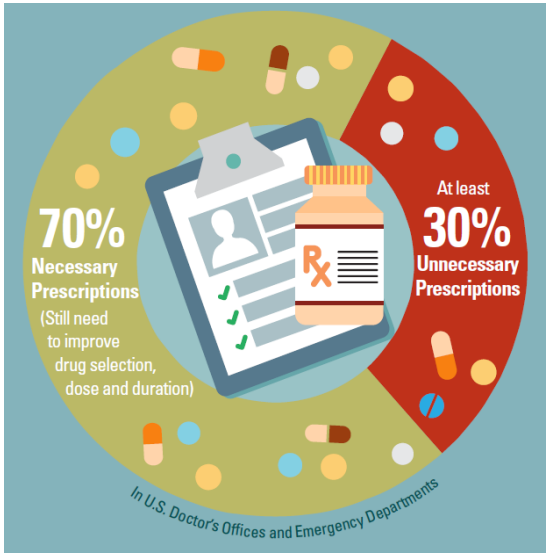
- Antibiotic stewardship is the effort to:
  - Measure antibiotic prescribing
  - Improve antibiotic prescribing so that antibiotics are only prescribed and used when needed
  - Minimize misdiagnoses or delayed diagnoses leading to underuse of antibiotics
  - Ensure that the right drug, dose, and duration are selected when an antibiotic is needed



It's about patient safety and delivering high-quality healthcare.

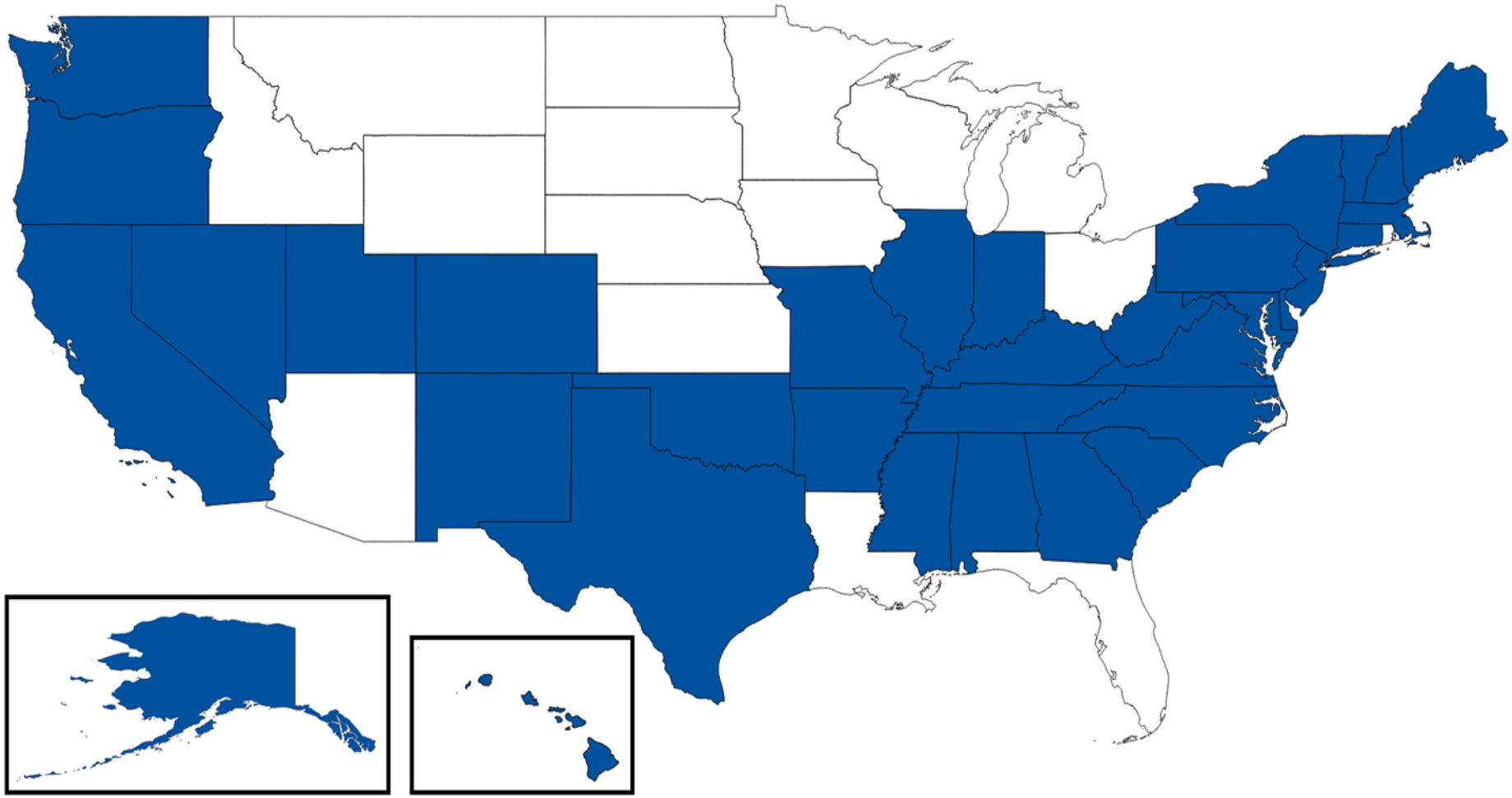
Why the Outpatient Setting?

- High levels of antibiotic use
  - Majority of human antibiotic use occurs in outpatients
  - 30% of outpatient antibiotic prescriptions are unnecessary
    - 50% of antibiotics for acute respiratory conditions are unnecessary
- It's a matter of patient safety
  - Side effects from antibiotics lead to an estimated 143,000 emergency department visits per year
  - Antibiotic treatment is the most important risk factor for *Clostridium difficile* infection
- Inappropriate antibiotic use is primary modifiable driver of antibiotic resistance



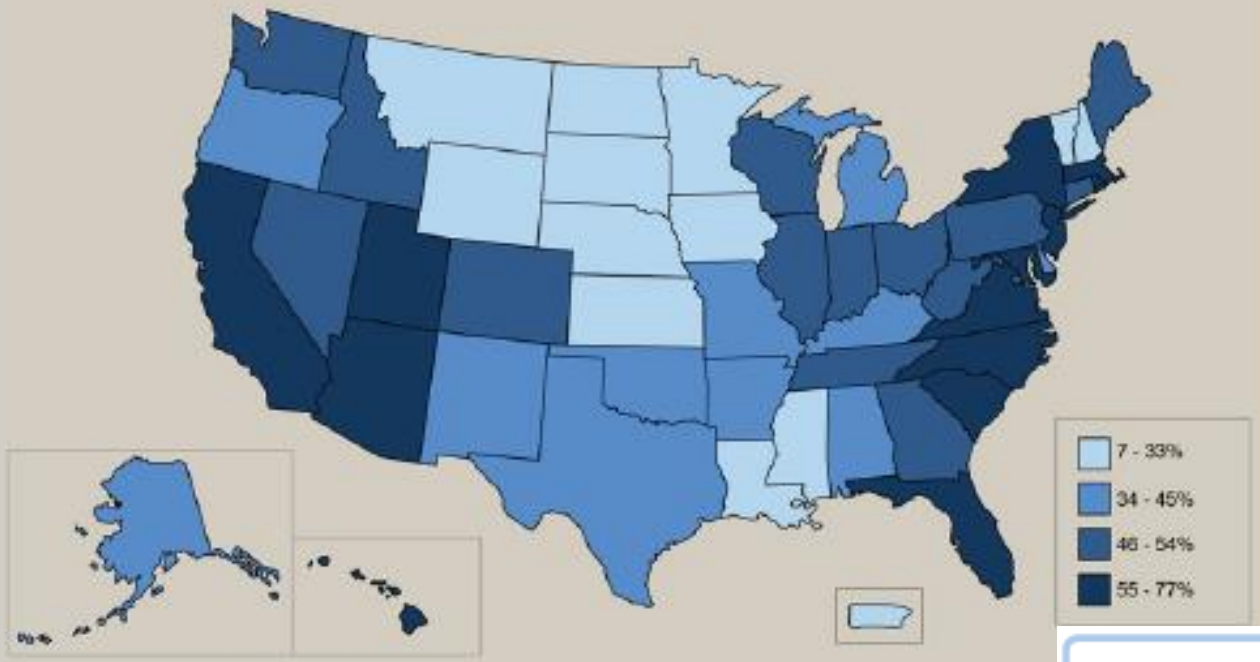
Shehab N, et al. Clin Infect Dis 2008;47:735–43. Gonzales R et al. Clin Infect Dis 2001;33:757–62. Suda et al. J Antimicrob Chemother 2013; 68: 715–718
Fleming-Dutra KE et al. JAMA 2016;315:1864–73
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/362374/ESPAUR_Report_2014__3_.pdf.
https://www.folkhalsomyndigheten.se/pagefiles/20281/Swedres-Svarm-2014-14027.pdf.

NHSN Reporting Required



Percent of Hospitals with Antibiotic Stewardship Programs by State, 2015*

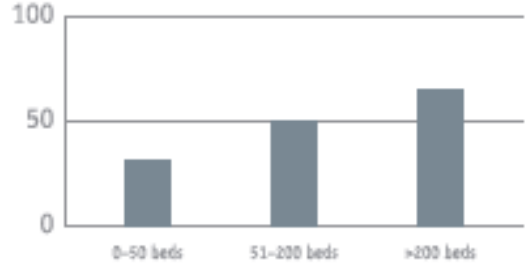
Nationally, 48.1% of all hospitals have stewardship programs (2,199 of 4,549); the national goal is 100% of hospitals by 2020.

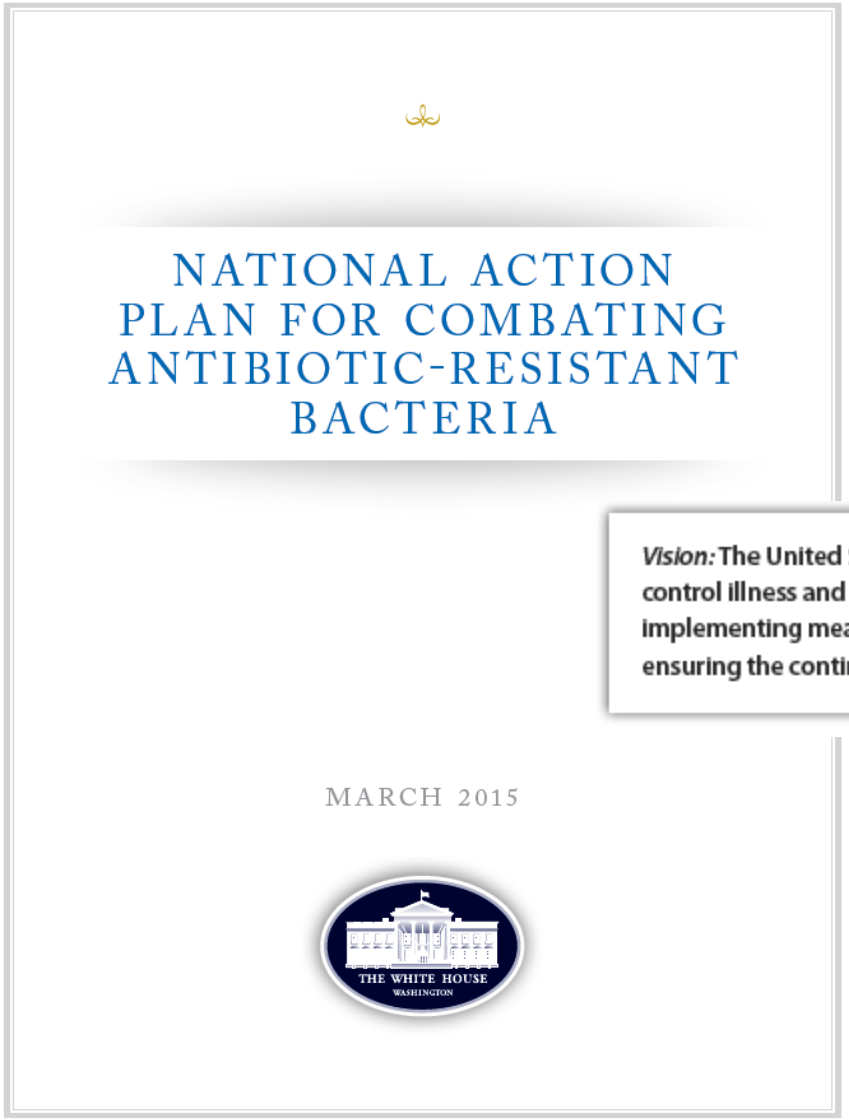


*A hospital stewardship program is defined as a program following all 7 of CDC's Core Elements of Hospital Antibiotic Stewardship Programs.

Source: CDC's National Healthcare Safety Network (NHSN) Survey

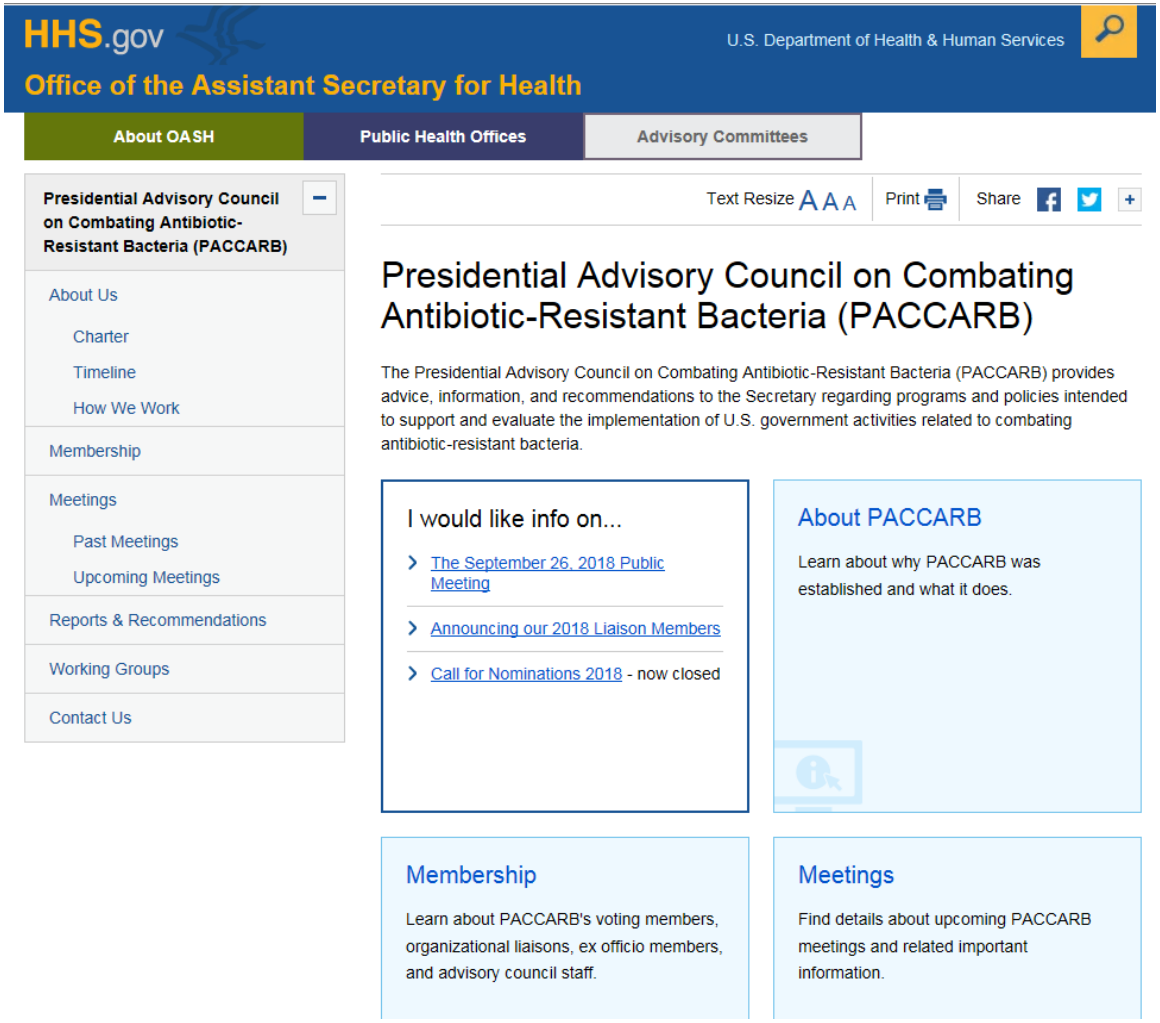
Percentage of U.S. Acute Care Hospitals (n=4,569) Implementing All 7 Core Elements of Hospital Antibiotic Stewardship Programs

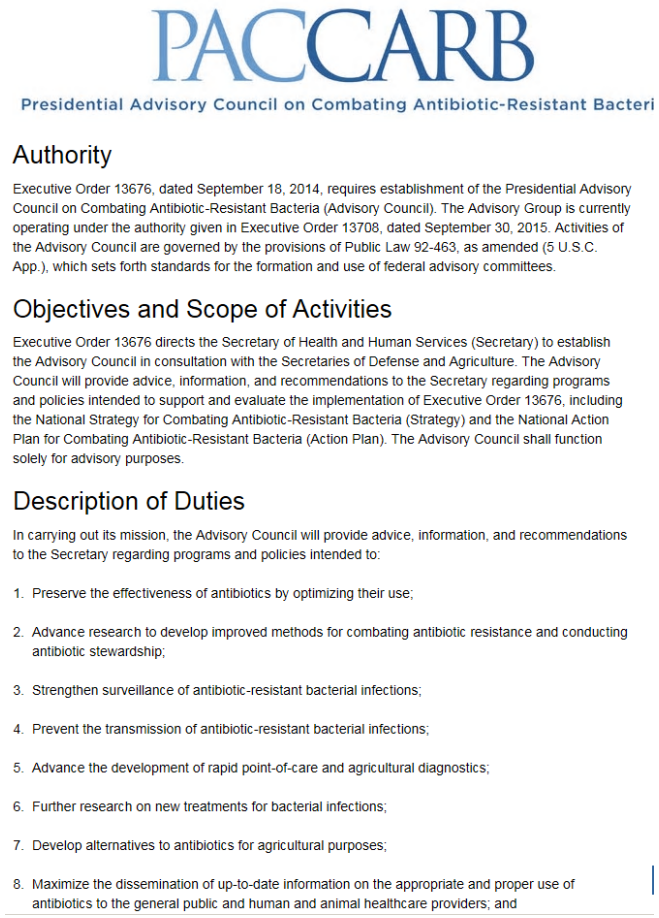




Vision: The United States will work domestically and internationally to prevent, detect, and control illness and death related to infections caused by antibiotic-resistant bacteria by implementing measures to mitigate the emergence and spread of antibiotic-resistance and ensuring the continued availability of therapeutics for the treatment of bacterial infections.

https://www.cdc.gov/drugresistance/pdf/national_action_plan_for_combating_antibotic-resistant_bacteria.pdf





https://www.hhs.gov/ash/advisory-committees/paccarb/index.html

CMS Conditions of Participation

- §482.42 The hospital must provide a sanitary environment to avoid sources and transmission of infections and communicable diseases. There must be an active program for the prevention, control, and investigation of infections and communicable diseases.

National Patient Safety Goals

Goal 7:

Reduce the risk of health care-associated infections.

https://www.jointcommission.org/assets/1/6/NPSG_Chapter_HAP_Jan2018.pdf

National Patient Safety Goals

- NPSG.07.01.01: Comply with either the current Centers for Disease Control and Prevention (CDC) hand hygiene guidelines or the current World Health Organization (WHO) hand hygiene guidelines.

  - *Applies to: Ambulatory, Behavioral Health Care, Critical Access Hospital, Home Care, Hospital, Lab, Long Term Care, Office-Based Surgery*

National Patient Safety Goals

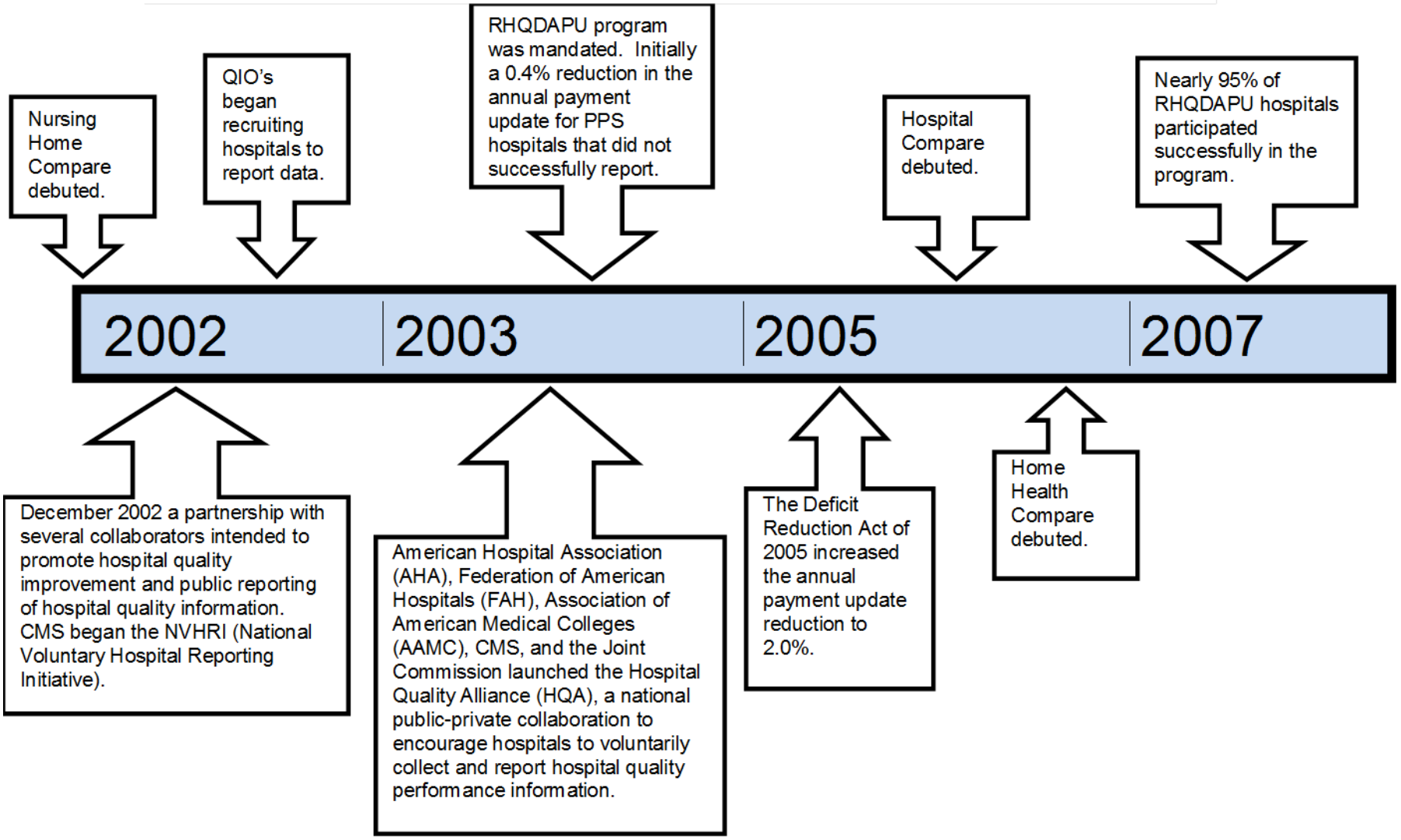
- NPSG.07.03.01: Implement evidence-based practices to prevent health care-associated infections due to multidrug-resistant organisms in acute care hospitals.
  - *Applies to: Critical Access Hospital, Hospital*

- NPSG.07.04.01: Implement evidence-based practices to prevent central line-associated bloodstream infections.
  - *Applies to: Critical Access Hospital, Hospital, Long Term Care*

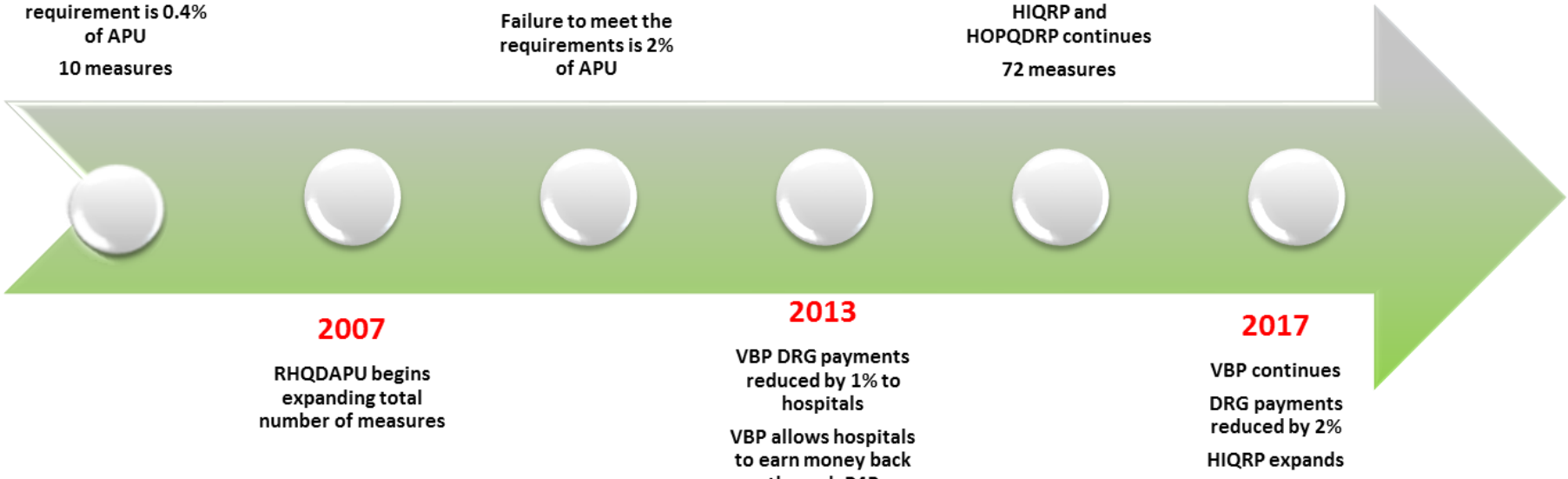
National Patient Safety Goals

- NPSG.07.05.01: Implement evidence-based practices for preventing surgical site infections.
  - *Applies to: Ambulatory, Critical Access Hospital, Hospital, Office-Based Surgery*
- NPSG.07.06.01: Implement evidence-based practices to prevent indwelling catheter-associated urinary tract infections (CAUTI).
  - *Applies to: Critical Access Hospital, Hospital.* (Note: This NPSG is not applicable to pediatric populations. Research resulting in evidence-based practices was conducted with adults, and there is not consensus that these practices apply to children.)

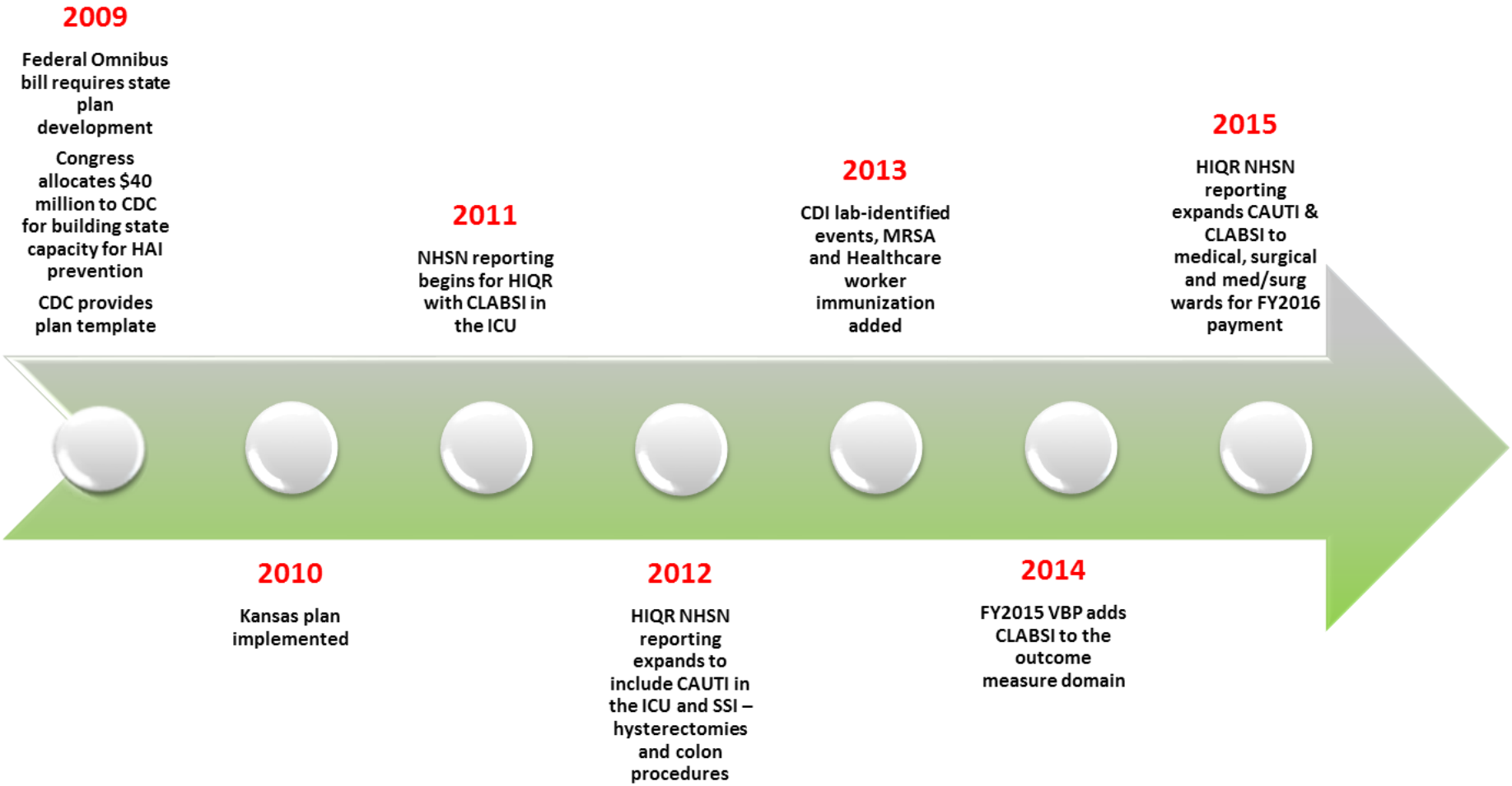
Data Reporting Timeline



Journey to Reporting



Infection Prevention Joins the Journey



Pending Legislation
CMS-3295-P

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Hospital and Critical Access Hospital (CAH) Changes to Promote Innovation, Flexibility, and Improvement in Patient Care CMS-3295-P

Docket Folder Summary | View all documents and comments in this Docket

Docket ID: CMS-2016-0095 **Agency:** Centers for Medicare Medicaid Services (CMS) **Parent Agency:** Department of Health and Human Services (HHS)

Summary:

These proposed changes would modernize hospital and critical access hospital (CAH) requirements, improve quality of care, and support HHS and CMS priorities. Specifically, we proposed to revise the conditions of participation (CoPs) for hospitals and CAHs to address: Discriminatory behavior by healthcare providers that may create real or perceived barriers to care; Use of the term "Licensed Independent Practioners" (LIPs) that may inadvertently exacerbate workforce shortage concerns; Requirements that do not fully conform to current standards for infection control; Requirements for antibiotic stewardship programs to help reduce inappropriate antibiotic use and antimicrobial resistance; and the use of quality reporting program data by hospital Quality Assessment and more...

RIN: 0938-AS21 **Impacts and Effects:** Small Entities (Business) **CFR Citation:** 42 CFR 482,42 CFR 485 **Priority:** Economically Significant

– View Less UA and Regulatory Plan Information and Docket Details

UA and Regulatory Plan Information

Publication Period: Fall 2016
Agenda Stage of Rulemaking: Long-term Action
Major Rule: Yes
Legal Authorities: 42 U.S.C. 1302, 42 U.S.C. 1395hh and 1395rr
Government Levels Affected: No

Federalism Implications: No
Unfunded Mandates: No
Requires Regulatory Flexibility Analysis: No
Small Entities Affected: Business
International Impacts: No
Included in Regulatory Plan: No

Legal Deadline

Action	Source	Description	Date
Statutory	Other	MMA section 902.	06/16/2019

Timetable

Action	Date	FR Citation
NPRM	06/16/2016	81 FR 39447
NPRM Comment Period End	08/15/2016	
Final Action	06/00/2019	

Docket Details

Related RINs: None
Related Dockets: None
Type: Rulemaking

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Regulatory Timeline

Pre Rule

Proposed Rule

Final Rule

Long Term Action
Current Stage

Agency Contact

CDR Scott Cooper
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CMS/HHS
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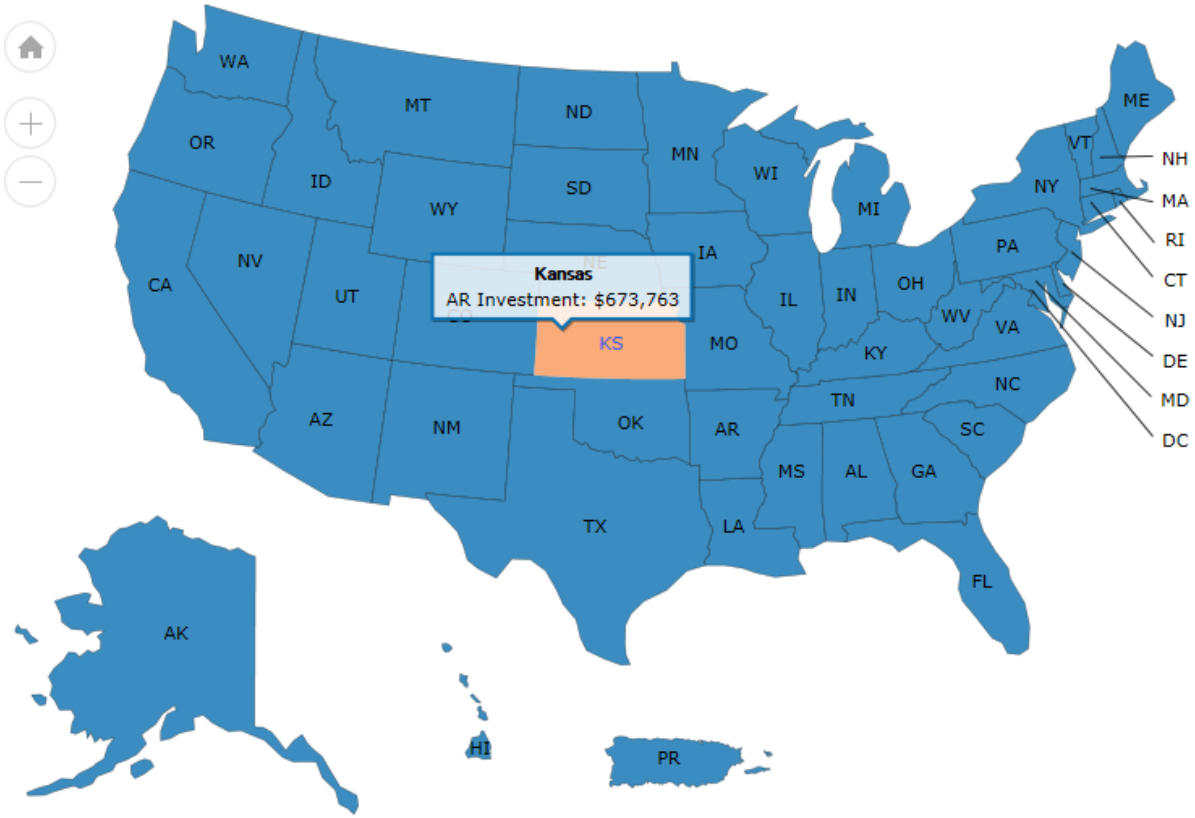
410 786-9465

www.regulations.gov/docket?D=CMS-2016-0095

Key Investments to Combat Antibiotic Resistance

Hover over and select state for more details.



This map represents CDC's largest funding categories for antibiotic resistance. It shows domestic, extramural funding that supports AR activities from multiple funding lines.

Investing to Defend the U.S. against Antibiotic Resistance

CDC is committed to protecting Americans and the future of healthcare, veterinary, and agriculture industries from the threat of antibiotic resistance. CDC supports most of these activities through its AR Solutions Initiative, while also leveraging investments from successful programs across the agency for maximum efficiency.

CDC partners with health departments, academia, and the healthcare, veterinary, and agriculture industries to grow the science and implement strategies that protect Americans from antibiotic resistance.

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AR Solutions *In Action*

CDC's Investments to Combat Antibiotic Resistance Threats Nationwide

FISCAL YEAR 2017

KANSAS

$673,763

Funding for AR Activities
Fiscal Year 2017

FUNDING TO STATE HEALTH DEPARTMENTS

$481,569

RAPID DETECTION & RESPONSE to emerging drug-resistant germs is critical to contain the spread of these infections.
With 2016 funding, Kansas worked with partners to increase the number of healthcare facilities reporting to National Healthcare Safety Network from 80 to 182. This data sharing increases the state's capacity to use timely and accurate data to target its HAI/AR prevention and response efforts.

$192,194

FOOD SAFETY projects protect communities by rapidly identifying drug-resistant foodborne bacteria to stop and solve outbreaks and improve prevention.
In Fiscal Year 2018, Kansas will ramp up testing to include whole genome sequencing of all *Listeria*, *Salmonella*, *Campylobacter* and *E. coli* isolates and simultaneously monitor these isolates for resistance genes. States upload the sequence data into PulseNet for nationwide monitoring of outbreaks and trends. When outbreaks are detected, local CDC-supported epidemiologists investigate the cases to stop spread.

Antibiotic Resistance (AR) Solutions Initiative

Improve antibiotic use through antibiotic stewardship, sepsis recognition, and prevention.

Set national goals to improve antibiotic use.
» Cut inappropriate prescribing practices by 50% in doctors' office and 20% in hospitals.

Implement effective stewardship programs using CDC's Core Elements and recommendations in doctors' offices, hospitals, and nursing homes, integrated with sepsis early recognition programs.

Support collaboration to develop and evaluate stewardship activities.

Provide data about antibiotic use and trends to better understand prescribing practices. For example:
» Expand and use CDC's National Healthcare Safety Network (NHSN) data to guide improvement of antibiotic use in hospitals.
» Better understand differences in prescibing patterns in doctors' offices by states and develop strategies for improvement.

Expand State HAI/AR Prevention Programs to help implement best practices around improving antibiotic prescribing.

Support early recognition of sepsis. Heighten public awareness to prevent sepsis and its complications, and to improve antibiotic use.

Core Actions to Combat Resistance

1 PREVENTING INFECTIONS, PREVENTING THE SPREAD OF RESISTANCE

Avoiding infections in the first place reduces the amount of antibiotics that have to be used and reduces the likelihood that resistance will develop during therapy. There are many ways that drug-resistant infections can be prevented: immunization, safe food preparation, handwashing, and using antibiotics as directed and only when necessary. In addition, preventing infections also prevents the spread of resistant bacteria.

2 TRACKING

CDC gathers data on antibiotic-resistant infections, causes of infections and whether there are particular reasons (risk factors) that caused some people to get a resistant infection. With that information, experts can develop specific strategies to prevent those infections and prevent the resistant bacteria from spreading.

3 IMPROVING ANTIBIOTIC PRESCRIBING/STEWARDSHIP

Perhaps the single most important action needed to greatly slow down the development and spread of antibiotic-resistant infections is to change the way antibiotics are used. Up to half of antibiotic use in humans and much of antibiotic use in animals is unnecessary and inappropriate and makes everyone less safe. Stopping even some of the inappropriate and unnecessary use of antibiotics in people and animals would help greatly in slowing down the spread of resistant bacteria. This commitment to always use antibiotics appropriately and safely—only when they are needed to treat disease, and to choose the right antibiotics and to administer them in the right way in every case—is known as antibiotic stewardship.

4 DEVELOPING NEW DRUGS AND DIAGNOSTIC TESTS

Because antibiotic resistance occurs as part of a natural process in which bacteria evolve, it can be slowed but not stopped. Therefore, we will always need new antibiotics to keep up with resistant bacteria as well as new diagnostic tests to track the development of resistance.

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This material was prepared the Great Plains Quality Innovation Network, the Medicare Quality Improvement Organization for Kansas, Nebraska, North Dakota and South Dakota, under contract with the Centers for Medicare & Medicaid Services (CMS), an agency of the U.S. Department of Health and Human Services. The contents presented do not necessarily reflect CMS policy. 11SOW-GPQIN-KS-C3.10-31/0918