# Chapter Legislative Representative Update

## June 28, 2015

**Lisa Tomlinson**
**Vice President, Government Affairs and Practice Guidance**

**Nancy Hailpern**
**Director, Regulatory Affairs**

**Laura Evans**
**Representative, Legislative Affairs**

**APIC Government Affairs Team Staff**
**Primary Role:**

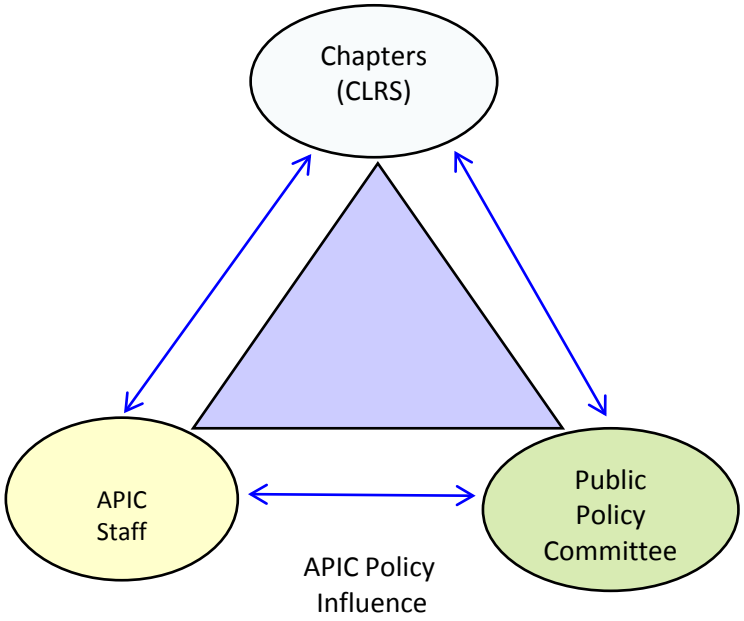
background in government affairs and advocacy

**Public Policy Committee (PPC)**
**Primary Role:**

clinical background with volunteer public policy experience

**Chapter Legislative Representatives (CLRs):**

clinical and chapter/local volunteer experience



# 2015 Public Policy Committee

**Committee Chair**
Annemarie Flood RN, BSN, MPH, CIC

**Committee Vice Chair**
Kirk Huslage RN, BSN, MSPH, CIC

**Members**
Becki Fitzpatrick DNP, RN, CIC
Patrick Kleinkort RN, BSN, MHA, CIC
Mary Alice Lavin RN, MJ, CIC
Rosie Lozano MPH, CIC
Nancy O'Connor MBSA, BSN, RN, CIC
Tarry Samsel BSN, RNC, CIC
Mary Virgallito RN, MSN, CIC

**Senior Advisor**
Susan Dolan RN, MS, CIC

# 2015 Chapter Legislative Representatives

Rebecca Stockwell
Mary-Lark Dupont
Mary Alice Lavin
Patricia Marquez
Angela Gerken
Stephanie Kreiling
Cindy York
Elizabeth Rall
Joanne Holman
Diane Bennett
Carol Ward
Maribeth Coluni
George Allen
Mary Shanks
Sharon Bradley
Brenda Roup
Christine Kettunen
Joan Bartholomew
Pongpetch Hansrisuk
Patricia Lafaro
Rosie Lozano
Katie Cary
Emily Mills
Amy Nichols

Jan Ratterree
Janet Suttmiller
Sharon Berry
Erica Disharoon
Patti Steger
Amy Jablonowski
Paula Lister
Kerry Flint
Nancy Barrett
Susan Slavish
Mary Wheaton
Cecilia Brown
Sarah Tice
Sheila Fletcher
Arlene Brumbach
Stephanie Lambert
Kelley Garner
Kitti Flood
Karla Walsh
Suzanne Mamrose-Hunt
Abby Kengersky
Barbara Roman
Patrick Kleinkort
Valerie Henderson

Shilla Patel
Ellen Bookin
Joan Cook
Beth Goodall
M. Jeanne Cummings
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Cathy Stampfli
Rhonda Reed
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Tarry Samsel
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Helen Garcia
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Linda Goddard
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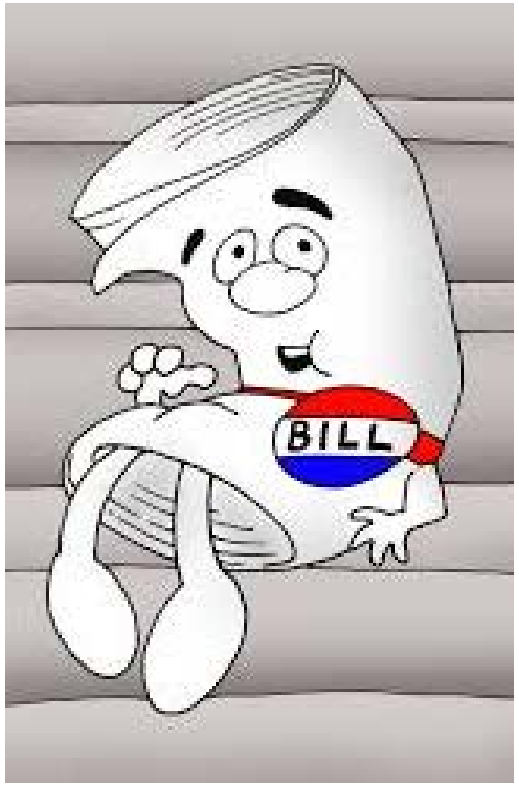
Donita Gorman
Ashlie Milford
Vicki Coyle
Barbara Brenchley
Vivian Nutsch
Pamela Webb
Carol Wilkie
Virginia Swindle
Connie Bush
Joyce Devaud
Janet Bacon
Troy Cutler
Candece Adkins
Charlotte Wheeler
Tobin Johnson
DeeAnn Vaage
Caroline Taylor

# Resources

- **Voice for infection Prevention (VIP) Public Policy Action E-List**: Infection Prevention Public Policy updates emailed directly to you.
- **What's new Page**: Webpage on APIC's website that provides brief articles on policy updates with links to original sources.
- **VIP Advocacy Toolkit**: A guide for planning legislative visits.
- **Interactive State Legislative Map**: Search Infection Prevention related legislation by on state or topic.  Updated as legislation is filed.
- **Presentation Ready Maps**: PowerPoint ready maps on state infection prevention legislation/regulations that can be used with attribution.
- **Take Action Page**: Webpage on APIC's website that allows members to contact their federal and state elected officials.
- **APIC's Regulation Table**: An easy to read table of APIC's comments to federal agencies.
- **VIP Chapter Presentation Slides**: A resource for chapter presentations.
- **APIC Public Policy Position Statements**: Webpage on APIC's position on issues.

# Legislative Process

- Idea generated
- Research issue and draft bill
- Bill introduced in House or Senate
- Bill referred to committee for consideration (some bills sent to subcommittee for further study)
- Committee holds public hearings, which may include presentations of testimony
- Committee votes to report bill out of committee

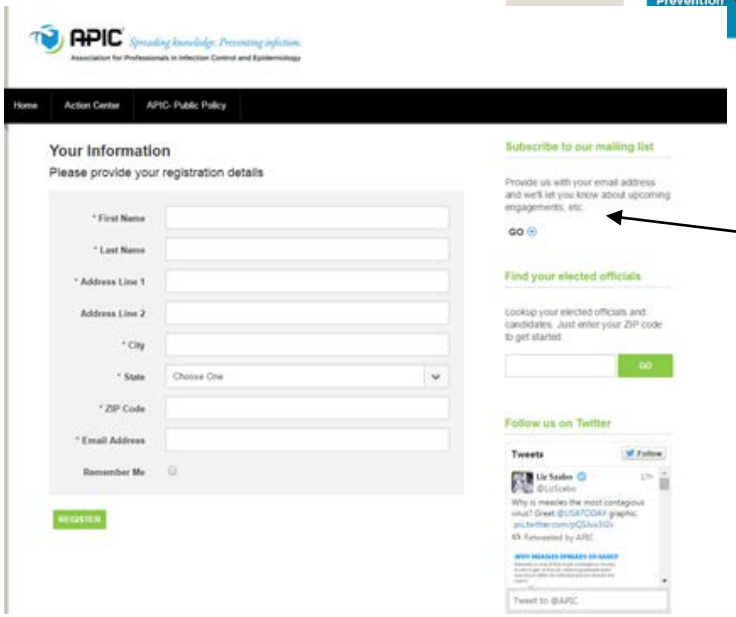



- Bill placed on legislative calendar and debated before the full House or Senate
- Bill approved by one chamber (engrossed) and send to the other chamber for consideration
- If the original bill is changed (amended) in the second chamber, it will go back to the original chamber for approval
- Once both House and Senate have approved identical bill, it become enrolled and is sent to the Governor
- The Governor can veto (reject) the legislation, sign the legislation, or do nothing

# Public Policy Action E-List

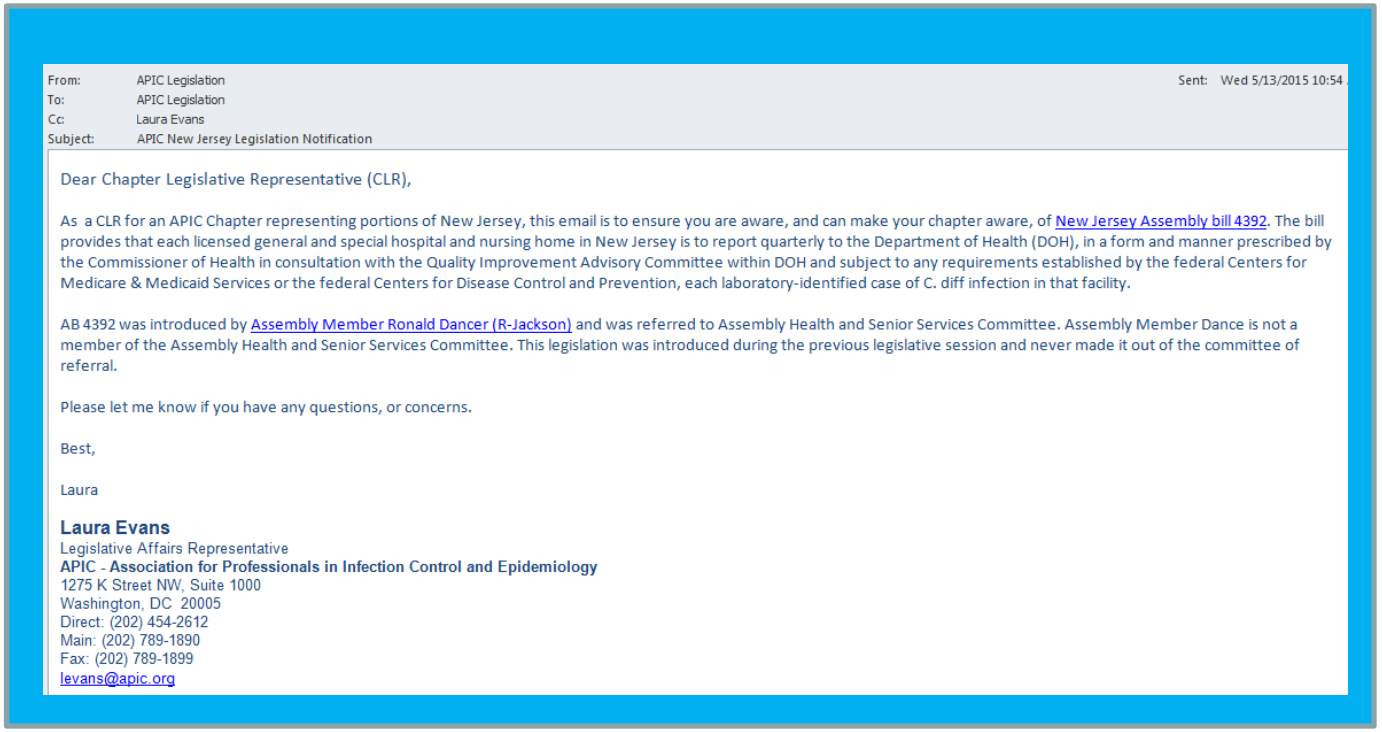
To sign up for the Action E-List, visit the Public Policy Overview page of the APIC website.

Within the “what’s new” page explanation, there is a link to join the Action E-List.




The link will open a webpage that allows a user to enter basic information before joining the Action E-List. Additional APIC information is helpful but not required. Managing your Action E-List subscription is also available at this site.

# Legislation Notification



From: APIC Legislation
To: APIC Legislation
Cc: Laura Evans
Subject: APIC New Jersey Legislation Notification
Sent: Wed 5/13/2015 10:54

Dear Chapter Legislative Representative (CLR),

As a CLR for an APIC Chapter representing portions of New Jersey, this email is to ensure you are aware, and can make your chapter aware, of New Jersey Assembly bill 4392. The bill provides that each licensed general and special hospital and nursing home in New Jersey is to report quarterly to the Department of Health (DOH), in a form and manner prescribed by the Commissioner of Health in consultation with the Quality Improvement Advisory Committee within DOH and subject to any requirements established by the federal Centers for Medicare & Medicaid Services or the federal Centers for Disease Control and Prevention, each laboratory-identified case of C. diff infection in that facility.

AB 4392 was introduced by Assembly Member Ronald Dancer (R-Jackson) and was referred to Assembly Health and Senior Services Committee. Assembly Member Dance is not a member of the Assembly Health and Senior Services Committee. This legislation was introduced during the previous legislative session and never made it out of the committee of referral.

Please let me know if you have any questions, or concerns.

Best,

Laura

**Laura Evans**
Legislative Affairs Representative
**APIC - Association for Professionals in Infection Control and Epidemiology**
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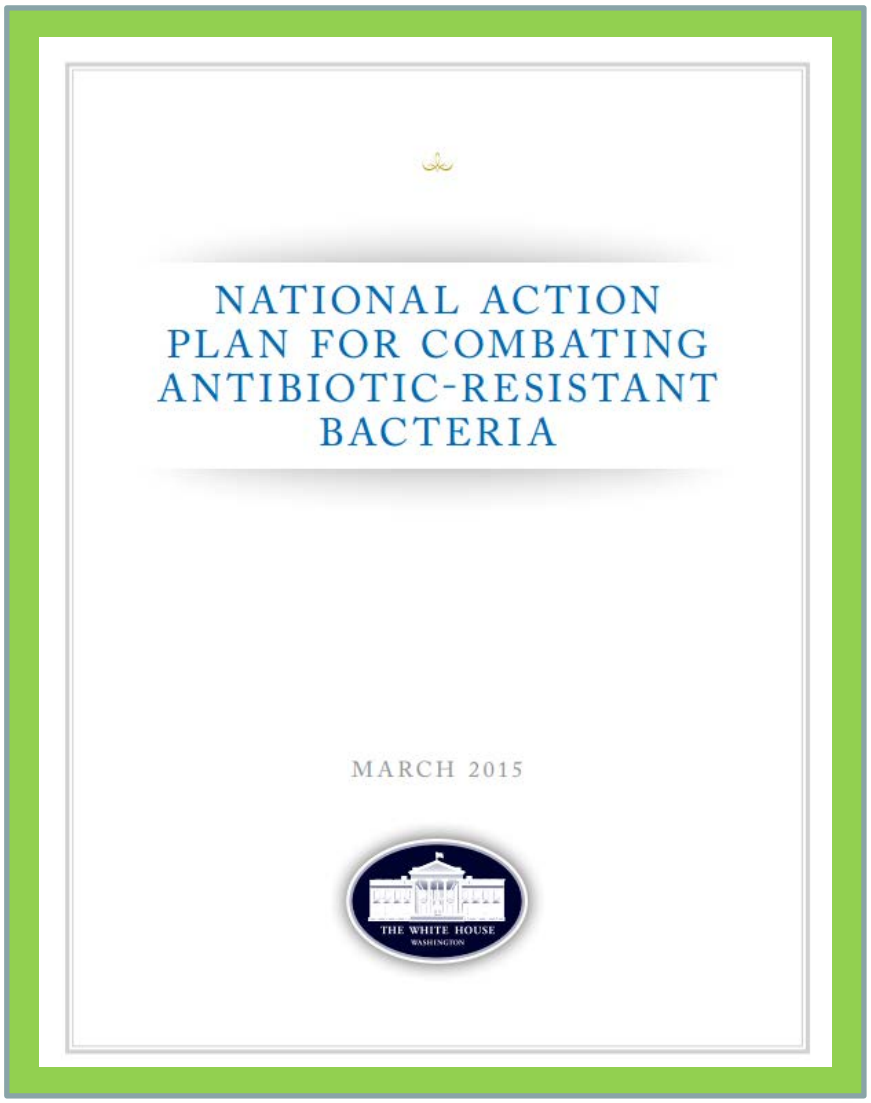
Washington, DC 20005
Direct: (202) 454-2612
Main: (202) 789-1890
Fax: (202) 789-1899
levans@apic.org

If a bill related to infection prevention has been introduced in a state represented by your chapter, you will receive an email that includes:

- Link to the bill
- Synopsis of the bill and how it relates to infection prevention
- Link to bill sponsor website
- Any relevant information on the bill and/or sponsor

# Federal and state efforts to combat antibiotic-resistant bacteria

# National Action Plan for Combating Antibiotic-Resistant Bacteria




**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.

# How the Action Plan came into existence

National Strategy to Combat Antibiotic-Resistant Bacteria

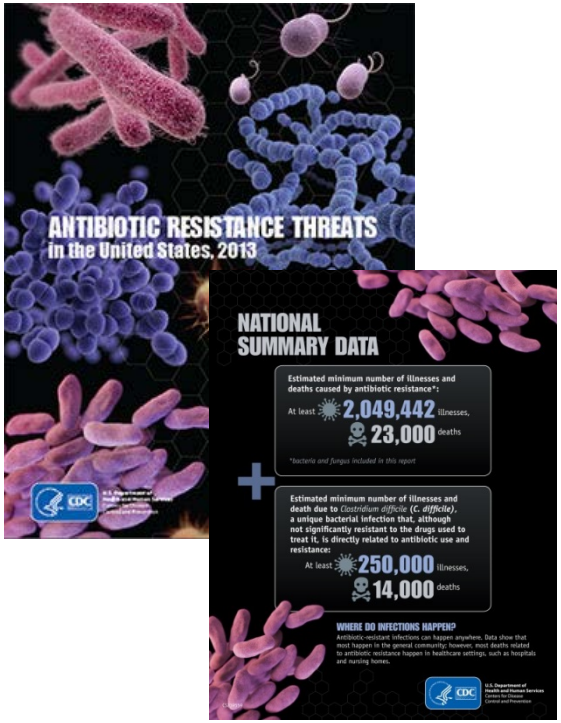
Executive Order

President's Council of Advisors on Science and Technology (PCAST) report on antibiotic resistance

5-year National Action Plan to Combat Antibiotic-Resistant Bacteria

# CDC Antibiotic Resistance Threat Report

- Antibiotic Resistance Threats in the United States, 2013
- First snapshot of the burden and threats posed by antibiotic-resistant germs




**Urgent and serious threats:**

- *Clostridium difficile*
- Carbapenem-resistant Enterobacteriaceae
- Multidrug-resistant *Acinetobacter*
- Vancomycin-resistant *Enterococcus*
- Multidrug-resistant *Pseudomonas aeruginosa*
- Drug-resistant *Shigella*
- Methicillin-resistant *Staphylococcus aureus (MRSA)*

**Four Core Actions to Fight Antibiotic Resistance:**

- Preventing infections, preventing the spread of resistance
- Tracking resistance patterns
- Improving the use of today's antibiotics (antibiotic stewardship)
- Developing new antibiotics and diagnostic tests.

*"Antibiotic resistance is rising for many different pathogens that are threats to health. If we don't act now, our medicine cabinet will be empty and we won't have the antibiotics we need to save lives."* - CDC Director, Tom Frieden, MD, MPH

# PCAST recommendations

- Federal Investment and Leadership: Making Antibiotic Resistance a National Policy
- Monitoring Antibiotic Resistance: Systematic Surveillance and Response Capacity
- New Antibiotics: Fundamental Research
- New Antibiotics: Clinical Trials
- New Antibiotics: Commercial Development
- Stewardship of Current Antibiotics: Human Health Care
- Stewardship of Current Antibiotics: Animal Agriculture
- International Cooperation

# Monitoring Antibiotic Resistance: Systematic Surveillance and Response Capacity

- Increase in funding to $60 million per year to bring state and local health departments up to a minimum level of capacity to deal with antibiotic resistance surveillance, prevention, and response activities in healthcare settings.
- Additional $30 million per year for high-risk areas to address some unique threats
- Establish a national laboratory network for pathogen surveillance comprised of regional labs and clinical laboratories in major healthcare facilities
- Produce an initial reference collection of genome sequences from diverse antibiotic resistant isolates
- Support the development of new computational methods and tools, able to carry out genomic analyses of thousands of isolates and specimens
- Create and maintain a publically accessible database and analysis tools
- Initiate surveillance efforts in diverse settings (i.e., healthcare, agriculture, food, environmental sites, and non-US healthcare)
- Develop surveillance and testing standards (CLSI, NIST)

# Stewardship of Current Antibiotics: Human Health Care

- CMS Conditions of Participation for hospitals, critical access hospitals, long-term care and nursing facilities to require antibiotic stewardship programs that meet the CDC recommendations by the end of 2017. Phase in other care settings rapidly.
- Expand the Physician Quality Reporting System to include quality measures that discourage inappropriate antibiotic use.
- Include in the IQR program and reporting on Hospital Compare quality measures based on NHSN AUR data. Quality measures submitted to consensus body by 2017 and implementation consideration through MAP by 2018. Mandatory nationwide implementation by 2020.
- Require implementation of antibiotic stewardship programs as a condition for receiving Federal funding for healthcare delivery.
- Government healthcare facilities should implement antibiotic stewardship programs and report via NHSN AUR module.
- Improve patient education and address social and behavioral factors that drive inappropriate antibiotic use.
- Create Global Challenge Inducement Prizes for the development of rapid diagnostics.

# National Action Plan to Combat Antibiotic-Resistant Bacteria

Slow Emergence of Resistant Bacteria and Prevent the Spread of Infections

Strengthen National One-Health Surveillance Efforts to Combat Resistance

Advance Development and Use of Rapid and Innovative Diagnostic Tests for Identification and Characterization of Resistant Bacteria

Accelerate Basic and Applied Research and Development for New Antibiotics, Other Therapeutics, and Vaccines

Improve International Collaboration and Capacities for Antibiotic-resistant Prevention, Surveillance, Control, and Antibiotic Research and Development

# Slow Emergence of Resistance Bacteria and Prevent the Spread of Infections

**Within 1 year**

- HHS, DOD, VA to propose new regulations requiring hospitals, ASCs, dialysis facilities, and other inpatient facilities to implement antibiotics stewardship programs that align with CDC core elements
- NHSN to begin tracking facilities with stewardship programs
- New healthcare facility antibiotic use measures will be proposed to NQF
- AHRQ and CDC to host stakeholder meeting to address knowledge gaps and identify potential interventions for prevention of infections

**Within 3 years**

- CMS will expand stewardship Conditions of Participation to long-term acute hospitals
- CDC to support state stewardship activities with State AR Prevention (Protect) Program
- CDC to provide annual national estimates of inpatient antibiotic use
- Prevention Epicenters program will evaluate novel AR prevention tools for use in diverse healthcare settings
- Expanded quality measures for antibiotic prescribing proposed

**Within 5 years**

- CDC will evaluate the use of quality measures on antibiotic use
- CDC to develop and implement stewardship programs in select nursing homes

# Strengthen National One-Health Surveillance Efforts to Combat Resistance

**Within 1 year**

- CDC to develop implementation plan for the Detect Network of AR Regional Labs
- CDC EIP sites will pilot methodology to incorporate at least one additional urgent or serious AR pathogen into surveillance activities
- CDC and FDA to develop defined set of pathogens that will be included in a repository of resistant bacterial strains
- FDA and NIH will pilot test a sequence database containing more than 550 drug-resistant bacterial strains and metadata

**Within 3 years**

- CDC to designate at least 5 public health labs as part of the Detect Network
- CDC will establish 10 additional EIP sites
- CMS to begin process of proposing new IQR rules once new NQF AR measures approved
- CDC and FDA will create repository and database for resistant bacterial strains and will provide isolates to diagnostic test manufacturers and research labs
- CMS will finalize a tool to help software developers certify electronic health records and other health IT for recording and submitting antibiotic use data

**Within 5 years**

- CDC to determine if additional reporting incentives are needed
- CDC and partners will develop an antibiotic use NHSN reporting measure in a standard file format that hospitals can use to achieve the Stage 3 Meaningful Use objective

# CDC Congressional funding request

**NHSN: $32 million**

- Expand NHSN to 17,000 facilities
- Provide real-time data about antibiotic use and trends
- Target facilities that need additional assistance using NHSN data
- Continue funding for Prevention Epicenters to conduct HAI research

**Antibiotic Resistance Solutions Initiative: $264 million**

- Establish State AR Prevention (Protect) Programs in all 50 states and 10 large cities
- New Detect Network of AR Regional labs to improve response to outbreaks
- Create AR Isolate Bank
- Measure impact of antibiotics on human microbiome
- Double number of EIP sites

**Advanced Molecular Detection Initiative: $30 million**

- Improved pathogen identification and detection using genomics and other advanced molecular technologies
- Tools for prediction, modeling and early recognition of emerging infections

# Public Policy Committee Lobby Days

- PPC member Congressional visits in Washington DC to educate about the role of the IP, and support for NHSN and antibiotic resistance initiatives at CDC

# APIC led coalition in support of CDC funding

# APIC led coalition in support of CDC funding

APIC
Spreading knowledge. Preventing infection.®

MICROBION CORPORATION
biosciences : industries

SHEA
The Society for Healthcare Epidemiology of America

Pediatric Infectious Diseases Society

Sealed Air
Diversey Care

The Peggy Lillis Memorial Foundation
*Fighting C. diff through Education & Advocacy*

The Joint Commission

Pediatric Nurse Practitioners
NATIONAL ASSOCIATION OF

SAFE CARE CAMPAIGN
PREVENTING HEALTH CARE AND COMMUNITY ACQUIRED INFECTIONS
www.safecarecampaign.org

XENEX
GERM-ZAPPING ROBOTS™

NACCHO
National Association of County & City Health Officials

NovaDigm™
THERAPEUTICS

SIDP
Society of Infectious Diseases Pharmacists

THE PEW CHARITABLE TRUSTS

NADONALTC
NATIONAL ASSOCIATION DIRECTORS OF NURSING ADMINISTRATION/LONG TERM CARE

National Foundation for Infectious Diseases

PDI

PREMIER

shm
Society of Hospital Medicine

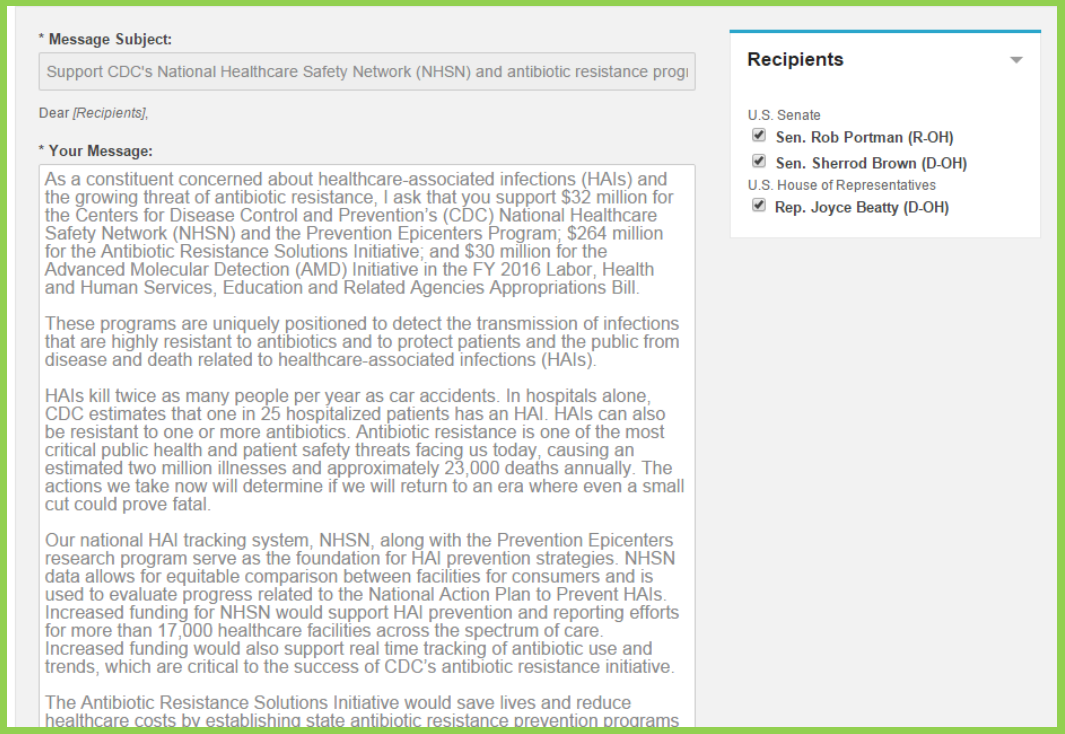
NCAL
NATIONAL CENTER FOR ASSISTED LIVING

Trust for America's Health
Preventing Epidemics. Protecting People.

RUSH UNIVERSITY MEDICAL CENTER

# What can you do to help?

**Take action: http://cqrcengage.com/apic/app/write-a-letter?2&engagementId=100215**



* Message Subject:

Support CDC's National Healthcare Safety Network (NHSN) and antibiotic resistance progi

Dear *[Recipients]*,

* Your Message:

As a constituent concerned about healthcare-associated infections (HAIs) and the growing threat of antibiotic resistance, I ask that you support $32 million for the Centers for Disease Control and Prevention's (CDC) National Healthcare Safety Network (NHSN) and the Prevention Epicenters Program; $264 million for the Antibiotic Resistance Solutions Initiative; and $30 million for the Advanced Molecular Detection (AMD) Initiative in the FY 2016 Labor, Health and Human Services, Education and Related Agencies Appropriations Bill.

These programs are uniquely positioned to detect the transmission of infections that are highly resistant to antibiotics and to protect patients and the public from disease and death related to healthcare-associated infections (HAIs).

HAIs kill twice as many people per year as car accidents. In hospitals alone, CDC estimates that one in 25 hospitalized patients has an HAI. HAIs can also be resistant to one or more antibiotics. Antibiotic resistance is one of the most critical public health and patient safety threats facing us today, causing an estimated two million illnesses and approximately 23,000 deaths annually. The actions we take now will determine if we will return to an era where even a small cut could prove fatal.

Our national HAI tracking system, NHSN, along with the Prevention Epicenters research program serve as the foundation for HAI prevention strategies. NHSN data allows for equitable comparison between facilities for consumers and is used to evaluate progress related to the National Action Plan to Prevent HAIs. Increased funding for NHSN would support HAI prevention and reporting efforts for more than 17,000 healthcare facilities across the spectrum of care. Increased funding would also support real time tracking of antibiotic use and trends, which are critical to the success of CDC's antibiotic resistance initiative.

The Antibiotic Resistance Solutions Initiative would save lives and reduce healthcare costs by establishing state antibiotic resistance prevention programs

Recipients

U.S. Senate

- [x] Sen. Rob Portman (R-OH)
- [x] Sen. Sherrod Brown (D-OH)

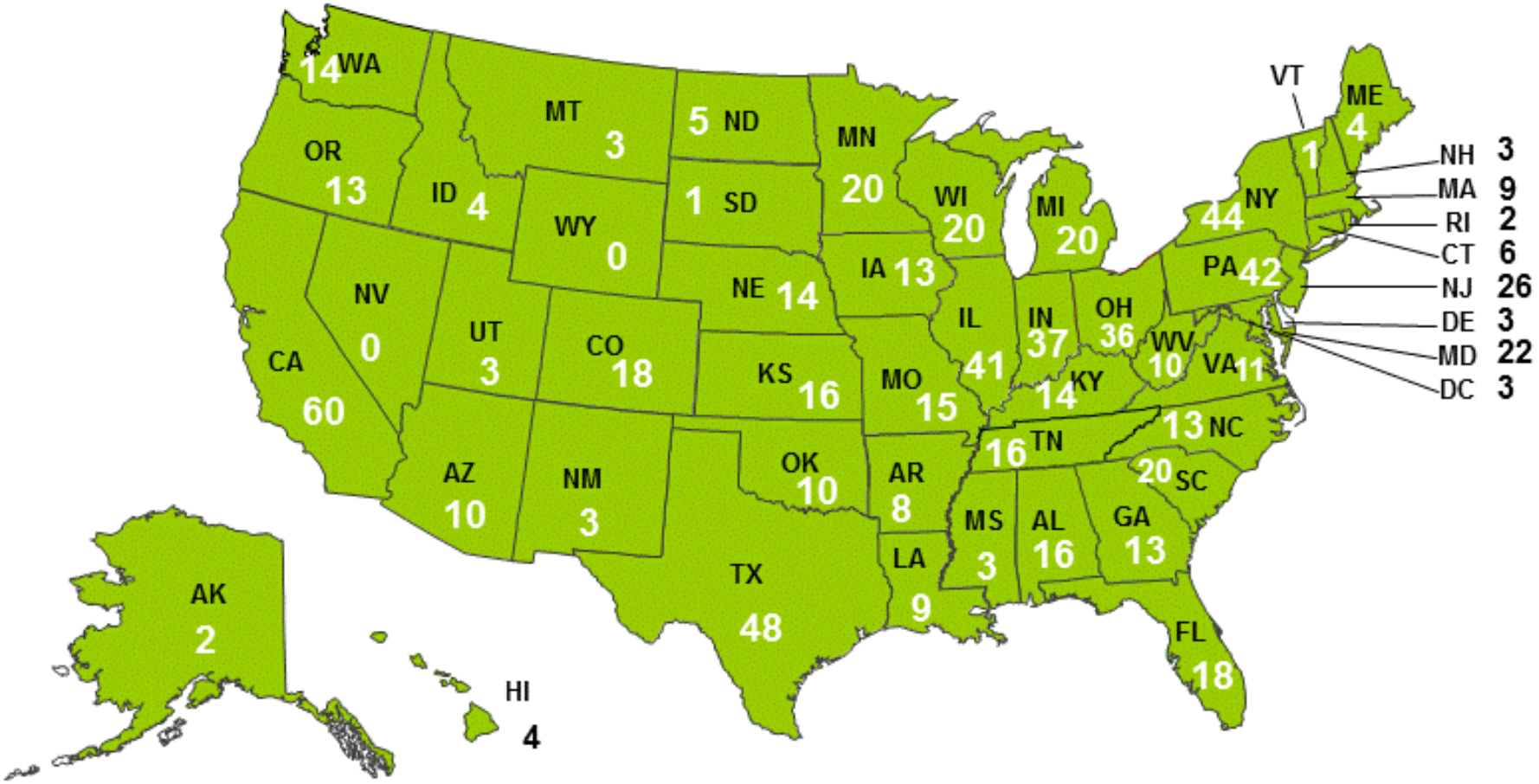
U.S. House of Representatives

- [x] Rep. Joyce Beatty (D-OH)

Ask your federal legislators to support a funding request of $32 million for CDC's NHSN and Prevention Epicenters program, $264 million for the Antibiotic Resistance Solutions Initiative and $30 million for the CDC's Advanced Molecular Detection Initiative.

Then ask your chapter, family, friends and colleagues to send a letter as well.

# Advocates by State



# The Antibiotic Development to Advance Patient Treatment (ADAPT) Act

- The ADAPT Act would allow a limited population approval pathway for antibacterial drugs to treat serious or life threatening infections
- Such drugs could be approved based on smaller clinical trials due to the limited numbers of patients in whom these infections currently occur
- Any drug approved under this new pathway would still need FDA standards of evidence for safety and effectiveness for the indicated population
- Drugs approved under this pathway would be clearly labeled to state that they are approved for a limited population
- APIC has joined 29 organizations in supporting the ADAPT Act

**Status: Bill awaiting consideration in House committee; language included in another bill awaiting consideration on House floor.**

# Developing an Innovative Strategy for Antimicrobial Resistant Microorganisms (DISARM) Act

- The DISARM Act would amend The Medicare Payment to Hospitals For Inpatient Hospital Services section of the Social Security Act to create an additional payment for use of “DISARM” antimicrobials. In order to be designated as a “DISARM” antimicrobials, a drug would have to be approved after January 1, 2015 and meet the following requirements:
    - Treat an infection caused by a qualifying pathogen
    - Meet the definition of a qualified infectious disease product
    - Treat an infection that is associated with high rates of mortality or significant patient morbidity
    - Is used by facilities that, to the extent available, participate in NHSN or a similar reporting program relating to antimicrobial drugs

**Status: Bill awaiting consideration in House committee; language included in another bill awaiting consideration on House floor.**

# Antibiotic stewardship programs

CDC recommends that hospitals institute an antibiotic stewardship program that includes:

- Leadership commitment
- Accountability
- Drug expertise
- Taking at least one prescribing improvement action
- Tracking prescribing and antibiotic resistance patterns
- Regularly reporting to staff prescribing and antibiotic resistance patterns
- Education

# Antibiotic stewardship state legislation

- **Missouri** legislation introduced that would require the Department of Health and Senior Services to issue regulations to require hospitals and ambulatory surgical centers to establish antibiotic stewardship programs with antibiotic use reporting beginning by January 1, 2016 and antibiotic resistant infection reporting beginning by January 1, 2017.

- **California** Senate Bill 361 would require the California State Department of Public Health to develop guidelines, in accordance with guidelines established by the federal government and professional organizations, extending the principles of antimicrobial stewardship to skilled nursing facilities by July 1, 2016.

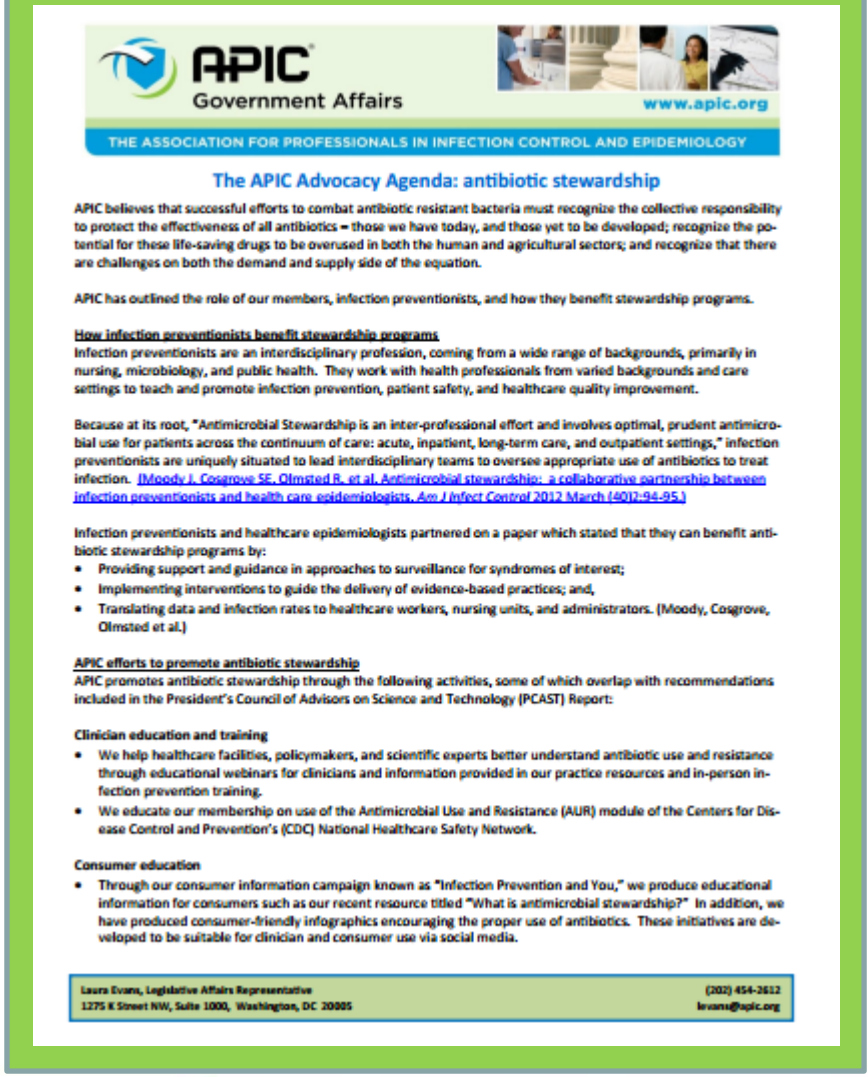
- **Pennsylvania** Senate Bill 740 would prohibit the use of certain antibiotics in nontherapeutic doses to animals, and prohibit the use of antibiotics for growth promotion.

# APIC Antibiotic Stewardship Agenda

Infection preventionists benefit stewardship programs by:

- Providing support and guidance in approaches to surveillance for syndromes of interest
- implementing interventions to guide the delivery of evidence-based practices
- translating data and infection rates to healthcare workers, nursing units and administrators

(Moody J, Cosgrove SE, Olmsted R, et al. Antimicrobial stewardship: a collaborative partnership between infection preventionists and health care epidemiologists, Am J Infect Control 2012 March (40)2:94-95.)



APIC Government Affairs

www.apic.org

THE ASSOCIATION FOR PROFESSIONALS IN INFECTION CONTROL AND EPIDEMIOLOGY

**The APIC Advocacy Agenda: antibiotic stewardship**

APIC believes that successful efforts to combat antibiotic resistant bacteria must recognize the collective responsibility to protect the effectiveness of all antibiotics – those we have today, and those yet to be developed; recognize the potential for these life-saving drugs to be overused in both the human and agricultural sectors; and recognize that there are challenges on both the demand and supply side of the equation.

APIC has outlined the role of our members, infection preventionists, and how they benefit stewardship programs.

**How infection preventionists benefit stewardship programs**

Infection preventionists are an interdisciplinary profession, coming from a wide range of backgrounds, primarily in nursing, microbiology, and public health. They work with health professionals from varied backgrounds and care settings to teach and promote infection prevention, patient safety, and healthcare quality improvement.

Because at its root, "Antimicrobial Stewardship is an inter-professional effort and involves optimal, prudent antimicrobial use for patients across the continuum of care: acute, inpatient, long-term care, and outpatient settings," infection preventionists are uniquely situated to lead interdisciplinary teams to oversee appropriate use of antibiotics to treat infection. (Moody J, Cosgrove SE, Olmsted R, et al. Antimicrobial stewardship: a collaborative partnership between infection preventionists and health care epidemiologists. *Am J Infect Control* 2012 March (40)2:94-95.)

Infection preventionists and healthcare epidemiologists partnered on a paper which stated that they can benefit antibiotic stewardship programs by:

- Providing support and guidance in approaches to surveillance for syndromes of interest;
- Implementing interventions to guide the delivery of evidence-based practices; and,
- Translating data and infection rates to healthcare workers, nursing units, and administrators. (Moody, Cosgrove, Olmsted et al.)

**APIC efforts to promote antibiotic stewardship**

APIC promotes antibiotic stewardship through the following activities, some of which overlap with recommendations included in the President's Council of Advisors on Science and Technology (PCAST) Report:

**Clinician education and training**

- We help healthcare facilities, policymakers, and scientific experts better understand antibiotic use and resistance through educational webinars for clinicians and information provided in our practice resources and in-person infection prevention training.
- We educate our membership on use of the Antimicrobial Use and Resistance (AUR) module of the Centers for Disease Control and Prevention's (CDC) National Healthcare Safety Network.

**Consumer education**

- Through our consumer information campaign known as "Infection Prevention and You," we produce educational information for consumers such as our recent resource titled "What is antimicrobial stewardship?" In addition, we have produced consumer-friendly infographics encouraging the proper use of antibiotics. These initiatives are developed to be suitable for clinician and consumer use via social media.

Laura Evans, Legislative Affairs Representative
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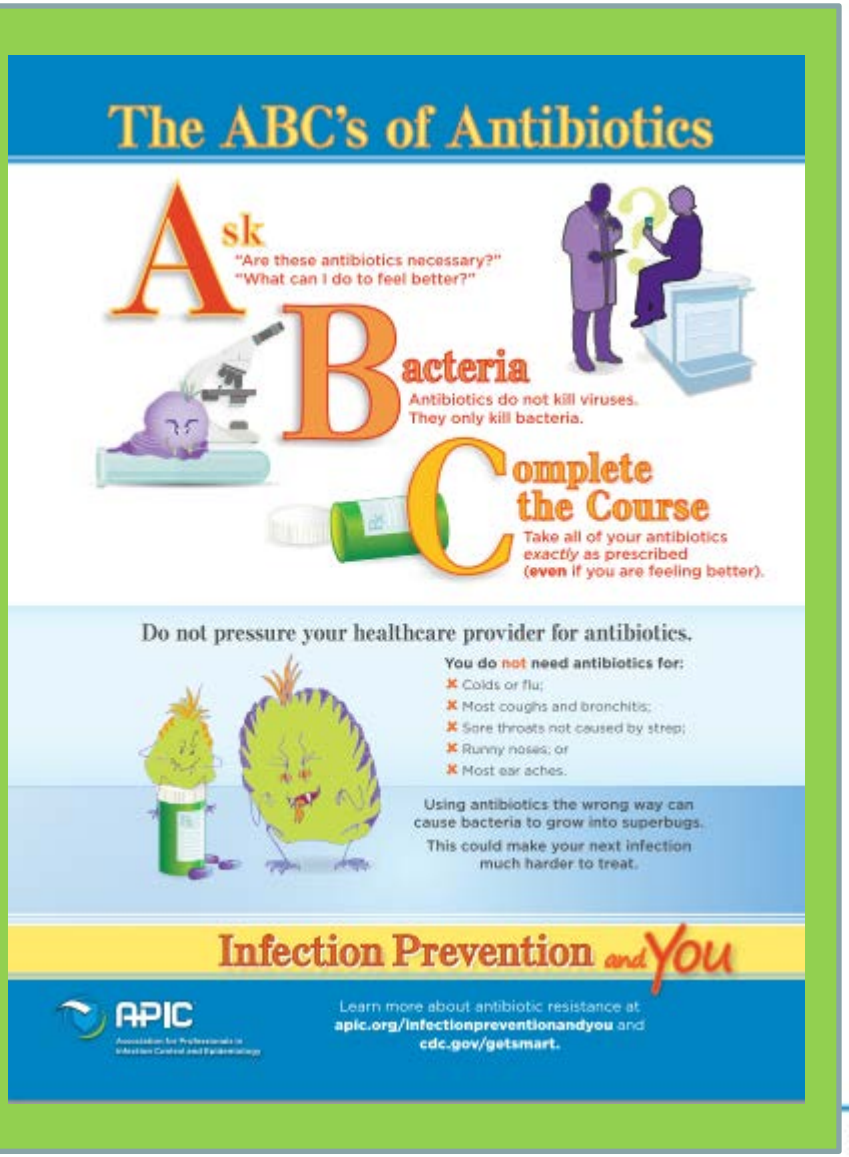
(202) 454-2612
levans@apic.org

# APIC Antibiotic Stewardship Resources




## For healthcare professionals

- Implementation guides
- APIC text
- Webinars

## For consumers

- Consumer alerts
- Infection Prevention and You campaign

# Regulatory Issues

# APIC Regulatory Table

For
- Updates on infection-related regulatory activity
- Links to proposed and final rules (when available)
- APIC comments to federal agencies

See Regulatory Table on APIC website [http://www.apic.org/Advocacy/Regulations](http://www.apic.org/Advocacy/Regulations)

Public Policy

- Overview
- What's new
- Regulations
  - AHRQ
  - CDC
  - CMS
  - EPA
  - FDA
  - GAO
  - HHS
  - NQF
  - OSHA
  - USDA
  - Government health agencies
- State legislation
- Federal legislation
- Advocacy Toolkit
- Position statements
- Take action



Home > Public Policy > Regulations

## Regulations

A A A 4

View CMS HAI Reporting Requirements to NHSN

Status of APIC comments on proposed infection prevention and control regulations.

| Proposed Regulation* | Impact on Infection Prevention | Committee Action and Status | Which of APIC Strategic Goals does this related to? |
|---|---|---|---|
| FDA: Healthcare Antiseptics proposed rule | Request for additional data from manufacturers on safety and effectiveness of healthcare antiseptic products. | Comments pending | • Patient Safety |
| NQF: Data for Systematic Improvement: Summarizing an NQF Meeting on the Data Needed for Sustainably Improving Healthcare | Recommendations from NQF meeting of stakeholders to identify opportunities to improve data and make it more useful for systematic improvement. | Comments submitted 6/15/15 | • Patient Safety<br>• Data Standardization |
| CMS: FY 2016 Hospital Inpatient Prospective Payment System (IPPS/LTCH) Update | Updates HAI measures in Hospital Inpatient Quality Reporting, Hospital Value-Based Purchasing, HAC Reduction Program, LTCH Quality Reporting programs for Medicare payment determination. | Comments submitted 6/10/15 | • Patient Safety<br>• Data Standardization<br>• Advocacy |
| CMS: FY 2016 Inpatient Rehabilitation Facility (IRF) Prospective Payment System update | Updates the HAI measures in the IRF Quality Reporting Program for Medicare payment determination. | Comments submitted 6/8/15 | • Patient Safety<br>• Data Standardization<br>• Advocacy |
| CMS: Meaningful Use Stage 3 | The Stage 3 proposed rule streamlines the program by reducing the number of clinical quality measures and aligning EHR measures with measures in other | Comments submitted 5/26/15 | • Data Standardization<br>• Patient Safety |

# Ethics and Ebola

- December 2014 – The Presidential Commission for the Study of Bioethical Issues requested public comments on **ethical considerations and implications of public health emergency response with a focus on the current Ebola virus disease epidemic**.

- Requested input on 7 specific issues within 3 particular areas of concern:
  - Quarantine
  - Use of placebos in clinical trials, and
  - Collecting and storing biospecimens during a public health emergency for use in future research.

# Ethics and Ebola

**APIC comments included:**

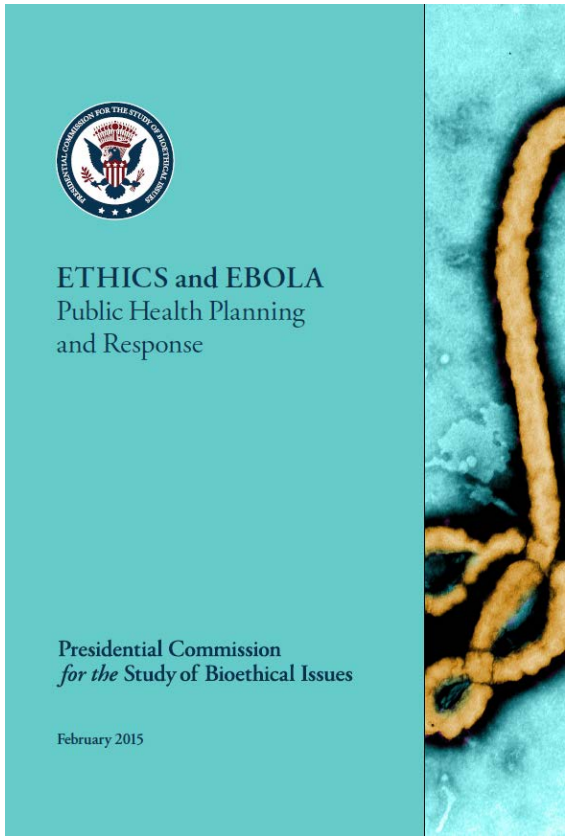
- EP planning should use community health and safety needs to guide actions for the public
- Better communication about plans for distribution of resources, along with rationale
- Policies based on best evidence available
- Government agencies should partner with professional organizations to rapidly disseminate crisis plans
- Quarantines should be consistent with CDC recommendations and be applied only when there is evidence of a specific threat to the community
- Mandatory quarantine can have the negative effect of discouraging healthcare professionals from volunteering in epidemic areas

http://www.apic.org/Resource_/TinyMceFileManager/Advocacy-PDFs/APIC_Ebola_Ethics_comments_Final_2-5-15.pdf

# Ethics and Ebola

February 2015 – Commission released brief on its findings. Among its 7 recommendations:

- A single U.S. health official should be accountable for all federal domestic and international public health emergency response activities
- Governments and public health organizations should employ the least restrictive means necessary to control spread of infectious disease.
- U.S. should help strengthen capacity of WHO to respond to global health emergencies
- U.S. should strengthen deployment capabilities of the U.S. Public Health Service




http://bioethics.gov/sites/default/files/Ethics-and-Ebola_PCSBI_508.pdf

# Health Information Technology

## Federal Health Information Technology Strategic Plan: 2015-2020

**Background:** American Recovery and Reinvestment Act of 2009 (ARRA) required the HHS Office of the National Coordinator for Health Information Technology (ONC) to develop a strategic plan to identify the federal government's HIT priorities. Development and compliance with the plan includes 37 different federal departments, agencies and offices.

- The Federal HIT Strategic Plan sets the priorities that then drive the CMS EHR Incentive Program (Meaningful Use)
- The Federal HIT Strategic Plan is updated every 5 years – this is the 3rd version.

**APIC comments:** An interoperable health IT system will improve the provision of healthcare at all levels.

- Encourage **expanded use of certified HIT products across the care continuum**.

The Office of the National Coordinator for Health Information Technology

# Health Information Technology Strategic Plan *(cont.)*

- Encourage **expansion of the HIT workforce**
  - Prevent tech problems from delaying quality improvement and prevention initiatives.
- **Secure exchange of health information leads to more informed decisions**
  - Enhanced care delivery involves patients, providers, public health departments and payers
- Expand **public health IT capacity**
  - Timely data analysis to **manage emerging infectious disease threats** and HAI clusters
  - **Securely utilize HIT** to ensure continuity of care and services, **especially during disasters or emergencies**.

**Information and data lead to knowledge; knowledge will in turn lead to informed decisions**.

http://www.apic.org/Resource_/TinyMceFileManager/Advocacy-PDFs/National_Action_Plan_to_PreventHAIs_draft_2020_Targets_3_27_14_Final.pdf

# Health Information Technology Proposed Rules

## ONC: 2015 Edition Health IT Certification Criteria proposed rule

- Identifies the capabilities that certified EHR technology must include in order to support achievement of the CMS EHR Incentive Program.

- APIC supports the following criteria in this proposed rule:
  - Transmission of syndromic surveillance to public health agencies
  - Transmission of reportable laboratory tests and values/results to public health agencies
    - These criteria would aid in rapid identification and intervention in an outbreak or pandemic
    - Exclusion of reporting when local health department not capable of receiving it
  - Transmission of case reporting to public health agencies
    - Model still under development; may not meet 2017-18 timeframe
  - Transmission of antimicrobial use and resistance reporting to public health agencies
    - Encourages use of NHSN Antimicrobial Use and Resistance (AUR) Module http://www.apic.org/Resource_/TinyMceFileManager/Advocacy-PDFs/ONC_HIT_Cert_criteria--final_5-26-15.pdf

# Health Information Technology Proposed Rules

## CMS: EHR Incentive Program (Meaningful Use) -- Stage 3

Stage 3 -- final stage of "voluntary" incentive program in 2011. Under the CMS proposal, Stage 3 would:

- **streamline the program into a single stage** that would be optional beginning in 2017 and **mandatory for all providers beginning in 2018**;
- establish a **single set of objectives and measures for all providers** (rather than separate measures for eligible providers and eligible hospitals/CAHs), and **reduce the number of measures from 20 to 8**;
- **continue efforts to align program measures with measures in other CMS quality reporting programs**, such as Hospital Inpatient Quality Reporting and Physician Quality Reporting;
- **promote interoperability** and health information exchange; and
- focus on the 3 part aim of reducing costs, improving access, and improving quality of healthcare.

http://www.apic.org/Resource_/TinyMceFileManager/Advocacy-PDFs/EHR_IP_Stage_3_Comments-_final_5-26-15.pdf

# Health Information Technology Proposed Rules *(contd.)*

- Neither the CMS Meaningful Use Stage 3 rule nor the ONC HIT Certification Criteria rule includes reference to HAI surveillance

- APIC focus:
  - Interoperability of all HIT systems across care settings, providers
  - Include IPs in the early stages of planning EHR systems to include HAI surveillance needs from the beginning

# Cross-Contamination of from Endoscope Accessories

FDA issued draft Guidance for Industry on Mitigating cross-contamination risk from irrigation accessories for flexible gastrointestinal endoscopes

- Draft Guidance is non-binding on industry

APIC Comments:

- Support use of standard (not similar) definitions to provide consistency and clarity for end user
- Agree that functional one-way valve to prevent backflow is essential
- Recommend that FDA guidance provide specific instructions to manufacturers as to its expectations for specifications for medical devices, including type and frequency of testing and by whom
- Suggest that FDA us definitive statements that make recommendations, rather than passive language
- Recommend that all FDA guidance on reusable medical devices comply with FDA's guidance on *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling*

http://www.apic.org/Resource_/TinyMceFileManager/Advocacy-PDFs/FDA_Scope_Irrigation_Accessories_Guidance_Final_4-8-15.pdf

# FDA Gastroenterology and Urology Devices Panel Meeting

Gastroenterology and Urology Devices Panel of the FDA Medical Devices Advisory Committee meeting May 14-15 to seek clinical and scientific opinion in order to make recommendations to FDA for minimizing patient exposure to infectious agents

APIC recommendations on reprocessing of duodenoscopes and other endoscopes:

- Shared responsibility for performing a risk assessment and gap analysis to determine best practices for reprocessing
  - GI Physicians
  - Perioperative services
  - Infection prevention and control
  - Organizational leadership
  - Manufacturers

# FDA Gastroenterology and Urology Devices Panel Meeting *(contd.)*

- Improve endoscope design to allow for proper cleaning and disinfection /sterilization

- Collaboration with scope manufacturers to determine appropriate reprocessing guidance
  - APIC should work to improve rates of compliance with processing steps

- FDA is urged to work in collaboration with CDC and other experts to develop a validation approach that determines when the process has been successful at eliminating the risk of transmission.

- Consider certification for instrument processing personnel

- If utilizing surveillance culturing, consider development of a tracking mechanism for identification of exposed patients and appropriate notification

# FDA Gastroenterology and Urology Devices Panel Meeting *(contd.)*

- Determination of culturing method should:
  - establish the sensitivity and specificity of the method
  - recommend appropriate time intervals for culturing of scopes
  - recommend interventions based on results

- Facilities should implement a standardized process for educating reprocessing personnel that includes:
  - didactic education
  - demonstration and return demonstration
  - creation of a job aid

- Facilities should develop and implement a comprehensive quality control program for reprocessing duodenoscopes and endoscopic ultrasound scopes

# FDA Gastroenterology and Urology Devices Panel Meeting *(contd.)*

**Possible Long-Term Solutions:**

- Develop new endoscope reprocessing technologies that reliably result in sterilization of duodenoscopes and other GI endoscopes via an FDA-cleared sterilization process

- APIC urges FDA to work toward sterilization of reusable endoscopes as the standard reprocessing approach
  - Disposable scopes a viable alternative

- If scopes to be routinely sterilized, manufacturers to provide users with total number of reprocessing cycles tolerated

http://www.apic.org/Resource_/TinyMceFileManager/Advocacy-PDFs/Duodenoscope_reprocessing_--_Final_4-29-15.pdf

# Healthcare Antiseptic Safety and Effectiveness

FDA proposed rule released 4/30/15

- Requests additional scientific data from manufacturers about the safety and effectiveness of healthcare antiseptic products

- FDA recommends that providers continue to use healthcare antiseptics consistent with infection control guidelines while more data are gathered

- Timeframe:
  - 6 month comment period
  - 1 year data submission period
  - 60 day rebuttal period

# Healthcare Antiseptic Safety and Effectiveness *(contd.)*

- Products addressed by this rule include:
  - Healthcare personnel handwashes and rubs
  - Surgical hand scrubs and rubs
  - Patient preoperative skin preparations, including pre-injection preparations
  - Active ingredients: alcohol and iodine

- Products not addressed by this rule include:
  - Products containing chlorhexidine gluconate
  - Consumer antiseptic products such as antibacterial hand soap and body washes (addressed in separate proposed rule in 2013)

Comments in process

# Possible Revisions to the Medicare Conditions for Coverage for ESRD

ESRD CfCs last updated 2008 – CMS considering possible updates:

- No proposed rule or CMS timeframe at this time

- APIC recommendations for CfC updates included:
  - Updating all references to current guidelines
  - Requiring employment or availability staff person with specific training in infection prevention

  - Requiring patient engagement including:
    - Patient education
    - Empowering patients to monitor for breaches in practice
    - Hand hygiene monitoring

  - Requiring screening for Hepatitis C Virus

http://www.apic.org/Resource_/TinyMceFileManager/Advocacy-PDFs/APIC_recommended_revisions_to_ESRD_CfCs_4-1-15.pdf

# FY 2016 Hospital IPPS Proposed Rule

**The Hospital Inpatient Prospective Payment System (IPPS) provides annual Medicare payment and policy updates for acute care hospitals**.

This rule includes updates to the following Medicare incentive and penalty programs:

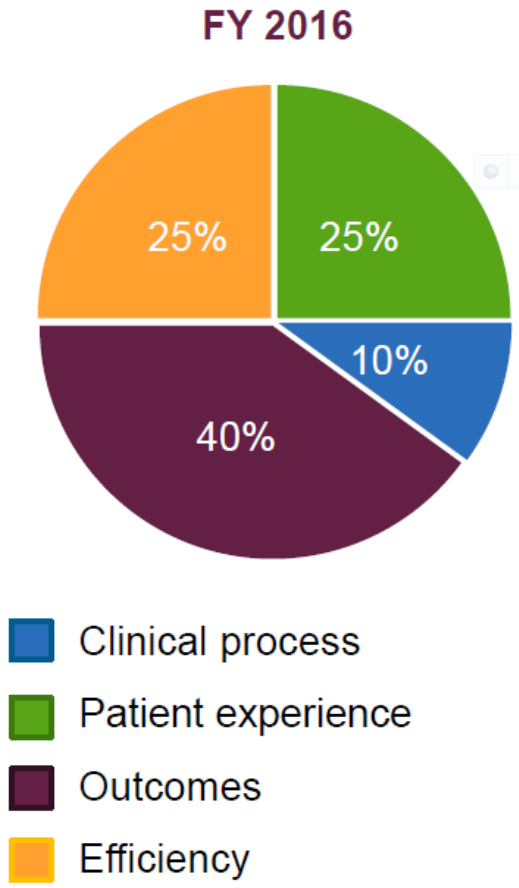
- Inpatient Quality Reporting (IQR)
- Value-Based Purchasing (VBP)
- Hospital-Acquired Condition (HAC) Reduction
- Hospital Readmission Reduction
- Long-Term Care Hospital Quality Reporting (LTCH QRP)
- PPS-Exempt Cancer Hospital Quality Reporting (PCH QRP)

# CMS HAI Reporting Requirements for Acute Care Hospitals

| Measure | Reporting to NHSN begin (CY) | IQR payment (FY) | VBP payment (FY) | HAC Reduction (FY) |
|---|---|---|---|---|
| CLABSI – ICU | 2011 | 2013 | 2015 | 2015 |
| CAUTI – ICU | 2012 | 2014 | 2016 | 2015 |
| SSI – Colo, Ab. Hyst. | 2012 | 2014 | 2016 | 2016 |
| MRSA Bacteremia – FacWide LabID | 2013 | 2015 | 2017 | 2017 |
| C.Diff Infection – FacWide LabID | 2013 | 2015 | 2017 | 2017 |
| HCP Influenza Vaccination | 2013 | 2015 | | |
| CLABSI – Med/Surg/MedSurg | 2015 | 2017 | 2019* Baseline period 1/1/15 – 12/31/15 Performance period 1/1/17 – 12/31/17 | 2018* |
| CAUTI – Med/Surg/MedSurg | 2015 | 2017 | 2019* Baseline period 1/1/15 – 12/31/15 Performance period 1/1/17 – 12/31/17 | 2018* |

* = Proposed

# IPPS -- VBP FY 2016 Domain Weights




| Measure ID | NQS-Based Domain |
|---|---|
| AMI-7a | Clinical Process |
| IMM-2 *NEW* | Clinical Process |
| PN-6 | Clinical Process |
| SCIP-Inf-2 | Clinical Process |
| SCIP-Inf-3 | Clinical Process |
| SCIP-Inf-9 | Clinical Process |
| SCIP-Card-2 | Clinical Process |
| SCIP-VTE-2 | Clinical Process |
| HCAHPS | Patient Experience |
| CAUTI *NEW* | Outcomes |
| CLABSI | Outcomes |
| MORT-30-AMI | Outcomes |
| MORT-30-HF | Outcomes |
| MORT-30-PN | Outcomes |
| PSI-90 | Outcomes |
| SSI *NEW* | Outcomes |
| MSPB-1 | Efficiency |

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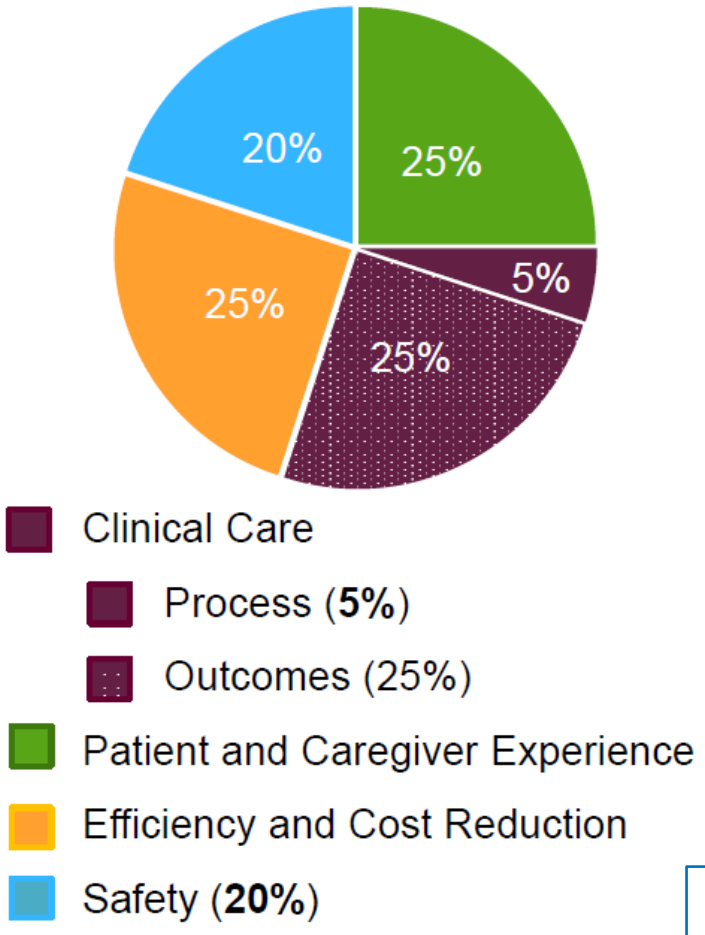
# IPPS -- VBP FY 2017 Domain Weights

## FY 2017 Finalized Revision




| Measure ID | NQS-Based Domain |
|---|---|
| AMI-7a | Clinical Care – Process |
| IMM-2 | Clinical Care – Process |
| PC-01 *NEW* | Clinical Care – Process |
| MORT-30-AMI | Clinical Care – Outcomes |
| MORT-30-HF | Clinical Care – Outcomes |
| MORT-30-PN | Clinical Care – Outcomes |
| HCAHPS | Patient and Caregiver Centered Experience of Care / Care Coordination |
| CAUTI | Safety |
| CLABSI | Safety |
| MRSA *NEW* | Safety |
| C. Diff *NEW* | Safety |
| PSI-90 | Safety |
| SSI | Safety |
| MSPB-1 | Efficiency and Cost Reduction |

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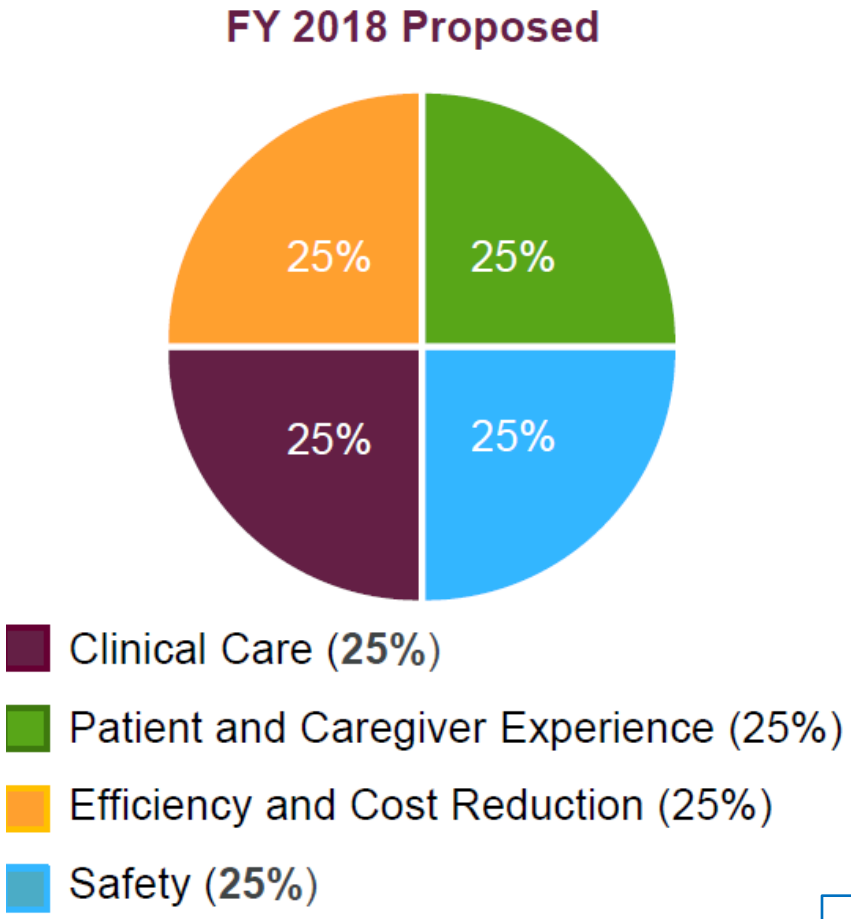
# IPPS -- VBP FY 2018 Domain Weights




| Measure ID | NQS-Based Domain |
|---|---|
| ~~AMI-7a~~ | ~~Clinical Care – Process~~ |
| ~~IMM-2~~ | ~~Clinical Care – Process~~ |
| PC-01 | Safety *PROPOSED CHANGE* |
| MORT-30-AMI | Clinical Care |
| MORT-30-HF | Clinical Care |
| MORT-30-PN | Clinical Care |
| HCAHPS | Patient and Caregiver Centered Experience of Care / Care Coordination |
| CTM-3 *NEW* | |
| CAUTI | Safety |
| CLABSI | Safety |
| MRSA | Safety |
| C. Diff | Safety |
| PSI-90 | Safety |
| SSI | Safety |
| MSPB-1 | Efficiency and Cost Reduction |

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# IPPS -- HAC Reduction Program Measures

**Domain 1: PSI-90 Composite**

- PSI-3
- PSI 6
- PSI-7 (CVC-related BSI rate)
- PSI-8 (Postoperative hip fracture rate)
- PSI-12
- PSI-13 (Postoperative sepsis rate)
- PSI-14 (Wound dehiscence rate)
- PSI-15

**Domain 2: HAI Measures**

- CLABSI – ICU (FY 2015 onward)
- CAUTI – ICU (FY 2015 onward)
- SSI
  - Following colon surgery (FY 2016 onward)
  - Following abdominal hysterectomy (FY 2016 onward)
- MRSA Bacteremia (FY 2017 onward)
- *C.diff.* (FY 2017 onward**)**
- CLABSI – non-ICU (FY 2018 onward) – proposed
- CAUTI – non-ICU (FY 2018 onward) – proposed

# IPPS – Hospital IQR Program

- Hospital IQR
  - No new HAI reporting requirements
  - Removal of 9 topped out chart-abstracted measures
  - Alignment with EHR Incentive Program – require submission of 16 electronic clinical quality measures beginning FY 2018 payment.

# IPPS -- PPS-Exempt Cancer Hospital Quality Reporting Program (PCHQRP)

**Already approved reporting requirements**

- CAUTI – reporting began 2013
- CLABSI – reporting began 2013
- SSI (COLO, AB HYST) – reporting began 2014

**Proposed additions to PCHQRP for FY 2018**

- **MRSA Bacteremia Outcome measure**
- ***C. diff* Infection Outcome measure**
- **HCP Influenza Vaccination**

**APIC position**

- Support inclusion of the 3 new measures
- Express caution on CDI measure
  - Agree that treatment and underlying conditions increases risk of CDI
  - Encourage CMS to monitor evolution of the science related to study of CDI in immunocompromised patient populations.

# IPPS – Long Term Care Hospital Quality Reporting Program (LTCH QRP)

Current LTCH reporting requirements:

- CAUTI – reporting began 2012
- CLABSI – reporting began 2012
- HCP Influenza Vaccination – reporting began 2014
- MRSA Bacteremia – reporting began 2015
- CDI – reporting began 2015
- VAE – reporting to begin 2016

- No new reporting requirements

- CMS proposed extension of submission deadlines from 1.5 months to 4.5 months beginning Q4 2015 for FY 2017 payment determination
  - Align with other CMS Quality Reporting Programs
  - Public display of NHSN outcome measures

# FY 2016 Inpatient Rehabilitation Facility (IRF) PPS

**Currently IRF reporting requirements**:

- CAUTI
- MRSA LabID Events
- CDI LabID events
- HCP Influenza Vaccination

**New proposals**

- Public reporting of CAUTI rates
- Modify data collection and submissions timelines from fiscal year to calendar year

# Preview of Coming Attractions

- **CMS**
  - OPPS, ESRD will be released any day
  - Reform of Requirements for LTC Facilities – proposed rule June 2015, will watch for infection-related provisions
  - Updates to HHA CoPs
  - Hospital and CAH changes

- **CMS/CDC**
  - Joint communique about intentional nonreporting of NHSN events

- **FDA**
  - Consumer hand wash products – unclear whether it will be included with healthcare antiseptics in same monograph

- **OSHA**
  - Bloodborne Pathogens Standard (?)– under review consider continued need for rule and whether there are duplications, overlaps or conflicts with other rules
    - APIC provided comments in 2014
    - Review period scheduled to be completed by September 2015
  - Infectious Diseases Standard (?)

# Questions?

**Laura Evans, Legislative Affairs Representative**

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- Federal and state legislation
- Legislative maps

**Nancy Hailpern, Director of Regulatory Affairs**

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- Federal regulatory issues
- HAI reporting at the federal level

**Lisa Tomlinson, MA, Vice President of Government Affairs and Practice Guidance**

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- Overall government affairs and practice guidance strategy