2016 Chapter Legislative Representative Update

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

Nancy Hailpern Director, Regulatory Affairs

with special guest Chapter 126 CLR Troy Cutler, RN

June 12, 2016

Legislative Advocacy

2016 Public Policy Committee Lobby Days

The Public Policy Committee lobbied Congress about the role of the IP, and supported NHSN and antibiotic resistance initiatives at CDC:

6 members of the Public Policy Committee educated 14 congressional offices























2016 Legislative Issues

\$21 million for the National Healthcare Safety Network in FY 2017

Continued support of NHSN would:

- Expand critical user support for NHSN to additional facilities across the care spectrum
- Enable expansion of NHSN's Antibiotic Use and Resistance (AUR) module reporting options.
- The AUR data will be used to guide local and regional efforts to reduce resistance and provide national benchmarks to promote safer use of antibiotics.

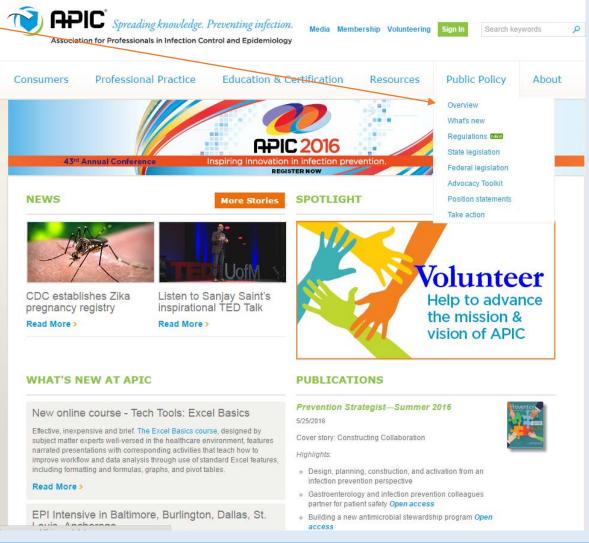


\$200 million for CDC's Antibiotic Resistance Solutions Initiative in FY 2017

An increase of \$40 million over the \$160 million in funding that was enacted in fiscal year 2016 would:

- Expand HAI and antibiotic resistance prevention efforts from 25 states to 50 states, six large cities, and Puerto Rico;
- Sustain an Antimicrobial Resistance Laboratory Network of up to seven AR Regional Labs to serve as a national resource for cutting-edge lab support to states and characterize emerging resistance;
- Implement antibiotic stewardship programs that align with CDC's Core Elements for Antibiotic Stewardship in inpatient, outpatient, and long-term care settings;
- Drive innovation through the CDC's Prevention EpiCenters network collaboration with academic research centers conducting applied research on interventions for infection prevention;
- Incorporate NHSN antibiotic use data to improve prescribing practices.

Navigating the Public Policy Section of the APIC website



Tell Congress to support funding for NHSN and antibiotic resistance programs at CDC

Show your support for important infection prevention programs





As a constituent concerned about healthcare-associated infections (HAIs) and the growing threat of antibiotic resistance, I ask that you support \$21 million for the Centers for Disease Control and Prevention's (CDC) National Healthcare Safety Network (NHSN); \$200 million for the Antibiotic Resistance Solutions Initiative; and \$30 million for the Advanced Molecular Detection (AMD) Initiative in the FY 2017 Labor, Health and Human Services, Education, and Related Agencies Appropriations Bill.

CDC estimates that one in 25 hospitalized patients will contract an HAI, totaling approximately 722,000 infections and 75,000 deaths annually. One in seven catheter- and surgery-related HAIs in acute care hospitals,

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APIC CLR Legislative Engagement Challenge

The Winner for the 2015 Legislative Year:

- Maine with 61% of the Chapter engaging their Members of Congress
- CLR Troy Cutler





Honorable Mentions Go To:

Vermont: 23%

West Virginia: 22%

Virginia: 20%

Use this link to send a letter for 2016:

http://tinyurl.com/APICNHSN2016

Coalition Issues: The Year in Review

Since our last meeting at Annual Conference 2015 in Nashville APIC supported 18 coalition efforts to address a variety of issues designed to address APIC strategic priorities through support for legislation related to antibiotics, funding for health programs, and other federal priorities.

Legislation:

✓ Antibiotic Development to Advance Patient Treatment Act (ADAPT) Act: would direct FDA to approve new antibiotics and antifungal drugs for specific, limited populations of patients who have infections for which few or no suitable options exist



✓ Reinvigorating Antibiotic and Diagnostic Innovation (READI) Act: would provide an R&D tax credit for antibiotics and antifungals that treat a serious or life-threatening infection that pose a serious risk to public health as well as for rapid infectious diseases diagnostics



✓ Promise for Antibiotics and Therapeutics for Health (PATH) Act in a Senate Medical Innovation Bill: establish a new limited population antibacterial drug (LPAD) approval pathway for antibiotics to treat serious or life-threatening infections when there is an unmeet medical need

Coalition Issues: The Year in Review (continued)

Funding for CDC programs including:

- √ antibiotic resistance programs
- √ the Combating Antibiotic-Resistant Bacteria (CARB) strategy including data collection efforts on farms
- emergency funding for Zika virus without cuts to other public health programs







Support for antibiotic resistance activities:

- √ the CMS rule requiring antibiotic stewardship programs
- √ the FDA's proposed antibiotic data collection rule
- ✓ new approaches for evaluation of on-farm antibiotic data collection
- ✓ release of the CARB Economic incentives working group report

Also support for:

- ✓ paid sick leave legislation
- ✓ NQF immunization measures







Regulatory Issues

Regulatory Trends: PPE

 OSHA request to OMB to continue information collection requirements in the PPE section of General Industry Standards.



 NIOSH pilot study to develop a PPT sentinel surveillance system in the hospital setting to monitor use and effectiveness of PPE, including Ebola response.



 FDA guidance for industry on premarket notification requirements concerning liquid barrier claims on gowns intended for use in healthcare settings.



Regulatory Trends: Medical Devices



- FDA draft guidance on selection of appropriate package type terms and recommendations for labeling injectable medical products packaged in multiple-dose, single-dose, and single-patient-use containers for human use.
 - Retire term "single-use"
- FDA proposal to reclassify blood lancets
 - Reclassify from Class I (general controls) to Class II (special controls): single-use only with or without integral sharps injury prevention feature; multiple-use for single patient only
 - Reclassify from Class I to Class III (premarket approval): multiple-use for multiple patient
- FDA medical device reprocessing
 - Request for comments on the service, maintenance, refurbishment and alteration of medical devices, including endoscopes by third-part entities

Regulatory Trends: Care Transitions

Improving Medicare Post-Acute Care Transformation (IMPACT) Act – enacted September 2014

- Requires the submission of standardized data by Long-Term Care Hospitals (LTCHs), Skilled Nursing Facilities (SNFs), Home Health Agencies (HHAs) and Inpatient Rehabilitation Facilities (IRFs).
- Interoperable data to:
 - Facilitate coordinated care
 - Improve outcomes
 - Allow for cross-setting quality comparisons
- Patient-centered focus to include patient preferences and goals



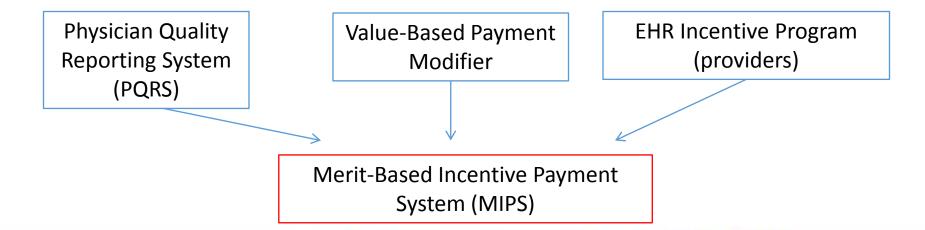
Regulatory Trends: Care Transitions

- Medicare Goal: 90% of payment based on value or quality of care by 2018
- Medicare goal + IMPACT Act driving regulatory activity, including:
 - Reform of long-term care requirements
 - Discharge planning
 - Home Health CoPs
 - NQF care coordination measures
 - AHRQ draft technical brief: Critical Analysis of the Evidence for Resident Safety Practices in Nursing Home Settings
 - Likely more to come



Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)

- **Purpose**: To develop a new approach to paying clinicians for the value and quality of care they provide.
- Changes to how Medicare pays clinicians:
 - Repealed the Sustainable Growth Rate (SGR) formula for determining Medicare payments for providers' services.
 - New framework to reward clinicians for value over volume of care.
 - Combined existing quality reporting programs into one new system
 - NOTE: Program does <u>not</u> apply to hospitals or facilities



Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)

What does this have to do with APIC?

- Infection prevention is everyone's job
- Support for principles that cross care settings, such as:
 - Reporting SSI measures through NHSN using standard definitions
 - Opposition to use of claims-based measures for payment programs
 - Avoiding inappropriate use of antibiotics
 - Supporting flexibility of clinicians to choose measures relevant to the type of care they provide
 - Supporting evidence-based resource utilization as a means to enhance quality outcomes
 - Supporting measures that promote population health, such as immunizations against vaccine-preventable diseases and screening for Hepatitis C and TB.

Update on APIC Regulatory Comments

Recent APIC comments submitted to federal agencies:

- **FDA** Draft Guidance for Industry on Injectable Medical Products
- FDA Draft Guidance for Industry on Enforcement of Policy Regarding IND Requirements for use of Fecal Microbiota for Transplantation (FMT)
- FDA Draft Guidance for Industry on Donor Screening Recommendations to Reduce Zika Transmission
- FDA Reclassification of blood lancets
- **FDA** Ban on powdered gloves
- AHRQ Draft Technical Brief on Resident Safety Practices in Nursing Homes
- CMS Revisions to Discharge Planning Requirements for Hospitals, CAH, and HHA
- HHS Revisions to Federal Policy for the Protection of Human Subjects (Common Rule)
- NIOSH Monitoring and Coordinating PPE in Healthcare to Enhance Domestic Preparedness for Ebola Response

Update on APIC Regulatory Comments

APIC comments in process:

- CMS Annual payment updates for:
 - Hospital inpatients
 - Long-term acute care hospitals
 - PPS-exempt cancer hospitals
 - Inpatient Psychiatric Facilities
 - Inpatient Rehab Facilities
 - Skilled Nursing Facilities (NEW)
 - Merit-based Incentive Payment System (MIPS) NEW
- FDA draft guidance on Infectious Disease Next Generation Sequencing Based Diagnostic Devices: Microbial Identification and Detection of Antimicrobial Resistance and Virulence Marker
- **HHS** RFI on strategies to combat antibiotic resistance





Hospital Inpatient Prospective Payment System (IPPS)

Includes:

- Hospital Inpatient Quality Reporting Program (IQR)
- Hospital Value-Based Purchasing Program (VBP)
- Hospital-Acquired Conditions (HAC) Reduction Program
- Hospital Readmissions Reduction Program
- PPS-Exempt Cancer Hospital Quality Reporting Program (PCHQR)
- Long-Term Care Hospital Quality Reporting (LTCHQR)
 Program
- Inpatient Psychiatric Facilities Quality Reporting Program (IPFQR)

Hospital Inpatient Prospective Payment System (IPPS)

Proposed updates:

- Adoption of modified PSI 90 (NQF#0531) for FY 2018
 - Name change to Patient Safety and Adverse Events composite
 - Removal of PSI 07: Central venous catheter bloodstream infection rate
 - Measure used in IQR, VBP, HAC Reduction
- Hospital Inpatient Quality Reporting Program (IQR)
 - Removal of 3 measures (FY 2019):
 - SCIP-Inf-1a: Prophylactic Antibiotic Received within 1 hour prior to surgical incision
 - SCIP-Inf-2a: Prophylactic Antibiotic Selection for Surgical Patients
 - SCIP-Inf-9: Urinary Catheter Removed on Postoperative Day 1 of Postoperative Day 2 with Day of Surgery Being Day Zero
 - Future measure for consideration:
 - NHSN Antimicrobial Use (NQF#2720)

Hospital Inpatient Prospective Payment System (IPPS)

Proposed updates:

VBP:

- FY 2019 change name of "Patient and Caregiver Experience" domain to "Person and Community Engagement" (will still account for 25% of total performance score)
- FY 2019 Expand CAUTI and CLABSI measures to include non-ICU locations

HAC Reduction Program:

FY 2018 – Adopt revised PSI-90

PCHQR:

 Delay public display of NHSN CLABSI and CAUTI measures due to low volume of data (originally adopted in FY 2015 rule)

New infection focus to old measure: hospital readmissions from post-acute care

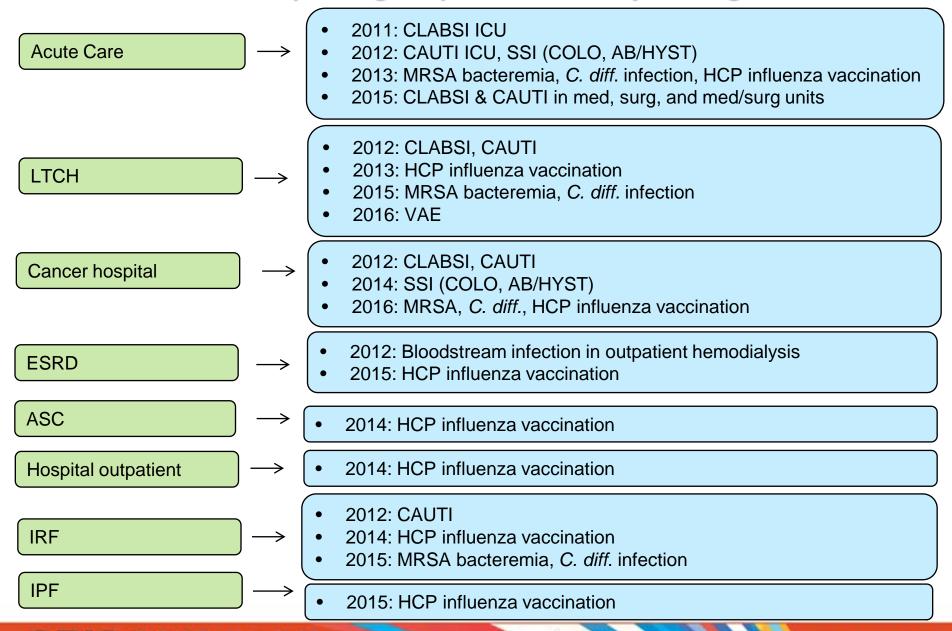
- The Problem: According to MedPAC:
 - 17-20% of Medicare beneficiaries discharged from hospital were readmitted within 30 days.
 - 75-84% of readmissions are considered "potentially preventable".
 - Annual Medicare spending on potentially preventable readmissions would be \$12 billion for 30-day, \$8 billion for 15-day and \$5 billion for 7-day.
- **The Solution**: Include in SNF, IRF and LTCH PPS rules a "Potentially preventable readmissions" measure
- Varies slightly in for each care setting, but for all, the measure definition criteria are
 - Inadequate management of chronic conditions;
 - Inadequate management of infections; and
 - Inadequate management of other unplanned events.



CMS HAI Reporting Requirements for Acute Care Hospitals – August 2015

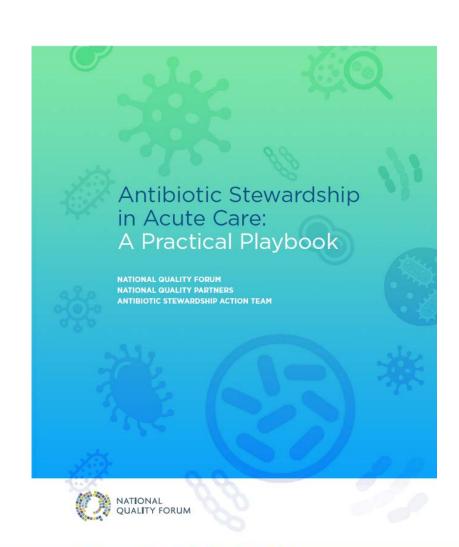
Measure	Reporting to NHSN begin (CY)	IQR payment (FY)	VBP payment (FY)	HAC Reduction (FY)
CLABSI – ICU	2011	2013	2015	2015
CAUTI – ICU	2012	2014	2016	2015
SSI – Colo, Ab. Hyst.	2012	2014	2016	2016
MRSA Bacteremia – FacWide LabID	2013	2015	2017	2017
C.Diff Infection – FacWide LabID	2013	2015	2017	2017
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

CMS HAI Reporting Requirements – by setting 2015



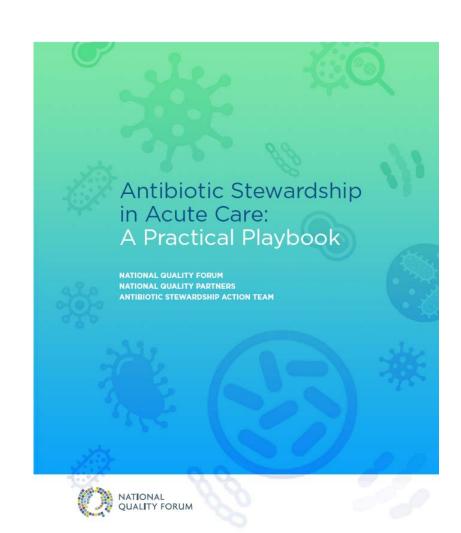
NEW: NQF Antibiotic Stewardship Playbook

- Provide concrete strategies for implementing successful AS programs in acute care.
- Corresponds to CDC's Core Elements of Hospital Antibiotic Stewardship Programs:
 - Leadership commitment
 - Accountability
 - Drug expertise
 - Actions to support optimal Abx use
 - Tracking/monitoring Abx prescribing, use, resistance
 - Reporting information on improving ABX use and resistance
 - Education of clinicians and patients and families



NEW: NQF Antibiotic Stewardship Playbook

- For each element, *Playbook* outlines:
 - Examples of basic, intermediate and advanced implementation activities
 - Potential barriers and suggested solutions
 - Suggested tools and resources
- *Playbook* also includes:
 - Measurement approaches
 - Additional potential strategies and directions
 - Links to additional resources



Preview of Coming Attractions

• Final Rules

- FDA: Consumer hand washes September 2016
- CMS:
 - o Home Health CoPs October 2017
 - Revisions to Long-Term Care Requirements September 2016
 - Revisions to Discharge Planning Requirements 2018
- HHS: Revisions to federal policy for the protection of human research subjects (Common Rule) – September 2016

Proposed Rules

- CMS: Hospital and CAH changes to promote innovation, flexibility, and improved patient care – May 2016 (?)
- OSHA: Infectious Disease Standard March 2017
- CMS: CY 2017 prospective payment systems for hospital outpatients (OPPS), ASC, ESRD – coming soon

HHS OIG Study of IQR Measure Validation 2016

- Validation of CMS Hospital IQR data
 - APIC contacted by HHS Office of the Inspector General (OIG) in late
 2015 to discuss CMS validation process.
 - President-elect Linda Greene represented concerns of IPs, including her own experiences, with data validation process.
 - Issues raised included:
 - Inaccurate validation results
 - Validation schedule not meeting penalty/public reporting timeframes
 - Not an accurate reflection of infection prevention efforts
- Don't know OIG schedule, but watching for more info

Spreading knowledge.

Preventing infection.



Association for Professionals in Infection Control and Epidemiology