APIC
Spreading knowledge.
Preventing infection.®

Infection Prevention:
The Legislative and Regulatory Landscape

July 23, 2014

Lisa Tomlinson, MA

Vice President, Government Affairs and Practice Guidance

Association for Professionals in Infection Control and Epidemiology (APIC)

Objectives

- APIC Overview
- State HAI Laws
- Federal Laws with HAI Provisions
- Federal HAI Incentive and Penalty Regulations
- National Action Plan to Prevent HAIs
- Antimicrobial Resistance and the Role of IPs
- Federal Legislative Issues

Strategic Plan 2020

Vision: **Healthcare without infection**

Mission: **Create a safer world through prevention of infection**

Patient Safety: Demonstrate and support effective infection prevention and control as a key component of patient safety.

Implementation Science: Promote and facilitate the development and implementation of scientific research to prevent infection.

IP Competencies and Certification: Define, develop, strengthen, and sustain competencies of the IP across the career span and support board certification in infection prevention and control (CIC®) to obtain widespread adoption.

Advocacy: Influence and facilitate legislative, accreditation, and regulatory agenda for infection prevention with consumers, policy makers, health care leaders, and personnel across the care continuum.

Data Standardization: Promote and advocate for standardized, quality and comparable HAI data.

www.apic.org/About-APIC/Vision-and-Mission

Core Programs

- **Education & Professional Development**
- **Public Affairs & Advocacy**
- **Practice Guidance & Research**

Foundational/ Infrastructure Services

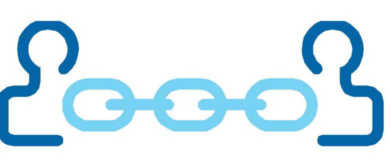
- Membership
- IT
- Finance
- HR
- Marketing

- Governance
- Communications
- Development
- Strategic Partnerships
- Consulting Services

Staff and APIC Members Working Together

Government Affairs Staff

- experience with legislators
- advocacy and influence
- insight into what motivates policymakers



Public Policy Committee and Chapter Legislative Representatives

- clinical experience
- scientific knowledge
- insight into member needs and state/local issues

Areas of Advocacy

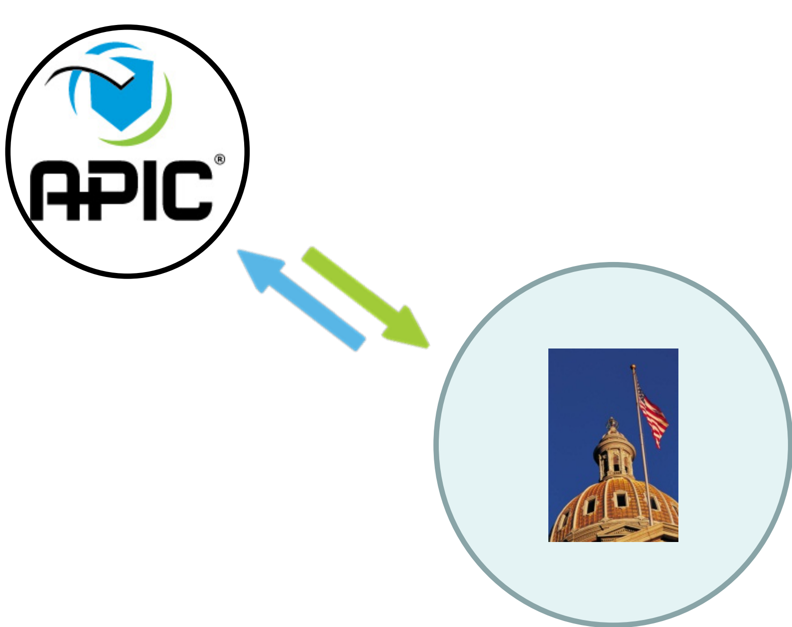
Federal Legislation

Federal Regulations

State Legislation

APIC®

State HAI Laws: Background & Recent History



It all started in 2003

WA OR CA ID NV MT WY UT AZ CO NM ND SD NE KS OK TX MN IA MO AR LA WI IL MI IN OH KY TN MS AL GA FL SC NC VA WV PA NY VT ME NH MA RI CT NJ DE MD DC AK HI

- States with study laws
- Mandates public reporting of infection rates
- * Mandates reporting only to state government
- ** Voluntary

2004

WA
OR
CA
ID
NV
MT
WY
UT
AZ
CO
NM
ND
SD
NE
KS
OK
TX
MN
IA
MO
AR
LA
WI
IL
MI
IN
OH
KY
TN
MS
AL
GA
FL
SC
NC
VA
WV
PA
NY
VT
ME
NH
MA
RI
CT
NJ
DE
MD
DC
AK
HI

- States with study laws
- Mandates public reporting of infection rates
- * Mandates reporting only to state government
- ** Voluntary

2005

- States with study laws
- Mandates public reporting of infection rates
- * Mandates reporting only to state government
- ** Voluntary

2006

- States with study laws
- Mandates public reporting of infection rates
- * Mandates reporting only to state government
- ** Voluntary

2007

WA OR CA NV * ID MT WY UT AZ NM CO ND SD NE ** KS OK TX MN IA MO AR ** LA WI IL MI IN OH KY TN MS AL GA FL SC NC VA WV PA NY VT ME NH MA RI CT NJ DE MD DC AK HI

States with study laws

Mandates public reporting of infection rates

* Mandates reporting only to state government

** Voluntary

2008

WA OR CA NV * ID MT WY UT CO AZ NM ND SD NE ** KS OK TX MN IA MO AR ** LA WI IL MI IN OH KY TN MS AL GA FL SC NC VA WV PA NY VT ME NH MA RI CT NJ DE MD DC AK HI

- States with study laws
- Mandates public reporting of infection rates
- * Mandates reporting only to state government
- ** Voluntary

2009

WA OR CA NV ID MT WY UT CO AZ NM ND SD NE ** KS OK TX MN IA MO AR ** LA WI IL MS MI IN KY TN AL OH WV VA NC SC GA FL PA NY VT ME NH MA RI CT NJ DE MD DC AK HI

- States with study laws
- Mandates public reporting of infection rates
- ** Voluntary

2010

- States with study laws
- Mandates public reporting of infection rates
- ** Voluntary

2011

WA OR CA NV ID MT WY UT AZ CO NM ND SD NE ** KS OK TX MN IA MO AR LA WI IL MS MI IN KY TN AL OH GA FL WV VA NC SC PA NY VT ME NH MA RI CT NJ DE MD DC AK HI

- States with study laws
- Mandates public reporting of infection rates
- ** Voluntary

2011: State and Federal Requirements

2011 State Laws

- States with study laws
- Mandates public reporting of infection rates
- ** Voluntary

2011 Federal Requirements

Federal HAI Reporting to NHSN – 2014

2011 →

- CLABSI – Acute Care ICUs (Jan.)

2012 →

- CAUTI – Acute Care ICUs (except NICUs) (Jan.)
- CAUTI – LTCH, IRF, Cancer Hospitals (Oct)
- SSI – Colon Surgeries and Abdominal Hyst. – Acute Care (Jan)
- Dialysis Events – ESRD (Jan)
- CLABSI – LTCH, Cancer Hospitals (Oct)

2013 →

- *C. Diff* LabID Events – Acute Care (Jan.)
- MRSA Bacteremia LabID Events – Acute Care (Jan.)
- HCP Influenza Vaccination – Acute Care (Jan.)
- HCP Influenza Vaccination – LTCH (Jan.)

2014 →

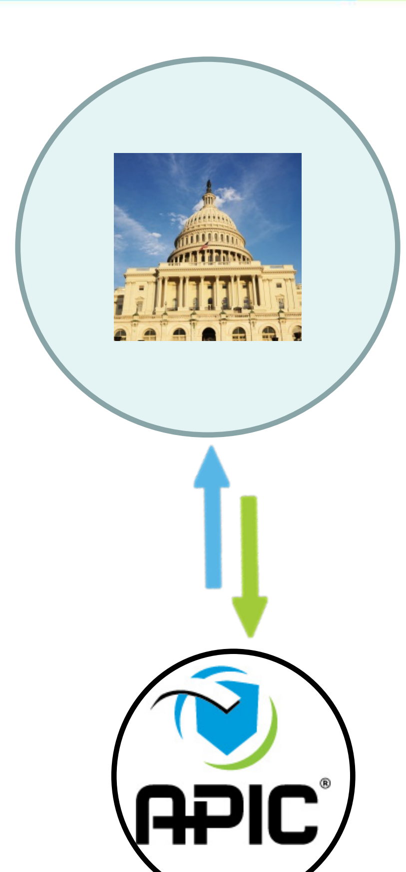
- HCP Influenza Vaccination – ASCs/Hosp Outpt Depts (Oct.)
- SSI – Cancer Hospitals (Jan.)
- HCP Influenza Vaccination – IRF (Oct.)

2015 →

- CLABSI – Acute Care Med, Surg, Med/Surg Units (Jan.)
- CAUTI – Acute Care Med, Surg, Med/Surg Units (Jan.)
- MRSA Bacteremia LabID Events – LTCH (Jan.), *IRF (Jan.) Proposed*
- *C. Diff* LabID Events – LTCH (Jan.), *IRF (Jan.) Proposed*
- *HCP Influenza Vaccination – Inpt. Psych. Fac. (Oct.) Proposed*

2016 →

- *VAE – LTCH (Jan.) Proposed*



Federal Laws with HAI Provisions: Background and Recent History

2006

- Congress passes the Deficit Reduction Act of 2005 which imposes the “**Hospital Acquired Conditions (HAC)**” provision on facilities paid through Medicare
  - First federal program to use funding as incentive for HAI quality improvement
  - Reimbursement impacted in 2008

2008

- The Government Accountability Office (GAO) issues a report which is highlighted at a Committee on Oversight and Government Reform Hearing : **“Leadership Needed from HHS to Prioritize Prevention Practices and Improve Data on These Infections”**

- **Then-Presidential Candidate Barack Obama** releases a healthcare reform plan known as **Plan for a Healthy America** which would require healthcare facilities to collect and publicly report measures of healthcare costs and quality, including data on hospital-acquired infections.

GAO

Report to the Chairman, Committee on Oversight and Government Reform, House of Representatives

HEALTH-CARE-ASSOCIATED INFECTIONS IN HOSPITALS

Leadership Needed from HHS to Prioritize Prevention Practices and Improve Data on These Infections

G A O

2009

- President Obama signs the **FY09 Omnibus Appropriations Act** into law
  - states required to submit an HAI reduction plan to the Secretary of HHS by January 1, 2010 or face loss of 25% of their Preventive Health and Health Services Block Grant funding

- President Obama signs the **American Recovery and Reinvestment Act (ARRA) "The Stimulus Bill"** into law
  - provides $50 million to states to carry out healthcare-associated infection reduction strategies

- **National Action Plan to Prevent Health Care-Associated Infections released**
  - response to the 2008 Congressional Hearing and GAO report
  - plan to better coordinate federal HAI activities
  - set targets and metrics

2010

Affordable Care Act - Obamacare

- **Congress passes, and President Obama signs into law The Patient Protection and Affordable Care Act (Public Law 111-148) March 23, 2010**

- requires HAI reporting as part of healthcare quality improvement programs
- linked Medicare payment to quality outcomes determined by specified measures.
- among the measures are “healthcare-associated infections, as measured by the National Action Plan to Prevent HAIs”

Key Federal HAI Actions

2006

Deficit Reduction Act Enacted
- HAC Policy to impact 2008 payment
- Uses funding as incentive for quality improvement

2008

GAO Issues Report on Need for HAI Coordination

2009

American Recovery and Reinvestment Act (ARRA)
- Grants to States for HAI Coordinators and activities

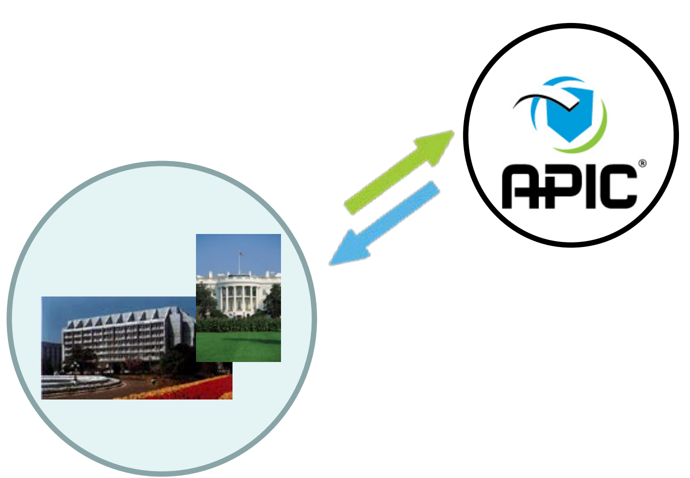
Omnibus Appropriations Act
- States to develop HAI Plans (or lose block grant funds)

National Action Plan to Prevent HAIs
- Response to Congressional Hearing and GAO report
- Plan to better coordinate federal HAI activities

2010

Affordable Care Act (Obamacare)
- Required HAI reporting as part of healthcare quality improvement programs

Federal HAI Regulations: Penalty and Incentive Programs



Hospital-Acquired Conditions (HAC)

- Non-reimbursement policy
- Prohibits reimbursement of designated HACs that were not present on admission
- HAI-HACs include vascular catheter-associated infections, CAUTI, and certain SSIs
- HACs identified through administrative data

Hospital Inpatient Quality Reporting Program (Hospital IQR)

- Incentive program for reporting quality measures
- HAI measures reported through NHSN

Hospital Value-Based Purchasing Program

- 2010 - Established by the Affordable Care Act as incentive program to improve quality of healthcare

- FY 2013 – first year of payment adjustments under the VBP program, based on performance period of July 1, 2011 – March 31, 2012

- Total amount available for incentive payments for a fiscal year will be equal to the total amount of the payment reductions for all participating hospitals that year
  - FY 2013 – 1% of base-operating DRG payment to all participating hospitals
  - FY 2014 – 1.25%
  - FY 2015 – 1.5%
  - FY 2016 – 1.75%
  - FY 2017 and beyond – 2%

- Total Performance Score – determined by hospital's achievement and improvement compared to a 9-month baseline period; calculated by scoring in 4 domains

Hospital Value-Based Purchasing Total Performance Scoring

- When VBP first implemented in FY 2013, TPS based on 2 domains
  - Process of Care 70% of TPS
  - Patient Experience of Care 30% of TPS

- In FY 2015, an outcome domain was added

- Proposed for FY 2017 – 4 domains
  - Safety 20% of TPS
    - CAUTI
    - CLABSI
    - SSI – colon surgery and abdominal hysterectomy
    - MRSA Bacteremia
    - *C. difficile* infection
    - PSI-90 composite
  - Clinical Care 30% of TPS
    - Clinical Care – Outcomes 25%
    - Clinical Care – Process 5%
  - Efficiency and Cost Reduction 25% of TPS
  - Experience of Care 25% of TPS

Hospital-Acquired Condition (HAC) Reduction Program

- Penalty for poor performance
- Hospitals that rank in the lowest-performing quartile of HACs would receive a 1% penalty
- Payment adjustment to account for HACs with discharges beginning October 1, 2014 (= FY 2015)
- Total HAC score based on measures in 2 domains:
  - Domain 1 includes certain AHRQ Patient Safety Indicators (which are determined by claims data)
  - Domain 2 consists of HAI measures reported through NHSN

PPS-Exempt Cancer Hospital Quality Reporting Program (PCHQRP)

- Incentive for quality reporting

Long-Term Care Hospital Quality Reporting Program (LTCQRP)

- Incentive for quality reporting

Inpatient Rehabilitation Facility (IRF) Quality Reporting Program

- includes HAI measures reported through NHSN
- Incentive program for reporting quality measures

Hospital Outpatient Quality Reporting Program and Ambulatory Surgical Center Quality Reporting Program

- Incentive programs for reporting quality measures
- Includes separate programs for hospital outpatient units and ASCs
- HAI measures reported through NHSN

End-Stage Renal Disease (ESRD) Quality Reporting Program

- Incentive program for reporting quality measures

The National Action Plan to Prevent HAIs: Roadmap to Elimination

Background: National Action Plan to Prevent HAIs (NAPHAI)

- **2009**
  - Phase I: Acute Care Hospitals
- **2010**
  - Phase II: Update to Action Plan included ASCs, ESRD, HCP Flu Vaccination
- **2013**
  - Phase III: Revised National Action Plan with LTCF chapter
- **2014**
  - Next Phase: expected any day now
  - All outpatient settings? Physicians offices? Injection safety?
  - HHS Steering Committee must approve the expansion

National Action Plan to Prevent HAIs: *Proposed* Targets for 2020

- Current measures expired December 2013
  - On February 25, 2014, HHS released new *proposed* HAI targets for 2020
- *Proposed* targets were established by a federal steering committee of HAI prevention experts from federal agencies, as informed by national stakeholders in September 2013
- Results of overall National Action Plan efforts will be available Summer 2014
- *Proposed* targets would use January 2015 as the baseline (with the exception of invasive MRSA infections in the population as measured by CDC's Emerging Infections Program (EIP) Antibacterial Core Surveillance (ABC) Program)
- SCIP measures will not be included in *proposed* 2020 targets as these processes are now widely accepted as standards of practice
  - this does not change any current reporting requirements related to SCIP measures

National Action Plan to Prevent Healthcare-Associated Infections Current Progress and *Proposed* Targets for 2020

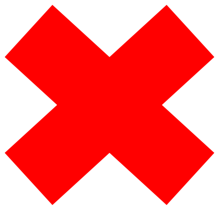
Measure	Data Source	Baseline Years	Baseline Data	2013 Target	Progress	Proposed Target for 2020
Reduce **central-line associated bloodstream infections (CLABSI)** in ICU and ward-located patients	CDC/ NHSN	2006-2008	1.0 SIR	50% reduction or .50 SIR	44% reduction or .56 SIR (2012)	**50% reduction from 2015 baseline[1]**
Reduce **catheter-associated urinary tract infections (CAUTI)** in ICU and ward-located patients	CDC/ NHSN	2009	1.0 SIR	25% reduction or .75 SIR	2% increase or 1.02 SIR (2012)	**25% reduction from 2015 baseline[2]**
Reduce the incidence of **invasive healthcare-associated methicillin-resistant Staphylococcus aureus (MRSA)** infections	CDC/EIP/ ABC	2007-2008	27.08 infections per 100,000 persons	50% reduction or 13.5 infections per 100,000 persons	31% overall reduction or 18.6 infections per 100,000 persons (2012)	**75% reduction from 2007-2008 baseline[3]**
Reduce **facility-onset methicillin-resistant Staphylococcus aureus (MRSA)** in facility-wide healthcare	CDC/ NHSN	2010-2011	1.0 SIR	25% reduction or .75 SIR	3% reduction or .97 SIR (2013)	**50% reduction from 2015 baseline**
Reduce **facility-onset Clostridium difficile infections** in facility-wide healthcare	CDC/ NHSN	2010-2011	1.0 SIR	30% reduction or .70 SIR	2% reduction or .98 SIR (2012)	**30% reduction from 2015 baseline**
Reduce the rate of **Clostridium difficile hospitalizations**	AHRQ/ HCUP	2008	11.6 hospitalizations with C. difficile per 1,000 discharges	30% reduction	13.6 hospitalizations per 1,000 discharges (2012 Projected)	**30% reduction from 2015 baseline**
Reduce **Surgical Site Infection (SSI)** admission and readmission	CDC/ NHSN	2006-2008	1.0 SIR	25% reduction or .75 SIR	20% reduction or .80 SIR (2012)	**30% reduction from 2015 baseline**

[1] Infections from Mucosal Barrier Injury (MBI) will be excluded from the calculation
[2] The target will reflect aggregate data, but interim assessments of the rate will also be stratified by ICUs and non-ICUs in order to better understand the areas needed for improvement
[3] This is a Healthy People 2020 Goal

Abbreviations:
CDC/NHSN - Centers for Disease Control and Prevention's National Healthcare Safety Network; **CDC/EIP/ABC** – Centers for Disease Control and Prevention's Emerging Infections Program Network Active Bacterial Core Surveillance; **AHRQ/HCUP** – Agency for Healthcare Research and Quality Healthcare Cost and Utilization Project; **SIR** – Standardized Infection Ratio

On Target?:

- Central Line-Associated Bloodstream Infection
- Surgical Site Infection
- Surgical Care Improvement Project
- Invasive MRSA (population based)



- MRSA Bacteremia (hospital based)
- *C. diff* infection
- *C. diff* hospitalization
- Catheter-Associated UTI

Antimicrobial Resistance and the Role of IPs in Stewardship

Regional Collaboration is Essential

Hospitals

Dialysis facilities

Ambulatory facilities

Long-term care

Antimicrobial Stewardship Programs: the Role of Infection Preventionists

How Stewardship Programs Benefit Infection Prevention and Control:

- identifying reported trends and outbreaks of epidemiologically significant organisms and educating about infection prevention policies

How IPs and Epidemiologists Benefit Stewardship Programs:

- 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.

"Antimicrobial Stewardship (AS) 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."

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. *Italics added.*

Joint Statement on Antimicrobial Resistance

APIC joined 24 other national health organizations and the Centers for Disease Control and Prevention in support of a Joint Statement on Antimicrobial Resistance

- recognition of collective responsibility to protect the effectiveness of all antibiotics – those we have today, and those yet to be developed
- recognition of the potential for these life-saving drugs to be overused in both the human and agricultural sectors
- recognition that there are challenges on both the demand and supply sides of the equation – just as antibiotics are frequently overused, there are few new drugs in the development pipeline

See the full statement: http://cddep.org/sites/cddep.org/files/etc_consensus_statement.pdf

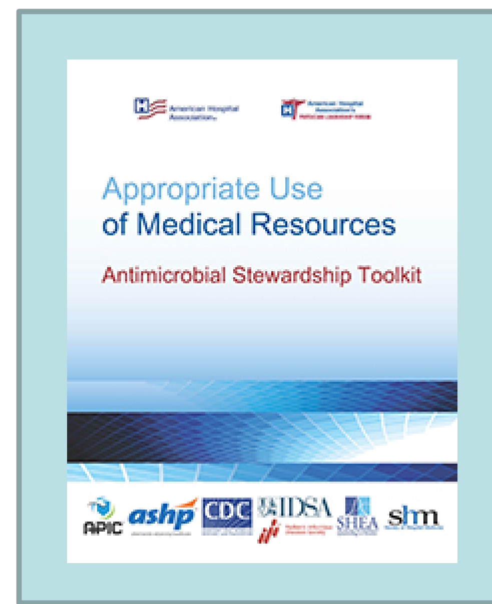
American Hospital Association Antimicrobial Stewardship Toolkit

American Hospital Association partnered with CDC, APIC, IDSA, PIDS, ASHP, SHM, SHEA

Toolkit to help hospitals and health systems enhance their antimicrobial stewardship programs.

Includes:

- resources for hospital leaders, clinicians, patients
- CDC tool to help hospitals assess their readiness for optimal antibiotic prescribing and use



http://www.ahaphysicianforum.org/resources/appropriate-use/antimicrobial/index.shtml

State Legislative Action

- Legislation was introduced in three states that would require reporting of antibiotic resistant infections. Additional states introduced legislation that would require antimicrobial stewardship programs
  - some states are moving directly to regulation
- More legislation and regulation is likely

APIC Government Affairs
www.apic.org
THE ASSOCIATION FOR PROFESSIONALS IN INFECTION CONTROL AND EPIDEMIOLOGY

Summary of State CRE Reporting Requirements

APIC has compiled CRE reporting information for the states that require statewide reporting. Helpful links are included in each summary to provide easy navigation to state government websites.

Alaska

Effective December 29, 2013, healthcare providers or laboratories are required to report carbapenemase-producing *Enterobacteriaceae* (CRE) to the Alaska Department of Health and Social Services - Division of Public Health within five working days after suspecting or identifying the condition. Reports should include information on the name, address, date of birth, sex, ethnicity, and race of the person diagnosed as having the reported disease or other condition, whether that person is pregnant, whether the diagnosis is laboratory-confirmed, and the name and address of the healthcare provider reporting the disease or other condition. The state is currently developing surveillance requirements for identifying carbapenemase-producing *Entrobacteriaceae*.

Alaska Department of Health and Social Services - Division of Public Health regulations

Colorado

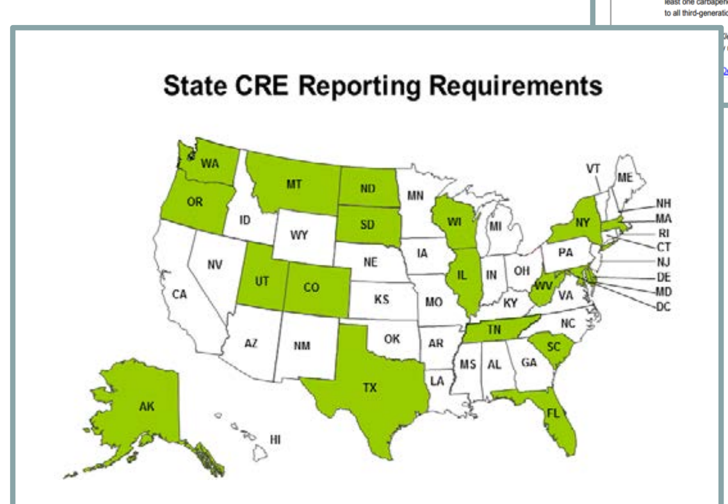
Through regulatory action effective November 30, 2012, the Colorado Department of Public Health and Environment (CDPHE) made CRE reportable to the CDPHE or can be reported through the state's web-based system, Colorado Electronic Disease Reporting System by laboratories within seven days. CRE is defined as:

- *Escherichia coli*, *Klebsiella* species, and *Enterobacter* species that are intermediate or resistant to at least one carbapenem (including imipenem, meropenem, doripenem, or ertapenem) AND resistant to all third-generation cephalosporins tested (including ceftriaxone, cefotaxime, and ceftazidime);

OR

- ...*lebsiella* species, and *Enterobacter* species that test positive for carbapenemase ... method, including the Modified Hodge Test, disk diffusion, or PCR).

...Department of Public Health and Environment reportable conditions



Federal Legislative Issues

CDC Budget: National Healthcare Safety Network

Calls for **$32 million** in FY 2015 for CDC to extend NHSN reporting to more than 3,000 additional sites and to enable CDC to continue to provide data for national HAI elimination efforts and targeted HAI prevention intervention

- Support the development of Antibiotic Use and Resistance (AUR) modules in NHSN that will enable rapid detection of highly antibiotic resistant pathogens causing HAIs and allow assessment and tracking of antibiotic use patterns.
- Initiate HAI prevention efforts to ambulatory surgery centers (ASCs), where an increasing proportion of healthcare is being delivered.
- Drive innovation through collaboration with academic research centers in CDC's Prevention EpiCenters network, which conducts applied research on interventions for infection prevention.

Source: CDC Budget Justification for NHSN

CDC's *Detect* and *Protect* Initiative Against Antibiotic Resistance

Calls for $30 million in FY 2015 for CDC to invest in the following priority areas:

- Support a network of 5 regional labs that will characterize emerging resistance and rapidly identify outbreaks of dangerous antibiotic resistance threats
- Scale up healthcare prevention collaboratives focused on improving antibiotic use and preventing deadly infections caused by:
  - *Clostridium difficile* (*C. diff.*)
  - Carbapenem-resistant Entererbacteriaceae (CRE)
  - *Pseudomonas*
  - Methicillin-resistant *Staphylococcus aureus* (MRSA)
- Improve outpatient antibiotic prescribing and target community AR threats including resistant *Salmonella*, and drug-resistant gonorrhea
- Establish lab library of resistant isolates to help support drug and diagnostic development

Source:
CDC

CDC Goals with $30 million annual investment in the AR Initiative

FY 2015	FY 2019
↓ **15% decline** in *C. diff* “deadly diarrhea”	↓ **50% decline** in healthcare-associated *C. diff*
↓ **10% decline** in healthcare-associated CRE, “nightmare” bacteria	↓ **50% decline** in healthcare-associated CRE
↓ **6% decline** in multi-drug resistant *Pseudomonas* and ↓ **6% decline** in invasive MRSA	↓ **30% decline** in healthcare-associated drug-resistant *Pseudomonas* and ↓ **30% decline** in invasive MRSA
↓ **5% decline** in multi-drug resistant *Salmonella*	↓ **25% decline** in drug-resistant *Salmonella* infections
↑ **5x increase** for AR isolates tested through regional labs to help support drug and diagnostic development	↑ **At least 10x more** drug susceptibility testing for high-priority pathogens
	Nationwide implementation of CDC antibiotic protection tools and **improved prescribing** in U.S. acute-care hospitals and outpatient settings

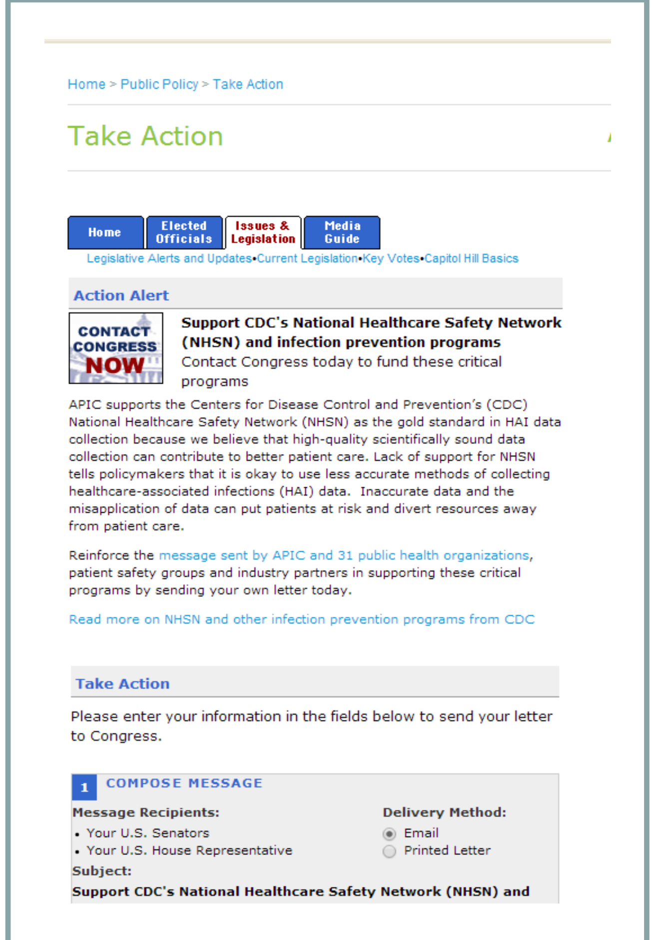
Source: CDC

APIC's NHSN Advocacy Initiative

Initiative calls on Congress to support funding for NHSN and other HAI prevention programs, including the CDC's antibiotic resistance initiatives.

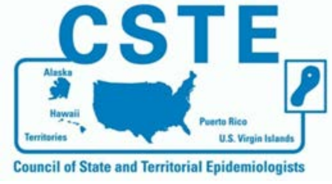
Why ask for NHSN funding?

- Healthcare facility reimbursement incentive and penalty programs have widespread support among policymakers and are here to stay.
- NHSN is the gold standard in identifying, monitoring and understanding the extent of the HAI problem.



http://capwiz.com/apic/issues/alert/?alertid=63215601

Joining Forces to Support NHSN

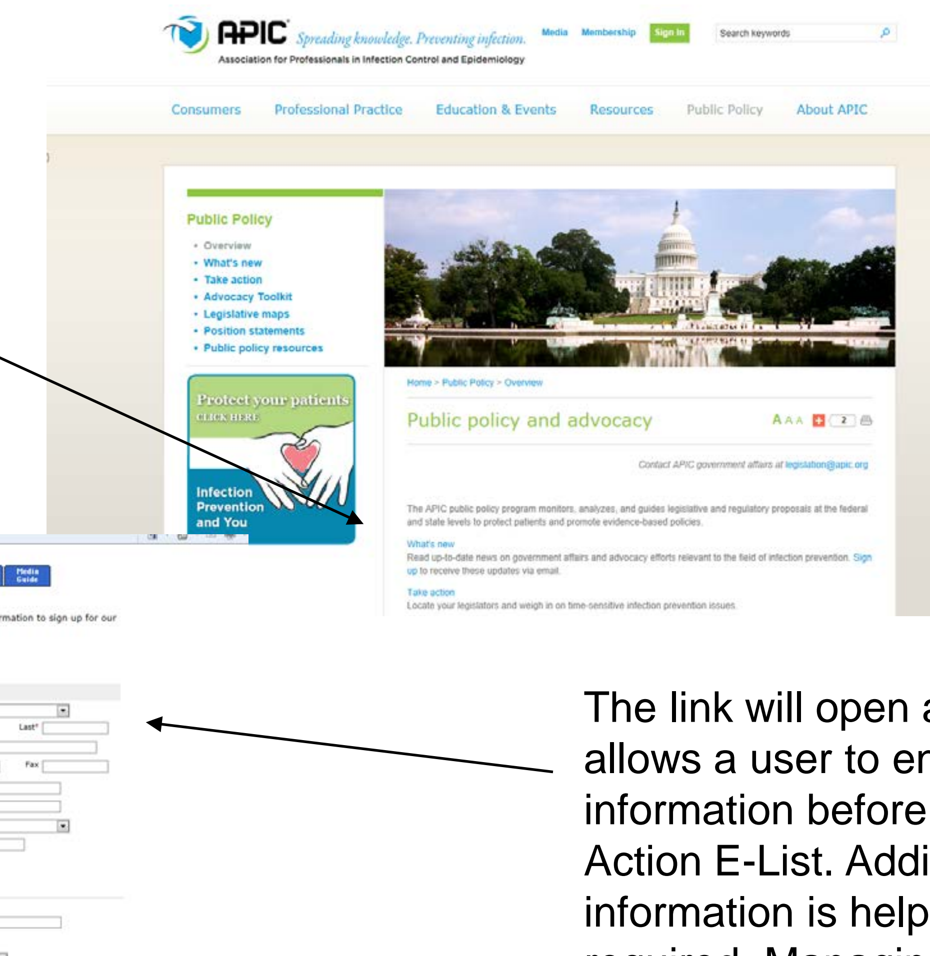


PREMIER

American Society of
Health-System Pharmacists®
TOGETHER WE MAKE A GREAT TEAM

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.

Lisa Tomlinson, MA, VP, Government Affairs and Practice Guidance
ltomlinson@apic.org

- Overall government affairs strategy
- Federal legislation

Nancy Hailpern, Director of Regulatory Affairs
nhailpern@apic.org

- Federal regulatory issues
- HAI reporting at the federal level

Laura Evans, Government Affairs Associate
levans@apic.org

- State issues
- Legislative maps