

A Legislative and Regulatory Update

**Rich Capparell
Legislative Affairs Representative**

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Two Major Types of Legislation

- **Authorization**

- Establish federal policies and sometimes make recommendations on how much money should be spent on them.
- Put another way they give the Federal Government the "Authority" to carry out a program or policy.

For example: Congress authorizes creation of a special education program and it may “authorize” up to \$20 billion or “such sums and may be necessary” to implement it.

- **Appropriations**

- Provide specific dollar amounts for agencies, programs and operations.
- Put another way, they appropriate funds, or writes the check for a specific amount for a program.

For example: \$12.3 billion will be provided to XYZ Special Education program, under x agency for a specified fiscal year.

Legislative Process: Appropriations (#'s 3-5)

The 5 Step Federal Budget Process



1.

The President submits a **budget request** to Congress.



2.

Lawmakers release their own budget plans and set overall spending levels with a **budget resolution**.



3.

House and Senate subcommittees set funding for each program through **appropriations bills**.



4.

House and Senate members come together to **resolve differences** in their appropriations bills.



5.

The budget returns to the President for his signature before it **becomes law**.

NATIONAL
PRIORITIES
PROJECT

www.nationalpriorities.org

Often this doesn't happen, so alternative approaches are:

- ✓ Continuing Resolution
- ✓ Omnibus Spending Bill

U.S. House Committees:

- Energy and Commerce Committee
- Ways and Means Committee
- Appropriations Committee

U.S. Senate Committees:

- Appropriations Committee
- Health, Education, Labor, and Pensions (HELP) Committee
- Finance Committee



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Federal Legislative Efforts

- Pandemic and All Hazards Preparedness (PAHPA) Reauthorization
- Re-Valuing Antimicrobial Products (RVAMP Act)
- Strategies to Address Antimicrobial Resistance (STAAR) Act
- FY 2019 Appropriations Process



Pandemic and All Hazards Preparedness (PAHPA)

- Enacted March 13, 2013
 - Being considered for reauthorization this year.
- PAHPA is focused on improving preparedness for any public health emergency (pandemic, epidemic, chemical, or nuclear)
- Trying to get language attached to encourage the development of new antibiotics (REVAMP Act)

Strategies to Address Antimicrobial Resistance (STAAR) Act

- Adds the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria to statute and extends it until 2024
- Authorizes the CDC to intensify and expand academic public health partnerships
- Authorizes the CDC to work directly with state health departments to implement prevention collaboratives
- Provides statutory authorization to an NIAID clinical trials network focused on antibiotic resistant pathogens

Timeline for FY 2018 Appropriations

- Continuing Resolutions passed:
 - September 8 – government funded through December 8
 - December 7 – government funded through December 22
 - December 21 – government funded through January 19
 - January 22 – government funded through February 8
 - February 9 – government funded through March 23 (budget caps increased)
 - FY 2018 Appropriations passed on March 23, 2018

FY 2018 Appropriations

Federal Government Program	FY 2017	FY 2018 President's	FY 2018
CDC Emerging and Zoonotic Infectious Diseases Programs			
Antibiotic Resistance Initiative	\$163,000,000	\$137,000,000 ^a	\$168,000,000
National Healthcare Safety Network	\$21,000,000	\$21,000,000	\$21,000,000
Advanced Molecular Detection	\$30,000,000	\$30,000,000	\$30,000,000
Prevention and Public Health Fund (PPHF)			
Immunizations	\$324,350,000	\$203,600,000	\$324,350,000
Epidemiology and Lab Capacity program	\$40,000,000	\$0 ^b	\$40,000,000
Healthcare-Associated Infections	\$12,000,000	\$0	\$12,000,000
AHRQ Program			
Healthcare-Associated Infections Prevention	\$36,000,000	\$0 ^c	\$36,000,000
NIH Program			
National Institute of Allergy and Infectious Diseases	\$4,900,000,000	\$3,783,000,000 ^d	\$5,260,210,000

^a Funding would be entirely from the Prevention and Public Health Fund, which was reduced by 25% and has been targeted in the past for large cuts.

^b This program was moved to the Emerging Infectious Diseases line item, which received an \$8M. Which could potentially slash funding.

^c AHRQ was moved under the National Institutes of Health line item.

^d Includes a \$30M increase in funding for antibiotic resistance research.

- The President released his budget on February 12.
 - Similar to last year, the President requested large cuts to many APIC priorities.
 - Eliminated the Prevention and Public Health Fund
 - Reduces CDC funding by more than 20%*
 - Merges AHRQ with the NIH; Reduces AHRQ funding by 21%*
 - Cuts \$26 million from the Antibiotic Resistance Solutions Initiative.*
- Appropriations committees have taken their own path on most CDC priorities.
- As part of the CDC coalition, APIC is requesting \$7.9 billion in CDC funding.

Federal Government Program	FY 2017	FY 2018	House FY 2019 Proposal
CDC Emerging and Zoonotic Infectious Diseases			
Antibiotic Resistance Initiative	\$163,000,000	\$168,000,000	\$168,000,000
National Healthcare Safety Network	\$21,000,000	\$21,000,000	\$21,000,000
Advanced Molecular Detection	\$30,000,000	\$30,000,000	\$30,000,000
Prevention and Public Health Fund (PPHF)			
Immunizations	\$324,350,000	\$324,350,000	\$324,350,000
Epidemiology and Lab Capacity program	\$40,000,000	\$40,000,000	\$40,000,000
Healthcare-Associated Infections	\$12,000,000	\$12,000,000	\$12,000,000
AHRQ Program			
AHRQ baseline funding (excludes PCORTF)	\$324,000,000	\$334,000,000	\$334,000,000
Healthcare-Associated Infections Prevention	\$36,000,000	\$36,000,000	\$36,000,000
NIH Program			
National Institute of Allergy and Infectious Diseases	\$4,900,000,000	\$5,260,210,000	\$ 5,368,029,000

APIC on Capitol Hill

- 8 members of the Public Policy Committee and an invited CLR participated in a lobby day
- 21 offices were visited to discuss the role of IPs, NHSN, and infection prevention and antibiotic resistance activities at CDC



Partnered on eleven coalition letters related to:

- Support for the CDC
- Support for the Prevention and Public Health Fund
- Support for the Strategies to Address Antimicrobial Resistance (STAAR) Act
- Annual appropriations testimony with SHEA





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2018 State Legislative Trends



Private Organization Certification

- Prevents professional employees from using the term “certified” unless it is through a government agency
- Legislation has been seen in Missouri and Louisiana





Legislation regarding Healthcare personnel (HCP) influenza vaccinations

- Requiring vaccines be accessible and available to HCP
 - Indiana, Nebraska
- Prohibiting healthcare facilities from making influenza vaccinations mandatory
 - Minnesota, New Hampshire (study bill), Ohio, Oregon
- Mandating certain facilities have their employees receive a vaccination
 - Missouri

Reporting HAIs and MDROs on death certificates

- California and US Senate legislative proposals
- Likely consumer focus on increased reporting that captures deaths from HAIs
- Passed the California Senate unanimously

Restricting the use of antibiotics in feed animals

- Maryland (passed), Pennsylvania

Requiring central service technicians to be certified

- Massachusetts, Pennsylvania, Rhode Island





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CERTIFICATION

THE DEFINING DIFFERENCE

An APIC Strategic Initiative

To be employed by a hospital an IP would be required to:

- successfully pass an exam from a nationally accredited infection prevention and epidemiology accrediting organization such as CBIC;
- provide evidence that he/she was employed for one year prior to the bill's passage; or,
- be a student or intern performing the functions of an IP serving under direct supervision of an IP.

An IP not meeting certification requirements:

- will have three years from the date of hire to obtain an infection prevention and control credential.

A hospital may employ an IP not certified if:

- The hospital is unable to hire a certified infection preventionist after a diligent and thorough search.
- An IP earns his/her certification within three years of the start of hire.
- The IP was employed for one year prior to the bill's passage.

Facilities must share their employment records

The hospital must provide employment records of an IP to other healthcare facilities upon request.

Scope of Practice

The language for this bill is intended only for IPs and not other healthcare professionals.



CERTIFICATION
THE DEFINING DIFFERENCE

An APIC Strategic Initiative



Infection Preventionist Advocacy Day in Albany



Status of the Legislation

- **A. 10671**
 - Amended by the Assembly Health Committee
 - Died at the end of session and will need to be reintroduced in 2019 legislation session.
- **S. 8185**
 - Amended to match Assembly Committee language
 - Passed Senate Health Committee
 - Died at the end of session and will need to be reintroduced in 2019 legislation session.



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Regulatory Report

FDA regulation

- N95s are regulated by FDA under the Federal Food, Drug, and Cosmetic Act as surgical apparel
- Classified as class II requiring special controls including premarket approval.

NIOSH regulation

- Manufacturing of respiratory protective equipment is also regulated by NIOSH under the Public Health Service Act .
- Address quality assurance.



FDA-NIOSH Memorandum of Understanding

- NIOSH will evaluate respirators first,
- If the devices meet the NIOSH threshold standards they will be exempt from FDA premarket approval requirements.
- [MOU](#)
- [FDA notice](#)





The Patient Protection and Affordable Care Act (ACA) of 2010 established quality incentive and penalty programs for acute care hospitals

- **Inpatient Quality Reporting Program (IQR)**
 - Penalty for not reporting designated measures
 - HAI measures reported through CDC/NHSN
- **Hospital Value-Based Purchasing (VBP) quality incentive program**
 - Incentive/penalty program determined by achievement or improvement of designated measures
 - Same HAI measures as IQR
- **Hospital-Acquired Condition (HAC) Reduction Program**
 - Top quartile of hospitals with the highest HAC rates would be penalized by a 1% reduction in Medicare reimbursement
 - Same HAI measures as IQR



- **HAI measures included in Hospital IQR Program:**
 - CLABSI
 - CAUTI
 - SSIs (Colon surgeries and abdominal hysterectomy)
 - MRSA Bacteremia LabID events
 - *C. difficile* infection LabID events
 - Healthcare Personnel Influenza Vaccination
- All but HCP influenza vaccination also included in Hospital VBP and HAC Reduction Programs.
- No HAIs have been included in the Hospital Admissions Reduction Program

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 changes:

- **“Meaningful Measures” Initiative to reduce regulatory burden and focus on patient outcomes**
 - CMS identified 19 Meaningful Measures areas and mapped them to six overarching quality priorities
 - **Measure area:** HAIs
 - **Quality priority:** Making care safer by reducing harm caused by delivery of care.
 - To achieve reorganization and reduction of measures:
 - Considering the Hospital VBP, HAC Reduction, and Hospital Readmissions Reduction Programs collectively as “value-based purchasing – each with different focus
 - ❖ **HRRP** (currently no HAI measures) – focus on care coordination
 - ❖ **HAC Reduction** – focus on patient safety/ harm reduction
 - ❖ **VBP** – focus on clinical outcomes such as mortality and complications, patient and caregiver experience, healthcare costs.

Proposed changes:

- Measures must start in reporting program, but once moved into a “VBP program”, may be removed from IQR.
 - All HAI measures *except HCP influenza vaccination* proposed to be **removed from Hospital IQR program** payment consideration beginning FY 2021 (data collection through CY 2018)
 - All HAI measures proposed to be **removed from Hospital VBP program** payment determination beginning FY 2021
- All current HAI measures will **remain in the HAC Reduction Program**
 - Propose adjusting scoring method for HAC Reduction Program
 - Current scoring:
 - Domain 1: PSI-90 composite -- 15% of Total HAC score
 - Domain 2: HAI measures – 85% of Total HAC score
 - Proposed equal weighting so PSI-90 and each HAI measure will have equal weight
 - Alternative proposed scoring – similar to current

Proposed changes to PPS-exempt Cancer Hospital QRP:

- **Current NHSN reporting requirement:** CAUTI, CLABSI, SSI, MRSA, CDI, HCP influenza vaccination
 - Public reporting of CAUTI and CLABSI has been deferred
 - Other HAI measures – because of 2015 NHSN rebaseline, will not have sufficient data to report publicly until 2019
- **Proposed:** Remove CAUTI and CLABSI Outcome measures beginning FY 2021 – cost outweighs benefit

Proposed changes to Long-Term Care Hospital QRP:

- **Current NHSN reporting requirement:** CAUTI, CLABSI, MRSA, CDI, HCP influenza vaccination, VAE
- **Proposed:** Remove MRSA and VAE measures
 - MRSA bloodstream infections would be included in CLABSI
 - VAE – other vent-related measures better indicators of patient outcomes

Proposed changes to Inpatient Rehab Facility QRP:

- **Current NHSN reporting requirement:** CAUTI, MRSA, CDI, HCP influenza vaccination.
- **Proposed:** Remove MRSA measure
 - Measure is reported as a SIR, but expected MRSA is so low in IRF setting that can't get a reliable SIR – benefit of reporting measure to improve outcomes is very small.

Proposed changes to Inpatient Psychiatric Facility QRP:

- **Current NHSN reporting requirement:** HCP influenza vaccination
- **Proposed:** Remove HCP influenza vaccination measure
 - Since this measure is the only NHSN measure for this care setting, the administrative burden associated with NHSN exceeds the benefit.

Check out the Regulatory Table on the APIC website for:

- All regulations that APIC follows and
- all comments APIC submits to federal agencies

<http://cqrceengage.com/apic/regulations>

Issues ▾	Legislation ▾	Take Action ▾	Regulations ▾	What's New	APIC Homepage	
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Regulations

[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?
CMS: FY 2019 Inpatient Prospective Payment System/ Long-Term Care Hospital Payment System (IPPS/LTCH) proposed rule.	Updates infection-related measures in the Hospital Inpatient Quality Reporting Program, Hospital Value-Based Purchasing Program, Hospital-Acquired Condition (HAC) Reduction Program, Long-Term Care Hospital Quality Reporting Program, and PPS-exempt Cancer Hospital Quality Reporting Program	Pending	<ul style="list-style-type: none"> • Patient Safety • Data Standardization • Advocacy
CMS: FY 2019 Inpatient Rehabilitation Facility (IRF) Prospective Payment System proposed rule.	Updates infection-related measures in the Inpatient Rehabilitation Facility Quality Reporting Program.	Pending	<ul style="list-style-type: none"> • Patient Safety • Data Standardization • Advocacy
CMS: FY 2019 Hospital Inpatient Psychiatric Facility (IPF) Prospective Payment System proposed rule.	Updates infection-related measures in the Inpatient Psychiatric Facility Quality Reporting Program	Pending	<ul style="list-style-type: none"> • Patient Safety • Data Standardization • Advocacy
CMS: Draft quality measures to satisfy the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014 domain of Transfer of	To comply with requirements of the IMPACT Act, CMS is developing new measures to ensure patient safety during care transitions. These proposed measures are intended to provide patient medication profiles to accompany patients when transitioning to new settings or to home.	Comments submitted 5/1/2018	<ul style="list-style-type: none"> • Patient Safety



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New Chapter Tools



An Economist Group business

APIC California Legislative Report
June 07, 2017

California 2017-2018

3 Bills

Number: CA [R] SB 43 - Updated (Status 06/01/2017)

Title: Antimicrobial-resistant infection: reporting.

Sponsor: Sen. Jerry Hill (DEM-CA)

Notes: [apic 06/06/17](#)

This bill would require general acute care hospitals and clinical laboratories to submit an annual report containing an antibiogram to the State Department of Public Health. The measure would also require the Antimicrobial Stewardship and Resistance Subcommittee of the Healthcare Associated Infections Advisory Committee to develop the acceptable electronic format for the report and a method to accurately estimate the number of deaths that result from specified antimicrobial resistant infections.

Status: In Assembly. Read first time. Held at Desk. - 05/31/2017

Profiles: View highlighted keywords

- HAI
- Other

Number: CA [R] SB 351 - Updated (Status 06/02/2017)

Title: Hospital satellite compounding pharmacy: license: requirements.

Sponsor: Sen. Richard Roth (DEM-CA)

Notes: [apic 06/06/17](#)

This bill establishes a license for a hospital satellite compounding pharmacy and allows a general acute care hospital without a consolidated license to obtain multiple site licenses from the Board of Pharmacy

Status: In Assembly. Read first time. Held at Desk. - 06/01/2017

Profiles: View highlighted keywords

- Compounding Pharmacy

Number: CA [R] SB 510 - Updated (Status 05/19/2017)

Title: Pharmacies: compounding.

Sponsor: Sen. Jeff Stone (REP-CA)

Notes: [apic 06/06/17](#)

This bill deletes current law relating to sterile compounding environments that conflict with recently adopted regulations. More information regarding these deletions can be found at http://leginfo.ca.gov/faces/billAnalysisClient.xhtml?bill_id=201720180SB510#.

Status: Referred to Com. on B. & P. - 05/18/2017

Profiles: View highlighted keywords

- Compounding Pharmacy



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New CLR Video



Pre-drafted invitations

- Pre-written messages inviting your elected officials to meet with you or attend a chapter meeting
- Messages can be edited
- Are available on the MyAPIC CLR website



Key Investments to Combat Antibiotic Resistance

Go to <https://wwwn.cdc.gov/arinvestments> to learn about investments in your state.



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Preventing infection.®