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# General Acute Care Hospital Infection Control

## Regulations Development

Presentation to the Healthcare Associated Infections  
Advisory Committee (HAI-AC),

Center for Healthcare Quality – RN Unit :

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Title 22 California Code of Regulations (CCR's)  
Infection Control & Prevention.

**What are our goals?**

**Our Goal is to develop meaningful and implementable infection control regulations for General Acute Care Hospitals within California.**

**How do we achieve this –**

❖ CDPH Processes – Involves a multidisciplinary Rulemaking Project Team (RPT) who work together with subject matter experts to develop the complete regulatory package -

1. RN Unit
2. Financial
3. Office of Regulations & Hearings
4. Legal Department

The RPT follows the Administrative Procedural Act (APA), and the final package is presented to Office of Administrative Law (OAL) for final approval and submission to the California Register for publication.

# State Regulations

When adopting regulations we are required to observe:

Whenever by the express or implied terms of any statute a state agency has authority to adopt regulations to implement, interpret, make specific or otherwise carry out the provisions of the statute, no regulation adopted is valid or effective unless consistent and not in conflict with the statute and reasonably necessary to effectuate the purpose of the statute.

--Government Code Section 11332.2

# Office of Administrative Law

The regulatory process must follow the Office of Administrative Law (OAL), Administrative Procedure Act (APA) guidelines and meet all six authority specific requirements before the regulation will qualify to be entered into the California Code of Regulations in accordance with (GC Section 11349.1)

## Administrative Procedure Act Guidelines

1. Clarity
2. Consistency
3. Necessity
4. Authority
5. Non Duplicative
6. Reference

These requirements are found in Government Code Sections 11340 through 11361, and the implementing regulations in Title 1 CCR Sections 1 through 280.

# APA Standards

The APA requirements are designed to provide the public with a meaningful opportunity to participate in the adoption of regulations to ensure the creation of an adequate record for the public, OAL and judicial review.

All regulations shall meet the following **six prescribed standards** for authority, reference, clarity, necessity, consistency and non-duplication. (GC Section 11349.1)

## Authority -

The provisions of law, which permits or obligates the agency to adopt, amend or repeal a regulation. [GC Section 11349(b) & Title 1 California Code of Regulations (CCR) Section 14].

## Reference-

The statute, court decision or other provision of law which the agency implements, interprets or makes specific by adopting, amending or repealing a regulation. [GC Section 11349(e) and Title 1 CCR Section 14].



# APA Standards Continued

## Non-duplicate

A regulation does not serve the same purpose as a state or federal statute or another regulation.

## Clarity

Regulations written or displayed so that the meaning of regulations will be easily understood by those persons directly affected by them. [GC Section 11349(c) and Title 1 CCR Section 16]  
(A regulation should have but one meaning)

## Necessity

The record of the rulemaking proceeding demonstrates substantial evidence and the need for a regulation. [GC Section 11349(a) and Title 1 CCR section 10 and 11]

## Consistency

"Consistency" means being in harmony with, not in conflict with or contradictory to, existing statutes, court decisions, or other provisions of law. [Government Code, Section 11349(d)].

# Development of the Regulations

## APA process includes -

- The regulation
- The purpose of the regulation
- Why it is necessary
- What alternatives were considered and why were they rejected?
- What material is relied upon for this regulation?(Statute, Senate Bill)
- What economic impact is there on business?

# APA Official Rulemaking Process

1. Text of regulations - Initial Statement of Reasons - Notice of Proposed Rulemaking
2. Rulemaking Record Open – California Regulatory Notice Register
  - ( Optional Pre Notice Meeting for public comment )
3. There is a 45 day minimum public comment period where the agency considers comments and makes any necessary changes to the regulations.
4. Final Statement of Reason – Department response to comments.
5. Agency adopts Regulation
6. Rulemaking Record is Closed

Must all be completed within one year of record being opened.

# Pre Notice - Public Meeting

Provides the public with an opportunity to submit regulatory text and or other helpful documents and or suggestions to contribute towards initial development of regulation.

This is not a mandatory requirement. Not all regulation will provide the pre notice meeting option.

Examples of input that would be helpful at his point -

- Recent research literature in support of a recommendation.
- Text written as an example of what would be helpful for the user.
- An outline for suggested regulatory text.
- Documentation to support anything submitted.

# Limitations



What we cannot do –

We cannot change statute in any way.

- Statute is written by the legislature and only the legislature may alter it in any way.

We cannot change regulations without following the APA process.

- Every change to our regulations must be submitted to OAL and be submitted following the APA process.

Alter manufacturers instructions.

# Integrated Infection Surveillance, Prevention and Control Program

Seven integrated systems -

- Surveillance
- Patient protection
- Employee protection
- Environmental protection
- Education, training and competencies
- Program evaluation and corrective action
- Program re-evaluation and revision

# Legislative History & Infection Control Regulations

Title 22, Chapter 1, General Acute Care Hospital,  
will be amended, repealed or added to the current  
Section 70739 by performing an in-depth  
Legislative History including reviewing the legislative updates.

- Senate Bill 739 (Speier, Chapter 526, 2006)
- Senate Bill 1058 (Alquist, Chapter 296, 2008)
- Senate Bill 158 (Florez, Chapter 294, 2008)
- Health & Safety Code sections 1288.5, 1288.6,  
1288.7, 1288.8, 1288.9, 1255.8, 1288.55,  
1288.6, 1288.95.



# Infection Control Program Section 70739

Pursuant to Section 70739 of Title 22 of the California Code of Regulations, at a minimum, shall include all of the following:

1. Develop Infection Prevention awareness & practices to enhance patient safety within the health care environment.
  - i) hand hygiene monitoring
  - ii) antibiotic stewardship
  - iii) MRSA & other resilient bacteria
2. Reduce health care associated infections (HAI's).
3. Reduce the current increase in growth of antibiotic resistant bacteria within the HAI population.
4. Develop public posting of data collected as a means of patient reference, facility tracking purposes and as an incentive comparison tool for facilities to review their current outcomes.

# Specific regulatory Infection Control goals:

## Infection Preventionist:

Ensure adequate numbers of qualified hospital infection preventionists to implement the total Infection Control Program.

## MRSA testing:

Develop regulatory guidance per statutory requirements for MRSA (Methicillin Resistant Staphylococcus Aureus) testing.

## Antibiotic use:

Develop regulatory guidance for antibiotic stewardship.

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# Questions?

Contact

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